

Pathology

GIRFT Programme National Specialty Report

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Foreword from Professor Tim Briggs

I am delighted to recommend this Getting It Right First Time review of pathology, led by Tom Lewis, Marion Wood and Martin Myers.

This report comes at a time when the NHS has undergone profound changes in response to the COVID-19 pandemic. The unprecedented events of 2020/21 – and the extraordinary response from everyone working in the NHS – add greater significance to GIRFT’s recommendations, giving many of them a new sense of urgency. Reliable testing has been a central focus of the UK’s pandemic response, and so has rarely been out of the headlines.

The key requirements for pathology during this pandemic reflect the priorities highlighted in this report. The recommendations set out here will help to ensure that people get the right test at the right time, with the right answer.

Tom, Marion and Martin have applied the GIRFT approach to their field, which provides expertise underpinning every aspect of patient care across all areas of healthcare, from diagnostic testing to treatment advice. Pathology covers a broad range of specialties, including the key areas of haematology, clinical biochemistry, microbiology and histopathology. Pathologists often lead scientific and medical advancement through their research, and the specialty itself is undergoing rapid and exciting change.

The recommendations set out in this report are based on the visits that the clinical leads made to labs and pathology networks across England, in addition to other data and audits. The recommendations cover the whole of the pathology pathway, from a clinician’s decision to order a test, through the sample’s journey to the lab, to the results being delivered to the requestor and understood by the patient. These recommendations will help to ensure that the request-result cycle works smoothly and efficiently, facilitated by – and yielding – more readily accessible and useful data.

Tom, Marion and Martin have found examples of excellence in every lab or centre they visited, and also opportunities for improvement. Like other clinical leads before them, they have found that their colleagues were dedicated to quality improvement work and an ambition to make a tangible, lasting difference to patient care.

That commitment and ambition is vital to the GIRFT programme, which can only succeed with the backing of clinicians, managers and everyone involved in delivering care.

My greatest hope is that GIRFT will provide support and impetus for all those involved in pathology to work shoulder to shoulder and continue making a real difference in patients’ lives, while ensuring that the service is ready and resilient to face the challenges and fascinating opportunities to come.



Professor Tim Briggs CBE

GIRFT Programme Chair and National Director of Clinical Improvement for the NHS

Professor Tim Briggs is Consultant Orthopaedic Surgeon at the Royal National Orthopaedic Hospital NHS Trust, where he is also Director of Strategy and External Affairs. He led the first review of orthopaedic surgery that became the pilot for the GIRFT programme, which he now chairs. Professor Briggs is also National Director of Clinical Improvement for the NHS.

Introduction by Dr Tom Lewis, Dr Marion Wood and Dr Martin Myers

Throughout our time with GIRFT, we have been hugely impressed by our pathology colleagues around the country, and we are very grateful to them for their commitment to this project: from providing the data that formed the backbone of our deep-dive visits, to the welcome and interest shown as we undertook those visits – all in spite of the immense pressures we have seen colleagues working under, magnified several-fold by the many impacts on pathology from the COVID-19 pandemic.

Pathology is critical to patient care, but may sometimes be viewed as simply a result-generating service. Where pathology is viewed in this way, it can make pathologists focus inward, on the processes within the lab.

In this project we have seen – and encourage others to see – pathology as an end-to-end service, starting with the clinical encounter that leads to the right test being requested, and ending with the right results going back to the right patient in the right timeframe. This broader perspective recognises the impact that activities outside the lab's walls have on the process, and the importance for pathologists of using their expert knowledge to extend their influence beyond the lab. If they can do this, they will ensure that correctly requested samples arrive in the best possible condition for testing, and improve the quality and timeliness of results.

We have seen fantastic examples where lab staff have worked closely with colleagues in primary care and the hospital, developing innovative solutions to common challenges such as transport, phlebotomy and centrifugation.

Pathology in the UK has a long history of measuring and delivering quality; the specialty is unique in having independently verified quality accreditation procedures already established in every lab. This infrastructure means there are excellent foundations for the specialty to build on to strengthen quality throughout the end-to-end process. As a result of our discussions and research, we have already begun conversations with the UK Accreditation Service (UKAS) about how broadening its approach can work for labs as they seek to influence areas beyond their traditional focus. This is an exciting outcome of the GIRFT process, and we are especially looking forward to seeing this develop further in the near future.

In our visits, colleagues have particularly valued the ability to see the variation in current practice. Seeing this data has enabled them to compare themselves with peers and understand underlying causes of variation. However, much of the data to enable these comparisons was not readily available when we started out, and we had to gather some of it via a questionnaire; in many cases, staff spent considerable time manually accessing local data to provide the information that we had requested. The adverse impact on the delivery of excellence in pathology due to the lack of consistently good data, data standards and digital systems across the service in England has been emphasised by our findings. We are therefore encouraged that NHS England and NHS Improvement is already exploring how to work with NHSX and NHS Digital to address this as a matter of urgency.

The pathology specialty has been going through yet another period of significant change as individual trust departments come together to form networks. This journey has been more difficult in some areas than others, and inevitably the rate of progress is variable.

We have been able to share learning from those who are further along the road with those who are just starting out. When examining progress, it has been clear to us that an essential component in the success of developing networks is excellence in the leadership and governance of these new organisations, with individuals who are willing to challenge and change, accepting – seeking out – responsibility rather than believing that it is outside their control.

Of course, no improvement is possible without the workforce to initiate, deliver and sustain it, and alongside many other specialties, pathology has a capacity shortfall that must be filled. However, unlike other specialties, we are fortunate to have a large, adaptable and willing pool of talent in the biomedical scientist workforce, and as a specialty we must focus on working together differently to make the most of this unique resource.

By embracing more flexible career paths, we can both expand the workforce and ensure that pathology continues to be a dynamic and satisfying career, with an exciting and fulfilling future. Discussions with the Royal College of Pathologists (RCPath) and Institute of Biomedical Science (IBMS) are already taking place, and we know that both share our enthusiasm to create a more flexible working environment – one that will ready pathology for whatever the future may bring.

There are extraordinary, and challenging, times ahead. But we are hugely encouraged by the resilience, adaptability and open-mindedness that we witnessed throughout this remarkable year. If we can harness the tenacity and creative energy that we saw in abundance during our visits, we are sure that pathology will meet those challenges head on.



Dr Tom Lewis

GIRFT Joint Clinical Lead for Pathology

Tom is a consultant microbiologist at Northern Devon Healthcare NHS Trust. As lead clinician for antibiotic stewardship, he has been involved in interventions to improve prescribing habits, focusing in particular on the behavioural science behind this. He has a particular interest in how pathology can be used to redesign health systems.



Dr Marion Wood

GIRFT Joint Clinical Lead for Pathology

Marion has been a consultant clinical and laboratory haematologist for 25 years. She has undertaken several other management roles, including medical director at Colchester University Hospital NHS Foundation Trust. She is a past chair of the Council of the Association of Clinical Pathologists and a member of the Pathology Alliance.



Dr Martin Myers

GIRFT Senior Clinical Advisor for Pathology

Martin is a consultant clinical biochemist at Lancashire Teaching Hospitals NHS Foundation Trust, and associate divisional medical director for pathology, having previously been clinical director of pathology for 14 years. He is also the lead scientist for the trust.

Statements of support

The Royal College of Pathologists

This is an ambitious report from the GIRFT team and we commend them for their thorough and comprehensive review of pathology services across England. The detailed route map to improve pathology services set out by the team, led by Dr Tom Lewis, Dr Marion Wood and Dr Martin Myers, is one we fully support. Pathology services are central to the delivery of healthcare. Without the right test, at the right time, with the right answer, safe and effective patient care cannot be delivered.

We particularly welcome the report's emphasis on high quality end-to-end pathology services focused on patients' needs. The principles of supporting best clinical working practice, building single-service, mutually supportive teams, and future-proofing pathology with strong data and digital foundations are central to the College's mission of supporting our members to deliver excellence in pathology practice for the benefit of the public.

The report advises investment in the workforce; this will be essential to implement its recommendations. Pre-pandemic demand for pathology services had been growing year on year, and these existing workforce pressures have been further exposed by the COVID-19 crisis. Having the right number of staff in the right places will be key to the delivery of this report's ambitious vision to build an agile and resilient pathology service with patients at its heart.



Dr Michael Osborn MRCS, FRCPath
President



National Specialty Advisor for Pathology, NHS England and NHS Improvement

I am pleased to see this review of pathology services by the GIRFT programme, with a focus on quality assurance, minimising errors, and delivering a pathology service that always supports patients, together with their clinicians, in making informed decisions about their treatment and care. Data and evidence collection are key tools in ensuring that we review and reflect on what we do, and how we do it, in all areas of clinical practice. This GIRFT report, as with all GIRFT reports, is important to help us in this continuing drive to improve our services.



Prof Jo Martin MA, PhD, RCPATHME, FIBMS(Hon), FRCPI(Hon), FRCPath
Professor of Pathology, Queen Mary University of London

Executive summary

What is pathology?

Pathology is the study of disease. Staff working in pathology study cells, tissues, blood and other fluids from patients' bodies to investigate, diagnose and monitor disease, and to guide clinicians in treatment.

Pathology tests are requested by providers in primary care, the community, and secondary care. Pathology labs in England carry out 1.12 billion tests per year – roughly 20 tests per person in England each year – representing £2.2 billion of NHS funding.¹

Current service organisation

In England, 141 trusts include a pathology lab. Most hospitals have a pathology lab; others are supported by labs within a pathology network.

Most hospital labs include the 'major' pathology specialties of haematology (including blood transfusion), clinical biochemistry, microbiology and cellular pathology (also called histopathology), which are the focus of this report.

The pathology workforce is primarily made up of medically qualified pathologists, clinical scientists and biomedical scientists, working in multidisciplinary teams (MDTs) across the pathology specialties.

End-to-End Pathology: improving quality across the health system

End-to-End Pathology aims to widen the focus of the pathology service to encompass the entire service, from a clinician considering a test to the patient's interpretation of results. It focuses on answers – **the right test, at the right time, with the right answer.**

This involves recommendations that include associated services as well as what happens within the lab itself.

This will enable us to centre the service on answering the patient's two most important questions: **Am I ok?** and **Can I trust your answer?**

From previous research, we can generate a universal purpose statement for pathology:

To help people who need tests, and the people caring for them, make informed decisions about that care.

We call this the outside-in way to judge success, looking at how patients and clinicians can use and understand tests, rather than the inside-out view, defining success according to criteria such as cost or internally derived accreditation standards.

The Clean Framework

We created an overarching quality framework helping networks and labs to widen their focus to include the pre-analytical and post-analytical stages of the diagnostic pathway.

Clean in

Are the tests appropriate?

We look at approaches to ensuring:

- there is a valid clinical question; and
- the tests are necessary, appropriate and sufficient to address that clinical question.

Variation in requesting of common analytes

We saw variation in how primary care providers and emergency departments (EDs) requested tests for common analytes (substances being measured).

We make specific recommendations for different analytes, but also recommend that labs implement Care Sets to improve consistency and reduce redundancy in many common tests.

¹ NHS Improvement: <https://improvement.nhs.uk/resources/pathology-networks>

Using Care Sets

Care Sets are groups of tests focused around a clinical question, which the requestor can usually select with a single click. There are multiple benefits to using Care Sets, especially in reducing error and redundancy, and improving shared decision making.

We recommend that pathology networks:

- establish Care Sets throughout their network and promote these to requestors;
- monitor, review and update the Care Sets, taking on board feedback.

To establish Care Sets, providers will need electronic requesting systems in place.

Creating consistency in Care Sets

We recommend that Care Sets are built into the creation of network-wide standards (see *Establishing network-wide standards and standardised national diagnostic pathways* on page 82), and that networks then monitor, review and revise these Care Sets.

Using common testing profiles

Where Care Sets are not yet in place, tests are often requested as part of a group, or test profile, such as urea and electrolyte (U&E) tests. Testing profiles may introduce over-requesting by including tests that are unnecessary to answer the clinical question. We found wide variations in the tests included in various common testing profiles and recommend auditing and removing redundant tests, especially from high-volume profiles, which will free up significant lab capacity and save unnecessary expenditure.

We believe testing profiles should be replaced with Care Sets in the longer term; however, as profiles are currently in common use and will still be required in some situations, there will still be benefit in adjusting the profiles.

Avoiding unnecessary repeat tests: minimum retest intervals

Some test results are unlikely to change over short to medium timescales, and so retests within those timescales are unnecessary. We found variation in the use of minimum retest intervals, and recommend networks implement consistent intervals as part of network standards.

Using variation to examine alternative diagnostic pathways

We found variation in how giant cell arteritis – a potentially sight-threatening condition – is diagnosed. We recommend trusts explore using ultrasound as a potential screening process, which has proved successful in some trusts.

We also found variation in the use of mid-stream urine tests to identify infection. We recommend ensuring that primary care colleagues are aware of all guidance, and potentially formalise this into Care Sets linked to the clinical question.

Are the samples collected, labelled and stabilised correctly?

Collecting samples correctly

We looked at phlebotomy and urine collection issues.

Phlebotomy issues

If phlebotomy (blood taking) technique is poor, samples may 'fail' on analysers – generating a non-numeric result. We found variation in the number of 'failed' samples, with EDs having a higher rate (1 in 12) than primary care, where there may be more experienced phlebotomists. We recommend networks work with phlebotomy teams to identify any issues affecting the quality of samples, and address these.

Urine sample collection issues

We found six-fold variation in the rejection of urine samples. We recommend all networks and trusts audit processes for urine collection and address any issues.

Labelling samples appropriately

Incorrect sample labelling can cause significant harm to patients, especially in relation to blood transfusion. Using the NHS number consistently (where appropriate) is a simple way to avoid this harm. We recommend that networks identify areas of inconsistent use, and address any issues.

Stabilising samples

If samples are not stabilised quickly, they can become unusable. To examine this, we looked at potassium tests, which deteriorate without stabilisation. We found variation:

- between samples collected in summer compared with winter, suggesting that temperature differences during transport had affected sample quality;
- in the number of patients who had been admitted to ED following tests showing potentially incorrect high potassium levels, suggesting a problem in either sample collection or transport.

We explore potential solutions to the problems, and recommend that networks audit their own data and rectify identified problems.

Are the samples delivered to the lab on time?

Looking at the impact of transport on turnaround times

We found variation in the total turnaround of test requests from the ED: the time taken between the sample being collected and receipt of results.

Some trusts are using mini-labs to improve turnaround times. We recommend that trusts also investigate dedicated portering or air tube transport as potentially cheaper solutions.

Where mini-labs are used, we give guidance on their proper use.

Electronic requesting: the gateway to other quality enhancements

We saw variation in how trusts are using electronic requesting. We see this as a basic requirement of modern pathology, which enables many of the improvements suggested in our report. We therefore recommend that networks implement this as standard.

Clean through

Understanding variation and minimising error

We recommend that labs continue to re-evaluate their quality control and quality assurance mechanisms, and that networks consider benchmarking labs' use of these.

Using quality assurance to minimise error: acute kidney injury (AKI) flags

We found significant variation in the number of AKI flags generated across the country, and recommend urgent action at national level to identify and rectify the causes of this variation.

Minimising error in low-volume tests

We saw that some centres were undertaking low volumes of specialist testing, which may not guarantee a high-quality service. We explore potential solutions to this issue.

Processing results in a clinically relevant timeframe

We found variation in turnaround time for tests that are sent to off-site specialist labs. We found that electronic lab-to-lab referrals and messaging systems were effective in speeding up these results, and therefore recommend increasing the use of these systems.

Improving lab oversight of Point of Care Testing (POCT)

We found that a substantial proportion of POCT happens without lab oversight, despite this being a Medicines and Healthcare products Regulatory Authority (MHRA) requirement. We recommend that labs work with POCT providers to ensure lab oversight.

Clean out

Results that describe normality for that patient – reference intervals

We look at some of the challenges with reference intervals, which are used to define ‘normal’ results. We found variation in the use of these, despite existing national guidance for some analytes. We recommend network-level and national actions to address this variation.

Results that help to define next actions clearly

We found variation in the ‘action limits’ used – the level at which clinicians should consider action. We recommend that networks follow national guidance, and continue to provide interpretative guidance to requestors.

Results that are visible when they are needed

We look at how standard turnaround times need to reflect the urgency of the test.

We found variation in how quickly test results were available for different settings, with different implications for each.

- In ED (where results are needed urgently): issues are similar to transport issues above.
- For inpatients (where results are generally needed in the afternoon): we recommend that trusts identify and work to reduce any phlebotomy-related delays.
- For primary care and community testing: we identified problems where tests are analysed out of hours, and test results phoned through urgently. This can cause problems for out-of-hours services and distress for patients. We look at potential solutions for this problem.

Applying the Clean Framework to end-to-end pathways for a sentinel condition

As an example, we look in detail at how the Clean Framework could help with the diagnostic pathway for venous thromboembolism. We make recommendations, based on the Clean Framework, for improving this pathway.

The three foundations underpinning the Clean Framework

This section covers the systemic changes required to deliver the Clean Framework and create a true End-to-End Pathology service. The three foundations that we need to rebuild are: Quality; Data and digital delivery; and Service delivery.

Foundation 1: Quality

Quality that flows from the local level outwards

We make recommendations on how to refocus on quality at every level, from lab to national initiatives.

Establishing network-wide standards and standardised national diagnostic pathways

We look at how variation could be addressed by:

- Creating consistent network-wide standards for many of the suggested measures discussed in the Clean Framework (such as Care Sets, reference intervals, action limits etc), based on peer-to-peer benchmarking and consensus;
- Sharing these effectively with all users;
- Building them into quality assurance and audit processes.

Where useful, these standards can also be collected by the National Pathology Board (NPB, previously known as the National Pathology Implementation Optimisation Delivery Group (NPIODG)) and become national standards, involving appropriate national bodies.

Improving lab quality: making greater use of External Quality Assessment (EQA) information

We suggest that the NPB can work with the National External Quality Assessment Service (NEQAS) and equipment manufacturers to make greater use of information uncovered during EQA processes. We also welcome the establishment of an EQA oversight board by the Royal College of Pathologists (RCPath).

Reshaping accreditation via the United Kingdom Accreditation Service (UKAS)

We suggest a paradigm shift for accreditation in the UK to better cover the end-to-end pathway, regardless of setting. We suggest ways that UKAS could work with the pathology community to evolve clinical accreditation to achieve this shift, based on how we believe ISO15189:2012 will evolve.

The role of practising clinicians in embedding quality

We recommend that working pathologists become more actively involved in the accreditation process by taking on assessment roles, and suggest ways that labs could encourage this.

Speeding adoption of new technology

We look at potential ways to speed up the validation and adoption of new technology, reducing the burden on individual labs.

Improving accreditation for POCT

We note the rapidly expanding role of POCT in diagnostics, and suggest ways that UKAS can work together with the pathology community to bring POCT more fully into the accreditation process, using a wider interpretation of ISO15189:2012 and ensuring that accreditation becomes more meaningful in the POCT sector.

Improving regulation for In-Vitro Diagnostic (IVD) devices

Similarly, we suggest ways that variation can be reduced in IVD devices, which are becoming more widely available. We look at how a group set up to approve devices during COVID-19 could become an archetype for this process.

Trust and network governance

We recommend more holistic management of shared services such as portering and phlebotomy, and recommend ways that labs, networks and trusts could work together to establish co-ownership models.

Foundation 2: Data and digital delivery

The urgent need for data interoperability

We look at the current urgent need for a national roadmap to establish common data standards to underpin all future digital initiatives, and call on the NPB to co-ordinate this with NHSX.

Patient-focused and clinician-focused pathology

We show how data interoperability and technology should ease the patient's healthcare journey, as well as easing administrative burdens on clinicians, and suggest ways in which this could develop. We highlight the importance of integrating results into clinical systems.

Internal lab systems

We show findings on how electronic referral and messaging systems were essential in the response to COVID-19, and recommend paperless end-to-end systems for all pathology.

Using data for analysis

We look at the huge opportunities for using pathology data to identify disease trends and plan accordingly, observe population or demographic changes, or identify issues with current diagnostic practices. We recommend making data accessible to support this analysis, and the creation of a common repository to collate the necessary data. We also look at various initiatives already in progress in this area and the valuable interpretation they can provide.

Embracing new technologies in pathology

We look at the use of digital pathology, decision support systems and artificial intelligence (AI) in pathology, focusing on some key examples of where these innovations are adding value, easing resource issues, and enabling better quality interpretation.

Foundation 3: Service delivery

The future of pathology delivery: flexibility above all

We explain how we see pathology developing with multiple inputs, multiple pathology settings, and multiple outputs in the request-result cycle, and note that pathology must be flexible to adapt to this rapidly changing landscape – as it did during the COVID-19 pandemic.

Pathology networks

We recommend that networks are implemented using locally relevant models, including Integrated Care Systems (ICs) where useful, and note how responding to local considerations may help to build successful networks.

Potential network roles

We see networks as engines of quality above all, and list roles that networks can take on to ensure this focus, such as creating centres of excellence, sharing and benchmarking best practice, and encouraging integration across the healthcare system, especially with primary care and community providers.

Taking a strategic approach to pathology delivery

We suggest how networks can develop a strategic approach to delivering different types of test, from POCT up to specialist testing. We also look at how the NPB can ensure there is sufficient national coverage for specialist testing.

Developing leadership in networks

During our deep dives, we noted the vital importance of strong, proactive leadership in networks, and recommend that networks engage with national guidance in developing clinical leadership skills.

Procuring as networks

We suggest ways that networks could achieve efficiencies and value by co-ordinating their procurement activities.

Minimising error and wastage in blood transfusion

Using data from the Blood Stocks Management Scheme, we show variation in wastage of various blood products, and recommend ways for trusts to identify and address any concerns.

Workforce

Using information provided by the RCPATH and the Institute of Biomedical Science (IBMS), we identify challenges in the pathology workforce, and suggest ways to approach these. We especially look at ways to upskill and retrain a variety of staff to take on higher-level work, and create a more diverse and flexible workforce, ready to meet future challenges.

Finance

We look at ways to restore and encourage the balance between value and productivity in pathology, including showing how recommendations throughout this report will help to balance value with cost.

Litigation

As with all GIRFT programmes, we look at ways to reduce the impact of litigation in pathology. In addition to the specific areas outlined in the table, the report has identified a total spend of £107.4m on litigation over a five-year period. Implementation of the GIRFT programme's five-point plan should improve patient safety and reduce litigation costs related to pathology.

Our five guiding principles

These principles reflect our learnings across the whole project. They are both a summary of those findings, and a guide to initiatives resulting from the report.

1. Centre our focus on the patient

- Right test, right time, right answer: consider everything through the eyes of the patient.
- Seek to improve patient understanding of tests and results.
- Ensure testing and results fit into the patient's life, provide benefit and avoid harm.

2. Prioritise quality from end to end

- Expand our view to assure quality throughout the process (End-to-End Pathology).
- Ensure quality is agnostic of setting, system or method.
- Improve quality assurance and accreditation mechanisms.
- Improve governance of pathology delivery in all settings.
- Ensure supporting systems are directed towards quality.

3. Support best clinical working practice

- Make it easier for clinicians and patients to choose and use the most effective tests.
- Continuously improve the tools pathologists use every day.
- Work towards best practice consensus.
- Embrace innovation: new tests, new methodology, new settings.

4. Build a single-service, mutually supportive team

- Dismantle current silos to become a more collaborative, single-service team across all settings; proactively sharing influence and governance.
- Work holistically and flexibly in labs, trusts, networks and regions, supported by national governance and leadership.
- Develop and support pathology leaders at all levels.
- Learn from each other: from all variation, warranted or unwarranted.
- Encourage and grow proactive, more agile approaches.
- Integrate all settings: from primary care and community through to secondary and tertiary care.
- Focus networks on delivering quality: in testing, in peer-to-peer sharing, in career progression, in knowledge sharing.
- Support a flexible workforce and nurture progression.

5. Future-proof pathology with strong data and digital foundations

- Continuously improve data interoperability, integration, utility and visibility.
- Improve and enable data analysis.
- Embrace and grow digital working.

Overview of recommendations

Core recommendations

Recommendation	Actions	Owners	Timescale
1. Establish the Clean Framework as the governing ethos, overarching quality framework, and basis of pathology accreditation throughout the healthcare system.	a UK Accreditation Service (UKAS) to work with the pathology community to redevelop accreditation using the Clean Framework as the basis of engagement with the ISO standard, with oversight from the National Pathology Board (NPB).	UKAS, labs, pathology networks (PNs), Primary Care Networks (PCNs), NPB	Pilots to be running within six months of publication
	b To deliver action 1a, labs and PNs to lead in setting up mechanisms for engaging with all teams to embed the Clean Framework across the end-to-end pathway, starting with primary care and emergency departments (EDs).	Labs, PNs	Progress within 12 months of publication
	c Labs, PNs and PCNs to develop a plan to: <ul style="list-style-type: none"> • apply this approach consistently to all settings, including Point of Care Testing (POCT); • ensure all POCT is supported by an accredited lab in line with Medicines and Healthcare products Regulatory Agency (MHRA) guidance. 	Labs, PNs, PCNs	12 months of publication
2. Establish network-wide standards, and where useful agree at national level.	a Labs and PNs to share peer-to-peer learnings on best practice in implementing the Clean Framework, and use these to establish and monitor network standards to establish end-to-end quality, including: <ul style="list-style-type: none"> • Care Sets; • diagnostic pathways; • decision support; • test specifications, to include: <ul style="list-style-type: none"> - reference intervals; - action limits; - turnaround times; - strategy for dealing with specialist tests; - stabilisation requirements; - sample quality requirements; • guidance for patients. 	Labs, PNs	Progress within 12 months of publication
3. Establish electronic requesting and messaging as standard in all labs and with all requestors.	a Labs to work with PCNs to ensure that electronic requesting is standard for all primary care requesting, where the percentage of requests received electronically from PCNs is below 80%, in line with the NHS Long Term Plan (NHS LTP).	Labs, trusts, PNs, PCNs	For immediate action
	b Labs, trusts and PNs to have agreed plan and timescale for introducing electronic requesting in other areas, where current percentage of requests received electronically is below 80%, in line with the NHS LTP.	Labs, trusts, PNs	Within 12 months of publication
	c Labs, PNs and PCNs to continuously monitor and update electronic requesting system to reflect feedback and guidance changes and to improve decision support.	Labs, PNs, PCNs	Following actions 3a and 3b

Core recommendations (continued)

Recommendation	Actions	Owners	Timescale
4. Future-proof pathology by developing a national roadmap for data interoperability and end-to-end paperless pathology.	<p>a The NPB to co-ordinate with NHSX to establish a roadmap for common data standards (and a realistic national commitment to drive this forwards), with clear aims of:</p> <ul style="list-style-type: none"> integrating results from any setting, including POCT and Community Diagnostic Hubs, and delivering results to any setting; ensuring data supports patient-focused pathology, including support for innovations such as wearables; ensuring data supports clinicians via improved decision support/AI, better interpretation and display, and automated reminders. 	NPB, NHSX	For immediate action
	<p>b Once the roadmap is established, the NPB to ensure that all subsequent initiatives use the data standards.</p>	NPB	Following action 4a
	<p>c The NPB to commission a data repository to enable analysis and comparison of local, network and national data.</p>	NPB	For immediate action
5. Create flexible pathology networks that reflect local needs, feed into national testing needs, and that are primarily engines of quality.	<p>a PNs to develop a plan to suit local needs, which could include assigning network centres of excellence, or sharing with other networks.</p>	PNs	Within 12 months of publication
	<p>b The NPB to ensure there are enough national centres of excellence to give sufficient specialist testing coverage across the country.</p>	NPB	Following action 5a
	<p>c PNs to:</p> <ul style="list-style-type: none"> develop network training plans, collecting data and identifying gaps; where a gap cannot be resolved locally, raise these nationally; ensure the workforce can flow around the network to improve resourcing and enhance career progression; ensure staff can access training, mentoring and tutoring within the network. 	PNs	Following action 5a
	<p>d PNs to use the NHS Clinical leadership framework to improve leadership in pathology networks.</p>	PNs	Following action 5a

Detailed recommendations

Recommendation	Actions	Owners	Timescale
6. Interrogate all tests to ensure all are: <ul style="list-style-type: none"> based on a valid clinical question; necessary, appropriate and sufficient to answer that question. 	a PNs to: <ul style="list-style-type: none"> develop network-wide Care Sets, in all possible areas, including primary care, ED and specialty; ensure guidance available as decision support; continually monitor, benchmark and review Care Sets. Labs to implement these Care Sets and promote their use to all requestors.	Labs, PNs	Progress within 12 months of publication
	b PNs to: <ul style="list-style-type: none"> within Care Sets, disaggregate common testing profiles as a network, as much as possible, working closely with primary care colleagues; remove urea and chloride from primary care testing profiles; eliminate routine co-ordering of C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) tests; identify and remove all other tests of limited clinical value; ensure requestors can still request these tests if they have a specific reason to do so. Labs to implement in line with above.	Labs, PNs	Progress within 12 months of publication
	c PNs to: <ul style="list-style-type: none"> check all minimum retest intervals are aligned to RCPATH guidance; build intervals into decision support and electronic requesting; where this is not possible, impose lab limits; educate requestors on the proper use of minimum retest intervals. Labs to implement in line with above.	Labs, PNs	Progress within 6 months of publication
7. Reconfigure transport and sample collection services to ensure that samples reach the lab in the best possible condition.	a Labs, trusts and PNs to monitor non-numeric potassium levels, and, if 5% or greater, intervene urgently to address issues identified.	Labs, trusts, PNs	For immediate action
	b Labs, trusts, PNs and PCNs to identify where there is a difference between summer and winter potassium levels of 0.5mmol/L at individual collection point level (for example an individual surgery), and wherever this occurs, intervene urgently to address issues identified.	Labs, trusts, PNs, PCNs	Progress within 6 months of publication
	c Labs, trusts, PNs and PCNs to audit processes for collection of urine, and address issues identified.	Labs, trusts, PNs, PCNs	For immediate action
	d Labs, trusts, PNs and PCNs to improve current monitoring of time of critical events along the end-to-end pathway, for example time of collection, and audit and address all identified issues.	Labs, trusts, PNs, PCNs	Within 12 months of publication
	e UKAS to link portering and transport quality to accreditation.	Labs, trusts, PNs, PCNs	Pilots to be running within 6 months of publication
	f Labs, trusts and PNs to ensure portering and transport arrangements are fit for purpose in line with anticipated UKAS approach to accreditation.	Labs, trusts, PNs	To be ready to meet UKAS accreditation within 6 months

Detailed recommendations (continued)

Recommendation	Actions	Owners	Timescale
8. Ensure all requestors are using NHS numbers consistently (apart from known exceptions).	a Labs, trusts, PNs and PCNs to identify barriers to use of NHS number, and address with requestors, aiming for a minimum of 90% of requests using the NHS number, starting with primary care and ED.	Labs, trusts, PNs, PCNs	For immediate action
9. Urgently investigate acute kidney injury (AKI) flags to understand variation.	a The NPB, in conjunction with the Renal Association and UK Renal Registry, to commission research to identify and, if appropriate, address causes of variation.	NPB	For immediate urgent action
10. Audit and overhaul approach to action limits, including out-of-hours protocols.	a Labs and PNs to audit results communicated out of hours, working with primary care colleagues, and change strategy where the numbers are causing problems for users or patients.	Labs, PNs	Within 6 months of publication
11. Ensure appropriate turnaround times, and address identified issues.	a Labs and PNs to identify pathways where turnaround times are impacting on patient care, and address issues.	Labs, PNs	Within 12 months of publication
	b Labs and PNs to report potassium from ED within one hour of collection.	Labs, PNs	Within 12 months of publication
	c Labs and PNs to ensure blood cultures are loaded onto analysers within four hours of collection.	Labs, PNs	Within 12 months of publication
	d Labs and PNs to ensure neonatal blood cultures are reported within 36 hours of the sample being taken, in line with NICE guidance.	Labs, PNs	Within 12 months of publication
12. Develop an integrated venous thromboembolism (VTE) pathway for network use.	a Trusts, PNs and PCNs to establish an agreed pathway for VTE diagnosis and management.	Trusts, PNs, PCNs	Within 12 months of publication
13. Make better use of EQA information at national level.	a The NPB and NEQAS to work together to establish national co-ordination and to ensure fuller use of the available information, also engaging with manufacturers to achieve greater consistency.	NPB, NEQAS	Within 2 years of publication
	b The RCPATH EQA Oversight Board to: <ul style="list-style-type: none"> • use EQA data to ensure methodologies are of an acceptable quality, with harmonisation where possible; • set performance standards that manufacturers must meet for tests supplied to the NHS, ensuring that a manufacturer's method is fit for purpose. 	RCPATH EQA Oversight Board	Within 2 years of publication
14. Establish a proactive, integrated approach to ensure new technology can be adopted at speed.	a The NPB to co-ordinate implementation of rapid technology framework.	NPB	Progress within 12 months of publication
15. Improve regulation of in-vitro diagnostic (IVD) devices.	a MHRA to work with the pathology community to develop a structured and risk-based UKCA governance framework.	MHRA	Within 2 years of publication

Detailed recommendations (continued)

Recommendation	Actions	Owners	Timescale
16. Increase diversity of staff involved in the accreditation process.	a Labs and PNs to make it easier for working pathologists to become quality leads, by allocating time for practitioners to develop quality initiatives and participate as assessors, and funding this as part of Continuous Professional Development (CPD).	Labs, PNs, UKAS	Within 2 years of publication
17. Embrace and support innovation in pathology, including digital pathology and improved decision support.	a The NPB to work with NHSX and NHS Digital to drive further development of digital pathology, including remote reporting, improved decision support, and artificial intelligence (AI) assistance, in line with the NHS LTP.	NPB, NHSX, NHS Digital	Within 2 years of publication
	b Labs, trusts and networks to plan for implementing digital pathology, as a means to address workforce challenges and improve patient experience.	Labs, trusts, PNs	Within 12 months of publication
18. Interrogate usage and wastage data for blood products, and address identified problems.	a Using Blood Stocks Management Scheme data, trusts to benchmark performance against other trusts and work to understand and address issues identified.	Trusts	Ongoing
19. Identify and close workforce gaps at a national level.	a Building on network-level metrics identifying gaps, the NPB to work with training bodies and Health Education England (HEE) to ensure a wide range of intake and increase the number of training positions available, to meet anticipated future demand.	NPB, PNs, HEE	Within 2 years of publication
	b Labs, trusts and PNs to allocate time for biomedical scientists to mentor and tutor colleagues to higher levels to fill gaps in the medical workforce in all relevant specialties.	Labs, trusts, PNs	Within 2 years of publication
20. Review funding models for pathology.	a NHS England and NHS Improvement to explore ways to incentivise effectiveness in pathology alongside continuing the drive for efficiency.	NHS England and NHS Improvement	Discussions to begin immediately

Detailed recommendations (continued)

Recommendation	Actions	Owners	Timescale
21. Reduce litigation costs by application of the GIRFT programme's five-point plan.	a Clinicians and trust management to assess their litigation claims covered under Clinical Negligence Scheme for Trust (CNST) notified to the trust over the last five years.	Trusts	For immediate action
	b Clinicians and trust management to discuss with the legal department or claims handler the claims submitted to NHS Resolution to confirm correct coding to that department. Inform NHS Resolution of any claims which are not coded correctly to the appropriate specialty via CNST.Helpline@resolution.nhs.uk	Trusts	Upon completion of action a
	c Once claims have been verified, clinicians and trust management to further review claims in detail including expert witness statements, panel firm reports and counsel advice as well as medical records to determine where patient care or documentation could be improved. If the legal department or claims handler needs additional assistance with this, each trust's panel firm should be able to provide support.	Trusts	Upon completion of action b
	d Claims should be triangulated with learning themes from complaints, inquests and serious untoward incidents (SUI)/serious incidents (SI)/Patient Safety Incidents (PSI) and where a claim has not already been reviewed as SUI/SI/PSI we would recommend that this is carried out to ensure no opportunity for learning is missed. The findings from this learning should be shared with all staff in a structured format at departmental/directorate meetings (including multidisciplinary team meetings, Morbidity and Mortality meetings where appropriate).	Trusts	Upon completion of action c
	e GIRFT clinical leads and regional teams to share with trusts examples of good practice where it would be of benefit.	Trusts	For continual action throughout GIRFT programme

What is pathology?

Pathology is the study of disease. It is the bridge between science and medicine, and underpins every aspect of patient care.

The staff working in pathology study samples of cells, tissues, blood and other fluids from patients' bodies to:

- investigate infections and diseases, both in symptomatic patients and as part of screening programmes;
- guide doctors on their options for treating diseases;
- monitor chronic diseases, such as diabetes;
- ensure patients receive the correct, properly prepared blood products or transplanted organ;
- learn how to prevent other people from becoming ill in the same way.

Pathology tests are requested by providers in primary care, the community, and secondary care. Every time a patient gives a blood or urine sample, has a swab or a biopsy taken, has an allergy test, or donates or receives blood or a body organ, this will usually involve the pathology team. To give an overview of pathology's impact throughout the healthcare system:

- Pathology labs in England carry out 1.12 billion tests per year, representing £2.2 billion of NHS funding² – roughly 20 tests per person in England each year.
- Most patient interactions with the NHS involve pathology services, equal to about 200 million requests for tests, or sets of tests, per year.³
- Each year, two million blood donations are collected and distributed across the UK.⁴

Pathologists also make important contributions to teaching and to research, advancing medicine and devising new treatments to fight infections and diseases like cancer, and introducing innovative diagnostics to improve patient care. In the last 100 years, there have been significant reductions across the world in illnesses such as polio, as well as major advances in blood transfusion, vaccination and treatment of inherited conditions, due to the pioneering work of pathologists.⁵

Pathology supports quality throughout the healthcare system. Effective diagnostic pathology investigations increase efficiency and make cost savings in other areas of the health service, by focusing treatment correctly and avoiding unnecessary interventions. Most importantly, a quality pathology service is vital for patients, to ensure they receive the best patient care and that harm is prevented.

Current service organisation

In England, 141 trusts include a pathology lab: by the end of the GIRFT process the GIRFT team will have visited all of these, either in person or in virtual deep-dive visits. Most (but not all) hospitals have a pathology lab; others are supported by labs within a pathology network.

Pathologists work in laboratories (generally known as labs, the term we have used throughout this report), which may be in hospitals or in other locations, in clinics and on hospital wards.

Within pathology, there are several specialties. Most hospital labs will include the 'major' specialties of haematology (including blood transfusion), clinical biochemistry, microbiology and cellular pathology (also called histopathology). These specialties support clinicians working in all areas of healthcare. For this reason, we have focused this first GIRFT pathology report on these specialties, particularly the blood sciences (haematology and clinical biochemistry). For more information on the other specialties within pathology, see <https://www.rcpath.org>.

NHS Blood and Transplant (NHSBT) is a national service established as a Special Health Authority, and an example of an area where pathology combines both diagnostics and treatment. The NHSBT collects, tests, processes and distributes blood and transplant organs, and also carries out clinical research in transfusion and transplantation. In larger hospitals, especially transplant centres, there will be a greater proportion of dedicated and specialised staff, whereas in smaller hospitals some tasks, such as cross-matching and blood stock management, will be carried out by general lab staff.

² NHS Improvement: <https://www.improvement.nhs.uk/resources/pathology-networks>

³ NHS England, National Pathology Programme, 2014. Digital First: Clinical Transformation through Pathology Innovation. <https://www.england.nhs.uk/wp-content/uploads/2014/02/pathol-dig-first.pdf>

⁴ NHS Blood and Transplant: <https://www.nhsbt.nhs.uk/what-we-do/blood-services>

⁵ The Royal College of Pathologists: <https://www.rcpath.org/discover-pathology/what-is-pathology.html>

The pathology workforce is primarily made up of medically qualified pathologists, clinical scientists and biomedical scientists. According to recent statistics, in the UK there are:

- 22,000 biomedical scientists, ranging from trainees to advanced clinical practice or consultant-level staff, along with high-level operational and service managers;
- 3,575 pathologists, including consultants, specialist registrars, and junior doctors;
- 264 consultant clinical scientists, with an equal number of trainees and other grades of clinical scientist.

Biomedical scientists, pathologists and clinical scientists work in multidisciplinary teams (MDTs), spread across the pathology specialties.

For more about the staff working in pathology, see the *Workforce* section on page 114.

About our analysis

Our review followed an adapted GIRFT process (see page 136). This ensured we could offer evidence-based findings and recommendations. Our recommendations are based on clinical data, deep-dive visits, current best practice and clinical experience of providing pathology services in the NHS and other settings.

- First, we gathered all of the relevant existing data related to pathology, including from Hospital Episode Statistics (HES).
- Recognising that there was little national pathology data available that would provide useful comparisons for local labs, we designed a questionnaire for all pathology labs to complete, which we sent to 141 trusts across England.
- 135 returned questionnaires; however not all response boxes were completed by all trusts. The number of relevant responses is noted on each chart.
- Using this data, we benchmarked providers on key measures to identify variation in practice and outcomes, and developed a data pack specific to each trust. These data packs provided insights into the way each lab was functioning. Over 70% of the information in the GIRFT pathology data packs came from trusts' own completed questionnaires.
- We then visited the pathology networks or trusts face-to-face or (during the COVID-19 pandemic) via virtual deep dives. We presented the data and discussed our observations with clinicians, senior management and all those involved in delivering services. The visits explored how pathology services are provided to primary care patients, emergency department patients and inpatients at each trust. We discussed the variation in the data and how the trust or network stood in relation to their peers. These discussions then informed our findings and recommendations.
- As around half of pathology requests come directly from primary care, we asked trusts to invite primary care colleagues to the deep dives where possible. Where this happened, it led to useful discussions, helping to give the primary care perspective on many of the issues covered.
- The original intention was to visit 141 trusts across England in person. However, we had carried out 37 visits when deep dives were suspended due to COVID-19. In their place, we undertook virtual deep dives via video conference from the end of June 2020.

Data sources

As well as the HES data, we have also used GIRFT's own research and a range of other sources. These include:

- NHS England and NHS Improvement Model Hospital;
- UK Antimicrobial Resistance Diagnostics Collaborative Blood Culture Survey;
- Public Health England Antimicrobial Resistance data – Fingertips;
- Blood Stocks Management Scheme data;
- NHS England and NHS Improvement Diagnostic Census Data;
- Public Health England mandatory surveillance;
- National Pathology Exchange (NPEX);
- The RCPATH's workforce data;
- National External Quality Assessment Service (NEQAS) Tumour Marker scheme;
- OpenPathology;
- OpenSAFELY.

When looking at some issues, such as the use of common testing profiles, we used aggregate data. This is because a lab cannot know whether tests are appropriate or sufficient for individual cases, so we can only look at the overall picture over a large group of tests.

What is covered in this report

Due to the exceptional range and diversity of pathology specialties, the nature of the GIRFT deep-dive visits, and the restrictions in the data and time available, the process was not designed to cover all potential areas of pathology or all current and future challenges.

Instead, we chose a selection of metrics that included the more common pathology tests where data was readily available, many of which fall under clinical biochemistry. These then acted as a barometer of the service, rather than attempting to cover the entirety of a very complex group of specialties.

Many of our findings may appear specific: however, they are applicable to all specialties. Where we have used data from one particular specialty, this does not mean that the recommendation only applies to that specialty. We have framed our recommendations to make this clear. We therefore believe the report to be highly relevant and applicable across all areas of pathology.

We avoided some areas, particularly the histopathological analysis of cancer, as other GIRFT workstreams were anticipated to cover this. Owing to a lack of sufficient data, we also did not cover some other areas, such as mortuary services.

In line with the standard GIRFT remit, the workstream objectives, and available data, we also did not cover labs outside of the NHS trust structure:

- private labs;
- NHSBT labs;
- genomics hubs;
- Public Health England labs.

Please note that GIRFT only covers NHS England, and does not cover the devolved nations, although we hope that learning from the project may be of use to other nations.

Learning from past initiatives

This report focuses on the current situation in NHS pathology, using the data gathered before and during our GIRFT visits. However, we have been mindful of previous reports, and reference these as relevant throughout our report.

The Barnes Review

In 2014, Dr Ian Barnes published the Pathology Quality Assurance Review (the Barnes Review⁶): an assessment of the quality assurance frameworks and governance for pathology. The quality of NHS pathology services compared favourably with the rest of Europe. Pathology has a dedicated and highly skilled workforce, good internal quality assessment and quality management systems, and mature external quality assurance. Together, these provide a safe, reliable and effective service.

However, the Barnes Review also found that:

- different parts of the country have different approaches to testing, with variation in provision, methods, turnaround times and communication of results;
- some elements of quality assurance had become outdated;
- there was a need for greater standardisation to provide all patients and their requesting clinicians, irrespective of location, with the best possible access and quality of service from pathology.

⁶ NHS England. 2014. Pathology Quality Assurance Review. <https://www.england.nhs.uk/wp-content/uploads/2014/01/path-qa-review.pdf>

The Carter reports

In 2006, Lord Carter of Coles published the report of the Review of NHS Pathology Services in England, followed up in 2008 with a second report. The main themes of the second report were:

- improving quality;
- improving patient safety;
- improving efficiency;
- identifying the mechanisms for delivering change.

The Carter reports outlined two kinds of recommendations: value-oriented, to improve the quality of the service, and cost-oriented. Pathology colleagues believed that the cost-oriented strategies recommended were being pushed hard, but the resulting savings were not being reinvested in their service. This had then hindered the development of the value-oriented strategies.

The main sections of the report

- **The Clean Framework** (page 27) – **operational recommendations** for local labs to implement in the short term.
- **The three foundations** (page 82) – **systemic recommendations** for networks and national bodies to work towards for the longer-term future of pathology.
- **Workforce** (page 114), **Finance** (page 127) and **Litigation** (page 129): looking at other operational issues.
- **Learning from the COVID-19 pandemic** – *Appendix 1: The coronavirus pandemic and lessons for pathology services* on page 146: A snapshot of current learning on the pandemic and lessons to take forward for the pathology service during recovery.

Findings and recommendations

End-to-End Pathology: improving quality across the health system

In producing this report, our key objective is to widen the focus of national and regional bodies, networks, trusts, and labs themselves, to encompass the entirety of the service provided by pathology: from the moment a clinician starts to consider a test, to the moment the patient receives – and seeks to understand – their results.

Pathology is not confined to a lab; ‘good’ pathology should not be defined by the number of tests performed; quality does not solely reside in the temperature set on a fridge. Pathology is not about results; it is about answers – **the right test, at the right time, with the right answer.**

We have therefore made recommendations that reach far beyond a lab’s walls: into primary care, transport logistics, accreditation services, and to regional and national bodies. We hope to achieve a paradigm shift that brings governance and consistency to the practice of pathology, in all its forms and at all stages of the diagnostic journey: from a patient taking a pinprick sugar level test in their pharmacy, to the guidance given to a GP interpreting results for their patient.

Above all, we need to restore pathology’s focus on the patient. How do we accurately, consistently and effectively answer the patient’s two most important questions: **Am I ok?** and **Can I trust your answer?**

These questions are the real meaning, and true reach, of pathology, and they are the basis of our continuing theme of patient-centred pathology.

Focusing on how patients see quality: the outside-in viewpoint

When we ask patients about health services, as we have in previous research,⁷ they generally list similar, simple requirements. They want to feel cared for, and they want to trust those looking after them. We can translate this into a universal purpose statement for pathology:

To help people who need tests, and the people caring for them, make informed decisions about that care.

We call this an ‘outside-in’ way to judge the success of laboratory medicine. In contrast, the existing, ‘inside-out’ view tends to define success according to criteria such as cost or meeting internally derived accreditation standards.

Our recommended approach to creating patient-focused quality

Our previous research⁸ demonstrated how far short we fall from our patients’ expectations. We saw:

- patients commonly having little idea why tests were being performed;
- patients who had received results for tests they did not know were being done;
- patients who had gained false reassurance from misunderstanding tests or results;
- numerous examples of tests that were not necessary to answer the clinical question being asked, often leading to significant harm from ‘treating the result’;
- conversely, evidence of delayed and suboptimal decision making due to a failure to carry out appropriate tests.

Once samples arrived at the lab, other problems became obvious. We saw:

- samples arriving in a state that compromised processing;
- success defined from the viewpoint of the lab, with insufficient attention to error and variation as they affected the patient;
- timeliness primarily defined by the process, rather than focused on what was clinically necessary or optimal to enable an informed decision;
- results presented in unclear ways that were easily misunderstood;
- results reflecting what was normal for a population, but which often did not help clinicians to determine significance for the individual.

^{7,8} Whiting, D., Croker, R., Watson, J., Brogan, A. and Lewis, T., 2019. Optimising laboratory monitoring of chronic conditions in primary care: a quality improvement framework. <https://bmjopenquality.bmj.com/content/8/1/e000349>

These findings, from the GIRFT process and from previous research, demonstrate a fundamental problem: how do we answer individual, unique, highly contextual needs that cannot be reduced to standardised outcomes? How do we answer that first fundamental and specific patient question: **Am I ok?**

Building on these findings, we believe pathology services need ways of measuring performance that are practical and meaningful, but also individual: ways that do not assume that the same outcomes matter in the same way to all patients and their clinicians in all circumstances.

We have considered the things that would be near universally true if diagnostic tests were performed with purpose and in ways that add value, regardless of the specific situation. These universal truths form the basis of the Clean Framework, which is at the heart of our recommendations.

The Clean Framework

The Clean Framework is an overarching quality framework designed to help networks and labs widen their focus to include all stages of pathology pathways, while focusing on the needs of the patient and user as the true meaning of quality. The framework describes the elements that need to be in place to ensure we can consistently deliver **the right test, at the right time, with the right answer**. It is based on our observations from several sources: questionnaire feedback, deep dives, and examples of innovative practice in networks and trusts.

The Clean Framework covers three areas: Clean in, Clean through and Clean out. Lab clinicians will recognise these as the pre-analytical, analytical and post-analytical stages, but importantly, we have framed them from the perspective of the patient, and the clinician working with them, rather than the perspective of the lab.

In this section, we expand on our recommendations in each stage of the framework.

Clean in

This covers the pre-analytic stage.

To deliver **the right test, at the right time, with the right answer**, these conditions must almost always need to be true:

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.

We have given more detail on each of these areas below.

Are the tests appropriate?

In this part of the framework, we look at approaches to ensuring:

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

Variation in requesting of common analytes

We saw wide variation in how common analytes were requested across the healthcare system, as shown in **Figures 1 and 3**. We know that a significant quantity of tests are generated by a relatively small number of symptom sets. For example, around 25% of tests requested in primary care are related to chronic disease or drug monitoring.⁹ It is likely that the conditions requiring tests will be similarly prevalent across the UK population, so the variation we saw is likely to be caused by differences in requesting patterns.

We looked in detail at primary care and the emergency department (ED). This is because the data provided is most likely to be consistent and straightforward to compare between trusts, and the question being asked is likely to be clear, such as 'does this patient have chest pain of cardiac origin?'

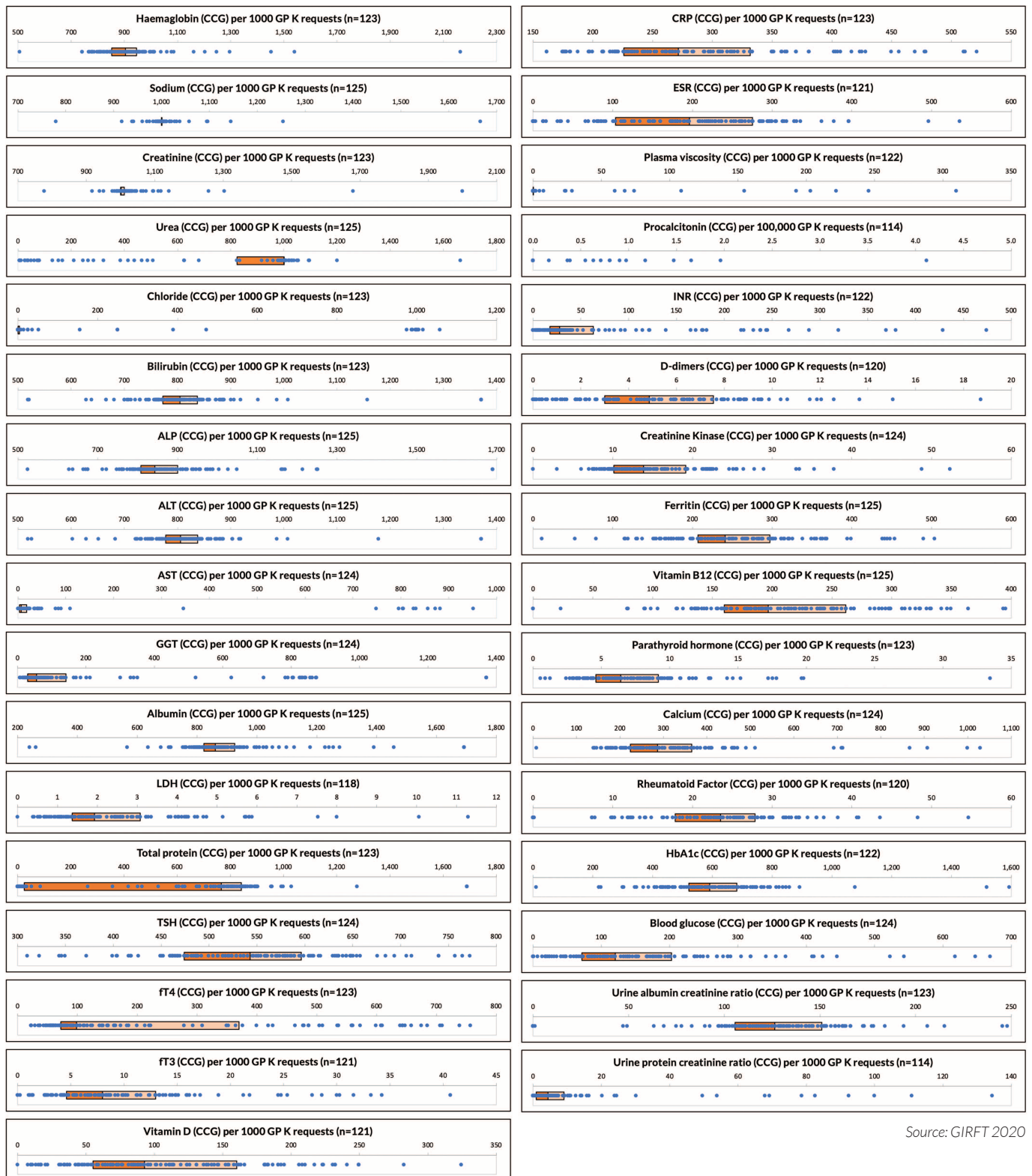
Variation in requesting in primary care

We found large variations in the requesting of blood tests in primary care. For example, we found a four-fold to five-fold variation in the requesting rates of urea and electrolyte tests (U&Es), full blood counts, liver function tests (LFTs) and thyroid function tests (TFTs). The reasons for this variation were unclear.

The following graphs show the variation in requesting rates of common analytes in primary care. While this data is traditionally presented using Clinical Commissioning Group (CCG) population as the denominator, it became clear to us from our deep dives that there are some issues with the aggregated practice list size and ED activity denominators (see *Improving accuracy of population data* on page 98). This has implications for many benchmarking exercises that use CCG population when comparing pathology departments. In order to avoid these potential issues, we show the variation in requesting using the number of potassium (K) test requests as the denominator, as the potassium requests were easily and reliably obtained. This data is used here to illustrate that there are different ways to look at variation, all of which give slightly different results. However, in terms of the overall picture of variation with all these analytes, this is the same whichever denominator we choose to use – large, unexplained and unwarranted variation in practice across the country.

⁹ Data from Northern Devon NHS Healthcare Trust, 2020.

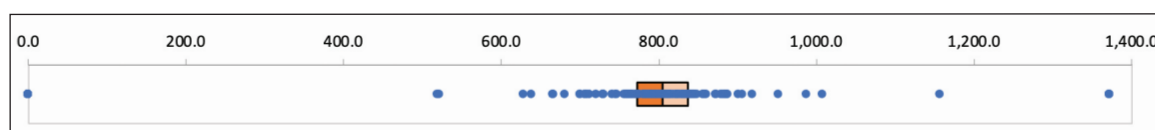
Figure 1: Number of tests per 1,000 primary care potassium requests for various analytes



Source: GIRFT 2020

Part of the underlying problem here is the lack of robust, evidence-based clinical guidelines on how to investigate common conditions, and how frequently to monitor them. As an example, we looked at the number of requests for LFTs (using bilirubin as a proxy) and U&Es (using potassium as a proxy). See **Figure 2** below. This showed that in most areas there was an almost one-to-one relationship between LFT and U&E requests, with 4 out of 5 requests for U&Es also including LFTs. This suggests that GPs may be ordering LFTs and U&Es together by default in many cases, despite a lack of clinical evidence supporting this approach.

Figure 2: Number of bilirubin tests per 1,000 potassium requests in primary care (n=123)



Source: GIRFT 2020

There is often a good reason for requesting a U&E in primary care. For example, this can show end organ damage from chronic conditions, and side effects of common drugs. In fact, most guidelines require annual U&Es for these conditions. However, the same is not true for LFTs, and yet this once relatively rare test has now crept into common use.

As LFTs have become cheaper, there may have been less scrutiny of use, and easier access. This is an unintended consequence of focusing only on cost; equal emphasis must be placed on the value of the test. If we are able to reduce the number of LFTs, there would be a small reduction in expenditure on the test itself – but the biggest wins are likely to be in reduced downstream costs and avoidance of iatrogenic harm (harm caused by unnecessary further investigation and treatment).

These downstream harms and costs are rarely captured in testing recommendations, but are likely to be substantial. In a small study, for a practice with a population of 15,000 people, the follow-up costs of further investigating unnecessary LFTs (as identified by GPs after review of chronic disease monitoring protocol) were £15,000 per year, equivalent to £1 per head of practice population. This would benefit from further investigation into potential cost savings.

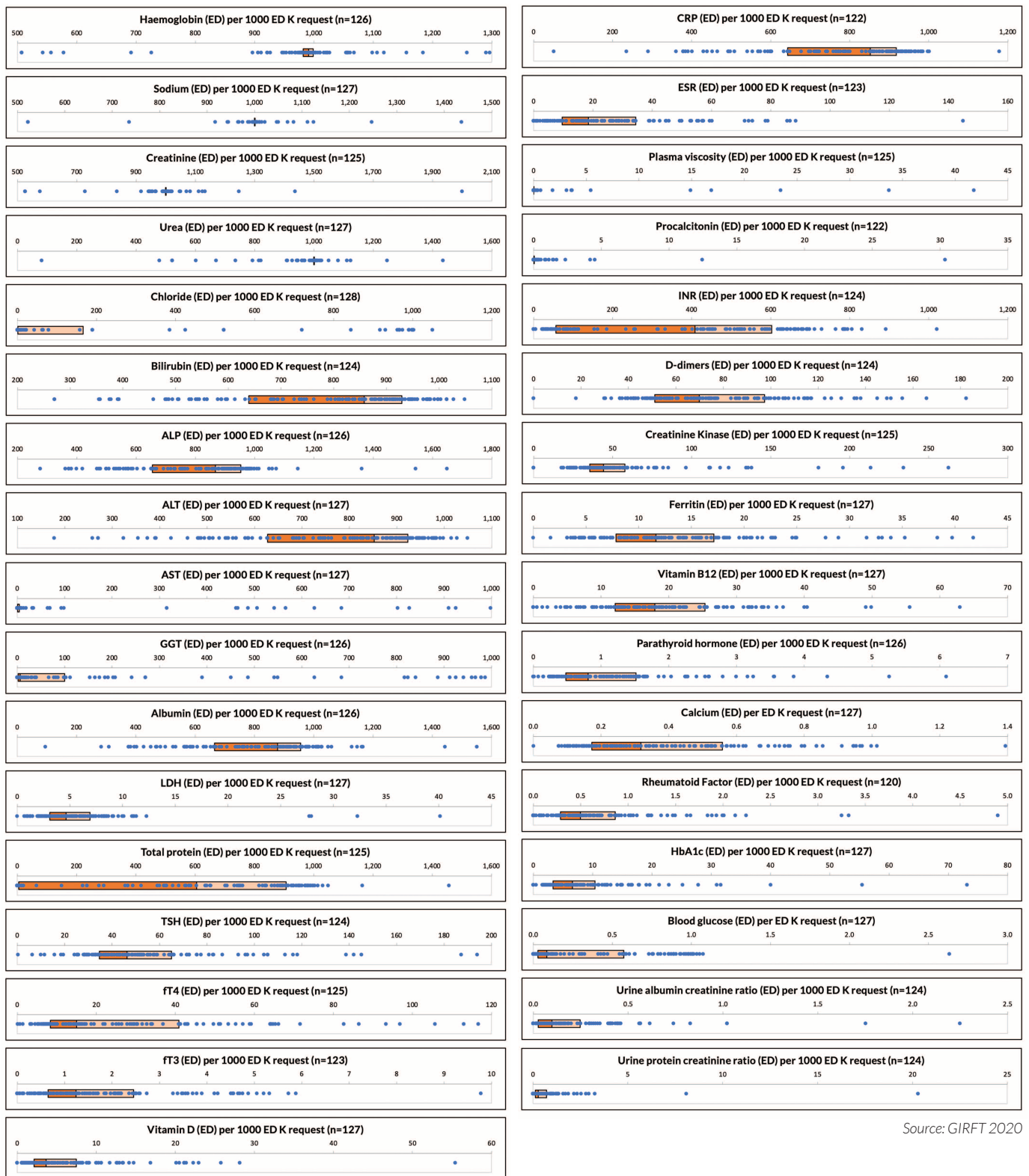
From our deep dives, we know it is possible to improve requesting patterns in primary care through working with primary care colleagues, most notably by using Care Sets (see *Using Care Sets* on page 33). We have seen these improvements in our own experience, and replicated by services that had strong links with primary care.

Variation in requesting of common tests in the ED

We also found large variation in volumes of common tests requested from EDs, with again a four-fold to five-fold variation in the rate for common tests. The reason for this variation is also unclear, as attendances at EDs across the country are likely to be due to similar reasons overall.

The following graphs show the variation in requesting rates of common analytes in ED.

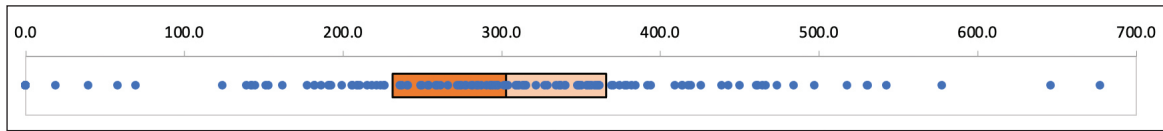
Figure 3: Number of tests per 1,000 ED potassium requests for various analytes



Source: GIRFT 2020

For example, we saw variation in LFT requests in EDs, as shown in **Figure 4** below, again using bilirubin as a proxy.

Figure 4: Number of bilirubin tests in the ED per 1,000 attendances (n=127)



Source: GIRFT 2020

To some extent, the variation we saw between EDs may reflect differences in approach to triage:

- Some EDs take blood early in the triage process, so that results can be available quickly to assist triage. However, where this happens, clinicians recognise that these requests have often not been considered in detail, and that unnecessary tests could reduce flow as well as creating unnecessary anxiety for the patient.
- Other EDs only order tests once there is a clearer working clinical diagnosis. This carries the risk that relevant results may not be available as speedily, leading to the patient spending longer in the ED (and adversely affecting targets).

In the ED setting, where timely results are vital, there needs to be a balance between the risk of over-requesting and the potential of delays to test results. Care Sets (see page 33) will help with this, but there also needs to be clear communication, and a mutually acceptable, regularly reviewed arrangement between the lab and the ED.

(Some of the variation noted here may be due to the use of Point of Care Testing in EDs. However, this does not affect our recommendations.)

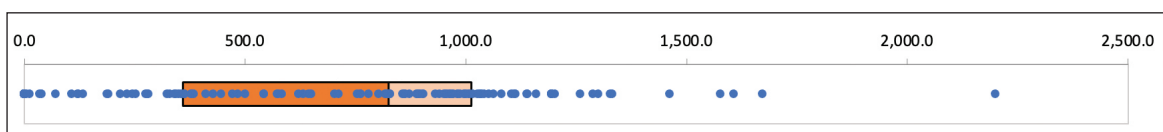
Variation in requesting of inflammatory markers

In some cases the clinician may feel uncertain about the clinical picture, which may require a broader, less focused approach to the initial testing. Essentially, in these situations the clinician is asking ‘is there something seriously wrong with my patient?’. For example, when a clinician is uncertain about the clinical picture, they may order tests to look for inflammation caused by an underlying condition. These inflammatory markers can be raised in many different conditions.

There are two inflammatory marker tests in common use: C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR). We found there was widespread use of both tests in primary care, with some labs measuring both for the same patient – see **Figure 5**. Generally, we heard that ESR is only valuable in very specific situations, is time-consuming and resource-intensive to perform, and may also involve taking an additional blood sample from the patient in some settings. In the majority of situations, the CRP test is adequate, and there is no clinical value in carrying out both these tests together.

There are two potential solutions to the over-requesting of these tests: educating colleagues not to request an ESR and CRP together (demand optimisation), or introducing Care Sets (see page 33) to link the correct tests to the clinical question.

Figure 5: Number of ESR tests carried out per 1,000 GP CRP requests per CCG (n=127)



Source: GIRFT 2020

Using Care Sets

We were surprised to see this level of variation across requestors, particularly as most tests are carried out for a limited number of reasons, such as monitoring chronic diseases, and so we expected to see more consistency of approach. However, the high proportion of a relatively small number of common tests also means that a common approach, such as using Care Sets linked to the clinical question, can be an effective and efficient solution.

With Care Sets, instead of choosing individual tests, or a group of tests (common testing profile), the requestor instead chooses tests grouped to match their clinical question for their patient, usually with one simple click. Care Sets are effectively electronic requesting with decision support built in, and therefore a first step towards full intelligent requesting (see *Electronic requesting: the gateway to other quality enhancements* on page 54). Critically, the choices that clinicians are given are focused around the patient and their needs, not around the test itself.

For example, instead of choosing individual tests, or selecting the U&E common testing profile, the requestor may choose 'chest pain', 'annual diabetes review', 'hypertension review' or 'dementia referral', and the appropriate individual tests will be requested.

Care Sets do not replace clinical expertise, which will always be essential to both choose the correct Care Set and to adjust it if necessary for the individual patient. However, they can ease everyday tasks and smooth processes for requestors. Where combined with decision support, they can also help distribute helpful and up-to-date information and guidance from labs to requestors and their patients.

For example, Care Sets can:

- Focus clinicians on getting the right answer for the patient, rather than on the test.
- Reduce requestor error and missed tests, as the system chooses the appropriate tests automatically, meaning there is less chance of a relevant test being missed.
- Remove duplication and redundancy, as the system is set up to only request the necessary tests, and tests that do not need to be part of the set are removed – this reduction in 'default tests' will free up capacity for better targeted tests.
- Reduce downstream costs from tests that are not clinically valuable.
- Make requesting faster and simpler for the requestor.
- Increase levels of guidance and support for the requestor, if contextual help is added – fitting in with the Advice and Guidance service, where GPs can request specialist help with referral and other treatment decisions.
- Make patterns of requesting more consistent, for example reducing the chances that consultants order novel tests without liaising with the lab first to confirm the value of these.
- Increase consistency across networks, enabling better audit and benchmarking.
- Introduce a greater level of governance to test requesting: for example it will improve adherence to NICE guidelines or other guidance, as these recommendations can be built into the system rather than relying on busy clinicians to implement them, which can lead to error and potentially a risk of litigation.
- Help to improve shared decision making with patients. Used carefully, Care Sets can create a better and more explicit match between the patient's clinical issue and the tests requested, rather than tests being requested 'by default'. This creates a better environment for consent, as the patient is more likely to understand each test they are having, and why. This also fits in with the aims of the Choosing Wisely campaign, which aims to improve clinical conversations.¹⁰
- Encourage discussion of appropriate tests for conditions at network and potentially national level, rather than ad hoc (see *Establishing network-wide standards and standardised national diagnostic pathways* on page 82).

This approach also removes redundancy that can occur with the more traditional common test profile approach. Requestors do not always need every test in a profile, but may find it easier to request the whole set. For example, when a patient starts on statin medication, they need to have their liver function checked over the first year, but this does not require a full LFT profile: an isolated transaminase test (alanine transaminase (ALT) or aspartate transaminase (AST)) is adequate.

¹⁰ <https://www.choosingwisely.co.uk/about-choosing-wisely-uk>

Care Sets can be used when the same groups of tests are requested together, as follows:

- In diagnosis: for example, looking for potential underlying causes of tiredness or dementia.
- In reviews: for example, annual reviews of patients with hypertension.
- In monitoring: for example, monitoring for side effects of disease-modifying anti-rheumatic drugs (DMARDs), where similar, and largely consistent, sets of tests are regularly ordered.

Care Sets must be granular, to match patient needs specifically. They must also be set up with different versions for 'first presentation' and 'monitoring' visits where necessary, to prevent repetition of tests that are only necessary at the patient's initial visit.

How to establish Care Sets effectively

Care Sets will work best where they are established consistently, which allows for knowledge sharing, audit and benchmarking. We therefore recommend that pathology networks:

- Establish Care Sets throughout their network, potentially targeting reviews and chronic disease monitoring first, then extending to other conditions.
- Promote Care Sets to all requestors, including primary care, sharing reasons for uptake and guidance on use.
- Monitor uptake of Care Sets by providers.
- Regularly review and update the Care Sets as needed, taking on board feedback from requestors. The evidence to support Care Sets is evolving, and therefore they must be reviewed frequently to match changing local understanding and needs.

This will ensure consistency for patients, as well as promoting discussion and sharing of best practice. All Care Sets need to be checked against relevant regulatory requirements including NICE guidance, as appropriate to the condition.

In future, Care Sets could be further extended to:

- Ease associated tasks – for example by automatically requesting particular information leaflets and discharge paperwork.
- Enable easier identification of particular patients: for example, having a Care Set associated with rheumatoid arthritis would help to identify these patients when necessary, such as if they need to shield in a pandemic.
- Identify cohorts of patients for research programmes.

A Care Set system requires electronic requesting to be in place. As electronic requesting is also key to multiple other improvements, we have discussed this in more detail in the section *Electronic requesting: the gateway to other quality enhancements* on page 54.

Care Sets in other departments

Although Care Sets will have most impact in primary care and the ED, a similar approach could also be applied to specialty work. Here the main benefit would be in streamlining requesting practice. For example, a hepatologist may suspect their patient has alcoholic liver disease, but want to rule out other – potentially reversible – causes of liver disease. A Care Set for this clinical question could rationalise a long list of tests that some clinicians request in this situation.

Care Sets already in practice

Care Sets are already well established with some labs and primary providers. Northern Devon Healthcare NHS Trust worked with local primary care services to design their own Care Sets, focusing on including only those tests that were necessary and sufficient to answer a clinical question.¹¹

These included Care Sets for chronic disease monitoring, which were based largely on NICE guidance. However, the relative lack of robust evidence behind this guidance led to discussion of the role of specific tests that were not recommended in some clinical contexts, but were traditionally requested. This led to a useful rationalisation of the Care Sets.

¹¹ Whiting, D., Croker, R., Watson, J., Brogan, A. and Lewis, T., 2019. *Optimising laboratory monitoring of chronic conditions in primary care: a quality improvement framework.* <https://bmjopenquality.bmj.com/content/8/1/e000349>

Below, we have listed some of the Care Sets created by this project. It is worth noting that the sets currently include some common testing profiles. In time, we expect these to be disaggregated into individual tests.

These Care Sets are examples only, rather than a recommendation, and are evolving with practice.

Table 1: Example Care Sets developed for use in Northern Devon practices

Indication / clinical question	Tests ordered
Diabetes Type 2: new diagnosis	ALT; FBC; HbA1c; Lipid profile; Renal profile (creatinine, sodium, potassium); TSH, ACR
Hypertension: annual review	HbA1c; Renal profile
DMARD: tocilizumab: 6-monthly	CRP; FBC; ALT; Albumin; Lipid profile
Dementia screen / memory referral	B12 & Folate; Calcium & Alb; FBC; HbA1c; LFT; Renal profile; TSH
Myeloma/MGUS monitoring	Calcium & Alb; FBC; Protein electrophoresis; Renal profile, Urine Bence-Jones protein
The names of these tests and conditions will be familiar to clinicians and so we have not explained them here. See the <i>Glossary</i> on page 137 or go to www.labtestsonline.org.uk for further explanation.	

This process is a reminder of the importance of wider discussion and agreement about the component tests: in general, and at network and national level.

Creating consistency in Care Sets

We were pleased to learn that Care Sets are currently being implemented by some other individual trusts or Clinical Commissioning Groups (CCGs), including as part of care bundles, which can incorporate other diagnostic elements (such as imaging) or other recommendations (such as follow-up reviews). However, comparative data is hard to come by, and success hard to measure due to variability in approach.

As part of creating network standards (see *Establishing network-wide standards and standardised national diagnostic pathways* on page 82), we recommend that networks:

- develop a consensus view on the default Care Set of tests that should be ordered for many conditions;
- allow clinicians to revise this set, if they need to do so to match a patient's particular needs;
- continue to update the Care Set to match guidelines as they change and in the light of specific diagnostic considerations;
- monitor and measure the effect on overall testing.

Networks should monitor their own data in conjunction with their users, establish whether they are high users of particular tests (for example LFTs), then understand the reasons for this. They can then use this information to establish network-wide standards for Care Sets. This approach can build on the progress already achieved in Care Sets by the Association for Clinical Biochemistry and Laboratory Medicine (ACB).

See also *Data in action: OpenPathology* on page 97, a platform for analysing data which should make this benchmarking easier.

Using common testing profiles

Where Care Sets are not yet in place, tests are often available as part of a test profile, such as U&E tests, LFTs, TFTs and others.

Testing profiles can be a logical way to group tests, and reduce the number of individual decisions that a clinician needs to make. However, testing profiles may also introduce over-requesting, for example if a clinician only needs one test from a profile, but ends up with three or more test results generated regardless of whether they are required or useful.

Why we reviewed testing profiles

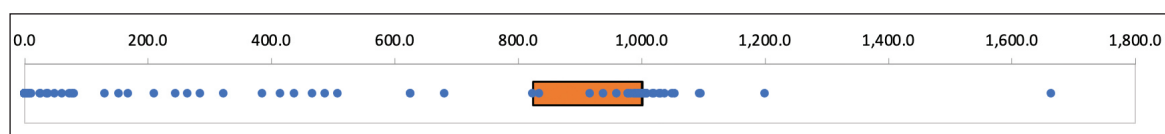
Tests that are part of testing profiles form a very large percentage of tests carried out by labs. In clinical biochemistry and haematology, around 63% of a lab's workload falls into six testing profiles.¹²

To examine variation in the tests included in common testing profiles in more detail, we looked at the ratios of potential analytes (substances being tested for) in a profile to a common 'base analyte'. This is because tests for these base analytes would nearly always form part of the relevant profiles, and therefore can be compared with the less standard tests that we are interested in reviewing.

For example, to look at U&E, we used potassium as our 'baseline' for comparison; for thyroid profiles we used thyroid stimulating hormone (TSH).

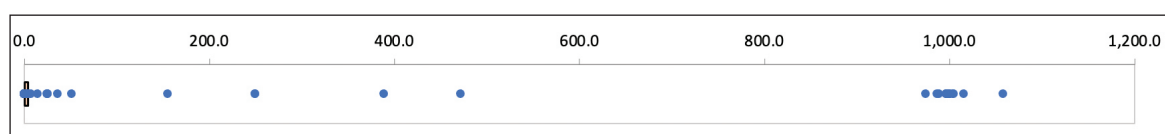
The following charts show the variation we observed in some common analytes.

Figure 6: Number of urea tests per 1,000 GP potassium test requests (n=125)



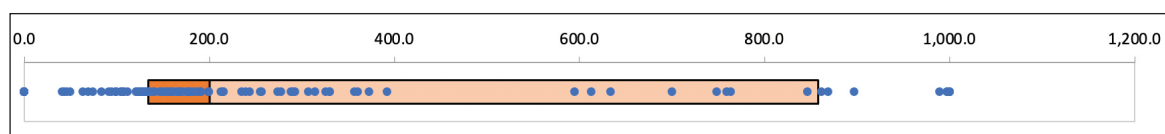
Source: GIRFT 2020

Figure 7: Number of chloride tests per 1,000 GP potassium test requests (n=123)



Source: GIRFT 2020

Figure 8: Number of free thyroxine (fT4) tests per 1,000 GP TSH test requests (n=126)



Source: GIRFT 2020

¹² Risebrow, H., 2020. Laing-Buisson Diagnostics UK Market Report. (extrapolated)

Improving common testing profiles for the longer term

We believe there should be a reduction in the use of common testing profiles in general, as the most effective way to introduce rationalised requesting would be to use Care Sets, linking each test back to a valid clinical question. On our deep dives, we saw that some labs were moving towards such disaggregated testing. For example, instead of using a full LFT profile, some trusts used standalone alanine transaminase (ALT) testing for some drug monitoring profiles. This is a more targeted test, meaning it will be easier for clinicians to analyse results, as well as reducing lab costs.

However, as profiles are currently in common use and will still be required in some situations, and as implementing change will take time, there is still benefit in reviewing and adjusting the profiles.

As an example, one large teaching hospital stopped providing a urea test as part of ED U&Es. They reported no clinical issues associated with this. Clinicians would still be able to request the tests individually as 'extras' when necessary.

While testing profiles are still in use, we recommend that networks agree common testing profiles as part of network-wide standards.

Reviewing tests of limited clinical value forms part of UKAS standards (ISO15189:2012). Section 4.14.2 states that 'authorised personnel shall periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received'.

CASE STUDY

A successful demand optimisation strategy based on network-wide Care Sets

Cheshire and Merseyside pathology network (North 4)

The network made financial savings and added value to patient pathways by removing unwarranted tests in primary care, and by carrying out more, or better-timed, tests using standardised Care Sets, drawing on existing good practice.

The network wanted to ensure that patients attending any hospitals or community providers across their area received broadly the same set of diagnostic tests for any given condition. They also wished to provide better advice for clinicians and users on the benefits of ordering the right tests at the right time, adding value and benefiting the wider system.

Using Care Sets developed by one trust as a basis, the network developed consistent trust- and network-wide Care Sets, and removed tests of limited clinical value from testing profiles.

The Care Sets were developed with clinical, operational and IT stakeholders and, once agreed, were implemented across the network. The network also included imaging and other diagnostics within the Care Sets.

Results

ED Care Sets were found to have the greatest potential impact in the hospital setting. Using the Care Sets removed around half the tests carried out in a week – a reduction from 3,000 to 1,500 tests.

Unnecessary legacy tests were removed from a clinical biochemistry testing profile, equating to about 936,000 tests a year. Such large volume reductions can result in quick and quantifiable savings. For example, cutting one million tests at 1p per reagent saves £10,000.

Avoiding other unnecessary investigations

As clinicians adopt the Clean Framework, they should ideally have a clear clinical question in mind when making all requests for tests. This includes asking whether:

- a repeat test being requested is likely to have changed from a previous test;
- there is an alternative diagnostic pathway that is more appropriate.

We explore these two issues below.

Avoiding unnecessary repeat tests: minimum retest intervals

Some test results are unlikely to change significantly over short to medium timescales, and therefore repeat tests within that timeframe are unnecessary. We found that some tests were frequently repeated in ways that could add little clinical information to the original result. If unnecessary repeat tests could be blocked, either using clinical decision tools at the point of requesting, or in the lab's own systems, this reduces both lab expenditure and unnecessary stress for the patient. During our deep dives we saw both of these methods in operation.

To examine this further, we looked at how labs manage minimum retest intervals for three investigations (vitamin D, vitamin B12 and ferritin – **Figure 9**, **Figure 10** and **Figure 11** below). These tests rarely need regular repeats, but we saw variation in approach across the country.

Figure 9: Minimum retest intervals for vitamin D (n=120)

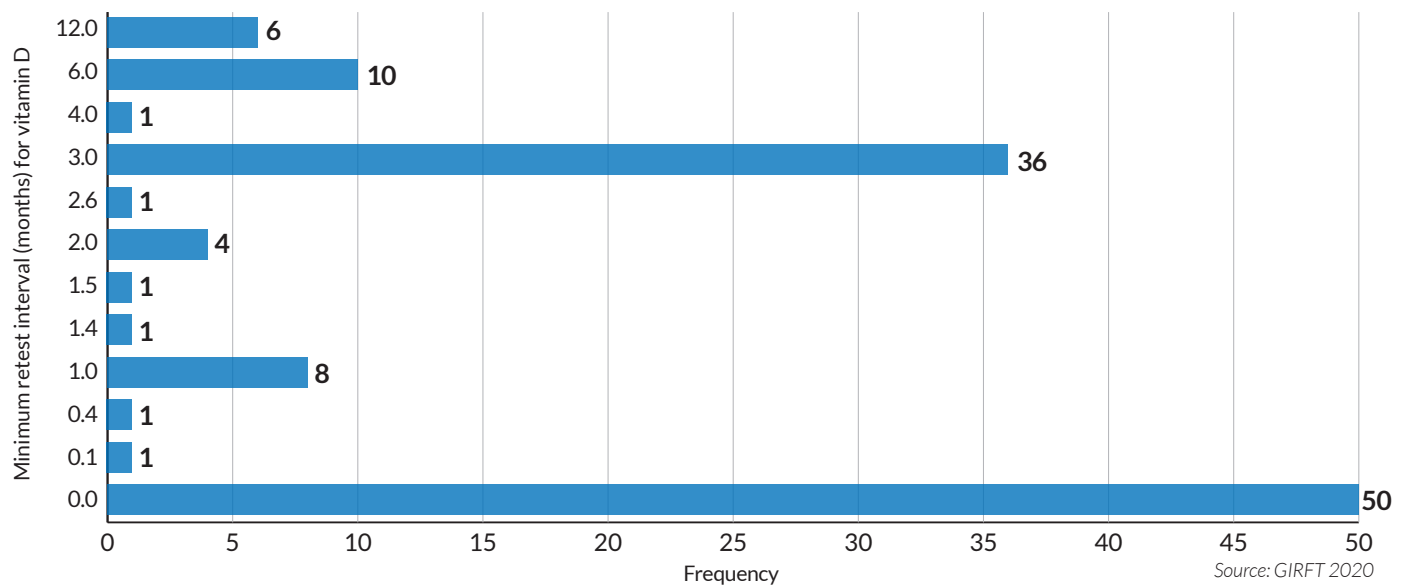


Figure 10: Minimum retest intervals for vitamin B12 (n=111)

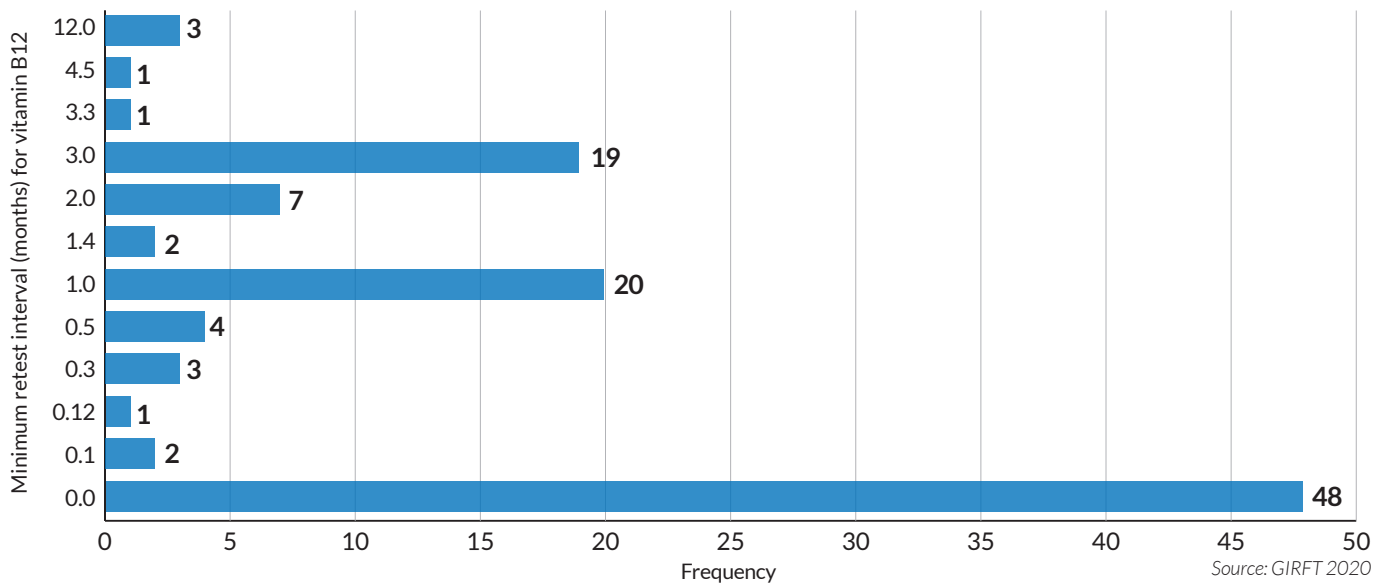
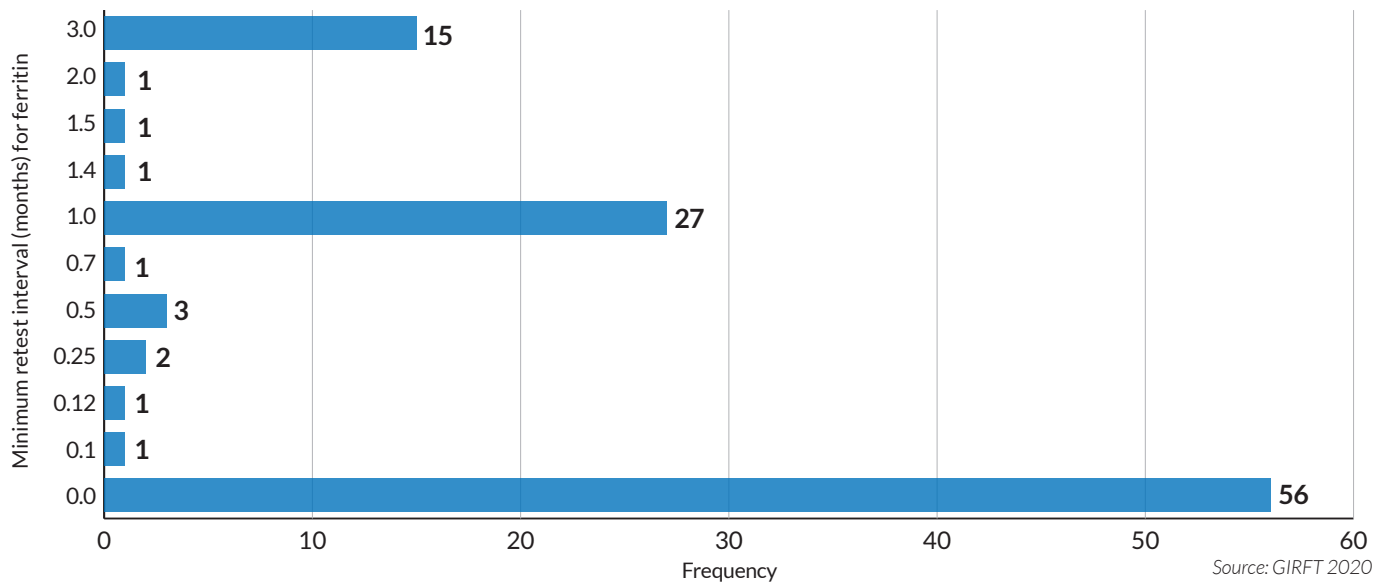


Figure 11: Minimum retest intervals for ferritin (n=109)



A few trusts had moved their minimum retest interval for vitamin D to 12 months, which is longer than specified in the RCPATH guidelines, making them clear outliers. We discussed this with one of these trusts, which reported no complaints from users: in fact some had commented on how it was helpful to be blocked from ordering a test they knew to have little value, and that this prompt also helped them to explain the situation clearly to patients.

Ideally, primary care colleagues should use clinical decision tools to prevent repeat tests before they are requested. Care Sets, as recommended above, will incorporate minimum retest intervals for many tests, which will therefore be built into decision support already. However, we also noted that decision support needs to be improved in many areas, and so labs may need to also implement their own minimum retest intervals as a backstop where requestor decision support is not yet in place to reduce unnecessary tests.

We therefore recommend that networks implement consistent minimum retest intervals across their providers for tests that are not covered by Care Sets, as part of network standards – see *Establishing network-wide standards and standardised national diagnostic pathways* on page 82. Where possible, these should be supported by improved decision support and guidance for requestors. The retest intervals can then be monitored and used as an evidence base for better practice.

It is important to note that the RCPATH has already produced guidance on minimum retest intervals,¹³ and we were surprised that this guidance has not been adopted more widely, especially as it is relatively conservative. The process of establishing network standards (and potentially progressing these to create standardised national diagnostic pathways) should create greater consensus and build understanding of the intervals, especially if labs reach out to primary care colleagues to educate them about the reasons for the minimum intervals. This will in turn increase compliance.

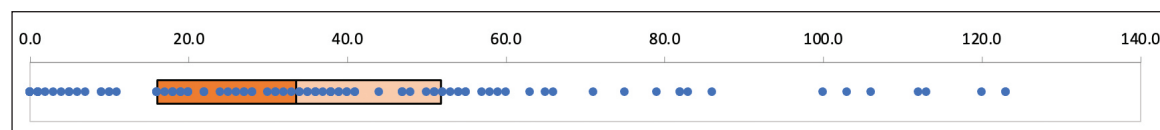
Networks can build on existing work in this area on several fronts: for example the National Immunology Audit Group (which includes representatives from the ACB, the IBMS, and the RCPATH) are planning their next national audit to cover the retest intervals in their area. In some areas, there is also a need for further evidence to support minimum intervals. Greater focus on the intervals and consistent implementation could lead to a better evidence base for further research.

Using variation to examine alternative diagnostic pathways: giant cell arteritis

The variation we saw throughout our visits helped us to identify many areas to target improvement, and we encourage trusts to continue to monitor their own data to identify further opportunities. For example, we used the GIRFT data to identify alternative diagnostic pathways that could benefit both the patient and the clinician working with them.

We found wide variation in how giant cell arteritis is being diagnosed. Historically, diagnosis of this potentially sight-threatening condition depended on examination of a biopsy from the temporal artery (located at the 'temple' at the side of the head). This is an invasive procedure for patients, and in some labs we found the volume of biopsies is significant (**Figure 12** below).

Figure 12: Number of temporal artery biopsies carried out (n=114)



Source: GIRFT 2020

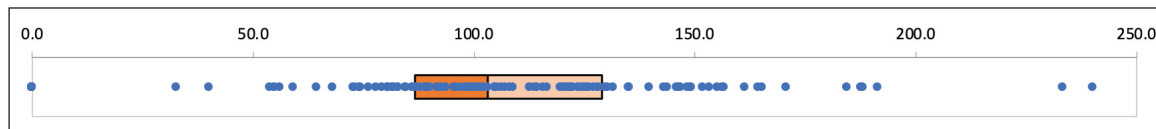
However, colleagues working on this condition at some centres, including a large teaching hospital, suggest that ultrasound of the artery can be an effective screening procedure in some patients, and may reduce the need for the biopsy. This has obvious benefits for both patients and labs. We therefore recommend that networks and trusts review this pathway in consultation with radiology and rheumatology colleagues.

¹³ The Royal College of Pathologists, 2015. National minimum retesting intervals in pathology. www.rcpath.org/discover-pathology/news/national-minimum-retesting-intervals.html

Using variation to examine alternative diagnostic pathways: urine infections

We also saw large variation in the use of urine tests (mid-stream urine tests or MSUs) to diagnose infections.

Figure 13: Number of urine samples requested in primary care, per 1,000 patients on GP list (n=115)



Source: GIRFT 2020

The use of MSUs has grown hugely over the last 20 years, which correlates with the introduction of the Quality and Outcomes Framework (QOF) in primary care. One component of this is dipstick testing of urine as part of the assessment of kidney disease. Anecdotally, we have heard that, on occasion, the person carrying out this dipstick test would send any that were positive to the lab for a microbiological culture. This may be due to confusion with other guidance on the use of urine dipsticks for the assessment of patients with infection symptoms. Not only is this unnecessary lab testing expensive, but it can also lead to inappropriate antibiotic treatment, as it is not uncommon for urine samples to yield false positive results due to sampling issues.

We found on our deep dives that some labs had low levels of MSU submissions. These labs have tackled the problem by ensuring that primary care colleagues were aware of Public Health England advice on how to diagnose urinary tract infections,¹⁴ including the 'To Dip or Not To Dip' initiative¹⁵ for care homes, and also ensuring that clear guidance was available on how to interpret dipstick results in other settings (such as in chronic disease clinics).

This work in rationalising requesting of MSUs could be formalised by creating Care Sets linking the patient's symptoms to the tests that are required (or not) to diagnose the condition correctly.

How lab clinicians can assist clinical users with choosing appropriate tests

In our deep dives, we saw great examples of pathology leads for some CCGs who had worked with all local GP practices to improve understanding of tests of limited value, minimum retest intervals, and other useful topics, with resulting decreases in unnecessary requests for their area.

We recommend that labs assist primary and secondary care clinicians to better understand where tests add value and where they may simply add confusion. They can do this by:

- Implementing Care Set systems, including adding suitable explanations to clinical question buttons. This is the most effective way to solve over-requesting. Ideally this should follow national guidance.
- Ensuring shared feedback and education, for example by running educational sessions with GP surgeries, or requesting information leaflets linked to the electronic request. This education should focus on both good requesting practice and result interpretation. See *Appendix 4: Example of decision aid to help clinicians interpret results* on page 152 for an example of a flowchart created by the British Society for Haematology (BSH) to aid clinicians.
- Encouraging primary care clinicians to access Advice and Guidance services, where they can check with pathology staff about test selection, or ask for advice on how to interpret a result.
- Continuously updating clinical decision systems with further explanations and contextual help wherever possible.

Are the samples collected, labelled and stabilised correctly?

In this section we look at approaches to ensuring the samples are:

- collected correctly;
- labelled appropriately;
- stabilised at the right time.

¹⁴ <https://www.gov.uk/government/publications/urinary-tract-infection-diagnosis>

¹⁵ https://www.england.nhs.uk/atlas_case_study/urinary-tract-infection-checklist-for-care-homes

Collecting samples correctly

The process of sample collection is a fundamental part of the diagnostic pathway, and yet often receives little attention. We looked at how the collection process affected a range of samples.

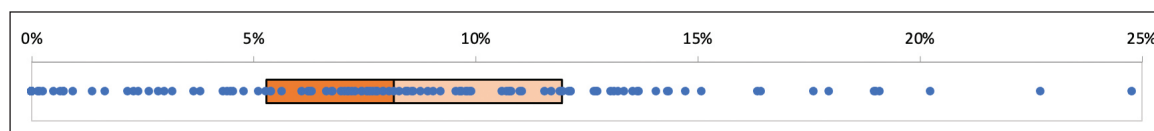
Phlebotomy issues

The standard of phlebotomy (blood taking) is a major factor in the quality of blood samples when they reach the lab. If phlebotomy technique is poor, then samples may be too small or haemolysed – where red blood cells have ruptured and leak out their contents. Some tests become impossible where this has occurred.

To get a sense of the scale of this problem, we asked labs how often they produced a non-numeric result for a potassium request. An analyser will generate a non-numeric result when there was a failure in some part of the process – usually this will be haemolysis.

Looking at requests from the ED (**Figure 14** below): on average, about 1 in 12 samples ‘failed’, and it was not uncommon for this rate to run at over 1 in 8 samples. The consequences of this failure would be widespread: for example, patients needing to have blood taken again, delayed clinical decision making, and interruption to patient flow.

Figure 14: Percentage of potassium tests in ED with a non-numeric result (n=121)

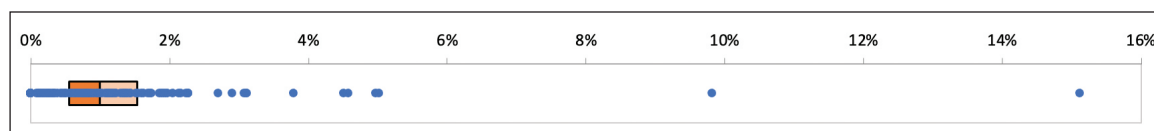


Source: GIRFT 2020

Many reasons have been put forward to explain this high rate of rejection in ED: a major reason given is poor phlebotomy technique, although it is also important to check whether transport is increasing haemolysis rates (see *Stabilising samples* on page 46). However, we could also clearly see from the data that some trusts were performing at a much higher standard, with failure rates below 1 in 50. We visited a number of these on our deep dives. At one trust, the lab worked with the blood tube equipment manufacturer on the phlebotomy pathway. They shared this learning with another trust in their network, who then saw similar improvements. We also saw how at another trust the lab worked with the ED and users to develop a best practice culture and protocols.

It was also noticeable that fewer potassium tests from primary care resulted in a non-numeric result, as shown in **Figure 15** below. This may be because most primary care samples are taken by more experienced phlebotomists, such as practice nurses.

Figure 15: Percentage of potassium tests from GPs with a non-numeric result (n=120)



Source: GIRFT 2020

One of the proposed functions of Community Diagnostic Hubs (see page 110) is to increase access to community phlebotomy. It is vital that these phlebotomists are properly trained and the quality of the service is continuously monitored.

We therefore recommend that networks and labs take a proactive role in continuously improving phlebotomy services in all settings. This may need to include integration with primary care or community teams. As rates of home phlebotomy increase (in the wake of the COVID-19 pandemic in particular), this may also need to include patient education.

This oversight role may include:

- monitoring the number of haemolysed samples received and seeking to identify whether this is the result of poor technique or poor stabilisation (see *Stabilising samples* on page 46);
- where poor technique is identified, working with all staff taking blood to increase skill levels – explaining the impact of poor technique on patients;
- seeking ways to influence or manage phlebotomy teams to improve standards.

(While some of the low rejection rates may be due to issues in sample collection or during transport, this does not affect our recommendation here.)

CASE STUDY

Reducing sample rejections due to pre-analytical errors

Great Ormond Street Hospital for Children NHS Foundation Trust

A staff education campaign on sample collection, plus improved portering, resulted in a significant decrease in sample rejection.

In 2017, Great Ormond Street's lab rejected close to 9,000 samples. As these samples were taken from children, it was especially important to reduce the number of repeat blood draws.

In 2018, the lab started a quality improvement project, overseen by a senior biomedical scientist, aiming to significantly reduce sample rejections due to pre-analytical errors by 2019.

The key issues identified were clotted blood samples and delayed blood cultures.

On average, 43 samples were rejected each week due to clotting. The main reasons for this were:

- insufficient mixing;
- delayed transfer from syringes;
- slow draws;
- expired bottles;
- sometimes, the patient's condition.

Blood cultures tended to be delayed because staff did not know about or use the air tube system.

The trust:

- raised awareness of the issues through posters and screensavers;
- introduced training on how to avoid clotted blood samples;
- created visual guides to remind staff to use the air tube system;
- increased the number of porter collections from wards.

Results

The mean number of samples rejected per week significantly decreased from July 2019 to September 2020. Average transport time for blood culture samples was reduced from 265 minutes to 116 minutes.

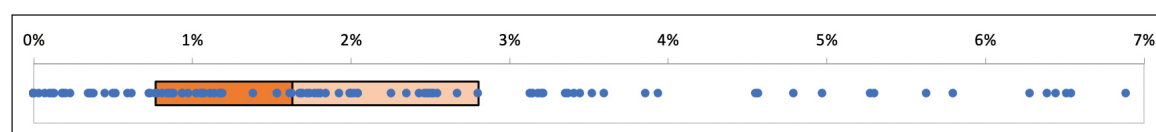
The trust has seen a cultural shift around pre-analytical errors, and the project was shortlisted for the Health Service Journal Awards 2020 'Best QI initiative of the year'.

Urine sample collection issues

As well as issues with collection of blood samples, we found significant variation in rejection rates for urine samples for microbiology analysis.

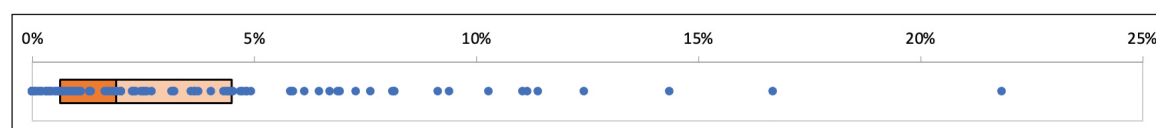
We found a six-fold variation in the rejection of urine samples from primary care, as shown in **Figure 16**, and in some places 5-7% of urine samples were rejected. There was greater unwarranted variation in samples from trusts, where we found a ten-fold variation in rejection rates, with several trusts rejecting over 10% of these samples – see **Figure 17** below.

Figure 16: Proportion of urine samples from GPs that were rejected (n=109)



Source: GIRFT 2020

Figure 17: Proportion of urine samples from trusts that were rejected (n=116)



Source: GIRFT 2020

We therefore recommend that all networks and trusts audit processes for collection of urine, and address any points of failure identified.

Labelling samples appropriately

Sample labelling is critical for ensuring that results can be given back to the right patient. ‘Wrong blood in tube’ incidents (WBITs) are a key example of how incorrect labelling can cause serious harm. These incidents are a significant patient safety risk, and are estimated to occur in about 1 in 2,000 blood draws.¹⁶ The Serious Hazards of Transfusion (SHOT) scheme record and analyse data on these, and publish many useful reports and recommendations at <https://www.shotuk.org>.

The Healthcare Safety Investigation Branch’s comprehensive *Wrong Patient Details on Blood Sample* report¹⁷ contains recommendations on how to reduce the number of WBITs, which are strongly in line with the recommendations of the Clean Framework, including the adoption of electronic systems for blood sample identification, collection and labelling. We encourage all clinicians to refer to this report.

There are many interventions that can ensure all samples are labelled correctly – such as patient barcode scanning and label printing at the point of collection. However, such innovations can be hard to implement, and require ongoing training and IT resources.

Nevertheless, there are two simple measures that can help reduce risk and should be seen as basic standards of care:

- using an NHS number consistently;
- using electronic requesting – see *Electronic requesting: the gateway to other quality enhancements* on page 54.

^{16, 17} Healthcare Safety Investigation Branch, 2019, *Wrong Patient Details on Blood Sample*. https://www.hsib.org.uk/documents/147/hsib_report_wrong_patient_details_blood_sample.pdf

Using an NHS number consistently

The patient's NHS number is a standardly used unique patient identifier. This should be present on almost all pathology samples.

To assess how well the NHS number is used currently, we asked labs the proportion of requests for potassium tests from EDs and from GPs that were booked in with an NHS number – **Figure 18** and **Figure 19** below.

Figure 18: Percentage of potassium tests in ED that included an NHS number

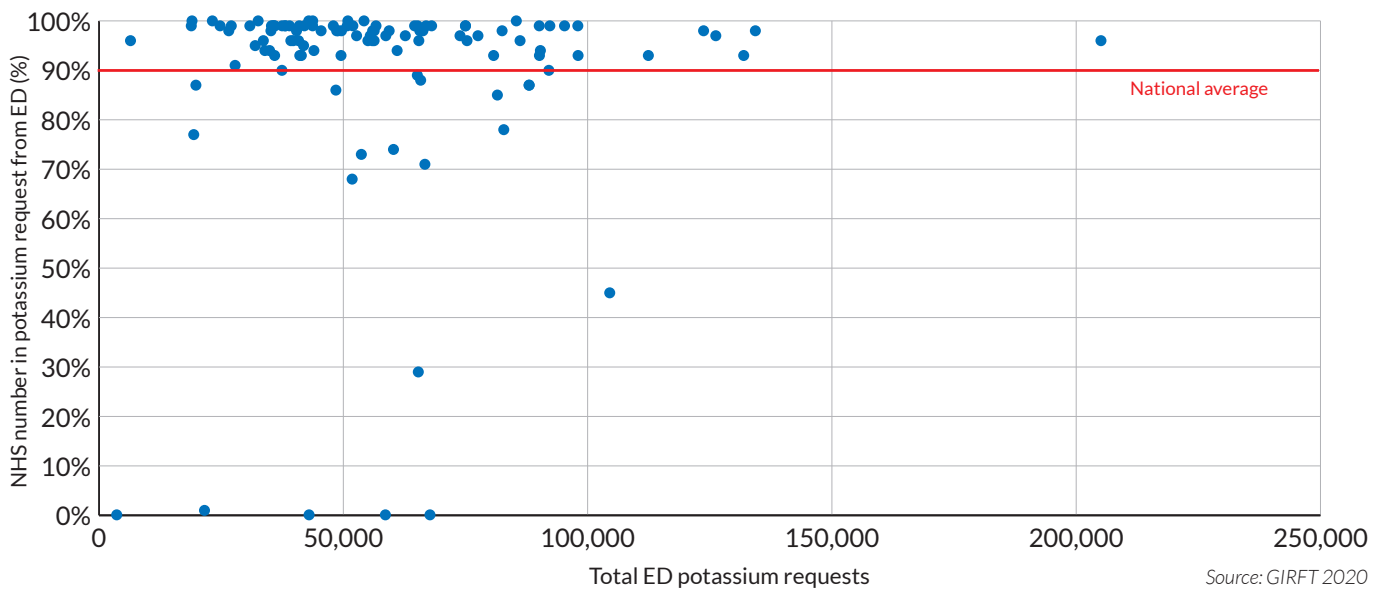
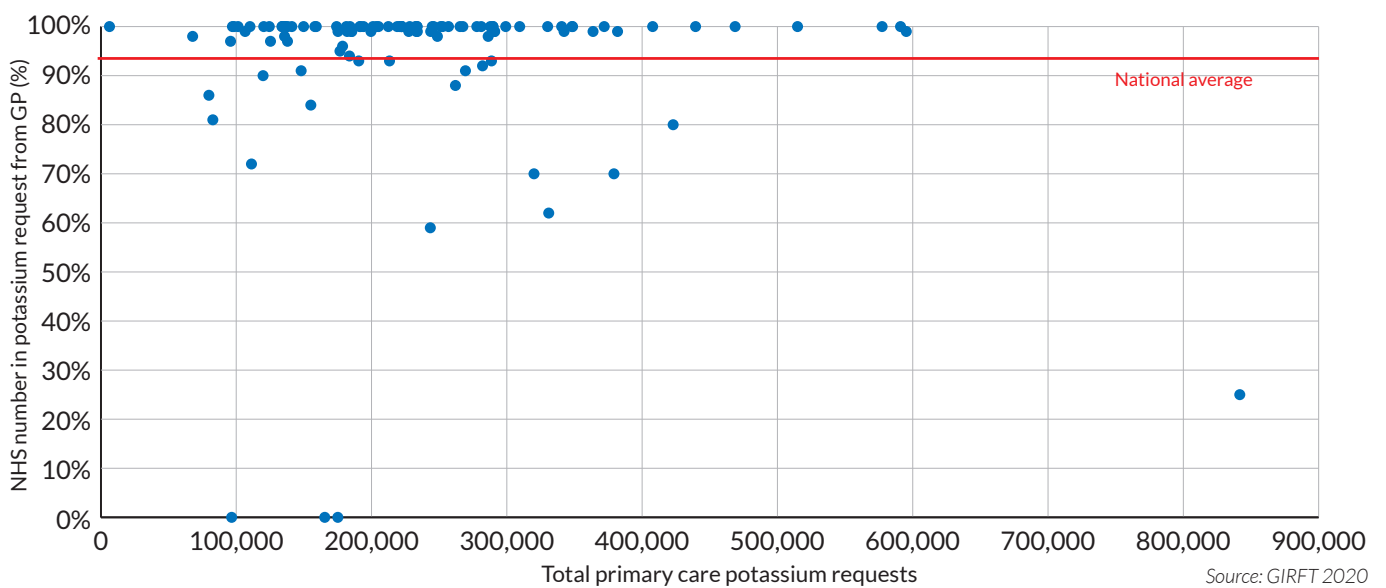


Figure 19: Percentage of potassium tests from GPs that included an NHS number



In general, organisations performed well on this metric. However, there were still some services that were using an NHS number less often than should be expected. This presents a clear patient safety risk and must be addressed.

There are a few exceptions where the number is not possible or appropriate, for example in anonymised sexual health services, non-UK-resident patients, newborn babies, or in trauma cases where the patient's identity is not yet known. Networks or labs should have consistent protocols in place to deal with these exceptions.

When systems change, there is also a need for robust protocols for associating patient records with the correct NHS number – for example to ensure historical blood transfusion history is accurately recorded, and the patient does not receive a transfusion of an incorrect blood product.

Overall, the main barrier to using the NHS number is the uptake of up-to-date electronic requesting, which links to our key recommendation on implementing these systems. Networks may also need to examine downstream processes and IT systems, as well as requestor processes.

Stabilising samples

The way that samples are stabilised and transported to the point of testing can have a significant effect on the result. This is particularly apparent whenever samples are collected at a distance from the lab, when there may be a long period between collection and processing, and samples may be exposed to uncontrolled environmental conditions.

Transport conditions affect different tests in different ways. For example:

- If the sample needs microbiological analysis, bacterial growth will generally start immediately, unless the sample is refrigerated or otherwise stabilised. This may cause an overgrowth of non-pathogenic bacteria. In automated blood culture systems, this may mean that a positive signal is missed, leading to a false negative result. (This is because the analyser looks for a growth curve, and cannot pick this up if it has already happened.)
- If testing for potassium, this can leak out of red blood cells over time if samples are not stabilised quickly by centrifugation, leading to a high level of potassium in the result – an 'artefactual' rise. This process is exacerbated when unstabilised samples are chilled.

The effect of stabilisation on potassium testing

To look at the issues of transport in more detail, we looked at potassium tests. Because potassium leaks out of red blood cells, its measurement in non-stabilised samples is time-critical.

The WHO and the Clinical and Laboratory Standards Institute both have standards governing the time between phlebotomy and sample stabilisation by centrifugation, but these have not been implemented in England. In addition, many labs do not record when the blood was taken, or the time the sample was centrifuged. This means that many labs cannot tell when:

- a raised potassium is due to delays in centrifugation (an artefactual rise);
- patients with abnormally low potassium (hypokalaemia) are being missed, because the potassium in their sample rose to normal levels during transport.

We found that some labs never saw a potassium below the lower reference limit of 2.5 mmol/L. However, labs that had invested in sample stabilisation reported results below this limit in 0.75% of tests. In other words, the labs that had stabilised their samples were picking up some patients with hypokalaemia, but other labs were (probably erroneously) not picking up any patients with hypokalaemia at all. Although 0.75% may seem a small percentage, a relatively small hospital lab may process 1,000 potassium tests every day. If that lab is not stabilising or transporting blood samples correctly, they could be missing seven or eight cases of significant hypokalaemia per day.

Looking at the effects of ambient temperature on unstabilised samples

Potassium leaks faster at low temperatures, and so samples transported in the cold, without stabilisation, are more likely to suffer from artificially raised potassium levels. We saw this in the effect of winter transport on potassium results from primary care.

We asked labs to provide us with data on the difference between the mean potassium result from primary care in July, compared with that in February. When samples are transported under optimum collection and transport conditions, there should be no difference, but instead there was a clear difference between February and July – see **Figure 20** below.

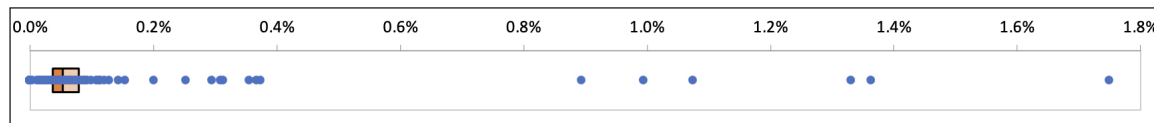
Figure 20: Difference in average potassium results for samples taken February 2019 and July 2018 (n=125)



Source: GIRFT 2020

We saw large variations across labs, including a knock-on variation in the rate of samples showing significant elevated potassium levels (hyperkalaemia), as shown in **Figure 21** below.

Figure 21: Proportion of potassium tests with elevated level (above 6.5 mmol/L) from primary care (n=123)



Source: GIRFT 2020

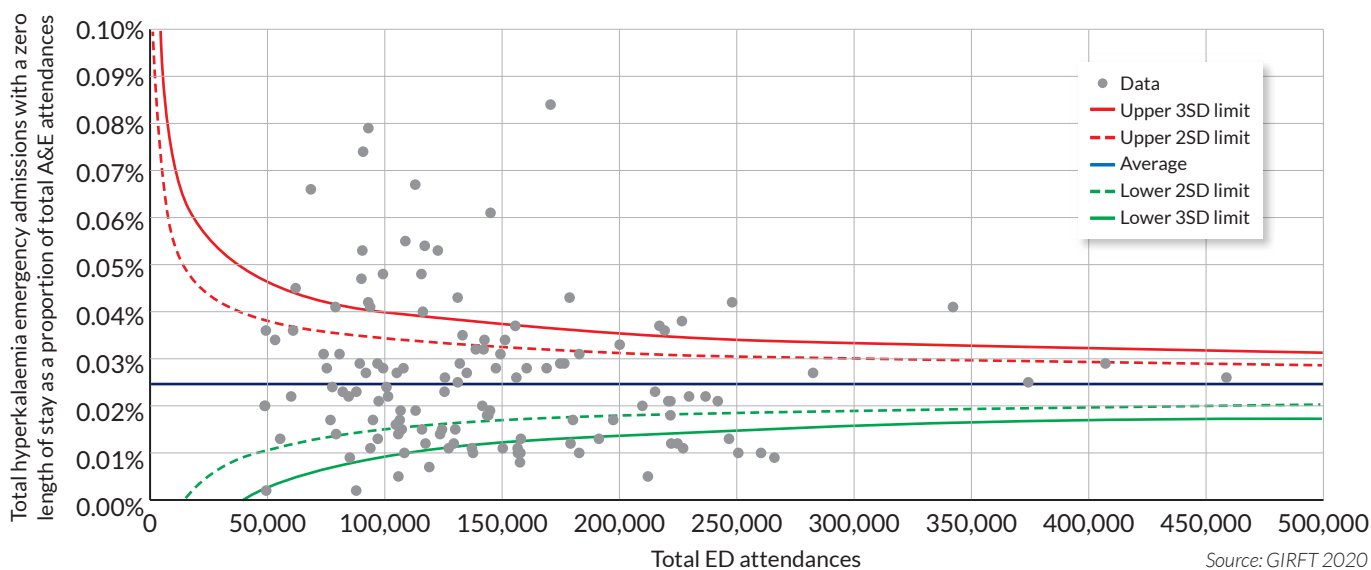
Looking at the downstream effects of poor stabilisation

To get an idea of the scale of the problem of poor stabilisation, we also looked at Hospital Episode Statistic (HES) data for patients where all of the following applied:

- admitted to an ED;
- coded with hyperkalaemia;
- zero length of stay, suggesting they did not have hyperkalaemia, as this would have resulted in an overnight stay.

Where this combination of metrics applies, it suggests that the patient may have had their blood rechecked at the ED, and then been discharged when the result turned out not to be elevated. This is shown in **Figure 22** below.

Figure 22: Number of patients with hyperkalaemia admitted to ED, but with zero length of stay, as a proportion of total ED attendances



The total number of zero length of stay hyperkalaemia admissions from A&E in 2108/19 was 4,721. The data is over-dispersed, which suggests coding problems, and we know from local audit that hyperkalaemia is frequently coded inaccurately. However, anecdotally and supported by this data, we are aware of many occasions when patients have been called to their local ED, usually at night, because of high potassium levels subsequently found to have been spurious. These are costs that sit outside the lab, with ED and downstream services, and cause unnecessary distress and anxiety for patients. As more labs look at centralising blood testing in order to save money, they need to be aware of the clinical consequences (and non-pathology costs) that could be caused by transport delays.

These variations may have a direct and significant effect on patient care. If a patient has a genuinely high potassium result, they require urgent care; however if a sample has a high level, and it is not understood that the result has been caused by poor management of the sample before it reaches the lab, this may result in an unnecessary patient admission to the ED. We videoed one patient’s experience of unnecessary ED visits, and the stress this caused, which you can view at: https://www.youtube.com/watch?time_continue=2&v=B17QgZWQN1c&feature=emb_logo.

Potential solutions to the stabilisation problem

We saw multiple examples of labs that had worked with primary care to tackle the stabilisation problem. Generally, this was where a network’s leadership team had taken a proactive, whole-system approach to the problem, seeking to influence or manage (as appropriate) services that traditionally fall outside the lab’s own remit.

For example, some labs put in place frequent sample pickups, alongside transport in a temperature-controlled environment – a service that is readily available in commercial environments. Although this reduces the problem, it will not be appropriate for all primary care settings: frequent pickups may not be possible, or the costs may be prohibitive. Also, even with temperature control, blood samples are not indefinitely stable. Networks may need to consider the full range of transport solutions available, including options such as courier motorbikes or (in future) drones.

CASE STUDY

Combining initiatives to ensure faster transport and more efficient sample processing

Eastern Pathology Alliance

Eastern Pathology Alliance is a merger of blood science labs from James Paget University Hospitals NHS Foundation Trust, Norfolk and Norwich University Hospitals NHS Foundation Trust, and The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust. It has successfully implemented improvements in transport, labelling and processing of blood samples.

Transport

- All surgeries have two pick-ups per day. This allows surgeries to time collection through the day while ensuring the samples are transported soon afterwards.
- The deliveries to the labs are spread out so that samples are not left too long before being processed.
- All transport pouches are insulated, helping to reduce temperature effects.

Labelling and processing

ICE requesting, combined with barcode labelling, was introduced to all surgeries in the catchment area. Barcodes include the lab number, so samples do not need to be re-labelled once they reach the lab.

This system was further enhanced by using the Indexor system, which enables large numbers of samples to be booked in at once:

- GPs scan barcodes on samples, then place them into a rack. This logs the date and time samples are taken using a chip in the rack (similar to the chip in a contactless credit card).
- The racks are collected and taken to the lab. Once there, they are placed in cradles, which link to the LIMS using the main Indexor IT systems. All samples are booked in at once using the information recorded on the chip.

Results

- Time from sample collection to receipt in the lab is usually within four hours.
- Up to 480 samples can be booked in at one time, and processed in less than five minutes. This frees up lab resource, but the fast processing times also help to preserve sample integrity.
- Time of collection is recorded and can be transferred to LIMS.
- Labs are seeing a reduction in the number of artificially raised potassium levels caused by processing delays.

CASE STUDY

Community blood testing turnaround times improved through transport review

Lancashire Teaching Hospitals NHS Foundation Trust

The trust has reduced the time it takes for blood samples collected in the community to reach the lab, resulting in more accurate test results.

Transport review

After a transport review, the trust aligned sample collection in the community with phlebotomy clinic operating hours, in order to keep blood samples stable before analysis.

Following discussions with all GP practices and community clinics, collection requirements and clinic locations were fed into a transport planning and logistics application to provide optimised routes for the trust's current transport providers.

Most of the alterations were made seamlessly. An agreement in principle was made with the transport providers that they would support additional runs and take responsibility for contracting a third party if they were unable to perform the pick-up themselves.

Result

The vast majority of community blood samples now arrive at the lab within two and a half hours of collection, and the number of incorrect blood results has reduced dramatically. This is demonstrated by regular audits.

In some cases, where there is no phlebotomy activity on site, collections have been reduced rather than increased. This has offset costs, making the project virtually cost-neutral.

CASE STUDY

Temperature-controlled transport to reduce sample deterioration: existing service and planned expansion

Pathology courier services provided by QE Facilities, a subsidiary of Gateshead Health NHS Foundation Trust; planned expansion to Coventry and Warwickshire Pathology Services (CWPS)

QE Facilities Limited has started to provide temperature-controlled transport across Coventry, Warwickshire and the Burton area, to reduce sample deterioration due to temperature fluctuation and reduce the number of repeat tests. This will help to reduce or eliminate some of the variation, including seasonality, that the GIRFT team identified in data.

QE Facilities Limited is a subsidiary of Gateshead Health NHS Foundation Trust, and is one of very few organisations to have set up temperature-controlled transport. Building on the success of its service across the North East, it is now working towards providing specialised pathology transport service across the West Midlands region, in partnership with CWPS.

In addition to controlling the temperature of samples, it is planned that the risk of deteriorating sample quality will be further reduced by the implementation of a number of community-based 'stabilisation sites', ensuring that samples are stabilised within four hours of bloods being taken from the patient. At the time of writing, this further planned expansion has been delayed due to the COVID-19 pandemic.

Results (based on results seen in areas already covered by the service)

- The trust is able to ensure samples are transported safely, within appropriate turnaround times, with much reduced temperature-related destabilisation.
- The service is also designed around the needs of users – GPs, patients and labs.
- The proportion of successful tests will increase, which also saves time and costs from repeat tests.
- This also improves the patient experience, as they do not need to be called back for repeat blood draws.
- The service also helps labs to maintain UKAS compliance.
- The financial benefits of the service are returned to the NHS through Gateshead Health NHS Foundation Trust, to support frontline patient service.

Another solution for this problem is to enable GP practices to centrifuge samples themselves, before transport. Most biochemistry tubes contain a gel plug which, when the tubes are centrifuged, separates the red cells from the plasma. Currently, the tubes are usually centrifuged when they arrive at the lab. However, this can happen at the GP surgery or local phlebotomy clinic, if there is a centrifuge on site and staff are trained to use it. This process is now in widespread use in Scotland, and we have seen a number of labs in England adopt this approach. (See one example of this, and the effect on potassium results, in our *Example OpenPathology findings* on page 98.)

Centrifuging at the GP surgery:

- allows phlebotomy to be carried out throughout the day, without needing to coincide with transport;
- completely removes seasonality of hyperkalaemia (so long as all samples are centrifuged).

This issue is particularly relevant where labs are considering a hub and spoke network, with potentially long transport times between blood collection and centrifugation. This may also be a consideration as Community Diagnostic Hubs are implemented, where these are not on acute hospital sites (see *Community Diagnostic Hubs* on page 110). We recommend introducing sample stabilisation techniques (such as on-site centrifugation) wherever it is not possible to centrifuge samples in labs within four hours of blood collection.

Governance of the transport and stabilisation stages

Due to the importance of transport and stabilisation, we strongly recommend that networks should seek to guide, influence, or take responsibility for the governance of transport and stabilisation as part of establishing network standards, and that this stage is built into the accreditation process.

We therefore recommend that:

- networks or labs introduce mechanisms to record and audit the time between blood collection and stabilisation;
- networks or labs monitor these metrics, including auditing the number of haemolysed samples received, and address any problems identified;
- networks and labs recognise the importance of transport, and proactively seek ways to influence trusts to achieve improvements;
- the transport part of the pathway is built into UKAS accreditation processes.

See also *Trust and network governance* on page 87.

Are the samples delivered to the lab on time?

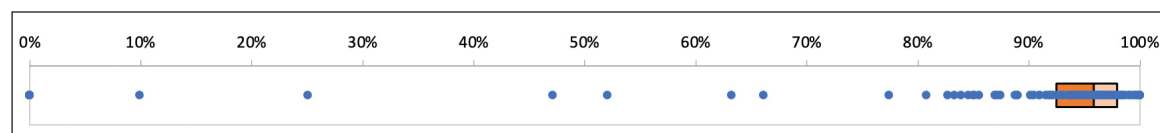
In this section, we looked at how to deliver samples to the point of testing in time for the lab to provide a timely result.

Looking at the impact of transport on turnaround times

To examine transport from point of sample collection to the lab, we asked labs for data on the turnaround time for samples collected in the ED. We compared the **total** turnaround time (from sample **collection** to being able to view results) to the **lab** turnaround (from sample **receipt** to being able to view results). This gave us a picture of how much time transport adds to the overall turnaround.

We used haemoglobin results to look at this. The **lab** turnaround, from receipt to results, was generally rapid, as shown in **Figure 23** below.

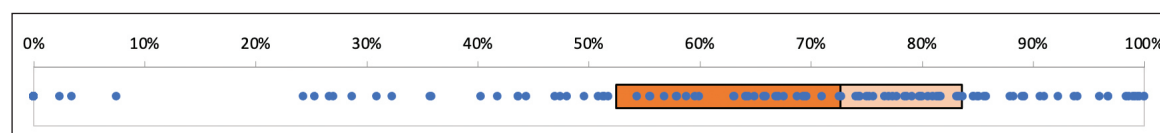
Figure 23: Lab turnaround of haemoglobin results (percentage of results available within one hour of lab receiving sample: requests from ED) (n=128)



Source: GIRFT 2020

However, when we looked at the **total** turnaround – the end-to-end pathway from the sample being taken to results – the picture was less rosy, as shown in **Figure 24** below.

Figure 24: End-to-end turnaround of haemoglobin results (percentage of results available within one hour of blood being taken from patient: requests from ED) (n=110)



Source: GIRFT 2020

Using mini-labs

On our deep dives, we also found that some labs were expanding Point of Care Testing (POCT) services in the ED, including developing mini-labs ('hot labs') staffed (where necessary) by biomedical scientists. These mini-labs can be an effective way of providing urgent results where they form part of a network with a remote lab – that is, if there is a central lab that is not close by, and there is no method of rapid transport to the lab. However, where hospitals already have an on-site lab, alternative solutions, such as increasing portering or installing air tubes to transport samples, may be cheaper and easier to monitor than a separate mini-lab, while also ensuring good governance and oversight of the testing system (see *Improving lab oversight of POCT* on page 61).

Where mini labs are an appropriate solution, it is vital that:

- the mini-labs is properly integrated with patient record systems;
- staff are properly trained to use all tests and equipment;
- the mini-lab is closely monitored by the overseeing lab;
- the mini-lab undertakes its own internal quality assurance and control.

The development of mini-labs as a solution to the transport problem may reflect the control that labs have (or do not have) over different aspects of the diagnostic pathway. They can organise testing equipment, with necessary staffing and quality control, but currently may have little control over transport and portering arrangements. This is a key reason why the End-to-End Pathology approach must become embedded – not just in labs themselves, but at all levels of the healthcare system – to ensure that networks and trusts take a holistic view of all services (see *Trust and network governance* on page 87).

Other solutions to the transport problem

It is vital that transport is seen as an integral part of the diagnostic pathway, and that appropriate governance – such as accreditation – is put in place to ensure that transport is consistently considered:

- We found labs that took a holistic view were able to provide an End-to-End Pathology service that met the requirements for timely clinical decision-making. Generally, they achieved this by overseeing the transport and portering arrangements themselves. We recommend that labs seek to do this, either via a contract with the transport supplier that has set performance indicators, or by managing transport directly.
- This is an area where procedures are generally set locally, but we also recommend that national bodies consider transport specifications that are tied to accreditation, in order to improve transport timeliness consistently.
- In our visits, we also found that few labs had metrics looking at transport performance. We recommend that labs collect minimum datasets to monitor and improve their performance – for example the time when the sample was taken and the time it was centrifuged.
- In future, we expect more labs to be able to timestamp samples electronically, and strongly encourage uptake of this functionality to enable audit and identify issues.

Electronic requesting: the gateway to other quality enhancements

Throughout this section of the report, we make several recommendations that require, or are significantly enhanced by, the use of electronic requesting. Electronic requesting helps in every stage of the Clean Framework – significantly in Clean in, but also in Clean through and Clean out, due to the related enhancements it brings to (for example) labelling or faster turnaround.

We see electronic requesting as a basic requirement of modern pathology, and it is a key recommendation of this report that all networks seek to establish this as standard throughout their network, including with community, primary and secondary care requestors.

Initially, this may be the simplest form of electronic requesting, seeking to eliminate paper requesting by sending orders electronically to labs. However, networks should see this as a pathway towards implementing more sophisticated decision support:

- Additional online decision support to rationalise requesting and help, which aligns with the move towards Advice and Guidance initiatives, where GPs can ask specialists for help with referrals.
- A prioritised structure to aid demand optimisation, where the tests that add the greatest value are immediately accessible on the front page, while if clinicians want to order other tests, they need to search for these, or justify why they are needed.
- Intelligent (computerised) requesting, which can include Care Sets, which will improve the quality and consistency of requesting, while easing the requestor's task (see *Variation in requesting of common analytes* on page 28).
- Guidance on minimum retest intervals (see *Avoiding unnecessary repeat tests: minimum retest intervals* on page 38).
- Guidance on interpretation, such as advice on reference intervals (see *Results that describe normality for that patient* on page 63).
- Easier integration of innovations – for example when test profiles or Care Sets are altered, this can be reflected in the decision support.

The benefits of electronic requesting to lab, requestor and patient will be familiar to many clinicians, but as a recap, it can:

- reduce transcription errors at multiple points in the sample's journey;
- enable consistent use of patient identifiers including the NHS number, and better transfer of identifiers to the correct patient record;
- incorporate label-printing, to help with correct use of patient identifiers on tubes;
- when used alongside barcoding, allow samples to be placed directly onto analysers, improving turnaround times;
- enable easier, and therefore more consistent, integration into the patient's record;
- increase interoperability between providers;
- enable easier audit and benchmarking – this is particularly useful in a network context, where labs can (for example) compare requesting patterns across the network.

A systematic review of 24 studies into decision support systems in 2010 found that they significantly improved practitioner performance in 15 out of 24 studies (62.5%).¹⁸

Where electronic requesting is not yet embedded into the pathology service, we recommend that networks co-ordinate its urgent introduction across all providers. Where it is already in place, we recommend that it is expanded at pace to include decision support, including Care Sets.

These recommendations are in line with:

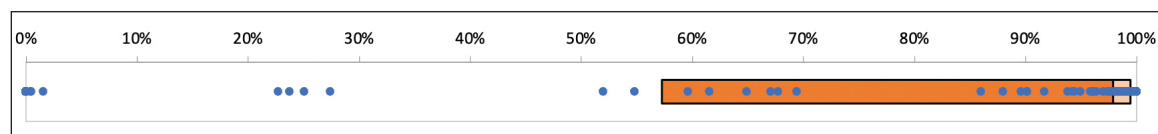
- The NHS Long Term Plan (NHS LTP)'s aim to 'Use decision support and Artificial Intelligence (AI) to help clinicians in applying best practice, eliminate unwarranted variation across the whole pathway of care, and support patients in managing their health and condition'.¹⁹
- The National Information Board Paperless 2020 drive.

The standard use of electronic requesting will gain further urgency with the introduction of Community Diagnostic Hubs (see page 110). These must have electronic requesting built in from the outset, alongside decision support, such as Care Sets. Networks will also need to consider how to integrate reference labs, which may be easier with increasing use of electronic referral systems (see *Increasing use of electronic referral systems and messaging* on page 94).

Current use of electronic requesting

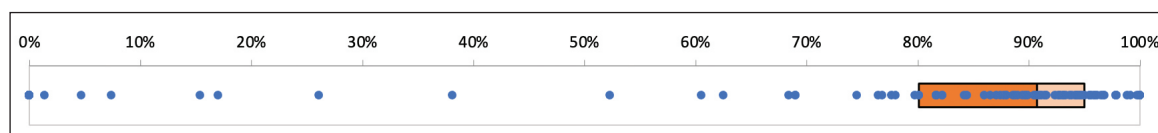
To examine how electronic requesting is currently being used, we asked labs whether they used this for potassium tests. We found wide variation, as shown in **Figure 25** and **Figure 26** below, with a few trusts using electronic requesting for very few tests, or no tests at all. For the ED, we found a large number of trusts were only requesting 60% of tests electronically.

Figure 25: Percentage of potassium tests in ED using electronic requesting (n=115)



Source: GIRFT 2020

Figure 26: Percentage of potassium tests from GPs using electronic requesting (n=109)



Source: GIRFT 2020

As the benefits of electronic requesting are well established, this low usage is clearly a problem. In discussions, it was clear that there were still some key barriers to implementing electronic requesting both within trusts and in the community.

¹⁸ Main, C., Moxham, T., Wyatt, J., Kay, J., Anderson, R., and Stein, K., 2010. Computerised decision support systems in order communication for diagnostic, screening or monitoring test ordering: systematic reviews of the effects and cost-effectiveness of systems. <https://www.journalslibrary.nihr.ac.uk/hta/hta14480/#/abstract>

¹⁹ <https://www.longtermplan.nhs.uk/online-version/chapter-5-digitally-enabled-care-will-go-mainstream-across-the-nhs>

Barriers to uptake of electronic requesting

Within hospitals, it can be difficult to interface electronic health records with lab systems. However, we recommend that, as part of the End-to-End Pathology approach, trusts consider gains in efficiency and performance where this integration can be put in place.

In primary care, it is less easy to understand why providers are not using electronic requesting in all cases. All primary care services work with electronic health records, and there are many software solutions that will interface with lab systems. These can also provide a degree of decision support.

We have heard in some localities that networks, trusts or labs do not see it as their role to pay for a primary care functionality. However, electronic requesting must be seen as a basic requirement of pathology and is clearly necessary as a foundation for future growth. Establishing electronic requesting should therefore be a key performance target for commissioners, networks, trusts and labs; all need to embrace a wider whole-system approach, focusing on the future, long-term benefits of electronic requesting to labs and providers, and to patients in particular, which will clearly outweigh the initial costs.

Clean through

The Clean through stage covers work that happens in the lab itself. Quality assurance regulations – and labs themselves – have focused on this area for many years, which means there is already infrastructure in place to address quality issues. We have looked at how to improve the infrastructure itself in more detail in *Foundation 1: Quality* on page 82.

In this section, we have focused on:

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

Understanding variation and minimising error

The vast majority of diagnostic tests carried out in accredited labs are supported by three approaches to quality control and quality assurance, although the different pathology specialties use the approaches in different ways.

Internal Quality Control (IQC) and test validation	IQC is used to determine whether the analytical quality is good enough to release patient results at the time of analysis. It also ensures that test performance is not declining.
Internal Quality Assurance (IQA)	In IQA, which is used more in some specialties than others, clinical samples are anonymously re-introduced back through the diagnostic lab process to check that they return the same results. This ensures the processes are operating at an acceptable level.
External Quality Assessment (EQA)	EQA methods compare a lab's testing to labs with the same or an alternative testing methodology. The lab may be compared to the performance of a peer group of labs, or to a reference lab.

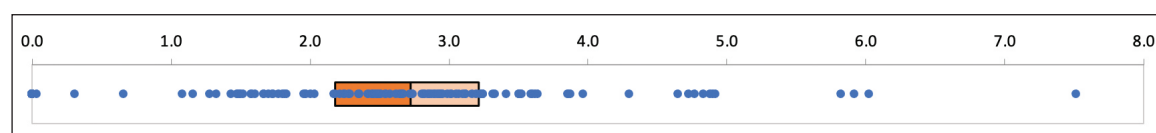
While we saw good use of all mechanisms in our deep dives, it is important that labs continue to re-evaluate their assurance systems and actively work to address any areas of concern – including improving and adding to the quality assurance systems themselves. This may be another useful role for the network – supporting and challenging labs’ approaches to quality, and driving the spread of innovation in this area.

Using quality assurance to minimise error: acute kidney injury (AKI) flags

We also need to ensure that our quality assurance schemes reflect, as closely as possible, the entire end-to-end diagnostic pathway. The example of AKI shows why this is important.

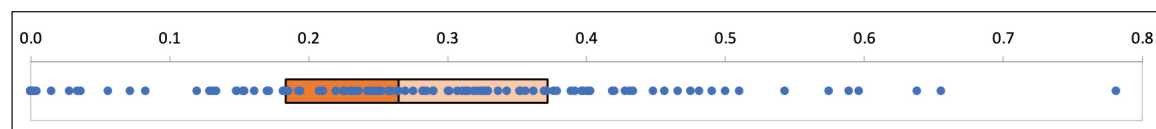
The AKI flag is produced from the measured serum creatinine level, using a nationally agreed algorithm. On our deep dives, we saw large disparities in the number of flags for AKI generated across the country, in both ED and primary care, as shown in **Figure 27** and **Figure 28** below.

Figure 27: Number of AKI level 2 flags per 1,000 ED attendances (n=123)



Source: GIRFT 2020

Figure 28: Number of AKI level 2 flags per 1,000 patients on primary care list (n=113)



Source: GIRFT 2020

There are many potential reasons for this, including the exact nature of the test used by individual labs to measure creatinine (chemical Jaffe method versus enzymatic method), particularly in samples with mild haemolysis. It also appeared that there are subtle differences in the way labs have set up the (apparently identical) algorithm. The fact that the variation seen is even higher in primary care suggests that this is not due to casemix.

Although creatinine analysis will be covered by quality assurance processes, there is currently no EQA process to check that the algorithm is performing as expected. We have therefore asked the EQA scheme suppliers to introduce an EQA system to identify variation in AKI flags.

The extraordinary variation that we saw in our own data regarding the amount of AKI detected in different settings suggests there are significant variables that need urgent investigation. A Renal Association and UK Renal Registry report using data from 2018 also found nearly four-fold variation between CCGs.²⁰

The GIRFT pathology and renal medicine teams are working together with the Renal Association and UK Renal Registry to investigate this further, and there is further discussion in the GIRFT national report on renal medicine.

We recommend that the NPB urgently commissions research to identify the cause of such variation. We also recommend that all labs perform audits to ensure that this critical algorithm is working correctly in their systems.

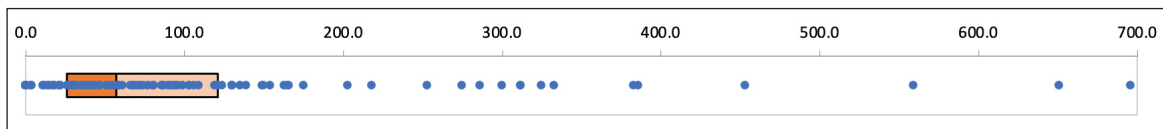
²⁰ The Renal Association and UK Renal Registry, 2020. Acute kidney injury (AKI) in England - a report on the nationwide collection of AKI warning test scores from 2018. https://www.renal.org/sites/renal.org/files/AKI_report_FINAL_13072020.pdf

Minimising error in low-volume tests

Where labs undertake low volumes of specialist work, such as complex biopsies, they may not build up sufficient experience to minimise the chance of error. Our data showed that some trusts were still undertaking low-volume specialist testing in cellular pathology, such as non-cancer liver, kidney and skin biopsies.

As shown in **Figure 29** below, labs that are not liver centres tended to work on relatively few liver biopsies, yet this is quite complex work. Looking at the data, we were concerned that some centres are reporting too few of these samples to guarantee a high-quality clinical service. This may be even more of a concern in complex kidney biopsies, due to the need to maintain technical skills in immunofluorescence and electron microscopy, and the relative high cost of electron microscopes that are then only used for a low volume of tests.

Figure 29: Number of liver biopsies reported (n=121)



Source: GIRFT 2020

Potential solutions for low-volume complex tests

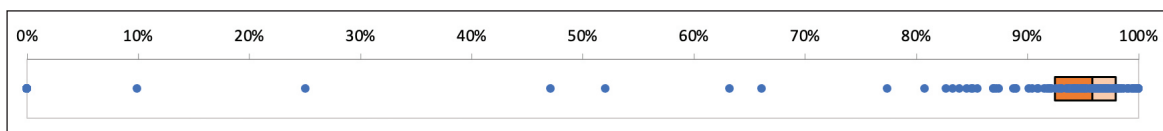
One way to solve this issue for liver biopsies would be to centralise all liver biopsy testing on fewer sites. However, this runs the risk of overwhelming these centres, and potentially making peripheral sites less attractive places to work. However, there is a clear opportunity for networks to manage low-volume tests across each network, allocating one or more sites to particular tests or groups of tests. These sites could develop to become centres of excellence for the network, or for a region, justifying the specialisation of skills and investment in expensive equipment.

One smaller trust we visited had an alternative approach: they linked with a large teaching hospital in London. The smaller trust filtered the work between low complexity and high complexity. They then worked on the low-complexity tests, and the two trusts approached the complex work collaboratively. As well as maintaining standards, this approach helps to build expertise and resilience in the histopathology workforce. Other specialties may be able to learn from this approach, and this training and quality assurance role could be seen as a key function of reference centres.

Processing results in a clinically relevant timeframe

In general, we found the timeliness of lab processing for many common tests to be acceptable. As shown in **Figure 30** below, most trusts were able to provide over 80% of haemoglobin test results to ED within one hour from time of receipt of the sample in the lab. Some outlying trusts clearly needed to improve on their results.

Figure 30: Haemoglobin requests from ED: percentage reported within one hour of receipt (n=128)



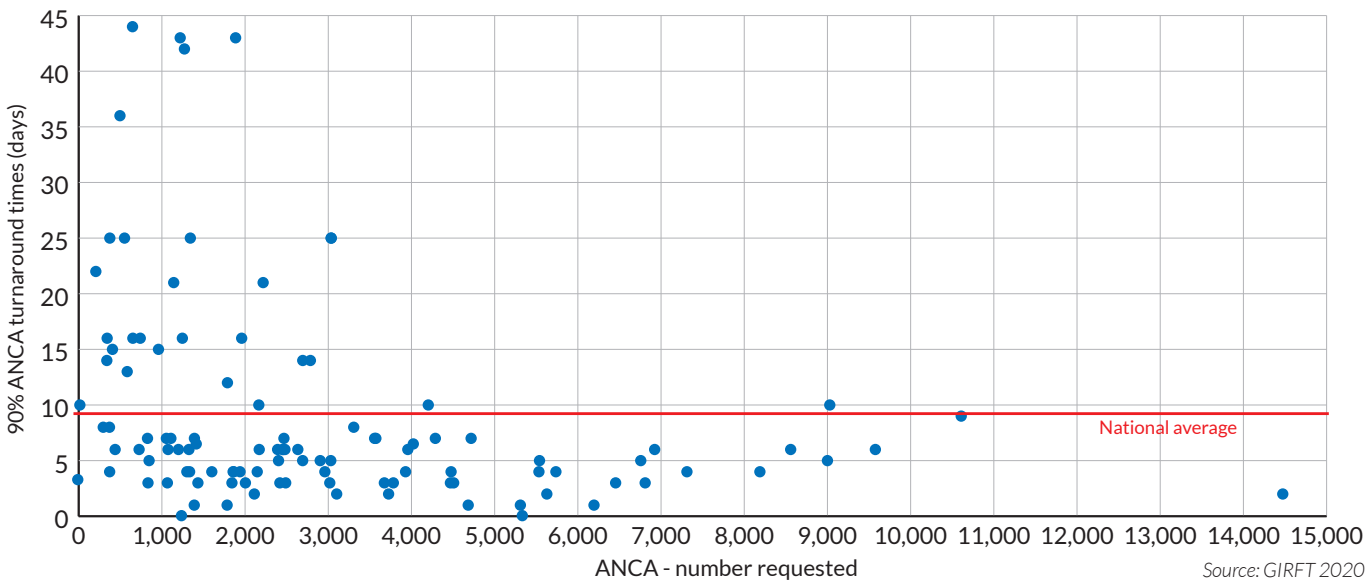
Source: GIRFT 2020

However, a substantial number of pathology tests are booked into a local lab but then referred elsewhere for testing. This happens either where the labs are part of a network, or where an uncommon test needs to be referred to a specialist centre. (See *Foundation 3: Service delivery* on page 104 for more about network models.)

To investigate the impact of this approach, we looked at test performance for a selection of tests that are often carried out in off-site specialist labs. In this report, we are focusing on anti-neutrophil cytoplasmic antibody (ANCA) tests, which are used for a variety of conditions including acute kidney failure. However, there were similar findings for other tests that we looked at.

As with liver biopsies, ANCA tests are relatively complex tests, carried out at relatively low volumes. It does not make sense, from either financial or quality standpoints, for these to be carried out in all centres. However, ANCA tests help clinicians manage patients who are severely ill with acute kidney failure, and so are also an example of a relatively time-critical test. We asked labs to tell us how long it took them to get 90% of ANCA results into their lab systems and visible to clinicians, from the time the lab received the sample. While some labs performed well – 42 labs out of 100 reported 90% of ANCA results in under five days – others did not reliably achieve acceptable results: 21 took over two weeks to report 90% of results, and five took over 35 days, as shown in **Figure 31**.

Figure 31: Turnaround times for ANCA tests, in days

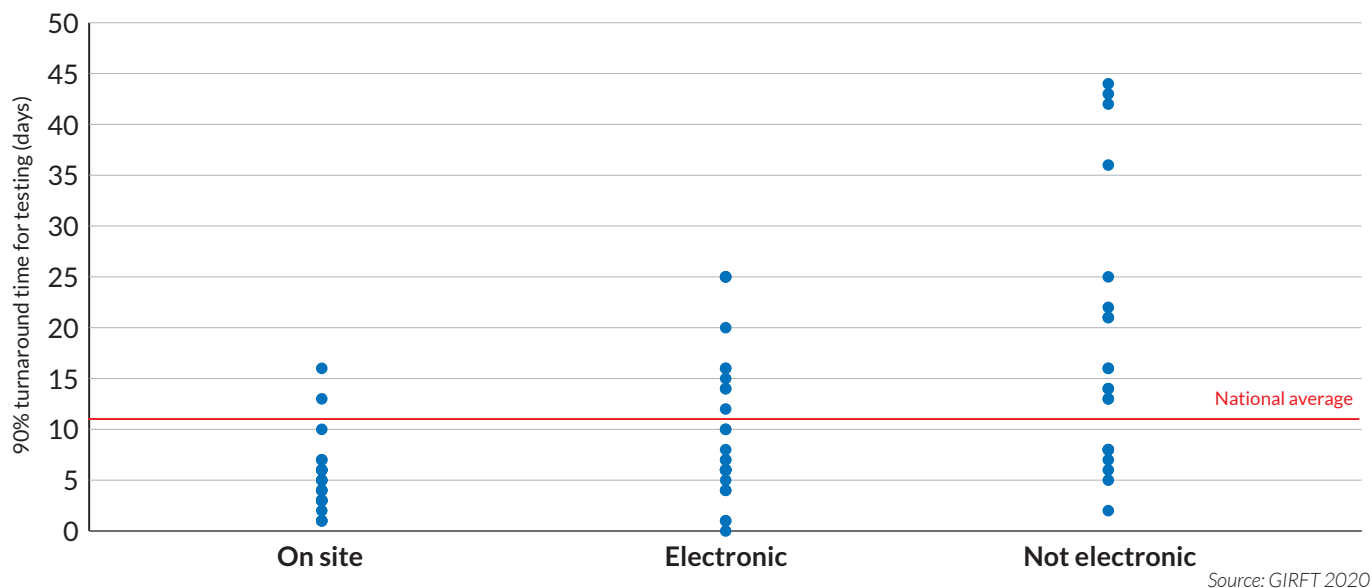


Source: GIRFT 2020

How electronic lab-to-lab referrals and messaging speed turnaround

We also asked labs where these tests were performed, and whether the referral and results were sent electronically using a Laboratory Information Management System (LIMS), as shown in **Figure 32** below.

Figure 32: Turnaround times for ANCA tests (days) separated by how referral and results were sent



We saw that the labs with the best performance figures were (as you would expect) those that could perform the test on site. However, labs that used electronic referral had a faster turnaround than those that used paper-based referral.

Electronic lab-to-lab messaging is now well developed, with many systems available, and offers multiple benefits;

- it speeds up result visibility;
- it reduces the risk of transcription error;
- labs report large efficiency gains, which offset the cost of installation several times over.

One commonly used electronic referral system is the National Pathology Exchange (NPEx²¹), which provides a simple means for labs to create electronic networks. This is not the only electronic referral system available, but may be one of the most easily accessed. As discussed in *Appendix 1: The coronavirus pandemic and lessons for pathology services* on page 146, during the peak of the pandemic NPEx enabled tests from an ED in one hospital to be carried out in a remote lab, with results available in the host reporting system within six hours.

However, data from NPEx suggests that, before the COVID-19 crisis, the system was not used as widely as it could be. We found that only 14 labs were systematically using NPEx to handle their ANCA requests, and this demand was served by three reference labs.

It is also important that reference labs are able to deliver to a clinically meaningful specification, agreed between referring lab and reference lab. Our recommendations on *Establishing network-wide standards and standardised national diagnostic pathways* (see page 82), alongside GIRFT's work on standardised national pathways, could help deliver meaningful, consensus-driven specifications that can be used across networks. These specifications must include acceptable turnaround times and how results will be transmitted.

²¹ The National Pathology Exchange: <https://www.npex.nhs.uk>

Improving lab oversight of POCT

Most labs are keen to support POCT, and see this as a key role. In 2013, the MHRA published guidelines recommending a governance structure for POCT, including involving the local ISO15189:2012 accredited lab (for example an NHS hospital lab). However, responses to our questionnaires suggested that a substantial proportion of POCT tests do not currently have lab oversight.

Figure 33: Percentage of hospital glucose POCT tests that only allow lab-authorized users (n=142)

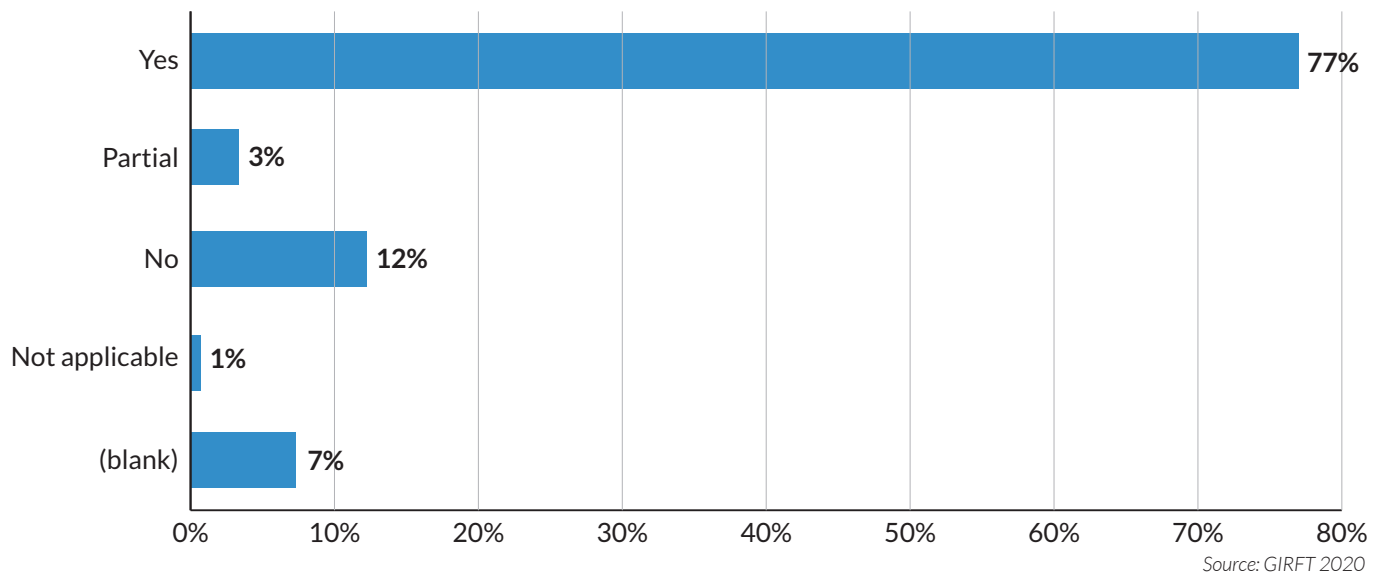
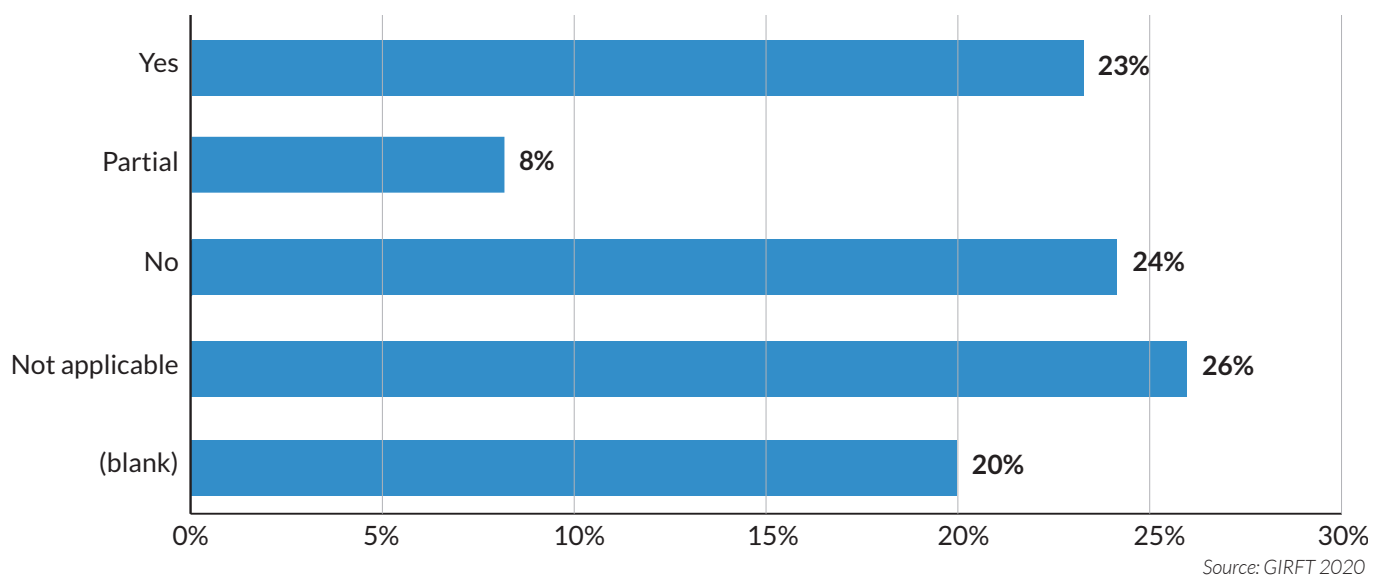


Figure 34: Percentage of hospital coagulometer POCT tests carried out with lab oversight (n=142)



We found that 65% of community glucose POCT and 69% of community INR testing (for patients on anticoagulants – see *A sentinel pathway: venous thromboembolism* on page 76) were not performed with lab oversight. See **Figure 35** and **Figure 36**.

Figure 35: Number of community POCT glucose tests carried out with lab oversight (n=142)

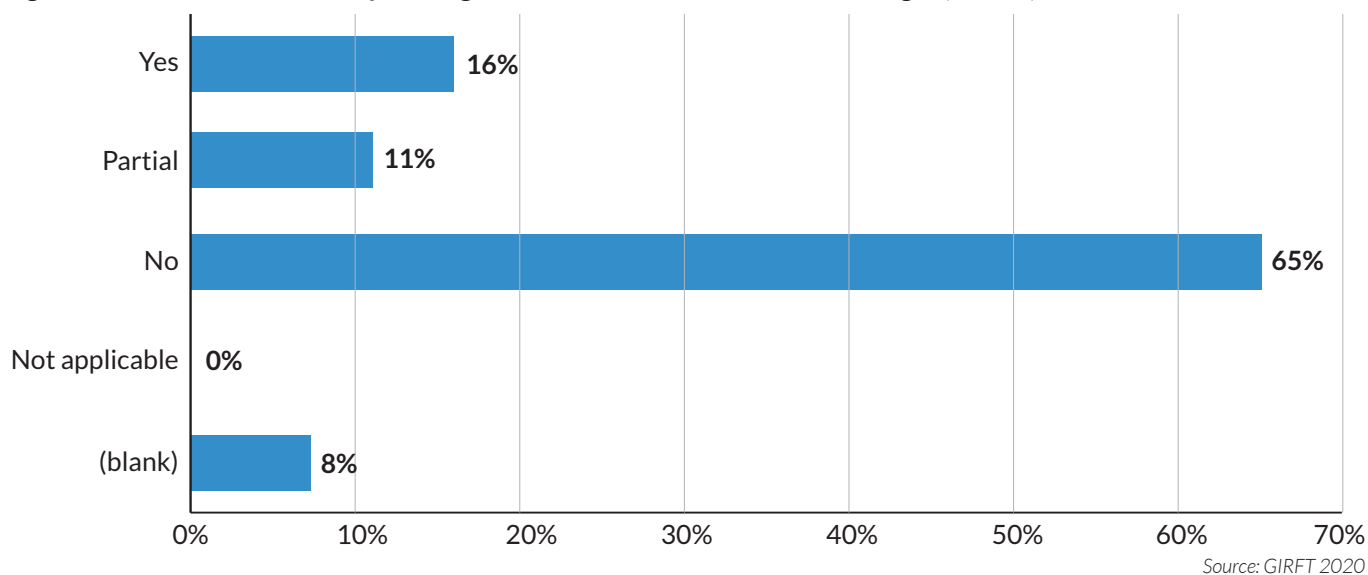
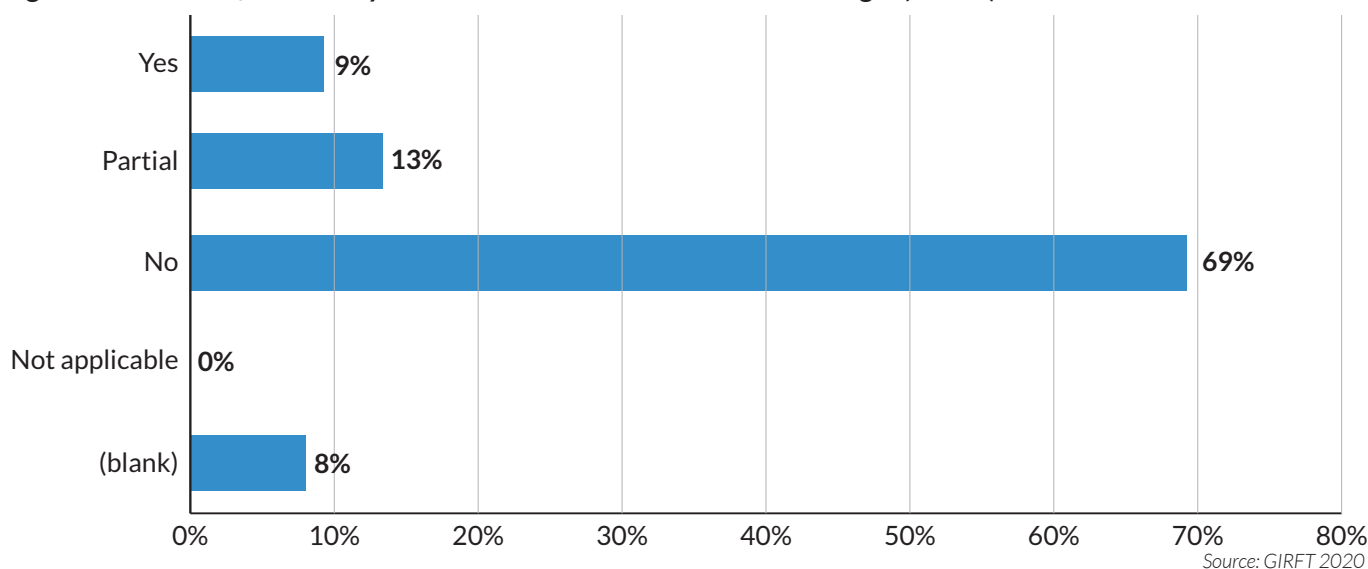


Figure 36: Number of community POCT INR tests carried out with lab oversight (n=142)



As POCT continues to expand, we believe the issues of quality in POCT require both a local and a national approach:

Locally:

- labs need to work with community POCT providers to ensure lab oversight, in line with the MHRA guidelines – this may involve training and greater engagement with primary care teams;
- labs and networks may also wish to set up dedicated POCT teams, where these are not already in place;
- labs and networks also need to ensure that POCT results are integrated with the patient record.

Nationally, there needs to be a change in approach for POCT accreditation, to develop greater governance and attainable standards of quality. See *Speeding adoption of new technology* on page 87 for more on this.

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.

Results that describe normality for that patient

When considering what is 'normal' for any patient, clinicians need consistent reference points. Reference intervals – definitions of high and low levels for any tests – are a common way to achieve this. If a patient has a test, they may be told that their result was in the 'normal range', and this refers to the reference interval.

Reference intervals are a key reason why we recommend 'getting the right answer', rather than focusing on the result of the test. The intention of reference intervals is to contribute to a wider clinical discussion: if a patient has an 'abnormal' result, the clinician must consider this alongside other factors in the individual case, such as the overall likelihood of a particular disease. However, clinicians and patients often see a result outside the reference interval as a way to define abnormality, without considering the wider situation.

Issues with the use of reference intervals

Reference intervals are usually defined statistically, as the interval that 95% of the values from a 'healthy' reference population fall into. Almost by definition, however, one in every 20 (5%) test results of healthy people will be outside this reference interval (half above and half below). Some of these patients are simply in the 'long tail' of a probability distribution for normal people.

Perhaps even more problematically, definitions of normality for one particular patient group may not hold true for another. 'Normal' populations, on which reference intervals are based, may be drawn from demographic groups that are not necessarily related to the patient being tested. 'Normality' may also not adequately account for expected variation due to age, ethnicity, pregnancy, and so on. At an even deeper level, reference intervals can unnecessarily medicalise any situation that deviates from the social norm.

Manufacturer reference intervals may have been worked out based directly on selected populations, or may be derived from literature (secondary sources). Where population studies create different reference intervals, it is not clear how to decide between these: one study²² that generated its own reference intervals found 25% of its biochemistry tests disagreed with the manufacturer's own reference intervals by more than a fifth.

As a result of the complex issue of reference intervals, the data from the manufacturers, and the complexity of developing local reference intervals, different labs may use very different reference intervals for the same test analyte, for no clear reason. This can cause confusion for the clinician interpreting the test, especially if they work across sites that have different approaches.

Variations in locally set reference intervals

In our questionnaire, we asked labs about the reference intervals they used for various analytes, and found levels of variation for each. The reasons for this variation were not always clear.

There is existing guidance on reference intervals for some analytes, set by a harmonisation group established by the RCPATH, the ACB and the IBMS (see *Harmonising reference intervals* on page 67). For potassium, this reference interval is set at 3.5 to 5.3 mmol/L. However, as **Figure 37** and **Figure 38** below show, many labs were not using this interval for potassium in a sample patient. For the high reference limit, we found that 26% of labs were not using the recommended limit.

²² Lee, G. R., Griffin, A., Halton, K., Fitzgibbon, M. C., 2017. *Generating method-specific Reference Ranges – A harmonious outcome?* <https://www.sciencedirect.com/science/article/pii/S235255171630049X#bib29>

Figure 37: Low reference limit used for potassium levels in a 25-year-old woman (n=134)

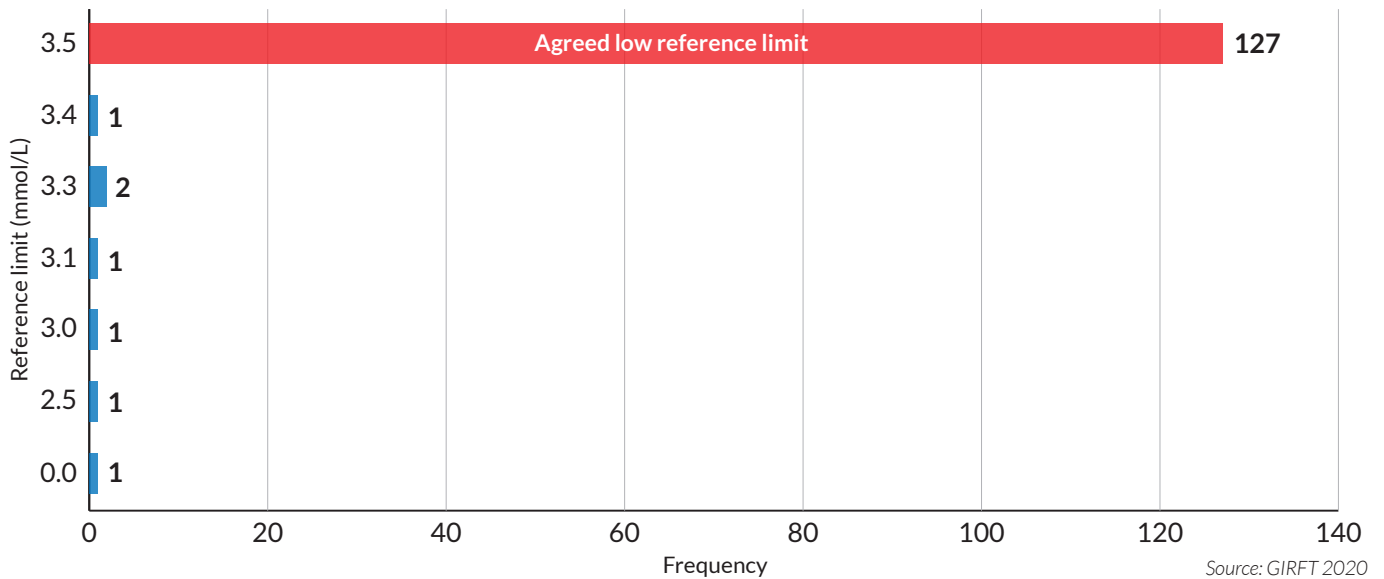
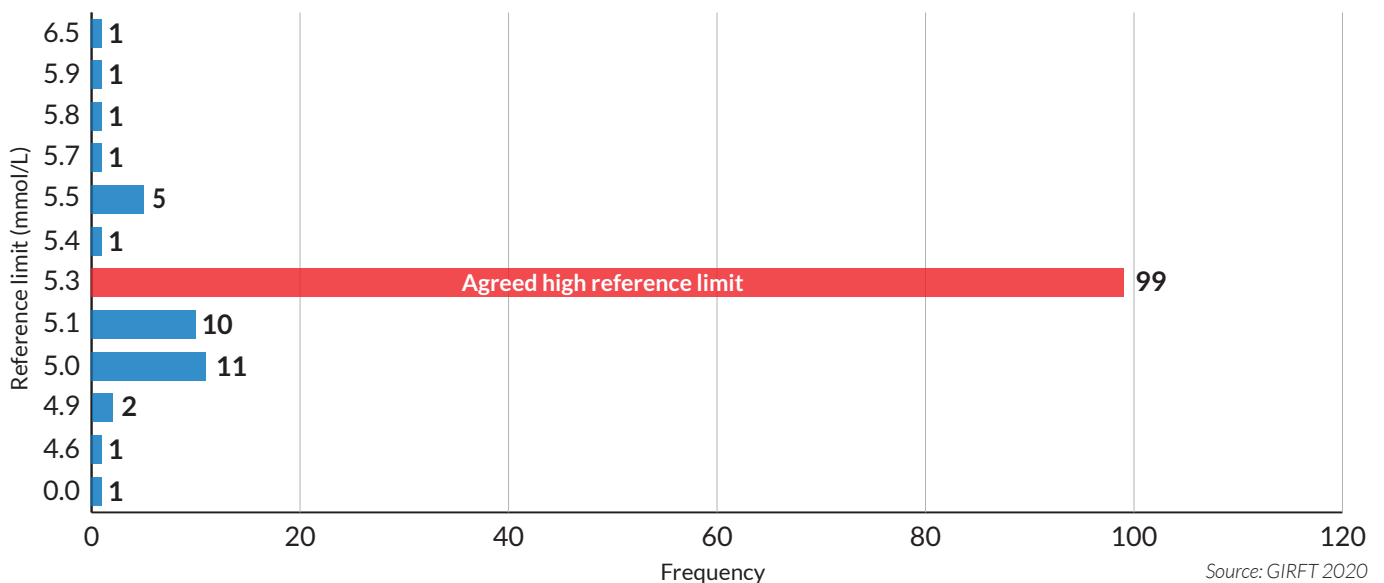


Figure 38: High reference limit used for potassium levels in a 25-year-old woman (n=134)



From discussions on our visits, we found that some labs may be adjusting their high reference limit to take account of process problems in pre-analytic stages – for example problems in transporting potassium samples, as discussed in *The effect of stabilisation on potassium testing* on page 46. However, the solution here is to address the transport issue, not to alter the reference limit.

Labs are unlikely to be using very different testing methodologies for potassium, and therefore should be able to follow the nationally agreed pathology harmonisation recommendations.

We found wider variations in reference intervals for haemoglobin levels in the same patient example, as shown in **Figure 39** and **Figure 40**.

Figure 39: Low reference limit used for haemoglobin levels in a 25-year-old woman (n=135)

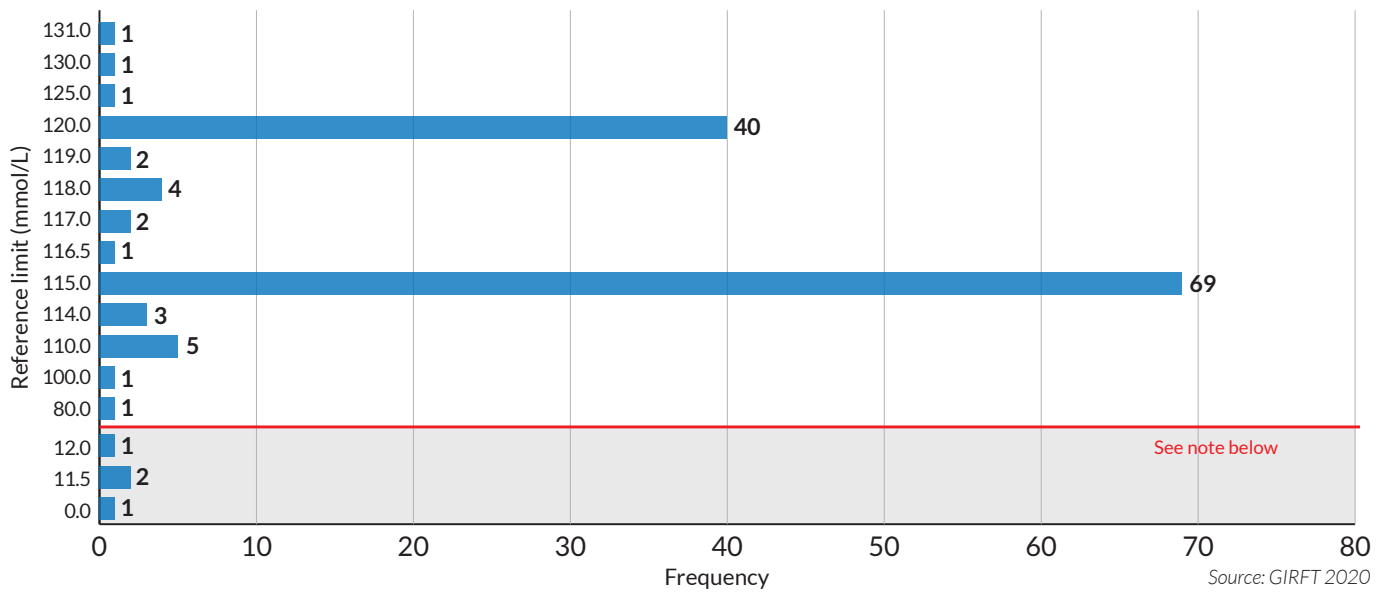
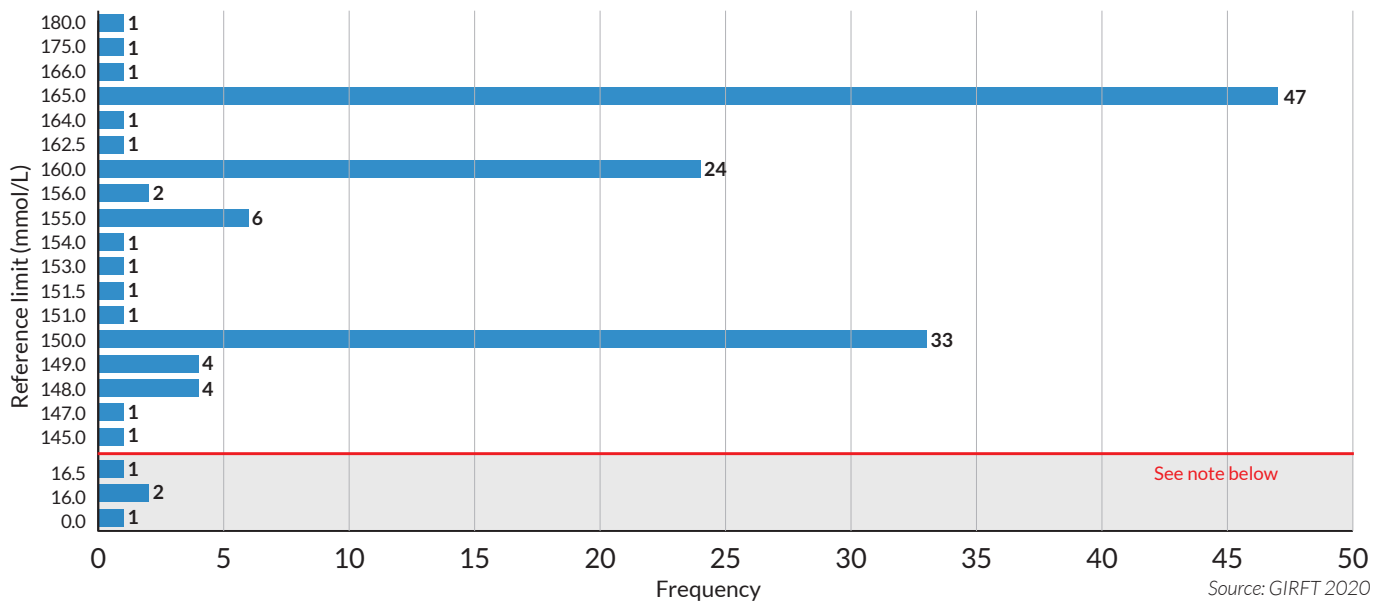


Figure 40: High reference limit used for haemoglobin levels in a 25-year-old woman (n=135)



Note: Limits under the red line (Y axis values shown in shaded box) in both graphs are using an out-dated measurement unit, where the result needs to be multiplied by ten. This use of non-standard measurement units further highlights the excess variation between labs.

The greater variation in this test may be due in part to the lack of levels set by pathology harmonisation (although trusts should still be following manufacturer-set guidelines – there are relatively few manufacturers for this test).

Finally, we also looked at the variation in reference intervals for alanine transaminase (ALT), an enzyme that can indicate liver damage. Here we found that variation was even more significant, as shown in **Figure 41** and **Figure 42**.

Figure 41: Low reference limit used for ALT levels in a 25-year-old woman (n=129)

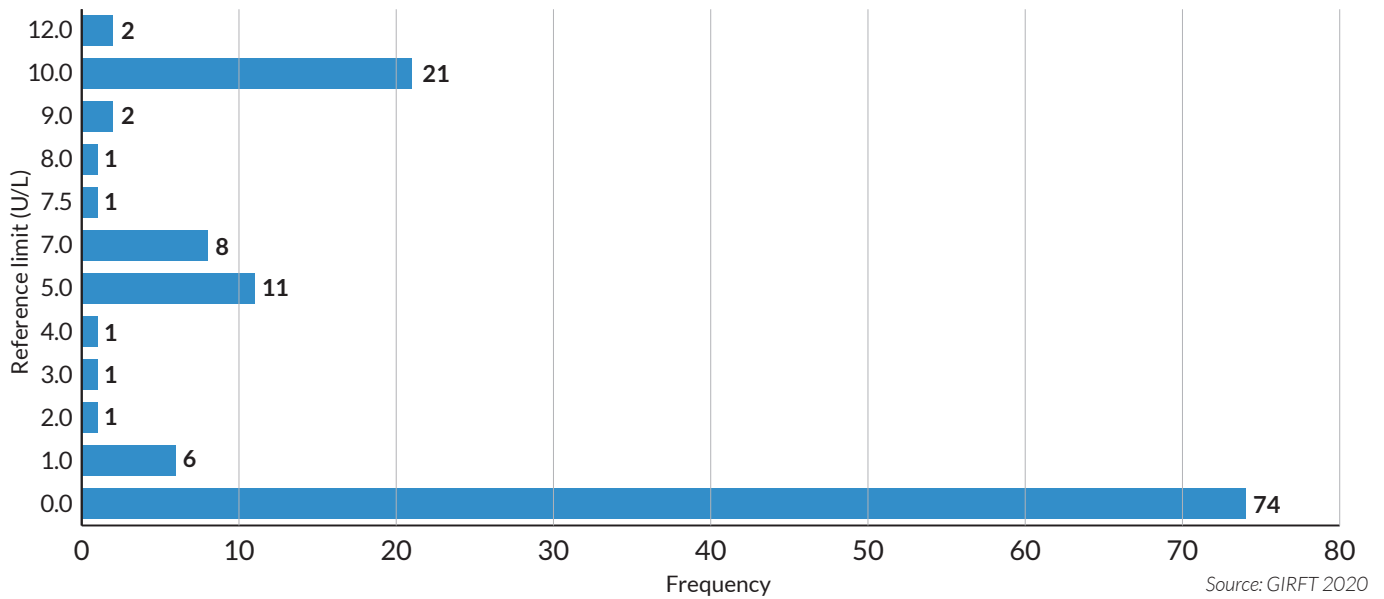
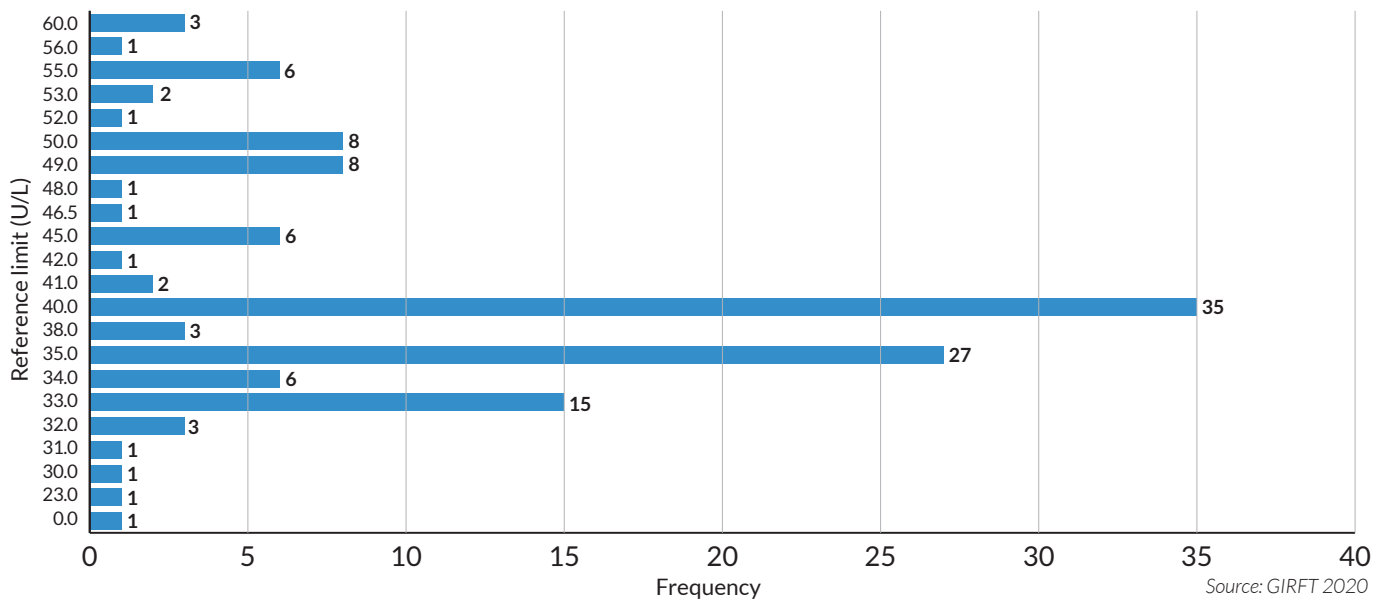


Figure 42: High reference limit used for ALT levels in a 25-year-old woman (n=133)



This high level of variation reflects in part that there are currently two methods to measure ALT, with variation in the results obtained and the manufacturers' reference intervals for each method. This is not necessarily the fault of the lab. Accreditation requires labs to show the provenance of the reference intervals they are using: to comply with this requirement, labs usually use the manufacturers' recommendations.

Variations in these reference intervals could have real impact on patient care. Many patients access care in multiple trust areas, for example if they live on a border, or work in one area and live in another. Currently, a sample patient could be flagged as suffering from low haemoglobin after visiting a hospital in one trust, and potentially offered further investigations, including invasive procedures such as endoscopy. However, if they were tested by a GP who happened to be in a different trust, the same result would not show as significant an abnormality, and no action would be taken.

Variations also interfere with the ability to examine trends in diseases. Where results fall outside some reference intervals used, but inside others, those results could not be identified as part of trend analyses. This is particularly an issue where there are variations in test location or method. For example, this could interfere with clinicians' ability to see trends in LFTs across an area, if they did not fully understand that results from different labs might have different reference ranges.

Harmonising reference intervals

For many tests, the different methods and ways of defining the reference intervals creates variation in reference intervals used. This variation, and the reasons behind it, has been known about for some time, but has to be addressed if manufacturers and labs are to reach consensus on many more reference intervals. This is therefore not something that can be controlled at a local level, but needs national (or international) harmonisation.

The ACB, the IBMS and the RCPATH previously established a programme to harmonise common reference intervals. They produced guidelines²³ outlining harmonised reference intervals for many commonly requested tests. The professional bodies recommended implementing this harmonisation by April 2011 and extending the harmonisation to other analytes. However, the next phase did not occur.

Not all tests will benefit from harmonisation – particularly where locally agreed intervals have more relevance – but having seen the degree of variation in reference intervals between labs, we concluded that the harmonisation group needs to be re-established, and its recommendations strengthened by being built into accreditation.

Re-establishing the group, and involving appropriate stakeholders, including manufacturers, colleges and other professional bodies, would help to address some of the issues involved with reference intervals. For example, the group could:

- address methodology differences directly with manufacturers to achieve consensus;
- establish a consistent approach for defining intervals across analytes;
- consider whether alternative intervals are required to reflect (for example) age, sex, ethnicity or other health considerations, such as pregnancy;
- remove administrative burden from labs, as they would no longer need to consider each interval separately;
- inform the development of test specifications.

It is equally important that where harmonisation exists, labs use the agreed intervals. One of the more startling findings from our research was that even where there is a harmonised interval set for potassium testing, 26% of labs were not using this interval.

We therefore recommend that pathology harmonisation is reinstated, but also that adherence to agreed reference intervals is built into accreditation for labs, to improve compliance.

Results that help to define next actions clearly

Although reference intervals help clinicians with interpreting results, we are often more interested in the results that are clearly abnormal and that require urgent action. Often, labs will phone these results to the clinical teams, and so the decision point for doing this is known as the 'phoning limit' or 'action limit'. Increasingly, these results will not be phoned but communicated using other, more robust channels that do not involve error-prone transcription, so we have used 'action limit' as the general term in this section.

Variations in action limits for urgent results

Again, we have looked at this from the perspective of biochemistry, but the principle applies to all pathology specialties. In each case, staff need to think through why a result might be urgent (results that may be life-threatening or require urgent action), and who should be told about it to ensure action. There are nationally agreed guidelines for action limits, produced by the RCPATH – for example, the lower limit for potassium is 2.5mmol/L.²⁴ These reflect the levels at which we would expect clinicians to consider action.

As these limits are agreed at national level, we expected to see that they had been universally adopted, or nearly so. However, as shown in **Figure 43** and **Figure 44**, this was not the case.

²³ *Harmonisation of Reference Intervals, 2011.*
<https://www.acb.org.uk/asset/EEA82309-7E93-417D-9B8991B0C65C52FB/>

²⁴ *The Royal College of Pathologists: The communication of critical and unexpected pathology results, 2017.*
<https://www.rcpath.org/uploads/assets/bb86b370-1545-4c5a-b5826a2c431934f5/The-communication-of-critical-and-unexpected-pathology-results.pdf>

Figure 43: Low action limits for potassium test reporting to primary care (n=126)

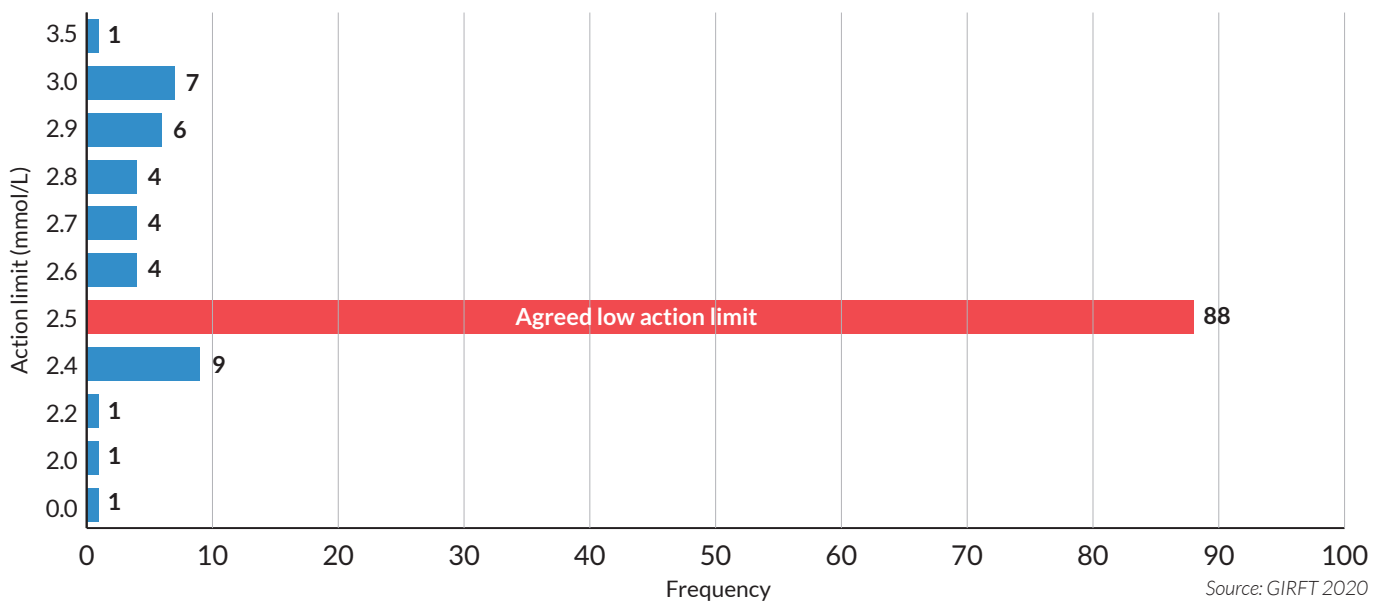
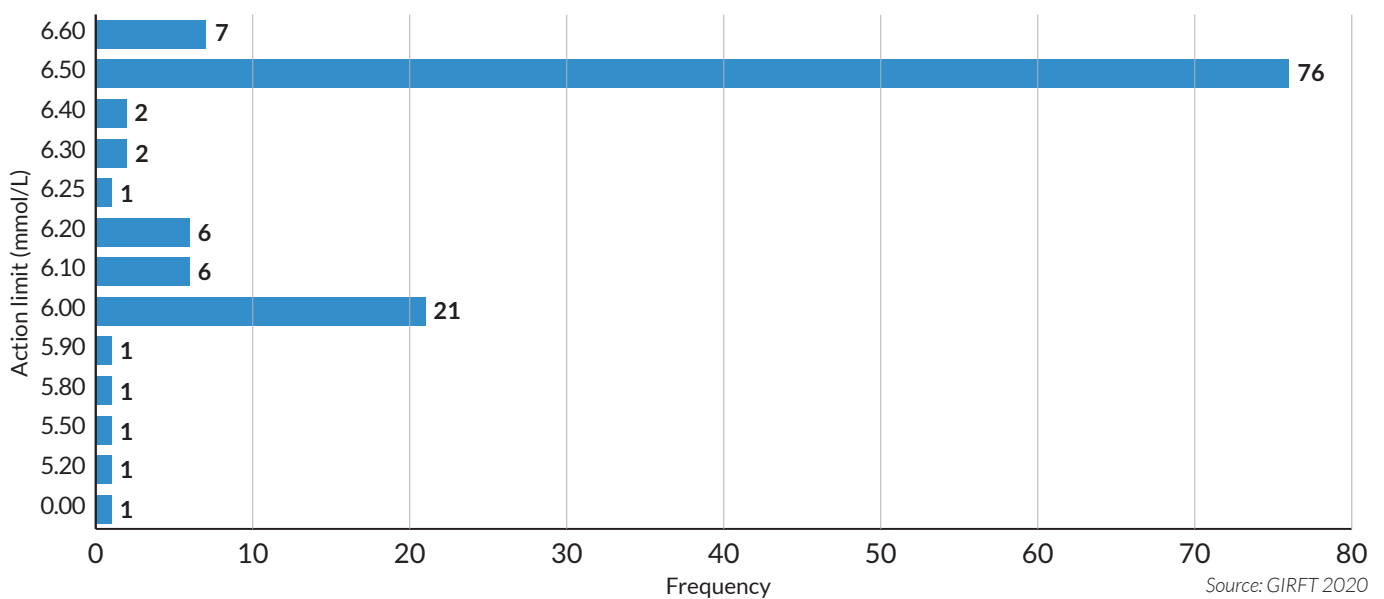


Figure 44: High action limits for potassium test reporting to primary care (n=126)



Although most labs had a common lower action limit for potassium, this was not universal, and there was considerable variation in the upper action limit. This locally produced guidance may have been implemented for good reason, but we believe it may not have fully considered the system costs, and distress to patients, created by potentially unnecessary calls and follow-up.

We therefore recommend that:

- networks and trusts follow the RCPATH guidelines on action limits;
- labs ensure that interpretation is provided alongside results where useful;
- there is continued development of network level and national guidance on action limits, as part of the more general development of test specifications as part of network standards (see *Establishing network-wide standards and standardised national diagnostic pathways* on page 82).

Results that are visible when they are needed

Many labs in our visits reported standard expected turnaround times for tests, as specified by the RCPATH,²⁵ showing that these are achievable.

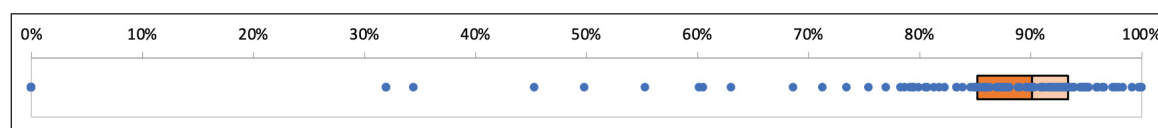
However, standard turnaround times do not take into account how urgently tests are needed in different situations. Turnaround times need to reflect the clinician's and the patient's need in different circumstances.

Turnaround times for the ED: the urgent transport issue

To examine this issue in the ED context, we compared turnaround times for potassium testing. An ED requesting a potassium result would expect it to be available within an hour of being taken, not within an hour of the lab receiving it. However, as **Figure 45** and **Figure 46** show, there was a wide difference between these two measures, along with much more variation in the turnaround time from time of the sample being taken to results being available.

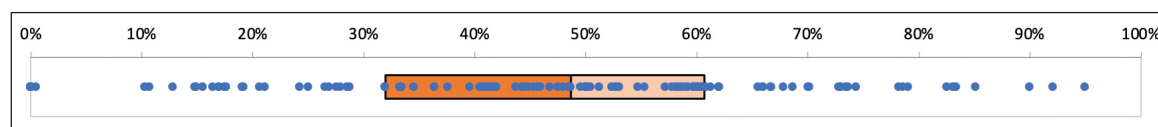
We discuss these issues further in the section *Looking at the impact of transport on turnaround times* on page 52, where similar issues were seen with turnaround times for haemoglobin results requested by EDs.

Figure 45: Lab turnaround of potassium results (percentage of results available within one hour of lab receiving sample: requests from ED) (n=128)



Source: GIRFT 2020

Figure 46: End-to-end turnaround of potassium results (percentage of results available within one hour of blood being taken from patient: requests from ED) (n=115)



Source: GIRFT 2020

CASE STUDY

Rapid serum tubes in ED

University Hospitals of Morecambe Bay NHS Foundation Trust

RCPATH recommends that the Key Performance Indicators (KPIs) for ED blood sciences should be 60 minutes from receipt in the lab to delivery of the result.

The clot activator additive used in standard serum tubes requires a period of time for the complex coagulation process to complete and yield a high-quality serum specimen.

Standard tubes have a recommended 30-minute clotting period to ensure the best quality specimen. A 30-minute period makes a 60-minute turnaround time nearly impossible.

The trust implemented use of a new rapid serum tube, which uses an innovative thrombin-based clot activator, accompanied by a separator gel. This means the specimen is far more likely to be completely clotted on receipt in the lab.

Results

Prior to the implementation of the new tubes, compliance with the 60-minute turnaround time KPI for acute care specimens was between 65%-75%. Immediately following the implementation of the new serum tube, compliance increased consistently to around 90% of samples.

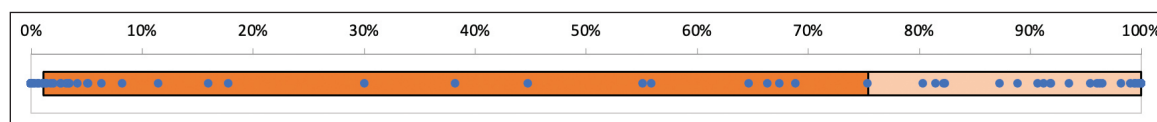
²⁵ Royal College of Pathologists, 2013. Key performance indicators – proposals for implementation. <https://www.rcpath.org/uploads/assets/a428b2af-7ae9-42da-bf9343e184ee05cf/Key-Performance-Indicators-Proposals-for-implementation-Current-version.pdf> and Royal College of Pathologists, 2013. Key assurance indicators for pathology services. <https://www.rcpath.org/uploads/assets/62de2970-42aa-4d73-9bf1122a1746331a/G181-Key-assurance-indicators-for-pathology-services.pdf>

Turnaround times for urgent conditions: neonatal blood samples

When managing neonatal sepsis, time is precious, which is why NICE Clinical Guideline 149²⁶ specifies that blood cultures for neonatal sepsis must be visible at 36 hours.

In our GIRFT visits, we found that a large number of labs did not deliver against this target, as shown in **Figure 47** below.

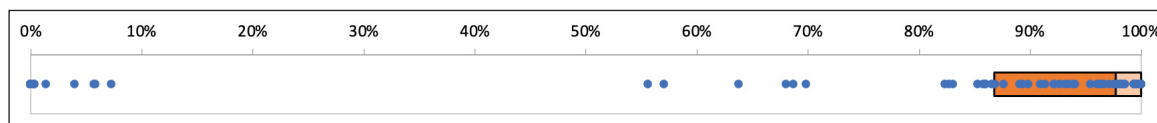
Figure 47: Percentage of neonatal blood cultures with time data where results were available within 36 hours (n=111)



Source: GIRFT 2020

In fact, many labs did not collect accurate data on this, and so could not monitor their performance, as shown in **Figure 48** below.

Figure 48: Percentage of neonatal blood cultures with time data (n=112)



Source: GIRFT 2020

We explored the reasons for these problems in our deep dives:

- Loading time: it is impossible to hit the 36-hour target without being able to load blood culture bottles onto analysers rapidly 24 hours a day.
- Incubation time: Many labs do not release a negative result until samples have had at least 36 hours of incubation. This means that results are never ready within 36 hours of being taken. Those labs that are able to hit the target send out presumptive negative results after shorter incubation periods. Audits for these results have shown that this is a safe approach: very few significant results occur after more than 24 hours.

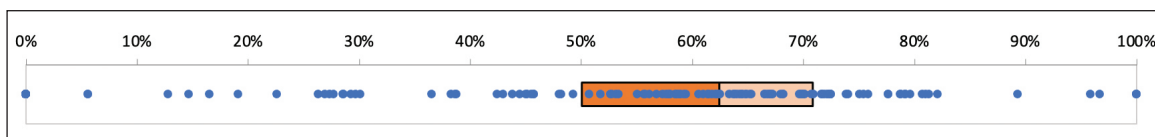
We therefore recommend that labs audit the end-to-end turnaround of neonatal blood cultures to ensure results are visible within 36 hours of the culture being taken, and review transport and culture practices where they are unable to meet this target in over 95% of cases.

²⁶ <https://www.nice.org.uk/guidance/cg149>

Turnaround times for inpatients: the phlebotomy issue

Blood tests for inpatients need a different approach to turnaround times: these results are usually needed to inform discharge plans, including shared decision making with patients, or other non-urgent decisions. Often, this means that results need to be ready for the early afternoon. We found wide variation in whether this was achieved in potassium results requested for inpatients, as shown in **Figure 49**.

Figure 49: Potassium level requested for inpatients: percentage available before 2pm (n=127)



Source: GIRFT 2020

We explored the reasons behind this variation in our deep dives. We found that sites with a lower proportion of blood test results reported before 2pm tended to have issues with phlebotomy services, mainly around staff recruitment and retention. Phlebotomy services may be managed directly by the pathology lab, or as part of hospital services. Regardless of how they are managed, the trust needs to:

- recognise the key role that phlebotomy services play in ensuring patient flow, and the delays that result where phlebotomists have limited availability;
- identify any phlebotomy-related delays to turnaround times, and adjust phlebotomists' working patterns to address these.

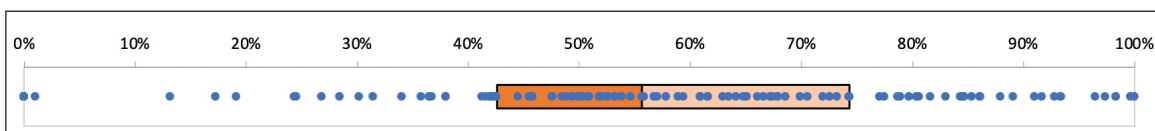
Turnaround times for primary care and community testing: the out-of-hours issue

The issue of turnaround is very different for samples taken in primary care and the community. While tests taken in the ED may need to be communicated urgently, tests taken in primary care are mainly carried out to monitor ongoing chronic conditions, and are rarely required urgently. However, if a lab finds immediately concerning results when a sample is tested outside of normal working hours, this can create significant management issues.

Taking hyperkalaemia as an example: most labs will phone the local out-of-hours primary care services with significantly raised results.

To examine this we looked at the percentage of potassium results that were reported out of hours, and found significant variation, as shown in **Figure 50** below.

Figure 50: Percentage of potassium levels reported to GPs out of hours (n=117)



Source: GIRFT 2020

Calling out-of-hours primary care services can cause significant problems: as examples of extreme cases, we heard of a patient who had his door broken down by the police in the middle of the night, and a pregnant patient who had to attend the ED at 2am. In both cases, the tests had shown misleading results due to pre-analytical failures (see also *Looking at the downstream effects of poor stabilisation* on page 47). In neither case was the blood test carried out because the patient was unwell, and the result did not need to be phoned out of hours.

Some services routinely run these tests out of hours because it allows them to use every minute of staff and analyser time. Although this is understandable, labs also need to have a strategy, agreed with the relevant services such as GP hubs, for informing out-of-hours services about significantly abnormal results. This strategy will need to support lab staff's clinical judgement about when a result needs urgent communication.

We heard about several approaches already used by labs on our deep dives. These will obviously reflect local circumstances and may not be appropriate in all settings.

- Some labs took on the risk assessment themselves, using clinical scientists. These staff risk-assessed results to filter any that needed to be phoned urgently.
- At another trust, the lab did not process primary care blood samples overnight. Instead, they ensured the samples were stabilised, and then processed them early in the morning. If a primary care request was signalled as urgent, these were processed using different lab pathways. This ensured that lab performance matched the clinical need, and was a good example of how labs need to work with users to work out how best to inform patient management.
- Other hospitals worked with primary care to ensure that phlebotomy at GP surgeries matched up to frequent sample pick-ups, as well as using advanced automated analysers for blood science. This has resulted in over 90% of GP samples being reported before 6pm. These can therefore be reported directly back to the GP during office hours.

We recommend that labs carry out audits of results communicated out of hours, in discussion with primary care colleagues, to establish whether there is a need for a change in out-of-hours strategy – especially where these rates are high compared with other trusts in the network.

CASE STUDY

Improving the out-of-hours telephoning strategy

Nottingham University Hospitals NHS Trust

Following a review of the out-of-hours telephoning strategy, and the number of patients attending GP emergency medical services to have blood taken, the trust now has a new process for handling these results. Before concerning results are telephoned to the GP or the GP's emergency services:

- The biomedical scientist processing the sample contacts the on-call duty biochemist to confirm whether the results require an urgent visit.
- The duty biochemist checks all high or low potassium results of clinical concern, and correlates these with previous clinical detail, information on drug history, and current and previous kidney and liver function.
- If there is no urgent clinical concern, the results are only telephoned during working hours.

Results

The new system will reduce the need for patients to make unnecessary night-time visits to emergency services.

Core recommendations: Clean Framework

Recommendation	Actions	Owners	Timescale
1. Establish the Clean Framework as the governing ethos, overarching quality framework, and basis of pathology accreditation throughout the healthcare system.	a UK Accreditation Service (UKAS) to work with the pathology community to redevelop accreditation using the Clean Framework as the basis of engagement with the ISO standard, with oversight from the National Pathology Board (NPB).	UKAS, labs, pathology networks (PNs), Primary Care Networks (PCNs), NPB	Pilots to be running within six months of publication
	b To deliver action 1a, labs and PNs to lead in setting up mechanisms for engaging with all teams to embed the Clean Framework across the end-to-end pathway, starting with primary care and emergency departments (EDs).	Labs, PNs	Progress within 12 months of publication
	c Labs, PNs and PCNs to develop a plan to: <ul style="list-style-type: none"> • apply this approach consistently to all settings, including Point of Care Testing (POCT); • ensure all POCT is supported by an accredited lab in line with Medicines and Healthcare products Regulatory Agency (MHRA) guidance. 	Labs, PNs, PCNs	12 months of publication
3. Establish electronic requesting and messaging as standard in all labs and with all requestors.	a Labs to work with PCNs to ensure that electronic requesting is standard for all primary care requesting, where the percentage of requests received electronically from PCNs is below 80%, in line with the NHS Long Term Plan (NHS LTP).	Labs, trusts, PNs, PCNs	For immediate action
	b Labs, trusts and PNs to have agreed plan and timescale for introducing electronic requesting in other areas, where current percentage of requests received electronically is below 80%, in line with the NHS LTP.	Labs, trusts, PNs	Within 12 months of publication
	c Labs, PNs and PCNs to continuously monitor and update electronic requesting system to reflect feedback and guidance changes and to improve decision support.	Labs, PNs, PCNs	Following actions 3a and 3b

Detailed recommendations: Clean Framework

Recommendation	Actions	Owners	Timescale
Clean in stage			
6. Interrogate all tests to ensure all are: <ul style="list-style-type: none"> based on a valid clinical question; necessary, appropriate and sufficient to answer that question. 	a PNs to: <ul style="list-style-type: none"> develop network-wide Care Sets, in all possible areas, including primary care, ED and specialty; ensure guidance available as decision support; continually monitor, benchmark and review Care Sets. Labs to implement these Care Sets and promote their use to all requestors.	Labs, PNs	Progress within 12 months of publication
	b PNs to: <ul style="list-style-type: none"> within Care Sets, disaggregate common testing profiles as a network, as much as possible, working closely with primary care colleagues; remove urea and chloride from primary care testing profiles; eliminate routine co-ordering of C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) tests; identify and remove all other tests of limited clinical value; ensure requestors can still request these tests if they have a specific reason to do so. Labs to implement in line with above.	Labs, PNs	Progress within 12 months of publication
	c PNs to: <ul style="list-style-type: none"> check all minimum retest intervals are aligned to RCPATH guidance; build intervals into decision support and electronic requesting; where this is not possible, impose lab limits; educate requestors on the proper use of minimum retest intervals. Labs to implement in line with above.	Labs, PNs	Progress within 6 months of publication
7. Reconfigure transport and sample collection services to ensure that samples reach the lab in the best possible condition.	a Labs, trusts and PNs to monitor non-numeric potassium levels, and, if 5% or greater, intervene urgently to address issues identified.	Labs, trusts, PNs	For immediate action
	b Labs, trusts, PNs and PCNs to identify where there is a difference between summer and winter potassium levels of 0.5mmol/L at individual collection point level (for example an individual surgery), and wherever this occurs, intervene urgently to address issues identified.	Labs, trusts, PNs, PCNs	Progress within 6 months of publication
	c Labs, trusts, PNs and PCNs to audit processes for collection of urine, and address issues identified.	Labs, trusts, PNs, PCNs	For immediate action
	d Labs, trusts, PNs and PCNs to improve current monitoring of time of critical events along the end-to-end pathway, for example time of collection, and audit and address all identified issues.	Labs, trusts, PNs, PCNs	Within 12 months of publication
	e UKAS to link portering and transport quality to accreditation.	Labs, trusts, PNs, PCNs	Pilots to be running within 6 months of publication
	f Labs, trusts and PNs to ensure portering and transport arrangements are fit for purpose in line with anticipated UKAS approach to accreditation.	Labs, trusts, PNs	To be ready to meet UKAS accreditation within 6 months

Detailed recommendations: Clean Framework (continued)

Recommendation	Actions	Owners	Timescale
Clean in stage (<i>continued</i>)			
8. Ensure all requestors are using NHS numbers consistently (apart from known exceptions).	a Labs, trusts, PNs and PCNs to identify barriers to use of NHS number, and address with requestors, aiming for a minimum of 90% of requests using the NHS number, starting with primary care and ED.	Labs, trusts, PNs, PCNs	For immediate action
Clean through stage			
9. Urgently investigate acute kidney injury (AKI) flags to understand variation.	a The NPB, in conjunction with the Renal Association and UK Renal Registry, to commission research to identify and, if appropriate, address causes of variation.	NPB	For immediate urgent action
Clean out stage			
10. Audit and overhaul approach to action limits, including out-of-hours protocols.	a Labs and PNs to audit results communicated out of hours, working with primary care colleagues, and change strategy where the numbers are causing problems for users or patients.	Labs, PNs	Within 6 months of publication
11. Ensure appropriate turnaround times, and address identified issues.	a Labs and PNs to identify pathways where turnaround times are impacting on patient care, and address issues.	Labs, PNs	Within 12 months of publication
	b Labs and PNs to report potassium from ED within one hour of collection.	Labs, PNs	Within 12 months of publication
	c Labs and PNs to ensure blood cultures are loaded onto analysers within four hours of collection.	Labs, PNs	Within 12 months of publication
	d Labs and PNs to ensure neonatal blood cultures are reported within 36 hours of the sample being taken, in line with NICE guidance.	Labs, PNs	Within 12 months of publication

Applying the Clean Framework to end-to-end pathways for a sentinel condition

A key theme throughout this report is the danger of seeing pathology tests in isolation from the clinical context. We must instead strive to see quality in pathology only through the lens of its impact within the wider, end-to-end clinical context of a patient pathway.

An end-to-end pathology approach would be:

- Built on the foundation of the Clean Framework, ensuring that all stages of the diagnostic pathway are considered, including Clean in (pre-analytic) and Clean out (post-analytic).
- Backed up by accreditation and quality assurance that does not focus purely on the lab itself, but establishes quality through the entirety of the end-to-end pathway.
- Supported by intelligent data, enabling faster communication, minimising error and embracing new approaches to analysis;
- Enabled by an effective, practical delivery model that ensures expertise is available when and where it is needed for each particular patient.

In the following section, we show an example of how this might look for a key sentinel condition – venous thromboembolism.

A sentinel pathway: venous thromboembolism

Venous thromboembolism (VTE) is a condition where a patient has developed a clot in a deep vein, usually a leg vein – a deep vein thrombosis or DVT. This can move to the lungs, where it is known as a pulmonary embolism or PE. A PE can be life-threatening.

As part of our review, we looked at the use of two blood tests that are important in the management of patients with venous thromboembolic disease, as well as other conditions. Both tests look at patients' blood to see if there is a problem with clotting.

- The D-dimer is a diagnostic test that looks for a protein fragment made as a blood clot dissolves.
- The international normalised ratio (INR) is a test that measures how long it takes blood to clot, which is used to monitor patients taking the anticoagulant drug warfarin.

Both tests can be measured in the lab or using POCT devices.

Understanding these tests

The management of VTE has evolved significantly in the last 30 years, and this change gives context to our interest in the use of these tests:

- Acute VTE (either DVT or PE) occurs in around 1 in 1,000 adults. VTE can be difficult to diagnose and may be easily missed, leading to significant harm and potentially death.
- Once diagnosed, patients are treated with anticoagulant medicines, initially with heparin injections, then an oral medicine. Patients generally take these for around three to six months.
- In the late 1990s, a version of heparin was developed that could be given as a simple daily injection. This meant that uncomplicated VTE patients could be treated out of hospital, which was a safer experience for most, and freed up hospital beds for other patients.
- Several hospitals created dedicated outpatient nurse-led DVT clinics, which take referrals from the ED or primary care, arrange investigations, and – if diagnosis is confirmed – stop the heparin and start oral anticoagulants.

How the tests are used

Test	How it is used	How it is carried out
D-dimer	<p>Diagnostic test</p> <ul style="list-style-type: none"> • If not raised, this helps to rule out VTE – there is no need for further investigation to look for a clot. • However, D-dimer can be raised by many situations or conditions, not just VTE. • Therefore clinicians use a scoring system (Wells score) to guide further management. • If the patient has a low Wells score, VTE is unlikely. The clinician will either arrange a D-dimer test within four hours, or prescribe anticoagulants as an interim measure until the test can be arranged. If the patient then tests negative on their D-dimer, they will not need further treatment or a scan, and the clinician will investigate other causes of the patient's symptoms. • If the patient has a high Wells score, ideally the patient needs to go straight to further investigations (such as a scan) without waiting for a D-dimer result. If a scan cannot be arranged immediately, the clinician will request a D-dimer and prescribe anticoagulants for the patient as an interim measure until the scan can be arranged. 	<ul style="list-style-type: none"> • Processed by all hospital haematology labs. • Also available as a POCT kit (although these are not reliable if they are not carried out properly).
INR	<p>Monitoring test</p> <ul style="list-style-type: none"> • Used to monitor patients who are taking oral anticoagulants, such as warfarin. • Doses for these medicines are not standard, and monitoring is needed to ensure patients are not being over- or under-treated, both of which can have serious consequences. 	<ul style="list-style-type: none"> • Processed by all hospital haematology labs. • Also available using a POCT device, which can be used in primary care, community-based anticoagulant clinics or hospitals.

Since the beginning of the 21st century, alternatives to warfarin, known as Direct Oral Anticoagulants (DOACs), have become available and are now in widespread use. These have many advantages over warfarin – in particular, they can be used at a standard dose related to simple patient characteristics (such as weight or kidney function). This means they do not require blood test monitoring, other than an annual check for patients on long-term treatment, and are often chosen above warfarin. However, warfarin remains the anticoagulant of choice in some situations, and for these patients the INR must be monitored regularly.

We believe that applying the Clean Framework to the treatment and monitoring of VTE and anticoagulant medicines could improve the care of patients.

Clean in

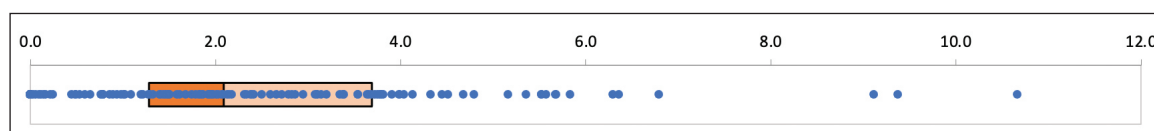
Is the test appropriate?

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

As explained above, diagnosing VTE can be challenging. An individual may present with a swollen leg, simply with discomfort in their calf, or with another non-specific symptom. If the clinician's clinical question is 'Does this patient have a DVT, or is there another explanation for their symptoms?', they will undertake a 'two-level Wells score' assessment to guide their next steps and help them decide whether to run a D-dimer test.

We found significant variation in the rate of D-dimer requests from primary care, as shown in **Figure 51** below.

Figure 51: D-dimer tests requested by GPs (per 1,000 patients on GP list) (n=121)



Source: GIRFT 2020

The incidence of DVT does not vary significantly across the country, and therefore we could not see a clinical reason for the variation. In our deep dives, we learned that the local pathways for investigating possible DVT are not always clearly described, despite the existence of national standards (NICE Quality Standard 29²⁷ and NICE guideline 158²⁸), and the requirement for running a Wells score as part of the diagnostic pathway is not always followed. This may lead to inappropriate D-dimer testing, both for patients with a high score, who should be referred straight to scan, and for patients with a low score, where D-dimer is not necessary if the scan can be arranged within four hours. In areas where a well-developed pathway for the investigation and efficient management of potential DVT has been agreed between the primary care teams, the hospital clinicians and the lab, more clinically-focused D-dimer testing supports patients and clinicians in making the right care choices.

This highlights the importance of focusing on the clinical question rather than requesting a test as default, as by using the Wells score correctly a clinician may reach the appropriate diagnosis faster.

Are the samples delivered to the lab on time?

In our deep dives, we heard concern from some labs that where the primary care team takes the sample for D-dimer and sends it to the lab, this almost inevitably leads to a delay in diagnosis. The primary care clinician has to wait for a positive blood test result before they can request a scan. A local patient pathway that enables a 'one-stop' approach (usually in a nurse-led clinic), with D-dimer and same-day scanning following a positive result, means that patients can be started on treatment speedily, with less risk of harm caused by delays.

²⁷ <https://www.nice.org.uk/Guidance/QS29>

²⁸ <https://www.nice.org.uk/guidance/ng158>

Clean through

- Understanding variation and minimising error.
- Processing results in a clinically relevant timeframe.
- Improving lab oversight of POCT.

Using POCT with D-dimer

The variation in D-dimer test requests shown above is further complicated by the use of POCT devices. We did not investigate the extent of this using our questionnaire, but anecdotal feedback in our deep dives suggested that in some areas POCT may be reducing the number of tests sent in to the hospital lab.

A study of POCT D-dimer test devices in 2014²⁹ indicated that when these devices were used in primary care, tests were not always being performed and interpreted by clinical staff, and in some cases interpretation of the result was incorrect.

The existence of an agreed local pathway, as some trusts reported, enables a consistent approach to the investigation and management of these patients, with co-ordination between primary and secondary sectors ensuring a safe and efficient pathway of care.

Using POCT with INR

We also looked at the use of POCT in INR testing. Once a VTE has been confirmed, the patient will usually need treatment with an oral anticoagulant for at least several weeks. In the past, warfarin was the only option, which necessitated regular INR blood testing. A lab INR test is done on a sample taken from the patient's vein: however, the development of POCT devices for INR has enabled some local areas to set up their own system to monitor patients on warfarin (whether they are taking this for VTE or another condition). These devices only need a drop of blood from a finger-prick and produce a result within minutes. In contrast, lab samples must be requested, transported, input into the lab system, tested, validated and then returned electronically to the requestor, who must then notify the patient of the result and whether any dose change is required. POCT devices therefore clearly help with delivering results to the clinician and patient on time.

However, users of POCT devices must still undertake quality control and quality assurance procedures on the equipment regularly, and be able to demonstrate that the result is valid. Most importantly, the test needs to be electronically integrated with the patient's records.

We looked at the variation in INR requesting from primary care across the country, as shown in **Figure 52**.

Figure 52: INR tests requested by GPs (per 1,000 patients on GP list) (n=123)



Source: GIRFT 2020

Low rates may be due to:

- all patients having been transferred to DOACs – this is unlikely, since warfarin remains a safer choice for some blood clotting disorders;
- a local POCT testing system having been established.

²⁹ Kitchen, D. P. *The what, why and how of D-dimer testing in primary care. Thrombus Volume 20 #2, Hayward Medical Communications, 2014, pp 29-31.*

We believe that where POCT systems are in use for any form of lab testing, it is best practice for the local lab to provide professional support to users, with oversight to ensure that regular quality control and quality assurance are carried out, and that the results are integrated into the patient record. This is reflected in the NHS LTP, which states that clinicians should be able to access and interact with patient records wherever they are.³⁰

However, our data suggested that this was rarely the case, whether the devices were being used within secondary care in local VTE clinics, or in the community – as shown in **Figure 53** and **Figure 54** below.

Figure 53: Community INR POCT (n=142)

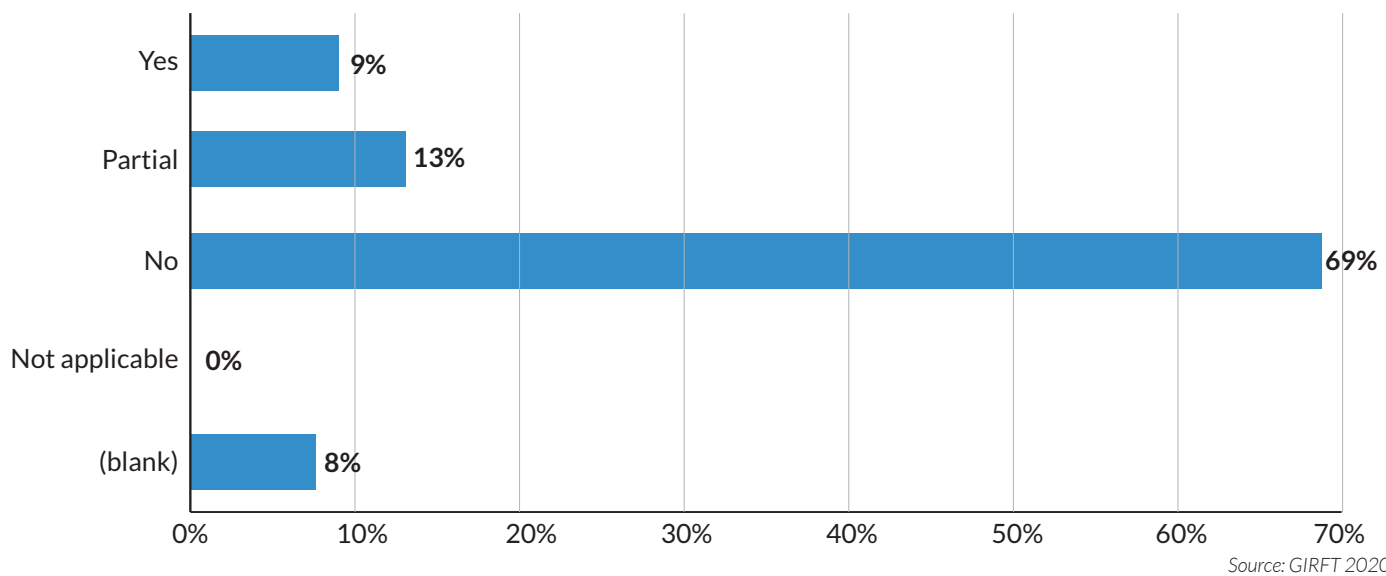
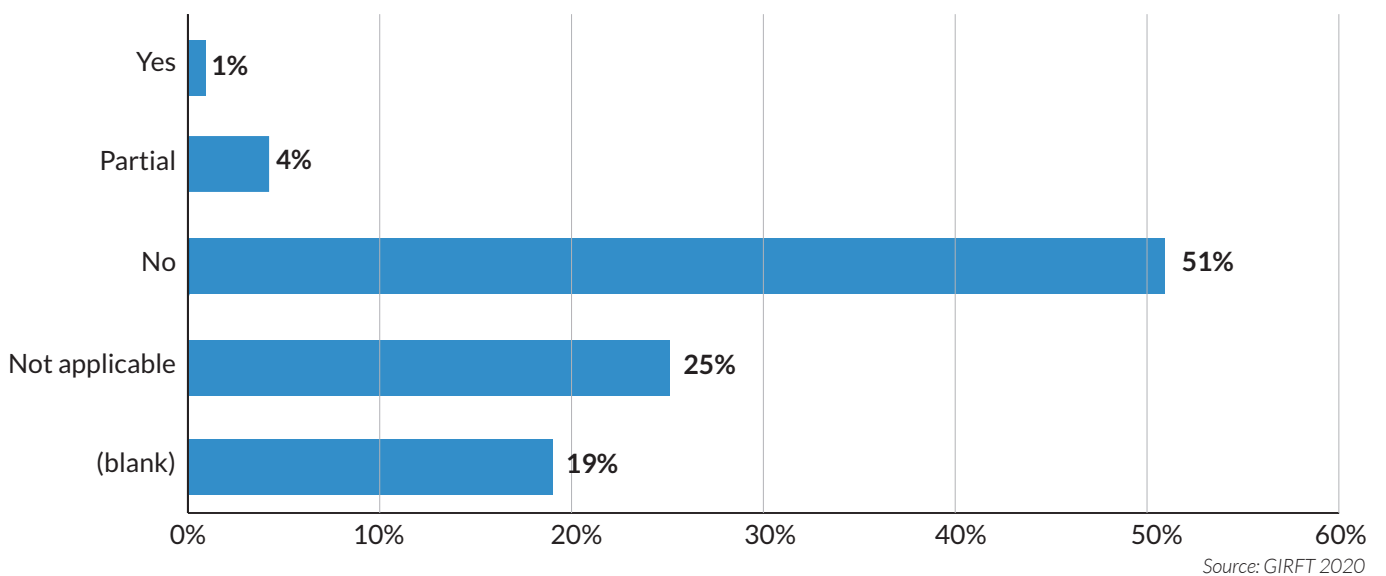


Figure 54: Secondary care coagulometer POCT interfaced with LIMS or patient record? (n=142)



³⁰ <https://www.longtermplan.nhs.uk/online-version/chapter-5-digitally-enabled-care-will-go-mainstream-across-the-nhs>

Improving POCT quality assurance and integration in VTE

Trusts and networks therefore need to focus on reaching out to all local clinicians (in the community, including primary care, and in secondary care) who are providing POCT for both D-dimer and INR testing, and ensure that:

- there is clear lab oversight, providing support and education as needed;
- results can be easily integrated into the LIMS or the patient's record.

Clean out

- Results that describe normality for that patient.
- Results that help to define next actions clearly.
- Results that are visible when needed.

If a patient is concerned that they may have a DVT, they will want this confirmed or ruled out as speedily as possible. The Wells score gives an indication of the likelihood of VTE, and guides further investigations including D-dimer testing and ultrasound scanning.

It is vital that DVT patients receive treatment fast, to prevent potential complications or even death. Therefore, where a D-dimer test is indicated, the clinician needs to know the result as quickly as possible so that they can act on a positive result – including treatment with heparin injections until the scan can be arranged, ideally within 24 hours.

Delivering test results this quickly requires a joined-up approach, working across primary and secondary care, and also involving other teams (such as radiology) if the patient is to experience the best possible management and care.

We know from our deep dives that the involvement of lab teams and personnel in the establishment and oversight of such a pathway is very variable, from a highly co-ordinated active process to one where the lab team appear to have no sight of the local approach to VTE and anticoagulant management.

Conclusion

The management and care of patients presenting with a possible VTE or requiring on-going anticoagulant management presents local labs with an ideal opportunity to share their expertise with other clinicians involved in these pathways, ensuring that:

- the whole pathway is considered, reviewed and optimised for patient care, including asking the right question at the right time (such as ensuring consistent use of the Wells score before ordering D-dimer);
- systems are safe and backed up by quality assurance and lab oversight, including appropriate training in the use of POCT devices;
- results can be delivered on time to aid clinical decision making;
- results are integrated with the LIMS or patient's record, including when the result comes from POCT.

Detailed recommendations: VTE pathway

Recommendation	Actions	Owners	Timescale
12. Develop an integrated venous thromboembolism (VTE) pathway for network use.	a Trusts, PNs and PCNs to establish an agreed pathway for VTE diagnosis and management.	Trusts, PNs, PCNs	Within 12 months of publication

The three foundations underpinning the Clean Framework

To deliver the Clean Framework and create a true end-to-end pathology service, and to meet our objectives of delivering **the right test, at the right time, with the right answer**, there will need to be extensive changes to the systems that support labs and enable their everyday work. This section covers some of these wider, systemic changes. The changes may take effort and commitment at all levels of the healthcare system, from national bodies to individual clinicians, but will be necessary to achieve lasting change.

The three foundations that we need to rebuild are:

Foundation 1 – Quality – see below.

Foundation 2 – Data and digital delivery – see page 90.

Foundation 3 – Service delivery – see page 104.

These foundations feed into and underpin the Clean Framework, which cannot be implemented without them.

Foundation 1: Quality

From our deep dives, it was clear that a 'culture of quality' is now embedded in all English labs. However, we believe there is an opportunity to be more challenging about the true meaning of quality in laboratory medicine, and more holistic in approach, focusing back onto the patient's interests and needs. This will build on the value-oriented recommendations in the Barnes and Carter reports to achieve a new level of quality across pathology throughout England.

Quality that flows from the local level outwards

At the heart of this foundation is a renewed emphasis on quality at every level, and integration and co-operation between these levels to ensure an unwavering focus on continuity of quality:

- **In labs:** extending the lab's sphere of influence to the Clean in (pre-analytic) and Clean out (post-analytic) stages, by nurturing greater integration and shared responsibility across trusts and networks, and by reaching out to offer greater guidance to primary care colleagues.
- **In trusts and in CCGs:** establishing a holistic approach to shared services such as transport, portering and phlebotomy, to allow greater quality control throughout all stages of the pathology pathway.
- **In networks:** making networks an 'engine' for quality – creating governance, benchmarking, quality assurance initiatives and network-wide standards – see below.
- **At national level:** the NPB can co-ordinate with other national bodies, including UKAS, the MHRA (especially in the context of transfusion and POCT), NICE, NHSBT, NEQAS, the Care Quality Commission (CQC), the RCPATH, the IBMS and other professional bodies to oversee and co-ordinate quality initiatives.

Currently, the focus is unequal, with the onus lying mostly with labs, regulated by UKAS. This leads to an inevitable focus on the parts of the process that are under the direct control of the lab. But we believe that all bodies must take responsibility for embedding quality throughout the entire system. From our deep dives, it is clear that many labs and networks have already made progress in this direction. We therefore anticipate quality initiatives starting at a local level, and flowing outwards, with each level proactively seeking responsibility and influence to strengthen quality throughout the service.

Establishing network-wide standards and standardised national diagnostic pathways

One of the most important and wide-reaching causes of variation in approach that we saw is the lack of robust, consensus-driven, consistent standards across the pathology service.

Where we saw networks working well, colleagues were sharing knowledge peer to peer, and building on that pooled experience to improve quality in many areas of practice. We believe that this collaborative attitude can result in practical, harmonised standards across networks, which will in turn drive greater quality and consistency.

Nationally, there is a drive to establish standardised diagnostic pathways that incorporate all diagnostic specialties. It is vital that pathology works proactively to develop its own standards, established by consensus, and grounded in clinical practice, and the GIRFT team is currently reviewing where it may be possible and valuable to create standardised national pathways. Network standards can form a first step towards these wider diagnostic pathways, but are also vital in improving quality in areas not covered by the nationally set pathways, and in driving faster local change.

What will local network standards look like?

Local networks can decide on how wide-ranging their own standards need to be, but we suggest they consider including the following:

- Care Sets (or elements of common testing profiles);
- diagnostic pathways;
- decision support, including comments for the Advice and Guidance service;
- test specifications, beginning with the most common tests, to include:
 - reference intervals (reflecting any national guidance);
 - action limits (including if a concerning result occurs out of hours);
 - end-to-end turnaround times for tests;
 - an approach for specialist tests, either within or outside the network (see *Foundation 3: Service delivery* on page 104);
 - stabilisation requirements;
 - lab quality requirements;
- guidance for patients, building into informed consent.

To create the network standards, network leaders will need to look at how to:

- Ensure standards retain a patient focus, and cover every stage of End-to-End Pathology.
- Involve commissioners (for example CCGs) and all providers, including primary and community care, in a full dialogue, to increase transparency and buy-in throughout. Committing to a mutually agreed way forward should then encourage compliance on all sides.
- Educate providers on the use and usefulness of the standards, ideally built into decision support.
- Establish a process for continuous evolution of the standards, for example to add new tests and technology, and to incorporate ongoing feedback.
- Balance the need for a secure evidence base with a focus on fast delivery and rollout, using feedback from existing local initiatives (already in place in some areas, as we discovered in our deep dives) to speed up this process.
- Make standards flexible to reflect individual cases and local requirements – for example, there will always be patients who do not fit into the standard protocol, and retaining patient focus is one of our core principles.
- Build into and facilitate audit and, in some cases, accreditation – for example via EQA.

We have included two examples of currently used, patient-centred pathways in our appendices: for CA125 testing (used to aid identification and monitoring of ovarian cancer – see *Appendix 2: CA125 testing: a candidate for network standard development* on page 150) and prostate-specific antigen (PSA) testing (used to aid identification of prostate cancer – see *Appendix 3: PSA testing: another candidate for network standard development* on page 151). Please note these may be amended as the GIRFT team completes further work on national standardised pathways.

Agreeing standards at a national level

Once networks have established local standards and diagnostic pathways, the NPB can collect and review these at a national level, involving appropriate bodies to establish consensus. Where appropriate, standards and pathways can be taken forward by a professional or regulatory body such as NICE, the RCPATH, or the MHRA, working in close collaboration with GIRFT.

This process could result in the production of the equivalent of the ‘Green-top Guidelines’, which are developed and regularly updated by the Royal College of Obstetricians and Gynaecologists,³¹ and are in widespread use. Compliance with these is ‘taken as read’, as the guidelines enable clinicians to apply proven, consistent approaches, with the reassurance that this is nationally agreed best practice. This means that clinicians want to abide by the guidelines, rather than feeling they are imposed rules, or not of value.

NICE already has processes in place to evaluate whether there is a clinical need for diagnostic tests, and we see this developing with NICE’s impact report on pathology in 2021. In our visits, labs told us that even NICE-recommended diagnostic devices and tests could take many years to be adopted, if at all. However, where NICE approves medicines, adoption of these is (almost) mandatory. We recommend that this model is expanded to pathology, and that NICE and pathology work in collaboration to establish ways to improve speed of adoption for agreed national diagnostic standards alongside compliance.

³¹ <https://www.rcog.org.uk/guidelines>

Network standards will reduce unwarranted variation within networks and (ultimately) nationally, and make pathology more efficient, as local labs will be able to re-use existing standards, and no longer need to establish their own in isolation. Critically, the standards will also balance quality and value with productivity and cost-saving: a refocusing of energy that is necessary to sustain a quality pathology service for the future.

Improving lab quality: making greater use of EQA information

We believe that more use can be made of data from EQA schemes to improve quality assurance in labs. Information about differences between lab and manufacturer methodologies is of significant value, as it enables wider comparison and discussions, and we believe this should be shared more widely in order to contribute to discussions at a network and national level.

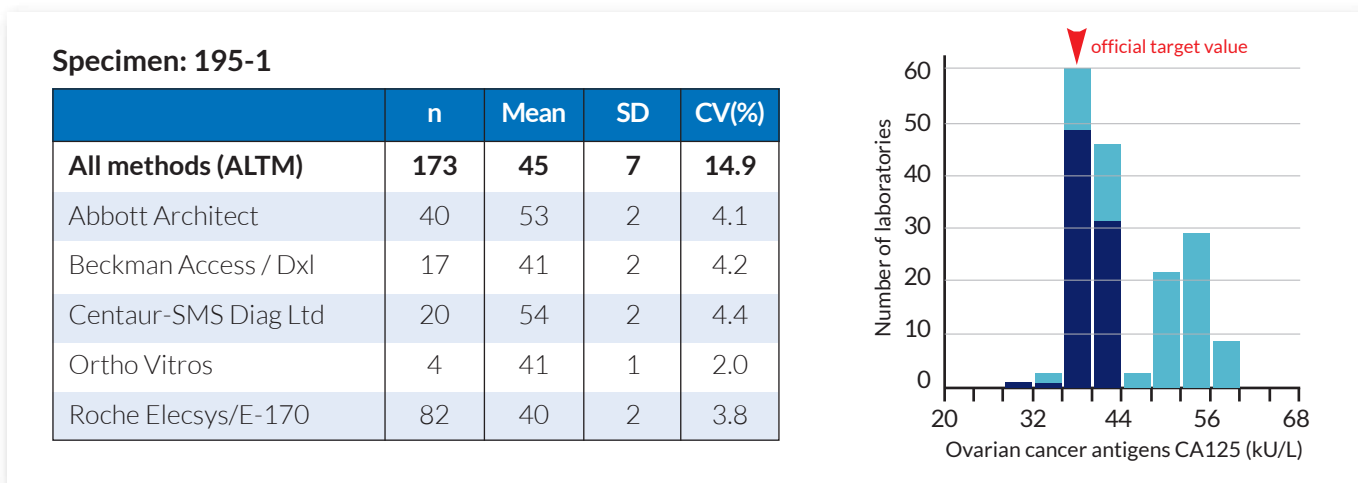
EQA comparisons of methodologies could show whether:

- any manufacturers are producing results that are not acceptable;
- any labs are outliers for acceptable quality;
- there is so much variation between the manufacturers that there is a need for better harmonisation – which can then be discussed with the manufacturing industry as part of pathology harmonisation.

The variation seen in the results for CA125 (a tumour marker) in the EQA process demonstrates how EQA can inform wider discussions about quality.

When thinking about how the Clean Framework would apply to the diagnostic pathway for ovarian cancer (see *Appendix 2: CA125 testing: a candidate for network standard development* on page 150), we were particularly struck by the variation in CA125 measurement across different testing platforms, as reported in EQA returns (see **Figure 55**). This shows a bimodal distribution related to the manufacturer used – around the current upper reference limit for CA125, which is 35kU/L.

Figure 55: CA125 results reported to an EQA scheme



Source: UK NEQAS Tumour Marker scheme

There are well-described methodological issues with measuring tumour marker levels, and this is reflected in systematic differences in results between manufacturers. However, the current nationally set action limit is the same regardless of how the test was carried out. There is an obvious potential here for the choice of testing platform to significantly affect outcomes for patients. This kind of issue clearly needs to be resolved at a national level, either by addressing differences between manufacturers, or by addressing how the reference intervals are used by clinicians.

We therefore propose that the EQA schemes are more open with this information, and work with the RCPATH to ensure that poorly performing methods, poorly performing labs, or unacceptable variation between tests can be discussed in a national forum, with appropriate actions assigned.

It is critical that the information obtained in EQA schemes is acted on at a network and a national level. While the NPB does not have governance over EQA schemes, we encourage the board to work with the various groups involved, including NEQAS and equipment manufacturers, to establish national co-ordination and to ensure fuller use of the available information.

We also welcome the establishment of an EQA Oversight Board by the RCPATH. We recommend that this board:

- uses EQA data to ensure that methodologies used are of an acceptable quality, with harmonisation of methods where possible;
- sets performance standards that manufacturers must meet for tests supplied to the NHS, ensuring that a manufacturer's method is fit for purpose.

The board may also have a role in supporting accreditation by challenging 'poor' lab performance in EQA schemes. It will need to take into account national regulations as appropriate to each specialty.

Reshaping accreditation via UKAS

The purpose of accreditation is to reassure users that the service is doing what they think it should be doing – to give them a way of judging whether they can trust their test result, with a reliable, recognisable name behind it. From a patient perspective, it helps to answer their second key question: **Can I trust your answer?**

The current system of accreditation, which is carried out by UKAS, provides detailed assurance about specific lab processes, based on the ISO15189:2012 standards, set by the International Organization for Standardization.

As written, ISO15189:2012 covers the entirety of the pathology pathway, including pre-analytic and post-analytic stages. Therefore, the Clean Framework aligns closely to a wider interpretation of ISO15189:2012, and labs implementing the Clean Framework will match the standard.

We recommend that UKAS continues to work closely with the pathology community, including the relevant national bodies, to create a revised clinical accreditation, based on how we anticipate the ISO15189:2012 standards will evolve, where:

- The Clean Framework becomes the core quality policy around which to frame ISO15189:2012 in its fullest interpretation.
- The external accreditation body works in partnership with the pathology service, discussing and collaborating on new approaches, with assessors working as 'trusted friends' to labs to advise on their total quality assurance systems alongside their ISO15189:2012 compliance, with points of common focus to facilitate benchmarking aligned to relevant national guidance.
- There is an increased emphasis on clinical audit to assess outcomes, and on the impact on the patient above all, rather than on details of specific lab processes.
- There is a focus on areas of error, rather than putting effort into areas that are already performing well.
- There is clear, trusted assurance that end-to-end systems are functioning to a high standard, regardless of which entities deliver which part of the pathway.

Improving accreditation in POCT

POCT is a vital and increasing part of an End-to-End Pathology service. POCT is convenient for patients, and enables rapid decision making and remote testing in both acute settings (such as ED or wards) and non-acute settings (such as GP surgeries and community clinics).

During our visits, we heard concerns that POCT was rapidly expanding in the community in a largely unregulated way, with an inadequate quality and governance framework outside NHS labs – and that this could lead to patient harm.

We believe that there should be the same focus on quality regardless of where or how a test takes place, and that pathology has a vital role to play in ensuring quality in POCT for our patients.

We therefore recommend that:

- Use and understanding of the ISO15189:2012 governance structure is updated to reflect the latest version of this standard, which will be broadened to incorporate POCT, whether performed within or outside the hospital.
- UKAS works together with the pathology community to make accreditation meaningful in the POCT sector, including clinically relevant and achievable standards for the use and governance of POCT devices across the health sector, linked to lab accreditation or another quality framework.
- All POCT, wherever it is undertaken, is performed to these agreed quality standards, and under a governance structure that is linked to and supported by an accredited lab.
- As part of this expansion of accreditation, national bodies such as the RCPATH, the IBMS and the ACB may need to consider how to improve education for all providers of POCT.

It is particularly important that patients can feel reassured that their tests are reliable and consistent when carried out in a new setting, and therefore this progress is essential in order to align with the implementation of Community Diagnostic Hubs (see page 110). These will be new settings for sample taking and some testing, including POCT, which will require robust and reliable accreditation to be in place. New settings must also use lab services that are appropriately accredited.

Moving ahead with accreditation changes

This altered process need not cost more to deliver, nor does it necessarily lessen labs' flexibility. However, it will require a paradigm shift in focus and approach from the accrediting body (UKAS), from labs themselves, and from other test settings, moving towards total quality management.

This shift in focus will reduce variation in assessment by clarifying the aims of accreditation, and free up both labs and assessors to focus on developing and implementing the new approach.

We are keen to push these reforms forward, and have begun conversations with UKAS about creating pilot sites to see how this could function in practice.

The role of practising clinicians in embedding quality

As part of this change in focus, we also recommend that labs and networks encourage practising clinicians and lab scientists to be actively involved with quality, or even take a lead in the accreditation process, rather than seeing quality as owned by external assessors and lab quality managers. Working clinicians, who are already part of the pathology team, are also in a better position to identify, implement and monitor quality initiatives.

When those who are 'in the job' take on assessment roles, creating an active and engaged accreditation process, this can result in a cross-fertilisation of useful and proven ideas – particularly if clinicians also engage with those in similar roles across networks.

In addition to taking an active part in the UKAS process, we also suggest that clinicians increase the range of audits carried out on their service. We have recommended many audits that would improve quality, and suggest that the RCPATH extends their current audit groups to identify best practice.

Currently, labs do not necessarily see it as their role to provide active support to this process. We hope that our recommendations about accreditation lead to greater involvement of practising pathologists, but to incentivise this, provider organisations may need to develop other mechanisms.

Labs can encourage working pathologists to become quality leads by:

- allocating enough time for practitioners to develop quality initiatives and participate as assessors;
- seeking to fund time spent on quality improvement as part of Continuous Professional Development (CPD).

Trust and network governance

Throughout the report, we have emphasised the need for trusts, and increasingly pathology networks, to recognise the end-to-end nature of the pathology service, and to support it holistically, including shared services such as transport, portering and phlebotomy, which are essential to the efficient functioning of the pathology network.

During our deep dives, colleagues were often frustrated by a lack of holistic management of shared services. However, to fit with the reformed end-to-end accreditation process, trusts and networks will need to work together proactively to increase their level of responsibility and governance for the entire diagnostic pathway.

Alongside national initiatives, it is important that labs and trusts work together with networks to:

- Seek to improve the visibility of pathology services, and the importance of effective shared services such as portering and phlebotomy, at board level.
- Proactively develop new ways to manage shared services to improve the end-to-end pathway.
- Establish effective governance covering the entirety of the pathway, working with primary and secondary care colleagues to cover pre-analytic and post-analytic stages.
- Move towards a co-ownership model, where the trust and lab work together with the network, with open and constructive discussions about how to shape continuous improvements, including in shared services.
- Use advice from external advisers to embed continuous quality improvement metrics where success is measured in progress, rather than setting binary targets that can lead to 'gaming' the system.
- Work together to establish effective data and metrics – again not with the aim of creating targets, but to establish and measure continuous quality improvement for the whole lab process; from initial thought processes about requesting a test to result interpretation. This could use the Pathology Quality Assurance Dashboard (PQAD) dashboard as a basis, alongside GIRFT's own data packs, and Model Hospital benchmarking data. See *Foundation 2: Data and digital delivery* on page 90.

Speeding adoption of new technology

During our deep dives, labs told us there was often a delay in the adoption of new technology. This was due to a lack of local funding; partly, this is because when a lab uses new reagents or equipment for the first time in the UK, these must currently go through a local verification process. This has led to slower adoption of technology.

Networks should be able to more easily choose a pre-accredited technology, clearly labelled as such on the NHS Supply Chain, and then move forwards quickly to build this into their network standards.

Currently, there is a robust response system if any users of the NHS Supply Chain raise any concern on a particular product. The Clinical and Product Assurance (CaPA) team work closely with the MHRA to ensure consistent action. However, a proactive approach, assessing quality before the product is added to the framework using a more structured technology adoption process, could achieve cost efficiencies by:

- reducing the burden on individual labs;
- shortcutting supply processes;
- making better use of available resources, for example by using staff with existing specialisms to validate relevant technology.

This process could be performed by a national network of 'validation' labs, which publish the validation reports in a way similar to the Technology Validation Group (see below).

We recommend that an integrated NHS rapid technology adoption model be implemented where:

- UK Conformity Assessed (UKCA)-marked tests (see below) undergo a national validation process before being made available on the NHS Supply Chain;
- all tests recommended for use by NICE are nationally funded;
- this process is followed up by technology deployment support.

We have seen excellent work by multiple stakeholders already, but also a lack of a national co-ordinated framework. We therefore recommend that the NPB co-ordinates with the various stakeholders to improve identification and adoption of new technology.

Improving accreditation for In-Vitro Diagnostic devices

The term 'In-Vitro Diagnostics' (IVD) refers to any test carried out on a sample of tissue or bodily fluids from a patient. Any equipment that carries out these tests is an IVD device. This includes everything from large lab analysers carrying out full blood counts to a pregnancy test bought from a pharmacy or supermarket.

During discussion and research for this programme, we saw that the accreditation for IVD devices was varied, causing more variation in adoption of technology. Currently, there is a two-level governance structure:

- The first level is CE-marking. This is required for all IVD devices sold in Europe, and shows that the device complies with the European In-Vitro Diagnostic Devices Directive (98/79/EC);
- The second level is ISO15189:2012 accreditation, managed by UKAS. This involves implementing a quality management system before the IVD device can be used.

At present, commercial organisations, including high-street pharmacies and online stores, can sell CE-marked IVD devices direct to the public without the second level of assurance. GPs and dentists often also use the first level of assurance only, despite MHRA guidance that tests such as POCT devices must be linked to an ISO15189:2012 accredited lab. This leads to variation in the approach to IVD devices.

There are some weaknesses in the CE-marking scheme:

- the mark is not a guarantee of analytical quality, so tests may deliver relatively unreliable results;
- there is little guidance on appropriate use cases, which may lead to patient confusion over the meaning of results.

Following the UK's exit from the European Union, the UK is introducing the UKCA marking scheme in 2023, led by the MHRA. As part of this work, there is an opportunity for the UK to review the IVD quality framework, and create a UKCA mark that is risk based. This would:

- help define use cases for IVD devices;
- allow for structured regulation of IVDs: for example, some could be approved for sale 'over the counter', whereas others would require more stringent regulation (such as the level of quality assurance required under ISO15189:2012).

There is an opportunity to harness the full range of NHS expertise to ensure that this process is robust, clinically led, and widely respected. We therefore recommend that when developing the UKCA mark, the MHRA works with the pathology community to develop a structured and risk-based UKCA framework that will support patient safety.

We also recommend additional governance of the use of IVD devices in certain areas. For example, as part of the UK's response to COVID-19 testing, the Department of Health and Social Care and the NHS (led by the NHS Chief Scientific Officer) set up the Technology Validation Group (TVG), which identified and validated suitable IVD devices for COVID-19 testing. Once the performance characteristics of the IVD device were understood in detail, these TVG-validated tests were deployed throughout the NHS for use in defined use-case settings. We suggest that the MHRA explores how to work with relevant bodies (such as Academic Health Science Networks and pathology networks) after the COVID-19 pandemic, as part of the rollout of the UKCA mark, potentially using the TVG validation approach as a basis.

Building the quality foundation

We have made significant recommendations in this section, which build into an ongoing programme of work spanning national, regional and local initiatives. This will establish a secure foundation on which we can build the Clean Framework, ensuring that the progress made during the creation of this report continues, and that its insights are maximised.

However, to deliver quality effectively, it must be underpinned by a resilient data infrastructure, which is the subject of our next Foundation.

Core recommendation: Foundation 1: Quality

Recommendation	Actions	Owners	Timescale
2. Establish network-wide standards, and where useful agree at national level.	<p>a Labs and PNs to share peer-to-peer learnings on best practice in implementing the Clean Framework, and use these to establish and monitor network standards to establish end-to-end quality, including:</p> <ul style="list-style-type: none"> • Care Sets; • diagnostic pathways; • decision support; • test specifications, to include: <ul style="list-style-type: none"> – reference intervals; – action limits; – turnaround times; – strategy for dealing with specialist tests; – stabilisation requirements; – sample quality requirements; • guidance for patients. 	Labs, PNs	Progress within 12 months of publication

Detailed recommendations: Foundation 1: Quality

Recommendation	Actions	Owners	Timescale
13. Make better use of EQA information at national level.	<p>a The NPB and NEQAS to work together to establish national co-ordination and to ensure fuller use of the available information, also engaging with manufacturers to achieve greater consistency.</p>	NPB, NEQAS	Within 2 years of publication
	<p>b The RCPATH EQA Oversight Board to:</p> <ul style="list-style-type: none"> • use EQA data to ensure methodologies are of an acceptable quality, with harmonisation where possible; • set performance standards that manufacturers must meet for tests supplied to the NHS, ensuring that a manufacturer's method is fit for purpose. 	RCPATH EQA Oversight Board	Within 2 years of publication
14. Establish a proactive, integrated approach to ensure new technology can be adopted at speed.	<p>a The NPB to co-ordinate implementation of rapid technology framework.</p>	NPB	Progress within 12 months of publication
15. Improve regulation of in-vitro diagnostic (IVD) devices.	<p>a MHRA to work with the pathology community to develop a structured and risk-based UKCA governance framework.</p>	MHRA	Within 2 years of publication
16. Increase diversity of staff involved in the accreditation process.	<p>a Labs and PNs to make it easier for working pathologists to become quality leads, by allocating time for practitioners to develop quality initiatives and participate as assessors, and funding this as part of Continuous Professional Development (CPD).</p>	Labs, PNs, UKAS	Within 2 years of publication

Foundation 2: Data and digital delivery

There are two key themes in this section:

- data: its use in making patient records available to clinicians and patients alike, and in allowing analysis and comparisons that will lead to improved care;
- digital delivery of pathology services: for example helping patients to access and understand their results from home, or clinicians to carry out tests remotely.

These go hand-in-hand: changes and improvements in one inevitably affect the other. Both are core elements of a dynamic, future-proof pathology service. The two themes require different approaches, but both are underpinned by one essential requirement: data interoperability. We therefore tackle this first.

Our fifth guiding principle is to **future-proof pathology with strong data and digital foundations**, and this underpins all of our other principles. We need to build a secure digital foundation: a base that supports and enhances pathology's use of data regardless of its future direction. If we fail to do this, we risk living with the repercussions – in inefficient or less useable data – for decades.

To achieve this, above all, there is an urgent need for co-ordination across the various digital workstreams that have been created across the NHS.

The urgent need for data interoperability

Data interoperability means ensuring we use a common 'language' so that data systems can talk to each other. It essentially means the ability to use and access data across locations. It is the mechanism by which 'technology' turns into useful applications, without their users needing to worry about how things work behind the scenes.

Data interoperability is necessary to deliver all of the improvements we examine in this section, whatever innovations the future holds.

What is the current situation?

During our deep-dive visits, we observed unwarranted variation in the way data was recorded, accessed and transferred, stemming from a lack of common data standards. These issues led to difficulties in data transfer across systems, and difficulty in extracting data for reporting, comparison or business intelligence purposes.

For example:

- clinicians working across sites were unable to see results for all their patients;
- test results did not follow the patient outside their usual place of care;
- POCT results were not added to the patient record;
- similar tests in different labs were referred to in different terms and using different formats, meaning it was harder to interpret results or compare between services.

It was a challenge to get accurate data in a format that allowed our own GIRFT analysis. Most of the data in this report has involved labs manually extracting information from their individual systems, which is time-consuming, not real-time, and makes comparison and interpretation harder and less useful. Again, this is due to lack of an overall interoperability foundation.

However, both the users and the providers of pathology services welcomed the opportunity to see our data (albeit not real-time) showing their performance benchmarked across a range of tests and measures, and appreciated being able to learn from other trusts in order to improve their patient care.

During the process of compiling the report we also learned about multiple workstreams across the NHS, each aiming to tackle some of these challenges, but not always aware of other workstreams developing alternative solutions to the same or overlapping issues.

What is the solution?

No single workstream can implement interoperability: this must be a co-ordinated national initiative. We therefore recommend that the National Specialty Adviser works urgently with NHSX to oversee the establishment of a national roadmap to develop common data standards for interoperability. The NPB will be essential to ensure national focus and drive – to ‘clear a path’ through currently disparate initiatives. We welcome that there are already discussions under way at the time of writing (early 2021).

Without national interoperability being in place before new systems are implemented, there will be an increase in middleware ‘patches’, and the new systems will not fully realise their potential benefits. This will in turn limit return on (substantial) investments. Interoperability must be established before investment is allocated, and common data standards must then become mandatory for all workstreams. It is particularly important that these standards are in progress to allow Community Diagnostic Hubs (see page 110) to use them as part of developing their requesting and recording systems.

Once common standards are established, other ‘building block’ workstreams can be added as and when they are developed. But without the firm foundation of interoperability, these workstreams will be built on shifting sands.

Three key requirements for data operability

- 1 – A holistic roadmap to establish common data standards (and a realistic national commitment to drive this forwards).
- 2 – Following this, ‘building block’ initiatives – discrete technology projects that can build on the same data standards.
- 3 – All focused on the clinical user and patient user view.

Patient-focused pathology

Patient-focused pathology is the use of technology to help the testing process fit more conveniently and easily into a patient's life. A key benefit of interoperability is to improve how clinicians and patients view and use their own medical data, and for results to be visible no matter where they happen to be, or which clinician needs to see the information.

An example of how interoperability should enable patient-focused pathology:

- Mr Potter feels ill while on holiday in Cornwall, and visits a local GP.
- The GP can see results from tests Mr Potter had at his home GP's surgery in Cumbria before his trip.
- She carries out POCT in the surgery. She can also see heart monitoring results from Mr Potter's smartwatch, which update automatically to his record every day.
- The GP sends Mr Potter to the local ED in Cornwall, where the clinician can see results from the Cornish GP's POCT, and the Cumbrian GP's previous results.
- The ED clinician requests further tests using the ED's mini-lab.
- Mr Potter is then admitted as an inpatient, and has tests that are processed by the hospital lab.
- One test is sent to a reference lab at a specialist centre.
- He then goes home, and has a follow-up blood test in a Community Diagnostic Hub, which is processed by a network hub lab.
- He then has an operation at his own local hospital, involving a pre-assessment clinic and investigations during the operation, all of which are processed by the hospital lab.
- He had a blood transfusion in 2004 and developed antibodies (which affect the type of blood he can receive during his operation).
- A pathologist checks his records after the operation and recommends a further test.
- He has previously had a COVID-19 test that was processed in a Lighthouse lab...

... and all these results would flow seamlessly and securely into Mr Potter's electronic patient record, and be visible in real time to all clinicians that he saw on that journey.

There are no scraps of paper saying 'please can this be emailed to...'. There are no sticky notes left on files, no waiting for letters to be written and transferred. The GP in Cornwall does not need to quiz Mr Potter on what his previous results said, nor call his home GP for clarification. There are no data security issues. At all points, Mr Potter can access his own record on his smartphone, and see this updated, with guidance, in real time.

What is really key is that Mr Potter, and Mr Potter's clinicians, do not see any of the data systems that ensure this visibility. It 'just works'.

Patient-focused pathology needs to follow the model of moving from data, to information, to knowledge, to wisdom. Currently a lab may produce data – a test result. They may add some information – a reference interval. But this does not help the patient understand the implications for their own personal situation. Usually, a clinician then generates knowledge by adding their interpretation and guidance. The goal is wisdom: where the patient knows and understands their own data comfortably enough to be a full participant in planning their own care, sharing in all decisions.

To future-proof pathology, this same progression must take place whether the patient has a test in a hospital, takes monitoring tests at home and feeds results into their own records using an app, or uses a wearable device that automatically sends information to their provider. However, without careful planning, digitalisation runs the risk of creating barriers to clinician-delivered guidance, instead of new channels for it, and providing nothing other than yet more information that we expect the patient to interpret by themselves.

So technological progress must be clinically driven, not the sole province of the technology developer, and must involve intelligent differentiation of reports as delivered to clinicians versus to patients, alongside careful ongoing monitoring of the effects on the patient. Just because something is now easier to develop and deliver, it does not follow that it is the right intervention for the patient. Our focus must continue to be on whether the innovation improves the patient's own 'wisdom' – their understanding and ability to decide on their care, alongside their clinician.

Integrating results into clinical systems – including POCT

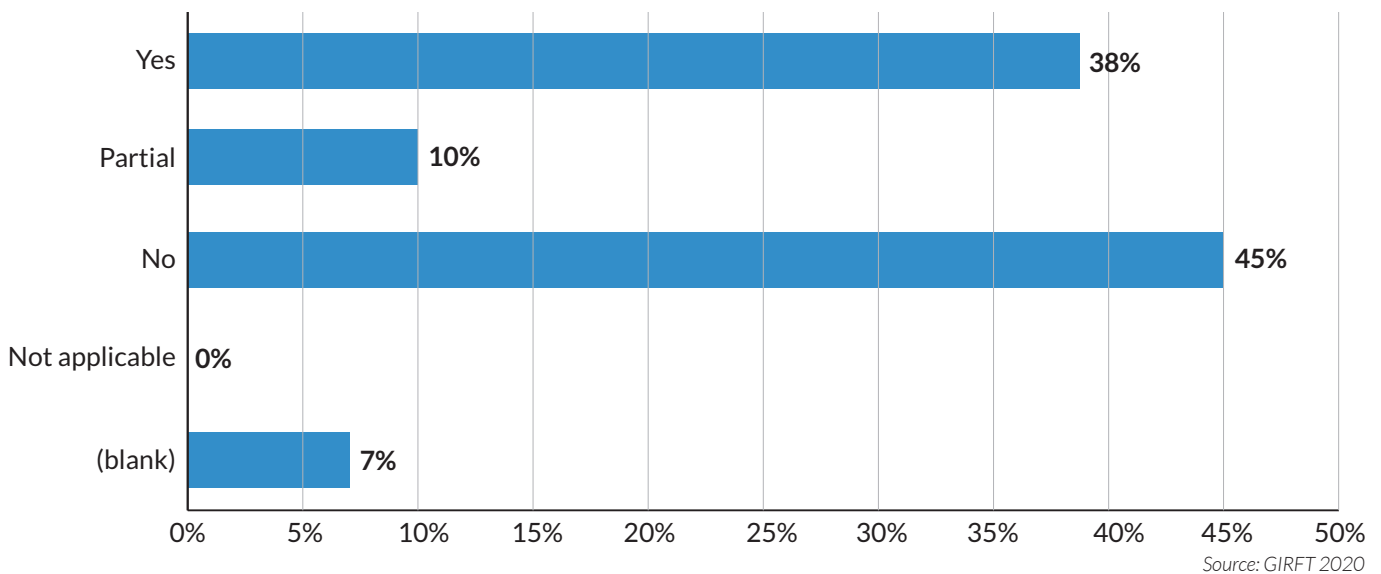
As pathology moves to a network model, and as the use of both POCT and remote lab testing increases, the need for accessible, integrated results has never been greater, and is part of the NHS LTP’s aim to ‘ensure that clinicians can access and interact with patient records and care plans wherever they are.’³² Increasingly, the electronic patient record (EPR) may serve this function, but for the moment, it is essential that labs maintain a complete record of local testing in a LIMS to ensure clinicians can manage patients effectively.

On our deep dives, clinicians often expressed frustration that they were unable to access results for patients. This was either because the tests had been performed at a non-local lab and were not visible in their local resulting system, or the tests had been performed as POCT, and there was no clear record of the result in the patient’s records, or the LIMS.

We saw some exemplar POCT infrastructures, where care was linked to accredited labs and information appeared reliably in the patient’s records. However, in many sites there was little evidence of a co-ordinated POCT approach, either in primary or secondary care.

For instance, we found that 45% of glucose meters in acute trusts were not linked to the LIMS or to the patient’s records (see **Figure 56**).

Figure 56: Percentage of trusts with glucose meters linked to LIMS or patient records (n=142)



As POCT is increasingly being used for decision making, it is critical that the results appear as part of the patient’s medical records, and we recommend that networks and trusts take an End-to-End Pathology approach to ensure that this can happen.

³² <https://www.longtermplan.nhs.uk/online-version/chapter-5-digitally-enabled-care-will-go-mainstream-across-the-nhs>

Clinician-focused pathology

Digital solutions, based on interoperable systems, also bring clear benefits for clinicians. Beyond the obvious and significant benefits of avoiding managing multiple systems (sometimes paper-based), and reducing the transcription and error potential that involves, there are other improvements to working practice:

- removing the burden of requests on clinicians, for example filtering of reports;
- better decision support;
- improved access to interpretation of results;
- better formatting and display of reports to clinicians;
- automatic creation of differentiated reports for patients, with clear interpretation built in;
- automated measures to follow up on reports, for example automatic alerts if a report is not followed up.

Internal lab systems

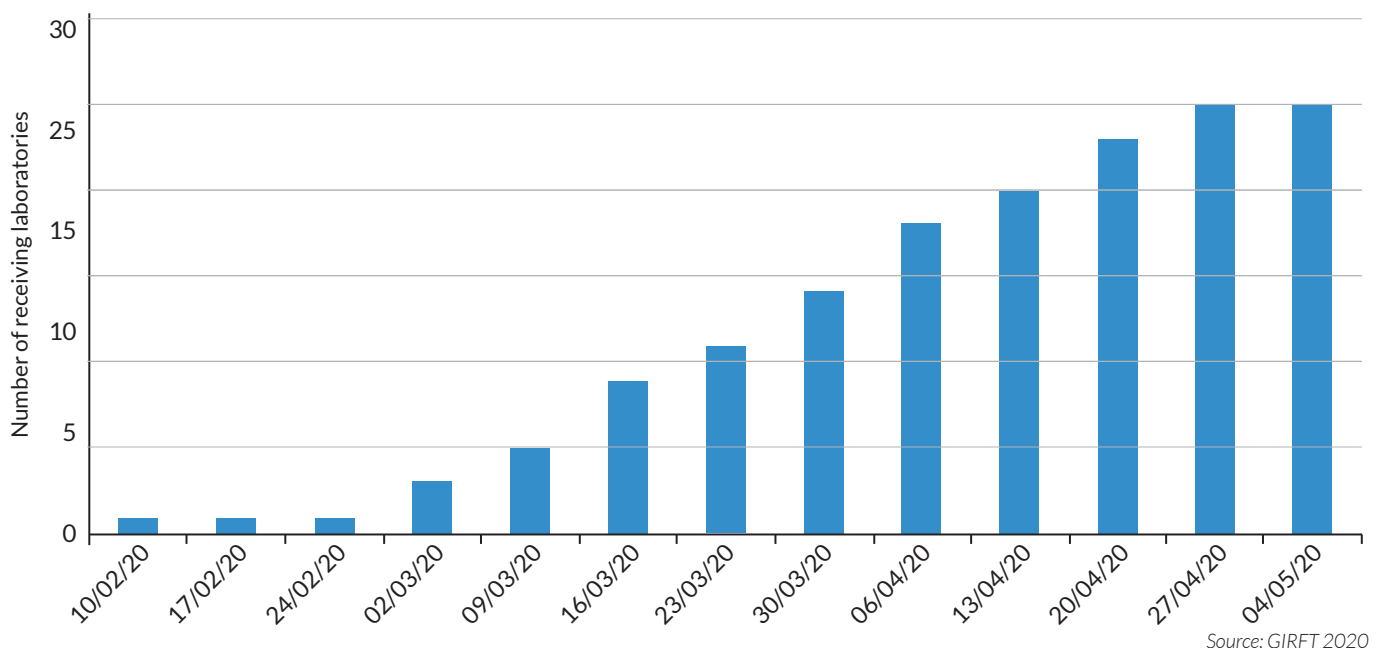
As emphasised throughout this report, there is a clear need for the pathology service to be digital from end to end – from decision support guiding choice of test, through electronic requesting, to electronic messaging and transfer, to digital results available anywhere.

Increasing use of electronic referral systems and messaging

In our deep dives, we found many labs were referring test requests to other labs using paper-based systems, rather than using electronic referral. However, as a result of the need for increased communication during the COVID-19 pandemic, all labs now have electronic referral capability, for example using the NPEX product, and other available electronic referral systems.

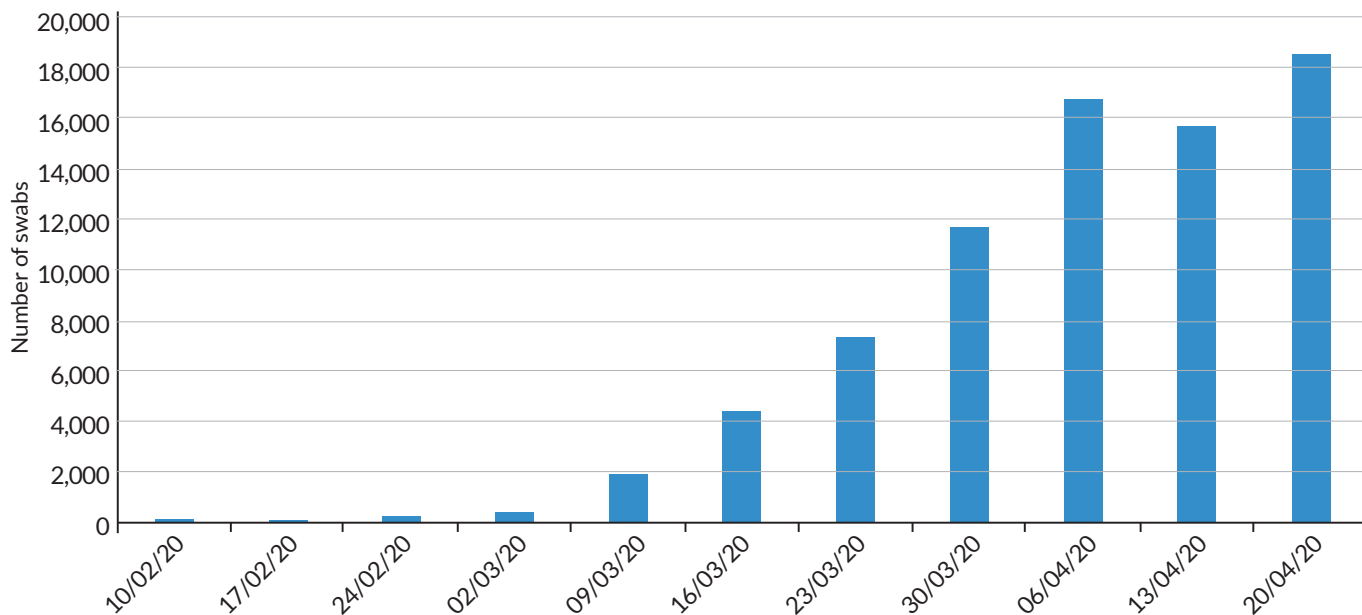
During discussions at the beginning of the pandemic, we were clear that electronic transfer of results between labs needed to be prioritised in order to speed up the delivery of results to patients. NHS Digital supported a rapid deployment of one electronic referral system, NPEX, across the NHS – a national hub that connects all labs, meaning that test requests and pathology results can be sent digitally from any lab to any lab in a matter of seconds. The rapid deployment of NPEX, combined with increased co-operation between labs, created an unprecedented collaborative NHS lab response, as shown in **Figure 57** below.

Figure 57: The increase in numbers of labs receiving requests for SARS-Cov2 PCR tests via NPEX



Source: GIRFT 2020

Figure 58: The increase in numbers of swabs sent for SARS-CoV2 PCR



Source: GIRFT 2020

We therefore recommend that, building on this existing investment, all pathology should now be paperless, and that electronic referral systems should be used for connectivity between labs, improving turnaround times and patient safety.

Connecting LIMS systems

We welcome investment into connecting LIMS systems between labs in order to share results more effectively, as this will be vital in the development of networks and of Community Diagnostic Hubs (see page 110). Again this will be more effective and efficient if grounded in common data standards and interoperability.

CASE STUDY

Successful integration of NPEX electronic requesting and reporting

Nottingham University Hospitals NHS Trust

The trust replaced a paper-heavy MS-DOS based system with an NPEX system supporting Lab2Lab connectivity, and reconfigured their LIMS to use NPEX. Requesting and reporting now flow electronically with minimal staff intervention.

Results

The new system removes a range of issues caused by the previous system. It has:

- made it easier to trace and track requests and results;
- reduced the paper trail for each process;
- reduced the risk of transcription errors;
- improved turnaround time;
- reduced drain on staff resources and clerical costs;
- allowed electronic reporting of NEQAS submission.

The trust has been asked to act as a testing and reference site during the COVID-19 pandemic, and has presented on behalf of NPEX in the UK, Ireland and the USA. The pathology IT systems manager now supports new and existing NPEX users.

Using data for analysis

When visiting trusts, we often found that a lab had already initiated further investigation or changes on the basis of our data pack. When data does its job, drawing colleagues' attention to a problem or a possible enhancement, they often already know what action to take. This is why we recommend that trusts sustain their own version of a measurement dashboard (see *Trust and network governance* on page 87).

We believe the use of data is often at a relatively basic 'transactional' level. This misses a large opportunity to use technology in a transformational way, that adds value and changes how we work, especially how we work together with patients.

The ability to usefully use and analyse lab data is a clear benefit of interoperability. For example, analysis of accessible, up-to-date data can enable us to:

- identify trends in disease and plan accordingly;
- observe population and demographic changes that may affect current and planned services;
- observe behaviour across the diagnostic pathway, from sample collection to visibility of results, and prioritise concerns that need to be addressed;
- measure how innovations and improvements are affecting patient care, and adjust programmes as needed.

The COVID-19 pandemic further highlighted how essential accessible, robust data is to delivering efficient and effective pathology services. If we are to develop quality improvement systems that use data-driven benchmarking, then that data has to be generated:

- automatically – without manual processing;
- in real time (or as close as possible), to give immediate feedback on the effect of improvements;
- in a format that enables straightforward comparative analysis, without increasing (and preferably decreasing) workload for trusts.

We therefore recommend that data is made accessible and available using open, transparent and reproducible methods, supporting analysis that generates new insights to improve patient care.³³

We have seen many examples of data being used in inspiring and transformational ways, many of which we used to develop the ideas in this report. We have described three such initiatives below: PQAD, which will feed into the NHS Model Hospital, OpenPathology and OpenSAFELY.

Data in action: PQAD

The Pathology Quality Assurance Dashboard (PQAD) is likely to become a key way to access data and use it effectively in everyday pathology, especially as it will feed into the Model Hospital data hub.

The PQAD is a set of metrics that labs can use to monitor and analyse performance across a range of areas, including:

- timeliness and turnaround times;
- workforce issues;
- user satisfaction;
- safety incidents;
- accreditation and EQA performance.

These metrics are presented in a simple dashboard that allows pathology labs to raise visibility of issues and discuss performance, internally and with trust stakeholders. The aim is to link this information to Model Hospital to widen accessibility of the metrics.

³³ Goldacre, B., MacKenna, B., 2020. *The NHS deserves better use of hospital medicines data.* <https://www.bmj.com/content/370/bmj.m2607>

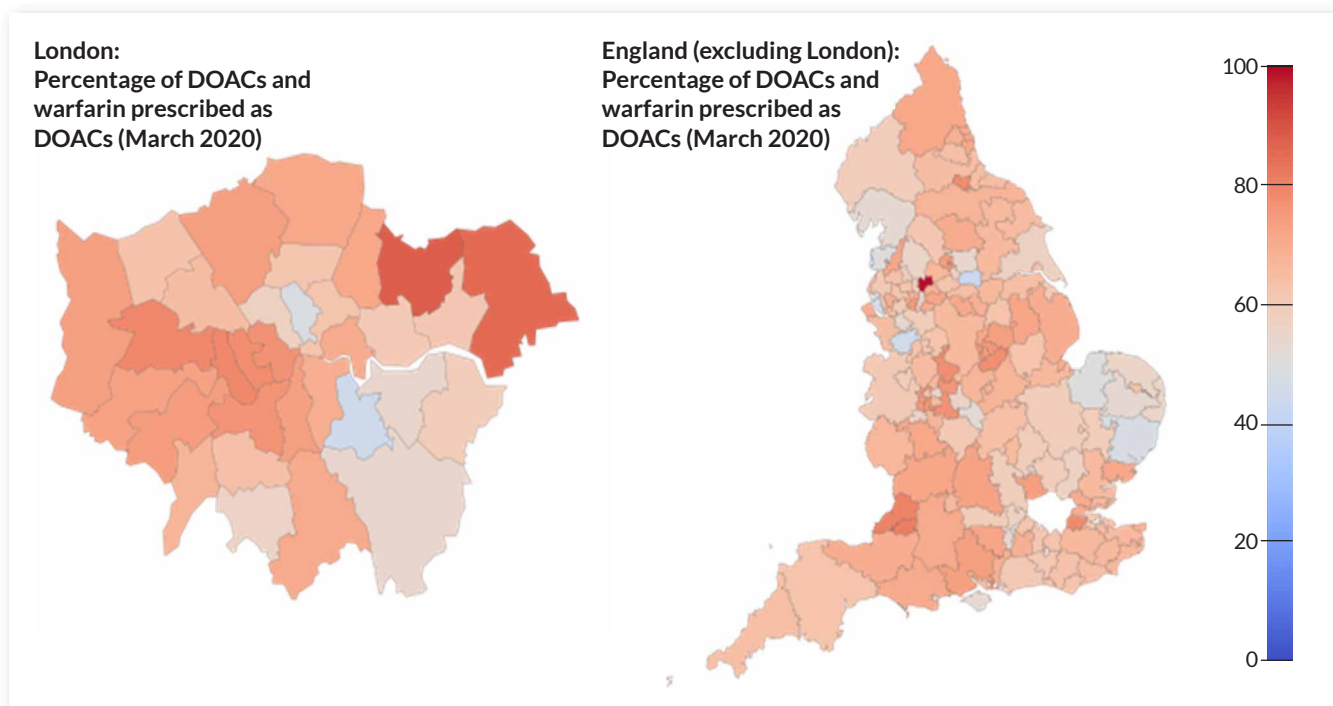
Data in action: OpenPathology

OpenPathology was an important pilot initiative to investigate how we can create more useful, real-time pathology data analyses. We supported the pilot as part of the GIRFT process, and it contributed valuable data to the report.

Data on medicine prescriptions in primary care in England is openly available, and can be analysed using the OpenPrescribing platform. These analyses are used widely to improve quality, safety and cost effectiveness of patient care.³⁴ The map below (**Figure 59**) shows an example using prescription data, but it is easy to see how this could be extended for pathology tests. Pathology has some similarities with prescribing: both are requested by clinicians, and results are 'dispensed'. Therefore, to investigate whether we could achieve similar improvements with pathology data, two labs agreed to send all result data, with patient identifiers removed, to the OpenPathology team, in a spreadsheet format. Using this data, we were able to observe many of the problems in pathology that we have described throughout this paper, but in greater granularity, and much nearer to real time. We have written a series of blogs on some of the findings from this project.³⁵

The project can be used as a replacement for the Atlas of Variation,³⁶ which used pathology data to generate maps of variation in pathology requesting rates across England. OpenPathology can produce similar reports but in real time.

Figure 59: Showing geographical variation in prescribing practice for Direct Oral Anticoagulants (DOACs)



Source: OpenPrescribing 2020

³⁴ Goldacre, B., MacKenna, B., 2020. The NHS deserves better use of hospital medicines data. <https://www.bmj.com/content/370/bmj.m2607>

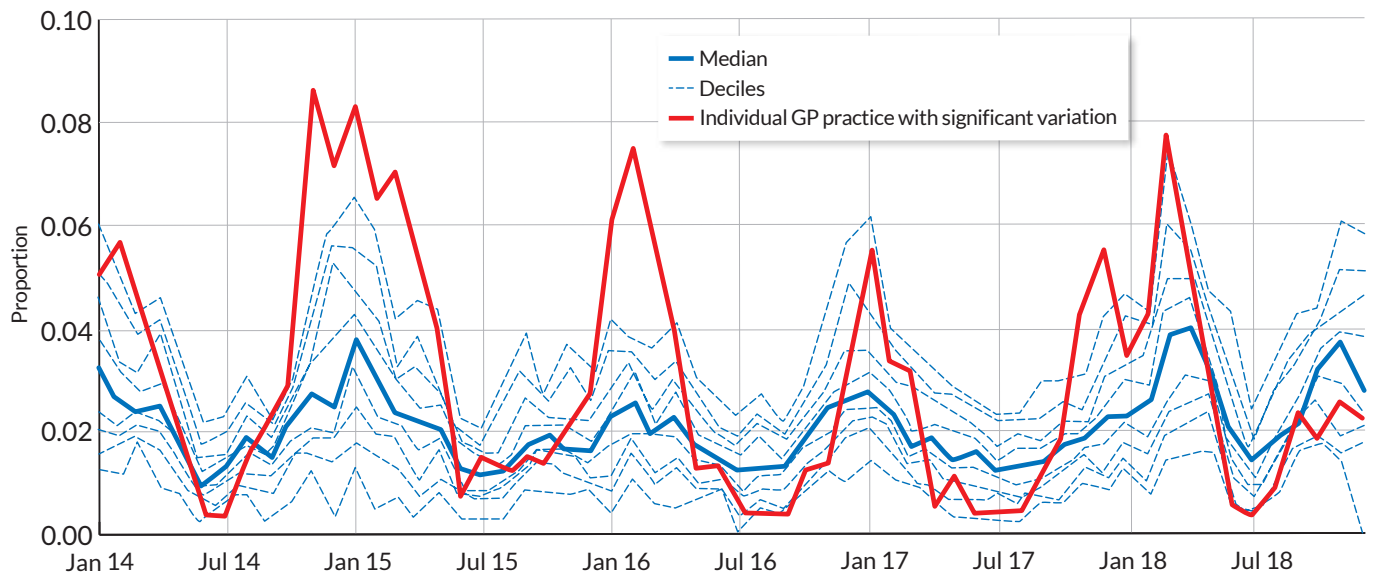
³⁵ <https://www.openpathology.net/blog>

³⁶ <https://www.england.nhs.uk/rightcare/products/atlas>

Example OpenPathology findings

The project generated a number of interesting findings, some of which we have described below.

Figure 60: Seasonality in proportion of potassium results from primary care that are above 6.0 mmol/L across a number of GP practices



Source: OpenPathology 2020

Figure 60 shows the result of our investigation into the proportion of potassium tests that were above the reference limit for individual GP practices each month. This data helps us to identify a number of issues:

- There was a marked seasonality in hyperkalaemia due to samples deteriorating in cold weather, as discussed in *Stabilising samples* on page 46.
- In some practices (at the bottom of the deciles), the seasonality is minimal.
- In other practices (top of the deciles, and the example practice shown in red), this is extreme, with around 1 in 12 samples suffering spurious hyperkalaemia during the winter season.

We visited some of these practices. Practices with low levels of spurious hyperkalaemia were usually close to the lab, and so exposure to extreme temperatures during transport was limited. However, some labs that had suffered from significant issues in the past were using centrifuges to stabilise samples before transport, and had therefore reduced the issue.

We shared this data with the practice shown with a red line, which had also had patients admitted to the ED for unnecessary investigations. Following discussion of the data, and viewing a patient story, they agreed that a centrifuge would be beneficial. Once the practice started using the centrifuge to stabilise samples, hyperkalaemia rates moved to the bottom decile. We have created a video of this experience (<https://www.youtube.com/watch?v=B17QgZWQN1c>).

Improving accuracy of population data

Many data analyses rely on correct population data – this is the denominator of many calculations. Population data also defines catchment areas for healthcare providers and is used to monitor activity, and so needs to be captured accurately. However, calculating population sizes has proved problematic in the past, including for Model Hospital.

By using the openly available, up-to-date, and accurate GP practice list sizes, and combining these with the actual requesting behaviour of each practice (which lab they send their requests to, as seen in real time through the data), OpenPathology was able to determine the primary care catchment area for individual labs. The results were often strikingly different to those obtained using other methods of estimating lab population sizes.

As an example, the lab at Addenbrookes Hospital (Cambridge University Hospitals NHS Foundation Trust) reported a primary care list size of 1.4 million people in our questionnaire. However, Model Hospital attributes it a list size of just 600,000 people. The sum of actual up-to-date practice list sizes of practices that currently regularly submit samples gives a result of 1.2 million people. These differences have profound implications when we consider the accuracy of all lab benchmarking: this could be out by a factor of two, purely due to an inaccurate denominator.

The methodology that the OpenPathology team used can be adapted to provide more accurate data to Model Hospital and other data platforms.

Data in action: OpenSAFELY

OpenSAFELY³⁷ is a secure analytics platform for electronic primary care health record in the NHS, created to quickly deliver data analysis during the global COVID-19 emergency – for example, showing how services were affected by the pandemic, and how they are recovering. It is led by a team of clinicians working hand-in-hand with software developers, and we spoke to them at length as part of the GIRFT process.

OpenSAFELY's work has already demonstrated some of the weaknesses of current data (and consequently the urgent need for common data standards) and the potential of the data we have.

For example, one of the tests that OpenSAFELY examined was for haemoglobin A1c (HbA1C). This is a common test, used to monitor and diagnose diabetes. Each test used is assigned a code, which appears in the primary care record (usually as a 'Read' code). The OpenSAFELY team found that tests were being mapped to three different codes. These codes referred to the same analyte, but there were differences in how the results were recorded. With one code, measurements were recorded as percentages, rather than as mmol/L, which is an out-of-date way of reporting this result. The other two codes apparently referred to the same result. The team also found similar code duplication in several other common tests.

Code duplication affects any analyst's ability to identify trends in testing for this analyte. As different codes were being used, it was also impossible to assign any hierarchy to the codes. A hierarchy can add granularity – for example linking the test to similar tests, or giving information about measurement methods.

This is in contrast to the approach used for coding medicines, where nationally established codes can inform clinicians about the exact formulation of a medicine, down to its dose and packaging. This enables analysis of exact types of medicine – for example, it is relatively easy to compare specific doses of a drug using the codes.

Despite such limitations, the team has been able to use the available data to show:

- geographical variation in approach to testing for HbA1C (confirming what we found in our questionnaires);
- variation over time – for example they have been able to quantify the drop-off in testing caused by the COVID-19 pandemic and examine demographic or regional variations that can guide recovery efforts (see **Figure 61**);
- out-of-date practices, such as where labs are using outdated measurement units.

This highlights the value of data to the pathology service as a whole, and to networks and labs in particular, and the need for this data to be fully interoperable to allow even greater levels of analysis.

³⁷ <https://www.opensafely.org>

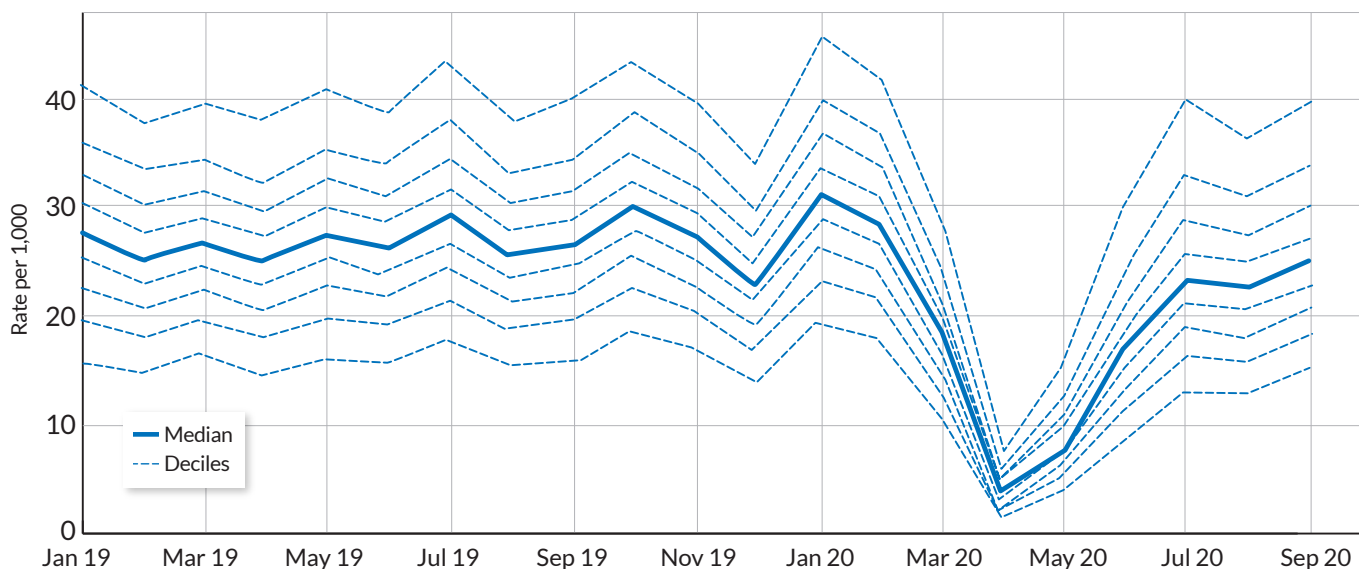
Figure 61: OpenSAFELY chart showing dip in HbA1C tests during the COVID-19 pandemic

“XaPbt” - Haemoglobin A1c level - IFCC standardised

(Practices included: 2.5k (100%); 2020 patients: 3.45m; 2020 events: 4.39m)

Feb median: 28.5 (IDR 24.1), April median: 3.4 (IDR 5.8), September median: 24.7 (IDR 24.3)

Change in median from 2019: April -86.3% (large drop), September -6.7% (no change); Overall classification: **Recovered**



Source: OpenSAFELY 2020

Creating a common data repository

It was clear from our experiences in collating data for this report that there is an urgent need for all pathology data to be added to a common repository: a ‘data lake’, which can be used for national level analysis of all tests. Dashboards can also be created for local, real-time monitoring of performance such as workload, turnaround time etc.

However this is achieved, it should enable labs, GPs, commissioners, trusts, networks and other appropriate bodies to compare local and national performance and focus on how to improve local patient care. This will ensure that the valuable data collected during the GIRFT pathology process continues to be accessible for all and feed into patient-centred improvements.

Embracing new technologies in pathology

During our deep-dive visits, we saw some labs embracing technological innovation in inspiring new ways. We have detailed some of these below – however, as technology in pathology is developing at an astounding rate, we are aware that this can only be a snapshot of current initiatives. We encourage networks to actively research and embrace these new tools, which have great potential to improve patient care and aid clinicians.

Implementing digital pathology

In histopathology, slides are traditionally examined under a microscope to make a diagnosis. However, in the last few years, digital pathology has developed significantly, meaning the image of a slide can be collected digitally and the image viewed remotely. This system, which is already being implemented in some areas, has a number of advantages:

- In our deep dives, we saw histopathology departments that were struggling to recruit and retain staff. Digital pathology enables pathologists in other labs to view the digital image and interpret the image, potentially reducing issues caused by local shortages.
- Second opinions, specialist review and sub-specialisation would become easier.
- There would be improvements to lab efficiency and turnaround times, as there would no longer be a need to wait for the right member of staff to be available.
- All of the above benefits would also feed into the rapid growth of pathology networks.

In some areas, transplantation teams have been working on a national 24/7 histopathology service using digital pathology. This process will in future give clinicians nationwide access to histopathology assessment of transplantable organs to check for pathology that would make the organ unsuitable for use. Images are captured on site, and can then be shared with a network of remote histopathologists, rather than waiting for a local histopathologist to be available. The aim is to ensure optimal use of organs for transplant. In future, this may be a useful exemplar that can be extended to other elements of the histopathology service.

This model of digital pathology, including remote viewing of images and analysis of samples, gained new urgency through the COVID-19 pandemic, as pathology staff were forced to self-isolate or work from home. We therefore expect to see a rapid expansion in digital pathology over the next few years.

Implementing decision support tools and artificial intelligence (AI)

In addition to digital pathology using remote viewing, during our deep dives we also heard about examples of decision support tools and AI being developed to aid interpretation of haematology samples, where AI was being used to identify different cell types to allow for speedier interpretation.

Where decision support tools/AI and digital pathology are used together, this would also allow for non-consultant grades to take on some of the interpretative work in histopathology and haematology.

Digital pathology is widely supported within pathology, but labs are struggling to introduce it because of cost and training implications, alongside issues with reorganising the service. However, there is an urgent need for the service, and we must overcome funding and organisational issues at pace. We therefore recommend that the Department of Health and Social Care authorises a Digital Pathology Enablement Fund to fund the roll out of digital pathology in England.

Data is central to the future of pathology

As the COVID-19 pandemic has proven time after time, interoperable, accurate, secure, accessible and up-to-date data will become ever more essential to the delivery of diagnostics in every setting. When we put so much weight on data, it needs to be built on firm foundations. This is recognised in the NHS LTP, which has a stated aim to ‘Encourage a world-leading health IT industry in England with a supportive environment for software developers and innovators.’³⁸

Data underpins many of the recommendations in our report:

- accurate data is needed to implement the Clean Framework and understand its impact;
- benchmarking and patient-level data is needed to improve audit, quality and accreditation processes to build Foundation 1;
- digital working, such as electronic requesting and messaging, are needed to develop pathology networks.

Perhaps most importantly, robust and flexible data infrastructure is essential to ensure that the pathology service has the resilience to face future challenges and embrace opportunities.

The collaborative nature of the OpenPathology and OpenSAFELY approaches can also show us a way forward: clinicians, academics and software engineers working closely together, across disciplines and different parts of the NHS, to find new approaches and validate existing ones.

It is vital that such initiatives are properly considered and suitably funded as part of a co-ordinated national roadmap. Without care and attention to this foundation, we risk falling behind other countries in the quality of service we can provide.

To achieve this future, a funding model will need to be created to support the development of data platforms to access the data lake. Following initial discussion, we estimate costs to be less than £5m across the country.

Bidding for funding could be an open, competitive process, much as occurs for academic funding. Groups could suggest ways to access and use the data, and win funding to develop their platforms: most likely, there would be several such platforms developed for specific functions. Funding could also depend on the publication of results that have an operational impact.

³⁸ <https://www.longtermplan.nhs.uk/online-version/chapter-5-digitally-enabled-care-will-go-mainstream-across-the-nhs>

Digital, data and the NHS LTP

All the recommendations we make in this section are drawn from our experiences on deep dives, and are fully in line with the NHS LTP (see panel).

Practical priorities will drive NHS digital transformation

This list is from the NHS LTP. We have quoted it in full as all recommendations are relevant to data in pathology.

- Create straightforward digital access to NHS services, and help patients and their carers manage their health.
- Ensure that clinicians can access and interact with patient records and care plans wherever they are.
- Use decision support and artificial intelligence (AI) to help clinicians in applying best practice, eliminate unwarranted variation across the whole pathway of care, and support patients in managing their health and condition.
- Use predictive techniques to support local health systems to plan care for populations.
- Use intuitive tools to capture data as a by-product of care in ways that empower clinicians and reduce the administrative burden.
- Protect patients' privacy and give them control over their medical record.
- Link clinical, genomic and other data to support the development of new treatments to improve the NHS, making data captured for care available for clinical research, and publish, as open data, aggregate metrics about NHS performance and services.
- Ensure NHS systems and NHS data are secure through implementation of security, monitoring systems and staff education.
- Mandate and rigorously enforce technology standards (as described in *The Future of Healthcare*³⁹) to ensure data is interoperable and accessible.
- Encourage a world-leading health IT industry in England with a supportive environment for software developers and innovators.

³⁹ <https://www.gov.uk/government/publications/the-future-of-healthcare-our-vision-for-digital-data-and-technology-in-health-and-care>

Core recommendation: Foundation 2: Digital delivery and data

Recommendation	Actions	Owners	Timescale
4. Future-proof pathology by developing a national roadmap for data interoperability and end-to-end paperless pathology.	<p>a The NPB to co-ordinate with NHSX to establish a roadmap for common data standards (and a realistic national commitment to drive this forwards), with clear aims of:</p> <ul style="list-style-type: none"> • integrating results from any setting, including POCT and Community Diagnostic Hubs, and delivering results to any setting; • ensuring data supports patient-focused pathology, including support for innovations such as wearables; • ensuring data supports clinicians via improved decision support/AI, better interpretation and display, and automated reminders. 	NPB, NHSX	For immediate action
	<p>b Once the roadmap is established, the NPB to ensure that all subsequent initiatives use the data standards.</p>	NPB	Following action 4a
	<p>c The NPB to commission a data repository to enable analysis and comparison of local, network and national data.</p>	NPB	For immediate action

Detailed recommendation: Foundation 2: Digital delivery and data

Recommendation	Actions	Owners	Timescale
17. Embrace and support innovation in pathology, including digital pathology and improved decision support.	<p>a The NPB to work with NHSX and NHS Digital to drive further development of digital pathology, including remote reporting, improved decision support, and AI assistance, in line with the NHS LTP.</p>	NPB, NHSX, NHS Digital	Within 2 years of publication
	<p>b Labs, trusts and networks to plan for implementing digital pathology, as a means to address workforce challenges and improve patient experience.</p>	Labs, trusts, PNs	Within 12 months of publication

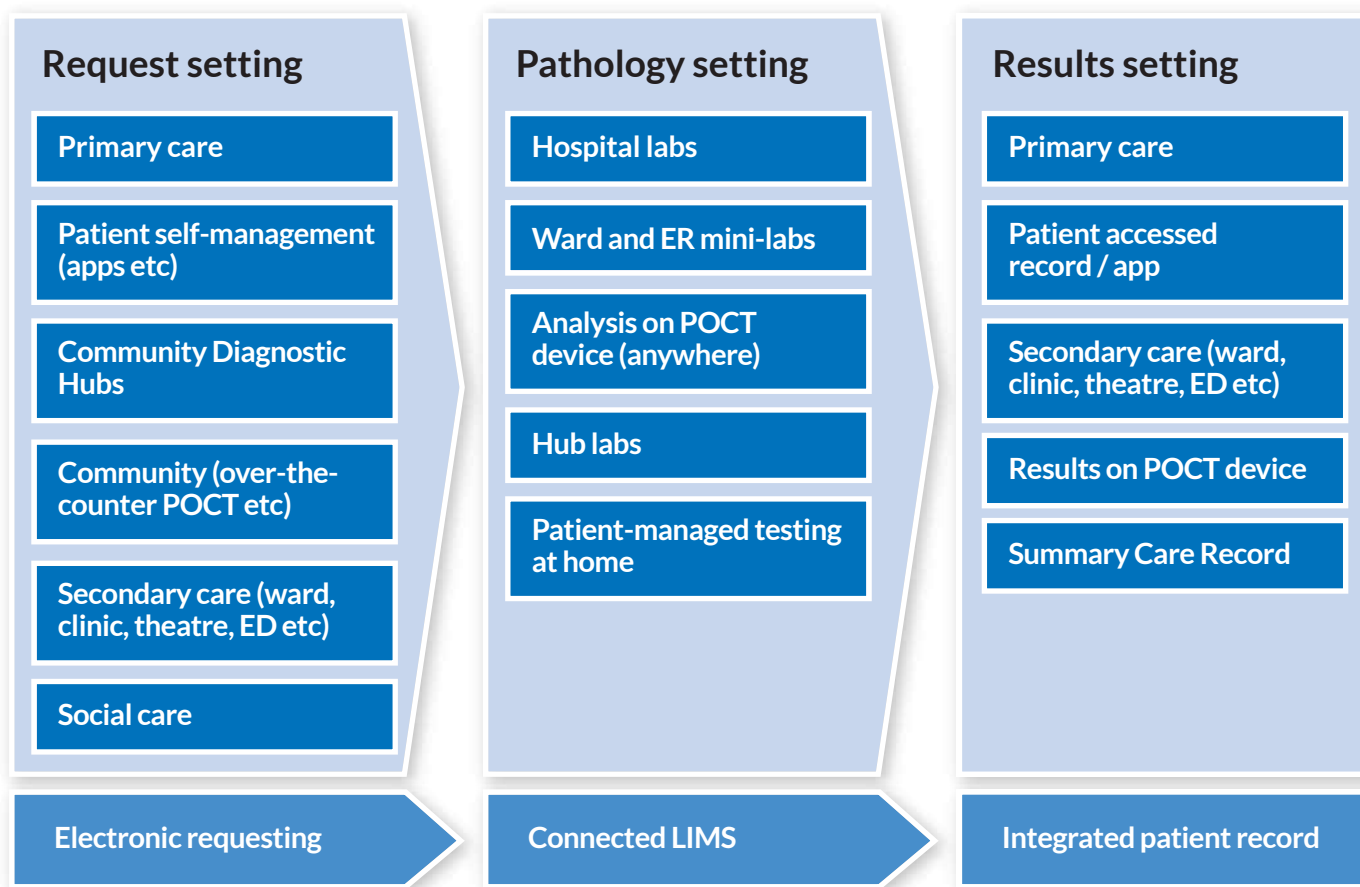
Foundation 3: Service delivery

NHS delivery is becoming more complex; traditional divisions – such as primary and secondary care, acute and elective work, public and private provision – are being transformed on all sides. Pathology must also adapt its delivery models if the service is to influence, shape and align with this changing landscape.

The future of pathology delivery: flexibility above all

We see a future of multiple inputs, multiple pathology settings, and multiple outputs: this is sometimes referred to as the request-result cycle, which patients will often experience multiple times during the course of diagnosis and treatment.

Figure 62: The request-result cycle in pathology



Note: Please note that this is not a comprehensive list, simply an idea of the types of settings we may see.

This picture is likely to become more complex and will differ across the country – but it is essential that **quality remains agnostic of method and setting** (although quality must be aligned to the appropriate use setting for each test). Wherever or however a sample is collected, analysed, or reported, it must be for the **right test, at the right time (for the patient and the clinician), with the right answer**. The Clean Framework is designed to achieve this focus on quality at all stages.

Service delivery models must be able to adapt to reflect changing local needs and priorities. We saw this vividly during the COVID-19 pandemic, where local setup had to adapt rapidly to support national need – and continue to adapt as the situation changed.

Pathology networks

In 2017, NHS Improvement committed to consolidating pathology services in England by developing 29 'hub and spoke' networks. These were intended to reduce costs by improving productivity.⁴⁰

During our visits in late 2019 and in 2020, we found near unanimous support for networking between labs, and we strongly support this going forward. We see the focus of networks as improving quality, sharing knowledge, driving best practice, and bolstering resilience – as well as improving productivity. From our discussions, it was clear that networks need to be seen as far more than just vehicles for optimising the efficiency of test delivery and reducing costs. At their best, we have seen how networks can act as engines of quality and generators of knowledge, ensuring that we continue to think about how we work together as teams of professionals to deliver the highest value to our patients and users.

In our deep dives, we visited individual trusts, but also collated data on a network basis. This allowed us to examine and discuss variation within the networks, and informed further discussion of the network proposals. We saw different models emerging, which built into a picture of local adaptability:

- The 'hub and spoke' model was working well in some areas, with 'hub' labs taking on more complex or lower-volume tests and 'spoke' labs running more everyday tests – however, this was not the only model we saw working well.
- Elsewhere, local networks had innovative adaptations to local needs, particularly where the network was large. Where there were geographical constraints, networks had adapted to a distributed model, with smaller lab clusters within the larger network structure.
- Often, networks worked well where they were mapped to local Integrated Care Systems (ICSs) or groups of ICSs, and, conversely, were harder to implement where the network boundaries did not align well with the ICS. (It is worth noting that the ICSs were developed **after** the networks were originally planned.)

We therefore strongly recommend the creation of flexible pathology networks that reflect local needs. This mirrors the views of the NHS England and NHS Improvement Pathology Programme, the RCPATH (which recommended that networks should be created to suit local circumstances) and the National Pathology Optimisation Delivery Board (now the NPB). In other words, structure must follow function.

Flexible networks must be built to respond to local issues such as:

- Geography – for example, in our work on *Stabilising samples* on page 46, we found significant variation in the rejection rate of samples from primary care, in part due to prolonged transport. Networks must allow for efficient transport from primary care. Transport geography will also need to be a key consideration in the siting of Community Diagnostic Hubs (see page 110).
- Patient flow – existing pathways and likely patient preferences.
- Existing relationships – where labs already have close working links.
- Existing knowledge bases – where a lab already has a particular established specialism.
- Continuity and resilience – for example, networks and their clusters that rely strongly on one test manufacturer may need to be paired with a network using a different manufacturer to retain continuity if there are supply issues. During our deep dives, we witnessed the results of disruption to the supply chain of a major supplier of reagents. This highlighted the need for resilience and continuity planning particularly acutely.

The focus of such flexibility should always be driving quality, value and resilience alongside cost savings. The networks need to remain flexible for the future, as major national initiatives, or indeed the COVID-19 pandemic itself, will inevitably alter networking needs.

We recommend that network footprints should be reviewed to identify whether current configurations are working effectively, are resilient for the post-pandemic landscape and ensure integration with ICS health economies, or whether alternative network footprints would encourage greater progress and ensure integration into the ICS health economy – in our deep dives, we saw that sometimes using the ICS as a 'building block' towards network creation had increased speed of delivery. However, mapping to any locally relevant model will encourage synergies of approach to diagnostics that move away from the purely transactional. Networks may also wish to consider a phased approach: establishing smaller 'clusters' to begin with that then build to larger networks.

So long as the networks are able to abide by the quality principles of End-to-End Pathology and the Clean Framework, we welcome the adoption of locally-adapted models, whatever their basis.

⁴⁰ <https://improvement.nhs.uk/resources/pathology-networks/>

Potential network roles

During our visits we saw networks taking varying roles according to local needs. These could include:

Establishing network standards	We discuss networks' role in establishing these above (see <i>Establishing network-wide standards and standardised national diagnostic pathways</i> on page 82).
Creating centres of excellence	Networks can create centres of excellence for particular tests or groups of tests. These will not only improve network capability, but can provide capacity for neighbouring labs or networks – or in some cases, national capacity. Centres of excellence will also greatly enhance training and retention opportunities. See also <i>Taking a strategic approach to pathology delivery</i> on page 108.
Sharing best practice, benchmarking and audit	Networks can share best practice, and harmonisation of services, from their own member providers, but also from other networks. We saw this in action in our deep dives. This best practice can then be built into network standards, but also measured in order to develop benchmarking and audit processes.
Integrating across the healthcare system	We encouraged trusts and networks to invite primary care colleagues to our deep dives, and where they attended, their input was highly valuable. However, we were generally struck by how rarely primary care was represented at pathology network board and operational level, especially when about 50% of clinical biochemistry and haematology requests are generated by primary care. Pathology networks should work proactively to include a variety of stakeholders in their clinical decision-making and governance processes, including primary care providers and CCGs. Where networks are aligned with the ICS, this governance structure should be easy to establish. The networks must include people who understand diagnostics and how these are implemented in the community, particularly if this involves behaviour change. Building these relationships will help to shape network priorities, and encourage adherence to network policies, while feedback from all stakeholder groups will lead to continuous improvements – all of which can only benefit the patient. As part of this role, networks should also build their relationship with primary care colleagues further by ensuring easy access to guidance on requesting and results – both general advice, for example by giving notes and aiding decision support, and specific guidance, in the form of one-to-one Advice and Guidance support.
Procuring as networks	Procuring as a network can lead to cost and time efficiencies. See <i>Procuring as networks</i> on page 111.
Developing workforce plans	Networks should develop integrated workforce plans, aiming to increase and balance out the skills mix across the network. A key part of this is collecting workforce data. This is currently co-ordinated by the RCPATH, the IBMS and the ACB. However, to help networks, NHS England and NHS Improvement could take on this role through the NPB, aiming to develop a national picture to feed into policy. This may be a more sustainable approach than relying on the colleges and professional bodies. Networks can also speed up recruitment processes by sharing common documentation, such as business cases and job specifications. When setting up networks, it is important that network leaders consider workforce holistically: there is a risk that network labs become budgetary silos, separate from the clinicians. We believe that that clinical leadership of pathologists is critical for pathology delivery, and recommend avoiding the separation of lab budgets (for example for biomedical scientists) from clinician budgets.

Developing leadership	Networks should work to identify and develop leaders, including resilient succession and continuity planning. See <i>Developing leadership in networks</i> on page 110.
Enabling and encouraging career progression	<p>Networks can actively encourage colleagues to progress their careers by seeking posts across the network. This may:</p> <ul style="list-style-type: none"> • help with retention, by preventing colleagues from feeling they have reached a ‘dead end’ in their current setting; • widen the range of skills available to the network overall (if workforce is seen as a network resource); • help to develop specialist expertise in test centres within the network; • enable movement between different staff groups: for example if a medical laboratory assistant wishes to train as a biomedical scientist, but is unable to do so at their own lab. <p>As digital pathology continues to expand, this will further enable a network’s workforce to work as one unit by enabling more remote analysis.</p>
Training and upskilling	<p>Networks should seek to co-ordinate training across the network, which should bring cost benefits as well as increasing the range of training available. For example, this could improve access to tutors to enable colleagues to reach higher levels of qualification (see <i>Biomedical scientists</i> section on page 114).</p> <p>As described above, the delivery of pathology is already changing, with pathology services likely to be delivered at Community Development Hubs and pop-up clinics as well as traditional labs, and with expanding use of wearable and implantable diagnostic devices. As this progress continues, networks must develop staff with different skillsets to support these developments.</p>

CASE STUDY

A successful network development

Berkshire and Surrey Pathology Service (BSPS)

BSPS, formed in 2016 with five acute sites, has developed into a successful hub and spoke model. The hub labs, which cover blood sciences, microbiology and cellular pathology, offer high-volume testing, while each acute site has a rapid response service, supported by extensive POCT in both the hospital and the community.

The network was able to reconfigure the service by:

- engaging staff and management in redesigning the workforce, ensuring the change could be delivered while maintaining the service;
- establishing 24/7 integrated transport to support the network;
- maintaining full UKAS accreditation and financial control throughout the change.

Combining clinical and scientific leadership

The network has embedded clinical and scientific leadership at its heart. The network executive is responsible for all aspects of the service, combining the skills of clinical, managerial and scientific teams.

Focusing on quality and governance

The BSPS Clinical Governance Committee oversees the quality of the network, ensuring it delivers safe patient care and a good patient experience across all specialties.

Results

The network has:

- created safer, better and more sustainable services for patients;
- retained accreditation or approval from UKAS, MHRA and other relevant bodies;
- increased the level of clinical expertise and leadership opportunities;
- improved integration with primary care services;
- achieved saving targets within two years, and reduced costs by just under £6.9m net per year;
- improved the efficiency and quality of the service, including integrating a single LIMS with each trust's patient administration system (PAS);
- generated investment and improvement in estate and transport services.

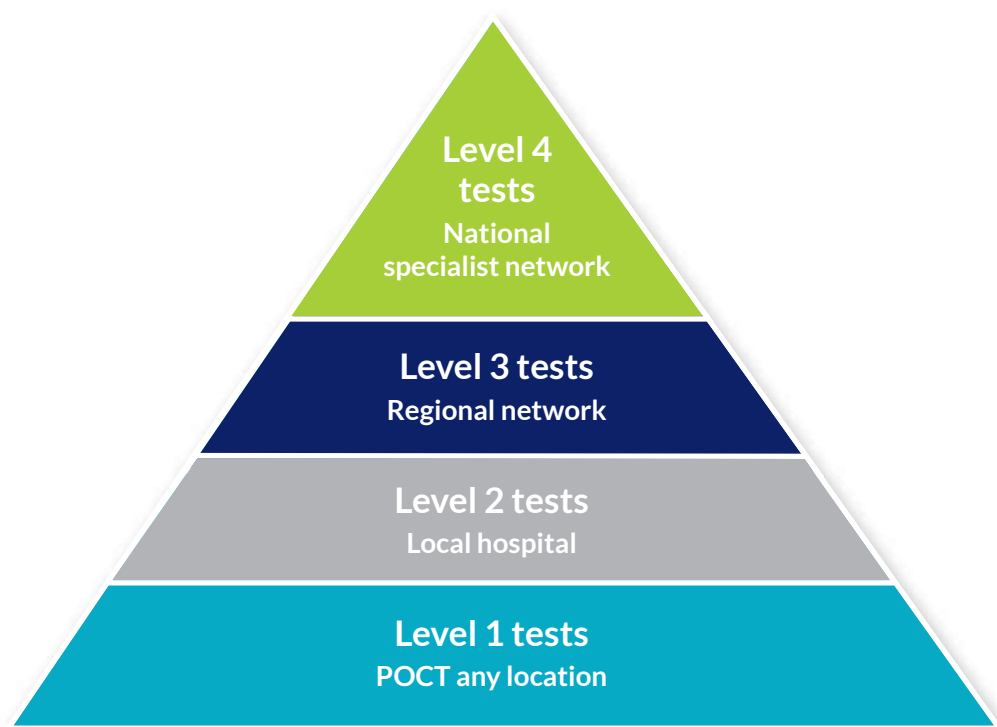
Taking a strategic approach to pathology delivery

We recommend that each network considers their own strategic approach to testing, especially in deciding where more specialist testing should occur, both inside and (where necessary) outside their network. Where networks identify a problem in their testing strategy, such as a lack of a nearby specialist centre for specific tests, the NPB can help to resolve this issue at a national level.

Testing strategies must focus, above all, on quality and the patient's needs. Whether the test works best as POCT at a Community Diagnostic Hub, or as a test in a single national specialist centre, it must be fit for purpose, and must always deliver the **right test, at the right time, with the right answer** for the patient.

The distribution of tests between these levels will differ locally, and each network will need its own strategy to reflect local needs. This must be based on the appropriate setting for each test, from a blood gas analyser in an ED, right up to specialist work such as newer genetic tests or complex biopsies. The strategy will need to reflect labs' experience and expertise, and also the frequency with which the test is needed. It will also need to be reviewed regularly: tests that are initially specialist can quickly move down levels to become routine as the frequency of testing increases, or the technology develops to facilitate testing.

Figure 63: Structured approach to co-ordinated pathology testing



National specialist network	See below
Regional network tests	Tests that are not needed at each trust – such as specialist tests – could be undertaken at network level, so specialist knowledge is maintained and developed.
Local hospital tests	The tests that are necessary to support every acute hospital. They will be less specialist, or high volume, or both, and therefore delivered by most hospital labs. NHS England and NHS Improvement have developed useful guidance on this. ⁴¹
POCT	Including in hospitals, ambulances, care homes, GP practices, pharmacies and other settings. This will also include POCT in Community Diagnostic Hubs once established (see below).

⁴¹ NHS Improvement, 2018. Template structure for essential services laboratory – blood sciences provision. https://www.england.nhs.uk/wp-content/uploads/2020/08/Template_structure_for_ESL_blood_sciences_RE03.pdf

Procuring as networks

During our deep dives, labs told us that the procurement of equipment, reagents and IT:

- can take up a significant amount of time and resource (approximately 9 to 12 months from when an advertisement is put out for a new service, through tendering, to signing a contract);
- is at risk of potential challenge from manufacturers unhappy at losing a contract;
- creates unwarranted variation in expenditure, making it difficult to compare costs effectively within the NHS.

We feel this is an area where networks can help to achieve a more co-ordinated approach, and recommend they move towards procuring from the Category Tower for equipment, reagents, IT and similar as a network. This would ensure that the NHS pays the best-value rates for services, while minimising waste and maximising workforce efficiencies. However, individual trusts would still have the freedom to manage some aspects of procurement themselves where useful.

If we can avoid the unwarranted variation in the price that individual trusts currently pay, which results in excess spending on NHS pathology services at a national level, the extent of the predicted savings is estimated to be around £200m per year.⁴⁴

As pathology networks develop, co-ordinated procurement will:

- speed up the procurement process for both the trusts and networks in the longer term;
- reduce resource demands on labs;
- reduce unwarranted variation in the price paid for the services;
- decrease the risk of legal challenges – for example, if labs share legally robust templates, example specifications, and evaluation scoring systems;
- add additional resilience to the testing capabilities of our pathology labs – this is more important than ever following learnings from both the COVID-19 pandemic and Brexit;
- enable more accurate comparisons between labs, networks, private providers, and even countries, to ensure we are achieving competitive rates for the NHS.

Core recommendation: Foundation 3: Service delivery

Recommendation	Actions	Owners	Timescale
5. Create flexible pathology networks that reflect local needs, feed into national testing needs, and that are primarily engines of quality.	a PNs to develop a plan to suit local needs, which could include assigning network centres of excellence, or sharing with other networks.	PNs	Within 12 months of publication
	b The NPB to ensure there are enough national centres of excellence to give sufficient specialist testing coverage across the country.	NPB	Following action 5a
	c PNs to: <ul style="list-style-type: none"> • develop network training plans, collecting data and identifying gaps; • where a gap cannot be resolved locally, raise these nationally; • ensure the workforce can flow around the network to improve resourcing and enhance career progression; • ensure staff can access training, mentoring and tutoring within the network. 	PNs	Following action 5a
	d PNs to use the NHS Clinical leadership framework to improve leadership in pathology networks.	PNs	Following action 5a

⁴⁴ Risebrow, H., 2020. Laing-Buisson Diagnostics UK Market Report.

Minimising error and wastage in blood transfusion

We have already looked at ways to minimise error and variation within the standard pathology pathway, by using the Clean Framework. Although we were not able to look in detail at the process of blood transfusion, we looked at ways to reduce variation and error in how donated blood is used, as part of the process of identifying unwarranted variation.

When looking at this issue, we were grateful to receive data from the Blood Stocks Management Scheme (BSMS: an independent resource hosted by NHS Blood and Transplant (NHSBT)).

Blood products: a unique resource

Every year in England, approximately two million donations of blood are given by unpaid volunteer donors. Each donated unit of blood is processed to produce different components such as red cells, plasma, platelets and other products. This maximises the value of the donation, ensuring that each patient receives only the blood components that they need.

Just like a prescribed medication, blood has the potential to cause harm or unwanted effects. Clinicians must be trained to understand how to use – or ‘prescribe’ – blood to minimise these risks, and how to use donations to maximise their potential benefit.

Although the blood is donated by volunteers for free, the resources expended in collecting, processing and testing each donation mean that there is a cost to the end product, which has to be passed on to the hospital where it is used. In 2018, each unit of red blood cells cost £133.44, and a unit of fresh frozen plasma cost £31.40. On average in 2018, a hospital would spend £1.25m on red blood cells for transfusion.

In addition to the cost of each component, the resource is finite, and each unit of cells, plasma etc has a relatively short shelf life. UK blood services collect, manufacture and distribute blood components to hospitals to meet patient requirements and optimise the supply chain. Blood stocks are managed nationally and by individual hospital blood transfusion departments to ensure best use of stock and minimise wastage.

BSMS is designed to help hospitals with stock control. Reporting into the scheme is voluntary, but provides hospital transfusion teams with the opportunity to benchmark their performance and understand where they may need to make changes in order to optimise their use of this valuable and expensive resource.

BSMS kindly shared the data for 2018 with us, and in our deep dives we asked colleagues to tell us:

- how much they understood about their data;
- whether their performance was discussed at a senior level in the trust;
- what, if anything, they had done in response to the figures.

We found significant variation in the levels of wastage. Average hospital red cell wastage in a year was around 200 units, but in one hospital the figure for the year was over 1,100 units wasted, a cost of over £150,000. In deep dives, the key reasons cited for the wastage were that the packs had passed their expiry date, or had experienced temperature variation during storage.

We are aware that there are some discrepancies in how trusts reported this data, and that results may be complicated by, for example, differences between how major trauma centres use blood versus smaller hospitals, which are reflected in the charts below. For example, in some trauma centres, plasma is kept on hand in the ED to be quickly available for trauma cases. While this may result in greater wastage, this is outweighed by the benefits for patients. In the charts below, major trauma centres are marked in green.

However, these differences in usage do not change our overall recommendations here: in particular, that trusts monitor and interrogate their own data on blood usage to determine whether there are issues that need addressing. Where trusts have found it difficult to record this data consistently, we recommend that they look at whether they need to allocate more time to specialist transfusion nurses to assist with this.

Figure 64: Percentage of red blood cell units issued that were reported as wasted

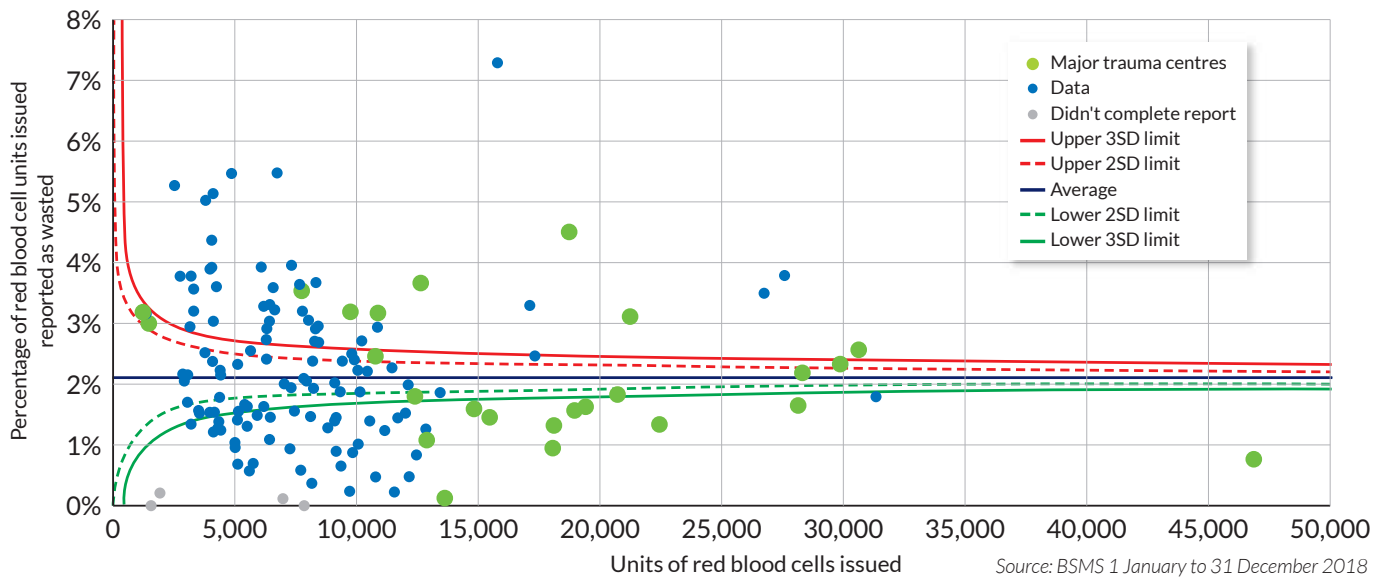
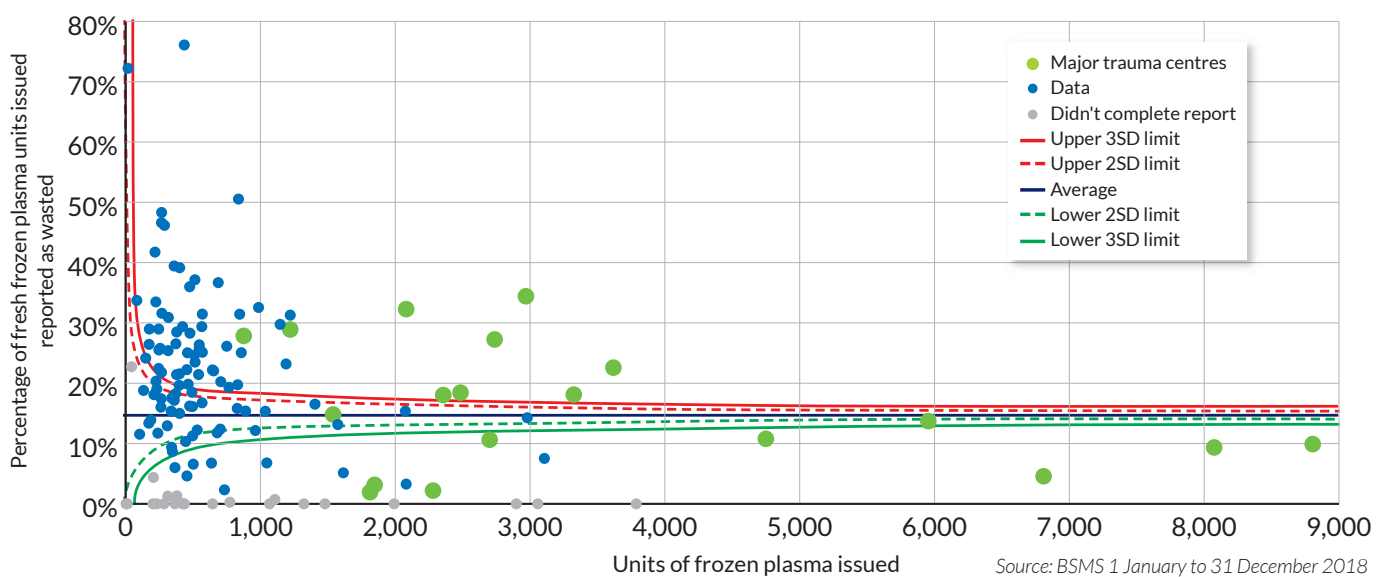


Figure 65: Percentage of fresh frozen plasma units issued that were reported as wasted



To address this variation, we recommend that trusts or networks:

- report into BSMS;
- actively use this data to benchmark their performance against other trusts;
- address any issues identified;
- assign appropriate resourcing to these activities;
- investigate implementing purpose-built transfusion management IT solutions, rather than using general pathology systems.

Detailed recommendation: Minimising error and wastage in blood products

Recommendation	Actions	Owners	Timescale
18. Interrogate usage and wastage data for blood products, and address identified problems.	a Using Blood Stocks Management Scheme data, trusts to benchmark performance against other trusts and work to understand and address issues identified.	Trusts	Ongoing

Workforce

Pathology needs more people – whether those are medical pathologists, clinical scientists or biomedical scientists. This will come as no surprise to anyone working in healthcare, and is a problem shared by many specialties. However, we believe it is equally vital that we embrace new solutions to meet workforce demands, as well as aiming to attract, and fund places for, new recruits.

In this section, we therefore look at ways to create a more flexible workforce, not just a larger one, by actively developing a wider range of opportunities for different staff groups, and supporting staff as they expand and strengthen skills. In particular we look at ways to offer wider opportunities to the large biomedical scientist community, encouraging these colleagues to deepen current skills and acquire further specialist qualifications.

The opportunities available to staff across pathology networks are key to the future of our workforce. Network-wide workforce planning (see *Potential network roles* on page 106) is critical to help attract, upskill and retain staff at all grades and in all specialties.

Staff working in pathology

The main staff groups within pathology are:

- Biomedical scientists (including newly qualified, specialist, advanced and consultant level (or equivalent)): around 22,000 in England.
- Medically qualified consultants (and trainees): 3,575 in England.
- Scientifically qualified clinical scientists (including consultant level and trainees): 264 in England.
- Medical laboratory assistants and assistant practitioners, who undertake a range of administrative and everyday clinical tasks: number unknown as trusts categorise these differently, but they are present in every lab.
- Associated staff, such as phlebotomists and porters: these are sometimes, but not always, managed by the pathology department. Increasingly, they may be based in different settings, such as Community Diagnostic Hubs (see page 110).

To understand the current situation within England, we have looked at each staff group in turn, including data for the four major specialties covered by the report.

Biomedical scientists

As biomedical scientists account for the largest number of staff working in pathology, we have worked with their professional body, the IBMS, to understand the workforce challenges and opportunities.

Biomedical scientists have a very wide range of roles, including carrying out tests, interpretation and authorisation of results, and providing advice on testing. Senior biomedical scientists are directly involved in the strategic and operational development of the lab, quality management and training junior staff. They are required to have a scientific degree to enter the profession.

Biomedical scientists usually provide a 24-hour service in the main specialties, to ensure that urgent tests can be carried out when needed.

Opportunities for expanding the biomedical scientist workforce

The biomedical scientist workforce is highly flexible: their IBMS-accredited biomedical science degrees, alongside Health and Care Professions Council (HCPC) registration, enable staff to work across the full range of pathology specialties. The IBMS professional qualifications are specialty-specific; at least 50% of the biomedical scientist workforce has such a qualification. Biomedical scientists can take further qualifications to Advanced Practitioner (AP) or other equivalent advanced levels, and there are increasing numbers of consultant biomedical scientists. Significant numbers also have professional doctorates, PhDs, and high-level management qualifications.

There is no shortage of appropriately qualified graduates to enter the profession, or to move on to higher levels. However, due to the limited availability of registration training places, many initially take support roles, for example as medical laboratory assistants, while awaiting an opportunity for further training. Further on in their careers, they may be unable to progress through specialist qualifications if there is no trainer available.

Biomedical scientists at the higher grades have potential to help fill gaps in the clinical scientist and medical workforce going forward, if their numbers can be expanded and training pathways are defined. There is therefore a critical need for a clearer, properly resourced career development structure, alongside experienced trainers with adequate time to train. This will then enable the recruitment, training and further development of the biomedical scientist workforce to advanced and consultant level, to support medical and clinical scientist colleagues.

To help achieve this, we suggest that trusts and networks explore ways to enable experienced biomedical scientists to have sufficient time and resource to train and become tutors. The development of pathology networks may also help with this, by enabling staff to access trainers and further career development opportunities in linked sites. There are also opportunities to use apprenticeships and equivalent processes to support biomedical scientists in transitioning to clinical scientist roles, and to enable further advanced practice.

Maximising the potential of the biomedical scientist workforce

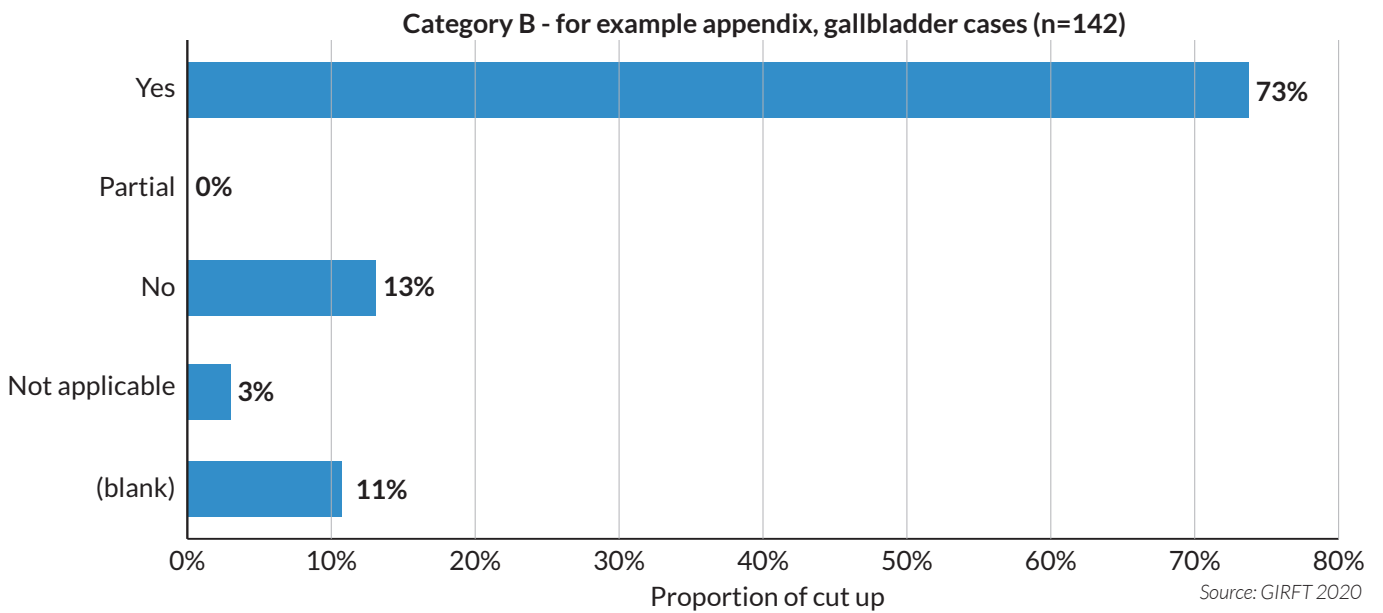
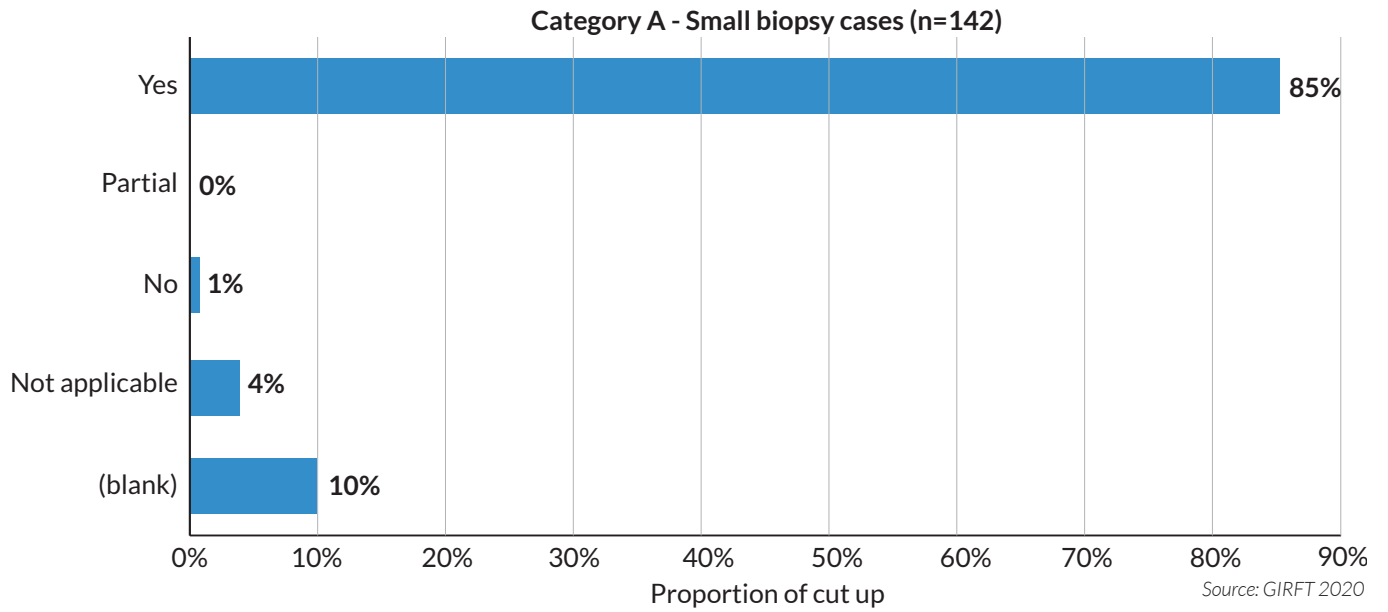
Maximising the potential of the scientific workforce could help to address issues in the recruitment and retention of medical staff in some areas of pathology, through upskilling biomedical scientists in areas of advanced and consultant level practice, similar to programmes such as consultant nursing. This should be carried out following the Modernising Scientific Career Framework, using Higher Specialist Scientific Training (HSST), which includes FRCPath qualification and eligibility to be on the Academy of Higher Specialist Scientist Register (HSSR).

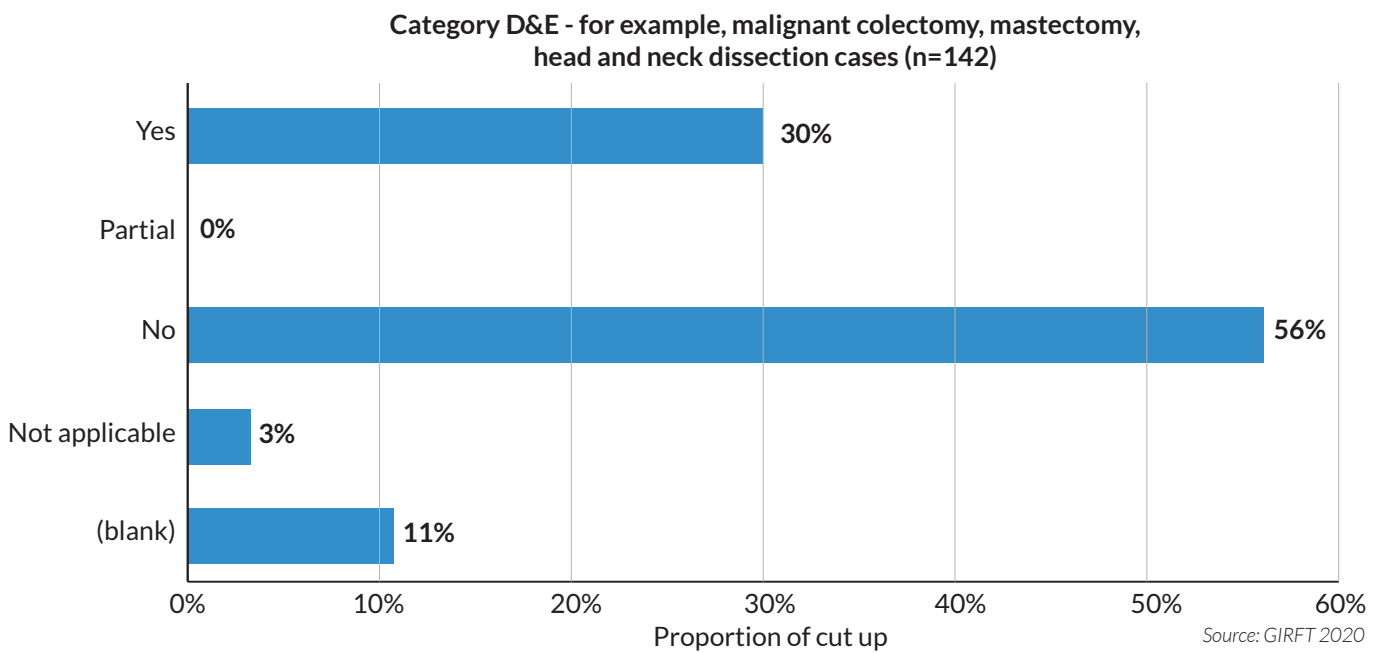
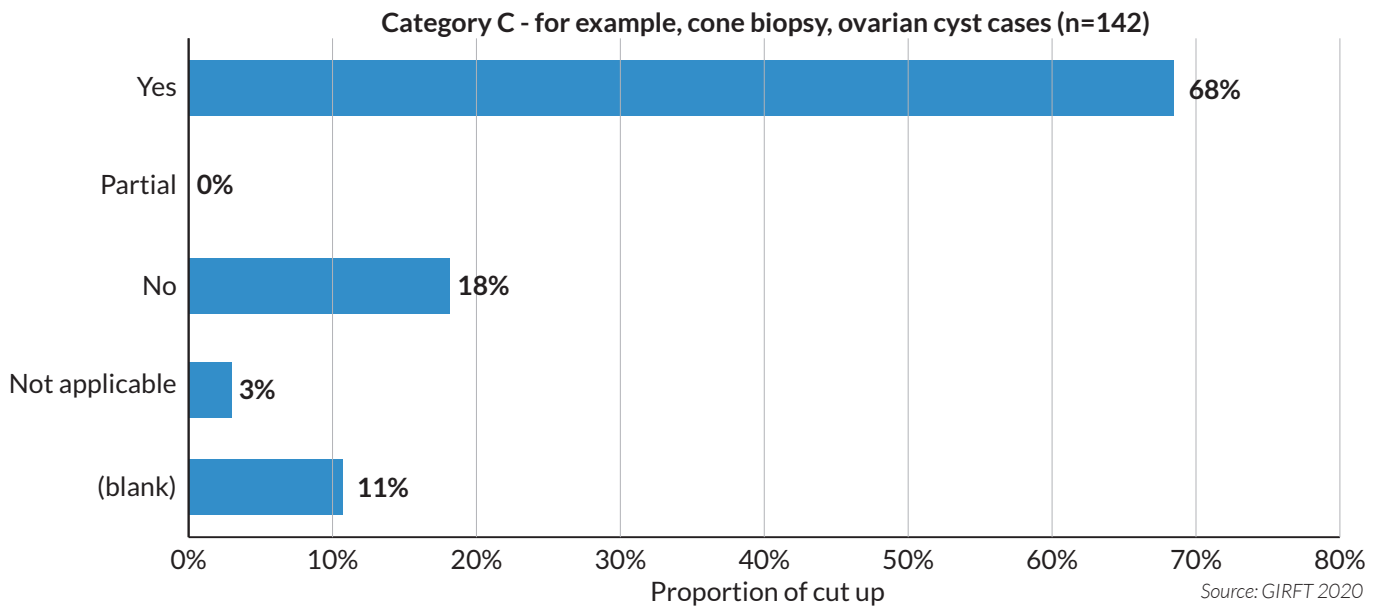
In general, we encourage a greater flexibility and a wider range of roles for biomedical scientists. This will not only boost retention (by providing more varied routes for career progression) but also increase the diversity of skills and experience in trusts and across networks.

For example, it is now widely accepted that biomedical scientists can train and qualify to perform histological dissection ('cut up') of surgical samples and, more recently, report some histopathology samples, activities that had previously been limited to medically qualified pathologists.

In our deep dives, we found variation in how biomedical scientists are involved in cut up, with some sites successfully training biomedical scientists to cut up all levels of samples, including the most complex. These programmes have been successful, and the feedback we received from biomedical scientists was positive. We therefore recommend that all networks enable biomedical scientists to train to work at this AP and consultant level.

Figure 66: Do biomedical scientist staff (including APs) carry out cut up (sorted by RCPATH's categories A to E)





CASE STUDY

Biomedical scientists undertaking advanced practice in sample dissection

St Helens and Knowsley Teaching Hospitals NHS Trust and (separately) Airedale NHS Foundation Trust

Faced with a shortage of medical histopathologists – a national problem – both trusts have opened up a career development pathway for biomedical scientists to carry out sample dissection.

St Helens and Knowsley: The trust developed training and ongoing competency assessments that ensured medical histopathologists could provide continuous feedback to biomedical scientists about the quality of their work, including its impact on the final histopathology report, helping to make the work more fulfilling.

Biomedical scientists at the trust can complete a Diploma in Expert Practice (DEP) or an advanced specialist diploma in histological dissection from the IBMS.

Airedale: At Airedale, the trust has partnered with the local Cancer Alliance to help build histopathology capacity using biomedical scientist Advanced Practitioners, with the Cancer Alliance providing some funding. This initiative started with training biomedical scientists to cut up category A to C samples; in 2011 this expanded to include breast cancer samples in the D and E categories. This has now expanded to most cancer specimens within the department.

Results

At St Helens and Knowsley, up to 95% of histology samples that the trust's pathology department receive are now dissected by biomedical scientists; at Airedale this figure is 90%.

A staff member at St Helens and Knowsley who completed the diploma described it as 'a wonderful career pathway for biomedical scientists, that incorporates the knowledge gained from an undergraduate and a Master's degree, along with leadership and managerial skills, providing an interesting and rewarding career.'

Pathologists and consultant clinical scientists

Consultant pathologists are medically qualified, while consultant clinical scientists are scientifically trained. Both work as clinical leaders in their own pathology disciplines. This includes strategic development of the lab, training junior staff, and providing advice on testing and interpretation of results.

Many medically qualified pathologists also see patients in clinics, such as haematology and metabolic clinics. Some clinical scientists now also undertake patient clinics.

Pathology is broken down into several specialties. In our discussion below, we have only covered the areas that account for the highest hospital-based workforce. Further information is available from the RCPATH's workforce surveys; we are very grateful to the RCPATH for providing the data used below.

When looking at regional breakdowns, please note that London carries out more referral work from other regions.

Histopathology

We found variation in the numbers of histopathologists, with unfilled vacancies in all areas.

In the workforce survey carried out by the RCPATH in 2017 (reported 2018),⁴⁵ only 3% of histopathology departments said they had enough staff to meet clinical demand; 45% indicated they were having to outsource work, and 50% had to use locums before the pandemic. The vacancy rate varies between regions.

⁴⁵ <https://www.rcpath.org/profession/workforce-planning/our-workforce-research/histopathology-workforce-survey-2018.html>

Figure 67: Number of histopathology consultants and vacancies per region

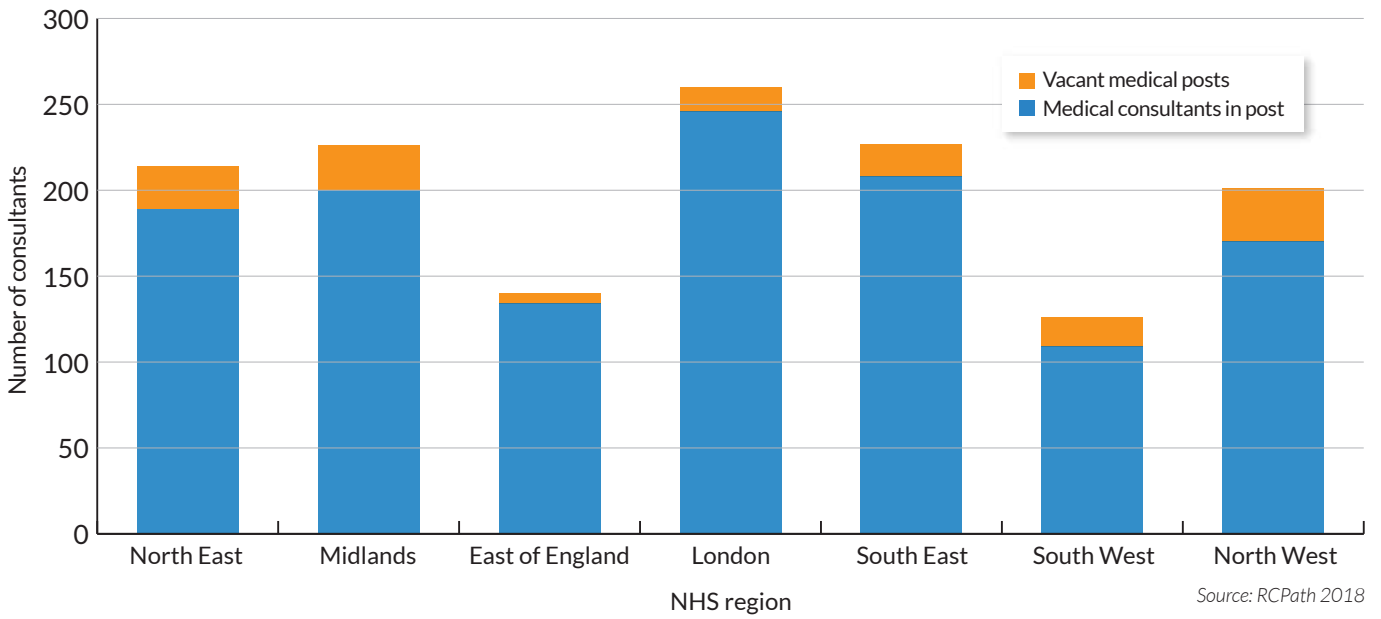
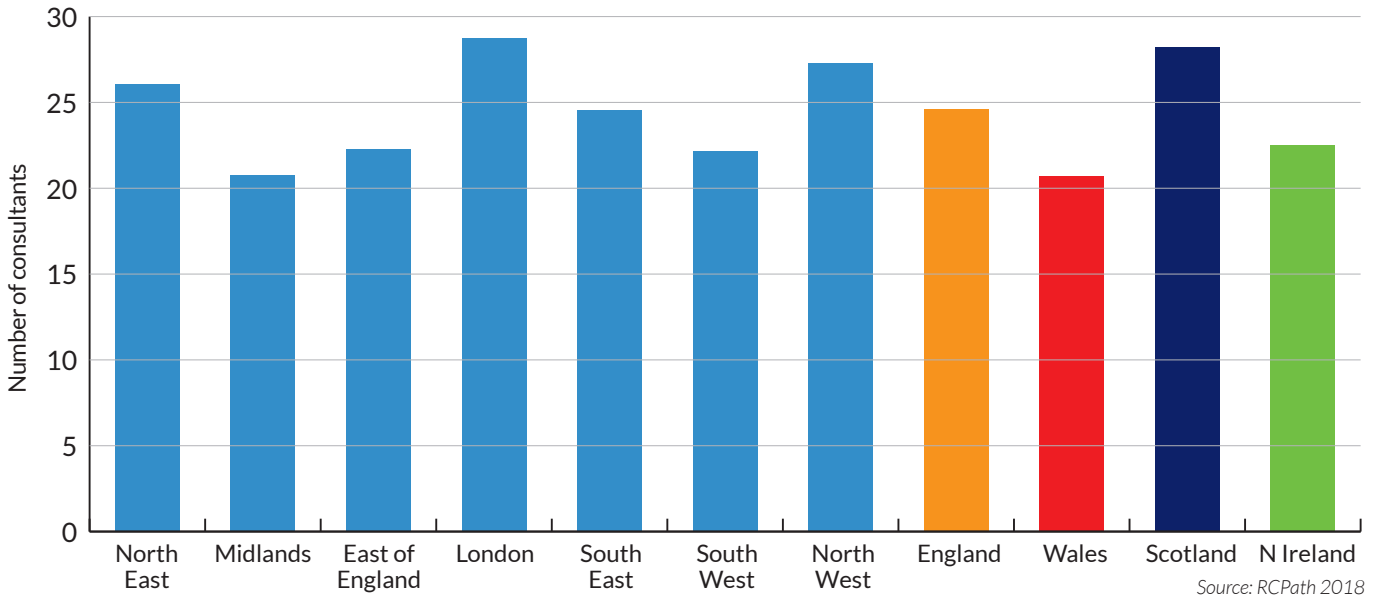


Figure 68: Number of histopathology consultants per million population



Overall our key findings for histopathology were as follows:

- As described in **Figure 66** above, we found significant variation in how much cut up was carried out by biomedical scientists. In some trusts, the vast majority of all cut up was performed by biomedical scientists, while in others the rate was very low. Trusts and networks need to consider how they involve and upskill their biomedical scientist workforce to take on more of this role.
- The workforce gap of up to 25% in histopathology consultants is clearly a concern, especially considering their key role in cancer diagnosis. We observed delays in reporting times as a consequence of the vacancies, which will have an impact on diagnosis and treatment for many patient pathways. It is critical that we understand and tackle problems with recruitment and retention, and also expand workforce capabilities (for example by upskilling biomedical scientists as above).
- There are no clinical scientists in histopathology.
- In some trusts, we saw consultants undertaking low volumes of specialist work. The further development of pathology networks, in which such consultants will form part of a regional team, together with the implementation of digital pathology, will help to address this, allowing for greater access to second opinions from within and outside the network.

To address the short-term and longer-term workforce issues in histopathology, we recommend that:

- The urgent need for widespread introduction of digital pathology within histopathology is recognised (see *Implementing digital pathology* on page 100). Introducing this capability will require proper funding to establish an effective service.

Clinical biochemistry

The clinical biochemistry consultant workforce involves both medically qualified consultants and clinical scientists. The overlapping and complimentary roles within the lab have ensured sustainability and development within this specialty. Vacancy rates are low, although there were variations for both, in terms of numbers per million population, throughout England.

Figure 69: Number of clinical biochemistry consultants and vacancies per region

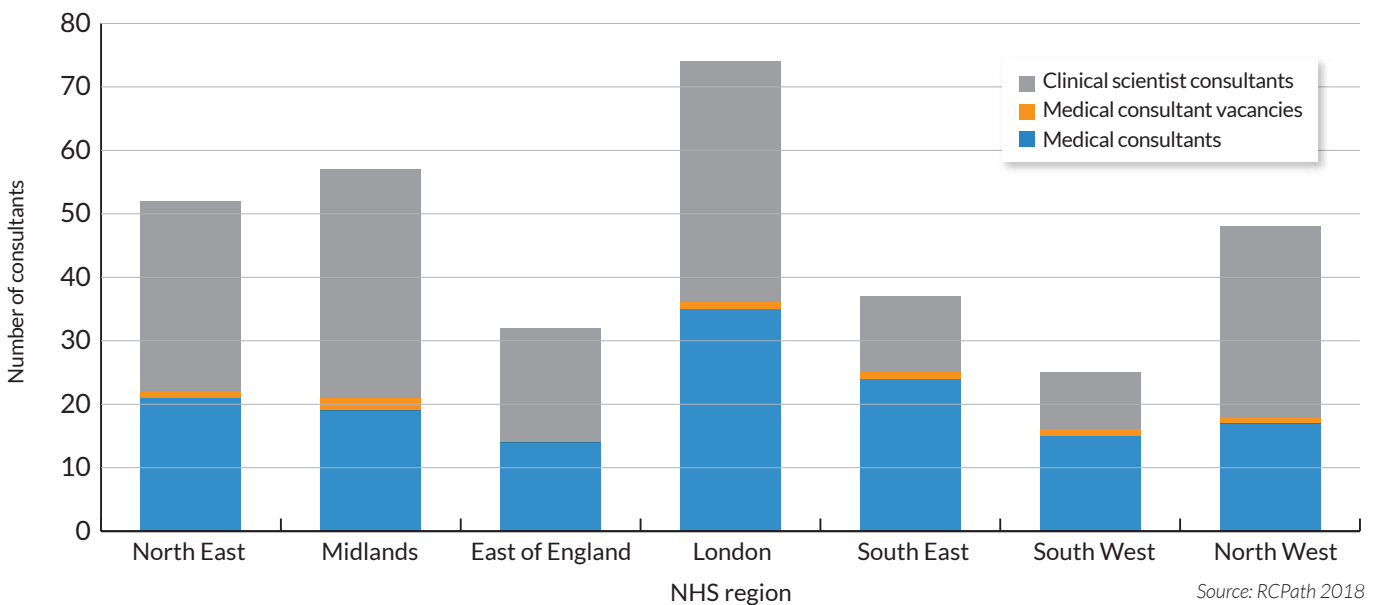
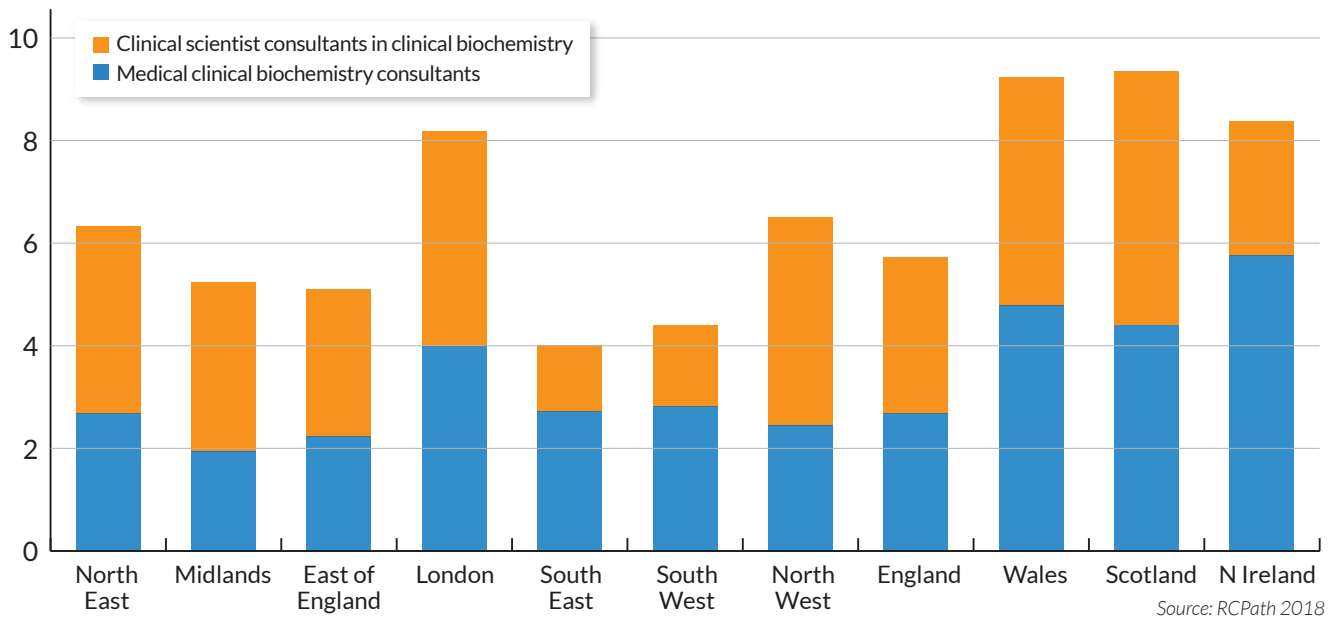


Figure 70: Number of clinical biochemistry consultants per million population



Clinical biochemistry clinics

In addition to lab duties, medically qualified consultants carry out patient-facing clinics in areas such as endocrinology and metabolic disease. Clinical scientists are now undertaking patient-facing clinics, but are currently not licensed to fully prescribe.

As we understand more about how metabolic risk factors affect outcomes for patients with COVID-19, there is an increased need for metabolic clinics in order to identify and control common metabolic disorders such as hyperlipidaemia, weight issues and metabolic syndrome. We saw some successful clinical scientist-led clinics in areas with few medical clinical biochemists.

We therefore recommend that priority is given to:

- enabling non-medical prescribing for clinical scientists (an Act of Parliament is already in process to enable this);
- increasing the number of metabolic clinics;
- increasing the numbers of medical and clinical scientist staff to match this need.

Haematology (including transfusion services)

We saw variation in vacancy rates for haematologists throughout England. It is notable that London had significantly the highest number of haematologists per population and the lowest vacancy rate.

There is clearly increased pressure on the haematology workforce. Respondents to the RCPATH's survey of haematologists in September 2019:

- expressed concerns that time spent in the lab is being reduced, as clinical pressures on haematology consultants increase;
- indicated that there were difficulties recruiting to consultant posts, both medical and clinical scientist, as well as Specialty and Associate Specialist (SAS) grade posts.

Figure 71: Number of haematology consultants and vacancies per region

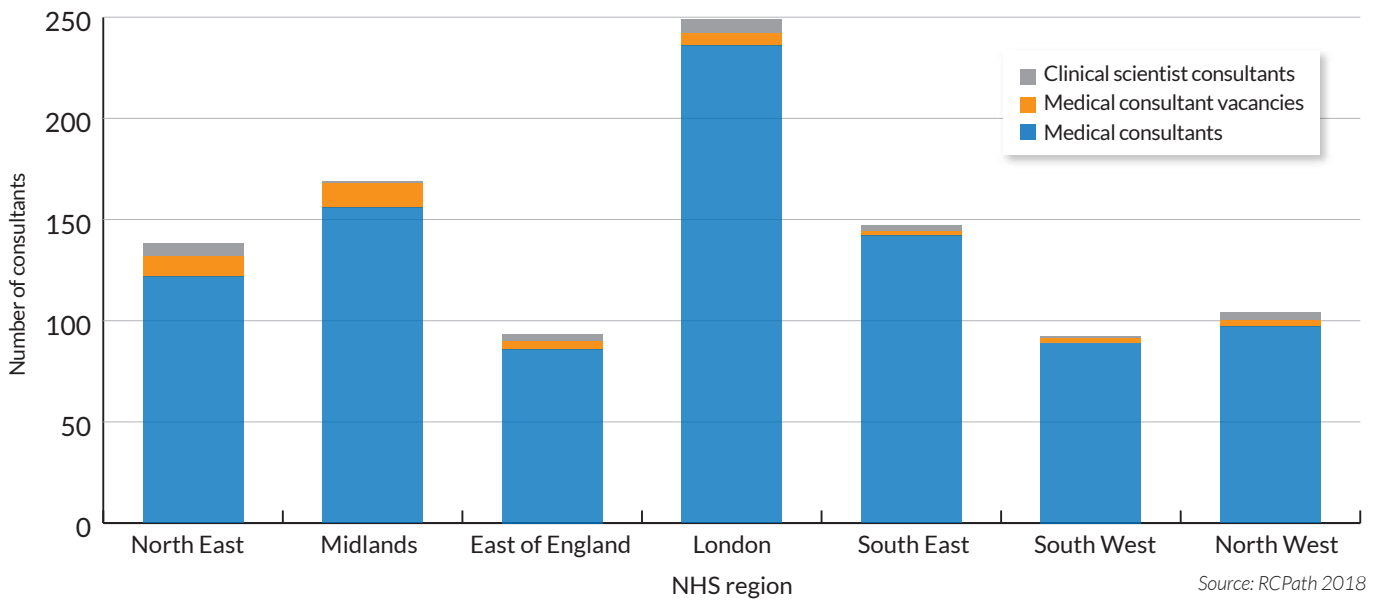
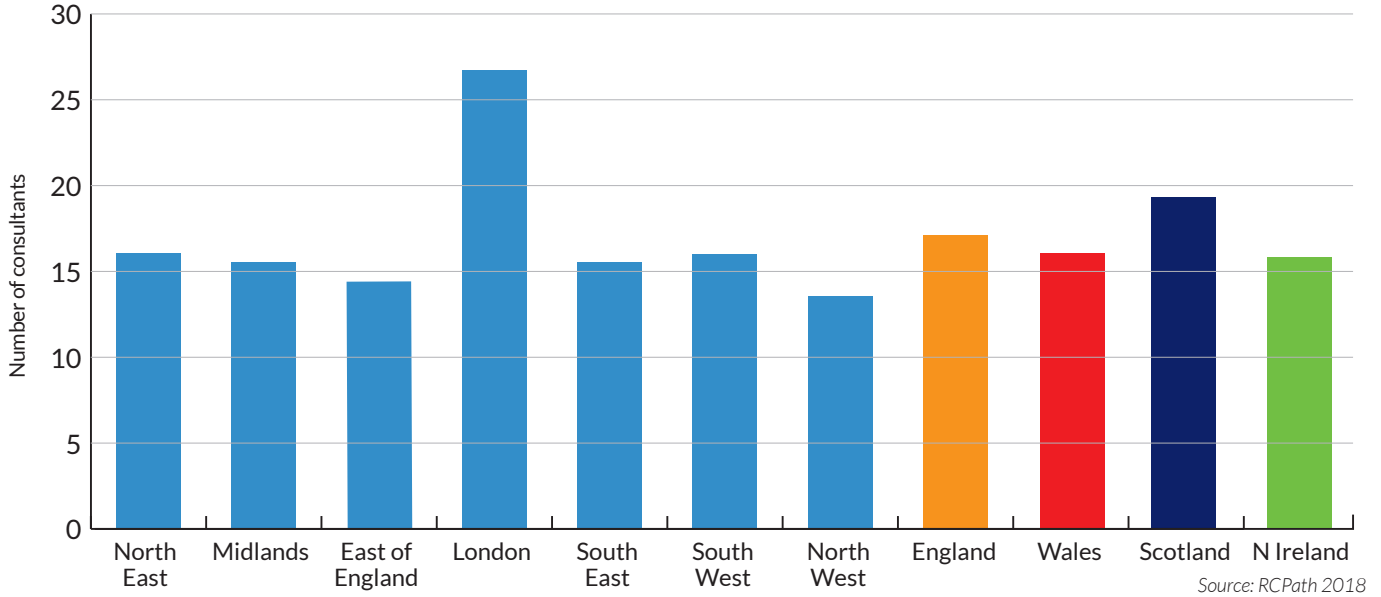


Figure 72: Number of haematology consultants per million population



Haematologists' roles have significantly evolved over the past 20 years:

- Most haematologists now spend the majority of their time on both inpatient and outpatient clinical duties, caring for patients with malignant and non-malignant blood disorders.
- They have responsibility for the hospital transfusion lab service.
- They provide out-of-hours cover for their own inpatients, and 24/7 advice to colleagues regarding abnormal blood test results.

The growth in clinical work has led to a reduction in the number of lab sessions undertaken by medically qualified consultants. While there are some consultant clinical scientists in haematology, the numbers are low. However, there are significant number of haematology biomedical scientists working at advanced and consultant level. We recommend:

- increasing the numbers of consultant clinical scientists in haematology and blood transfusion in order to increase consultant-level lab input;
- working with HEE to address the number of training places available for haematologists – both medical and scientific – at all levels;
- recognising and developing haematology biomedical scientists in advanced roles;
- encouraging and supporting biomedical scientists to access the Higher Specialist Scientist Training programme (HSST).

Transfusion services

The data above covers all of haematology and includes blood transfusion – a significant number of haematologists and haematology clinical scientists have key roles in blood transfusion services including the NHSBT Special Health Authority. Surveys by the UK Transfusion Laboratory Collaborative have highlighted staffing gaps and concerns regarding skill mix, training and safety in blood transfusion.

In our deep dives, we also noted the central importance of well-trained transfusion nurse specialists. These staff carry out multiple invaluable roles across hospital transfusion services, including training all staff involved in transfusion, encouraging engagement and understanding from other hospital specialties, and supporting lab staff regarding stock management. Nurse specialists must be allocated sufficient dedicated time to carry out their duties. This is a role where a network peer group and support will facilitate recruitment, development and retention.

Microbiology

As with other specialties, we saw variation in the vacancy rates for microbiologists across England, with higher rates in the Midlands and North West. The number of consultant clinical scientists in microbiology is relatively low, although higher in London.

Figure 73: Number of microbiology consultants and vacancies per region

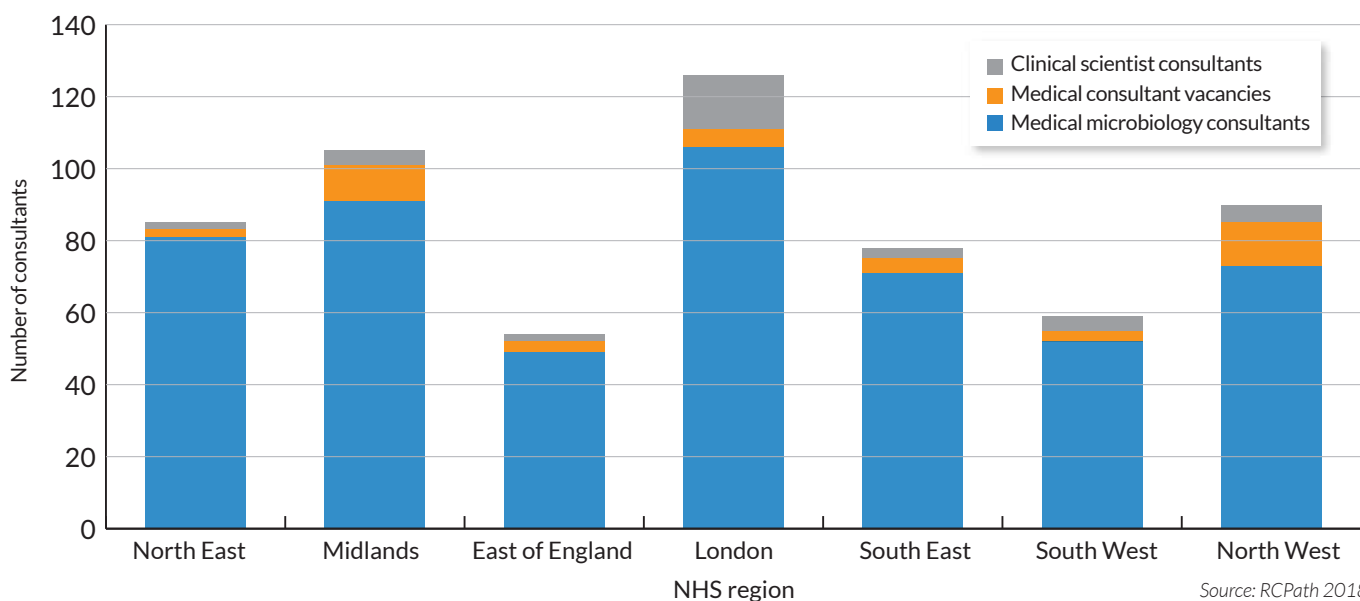
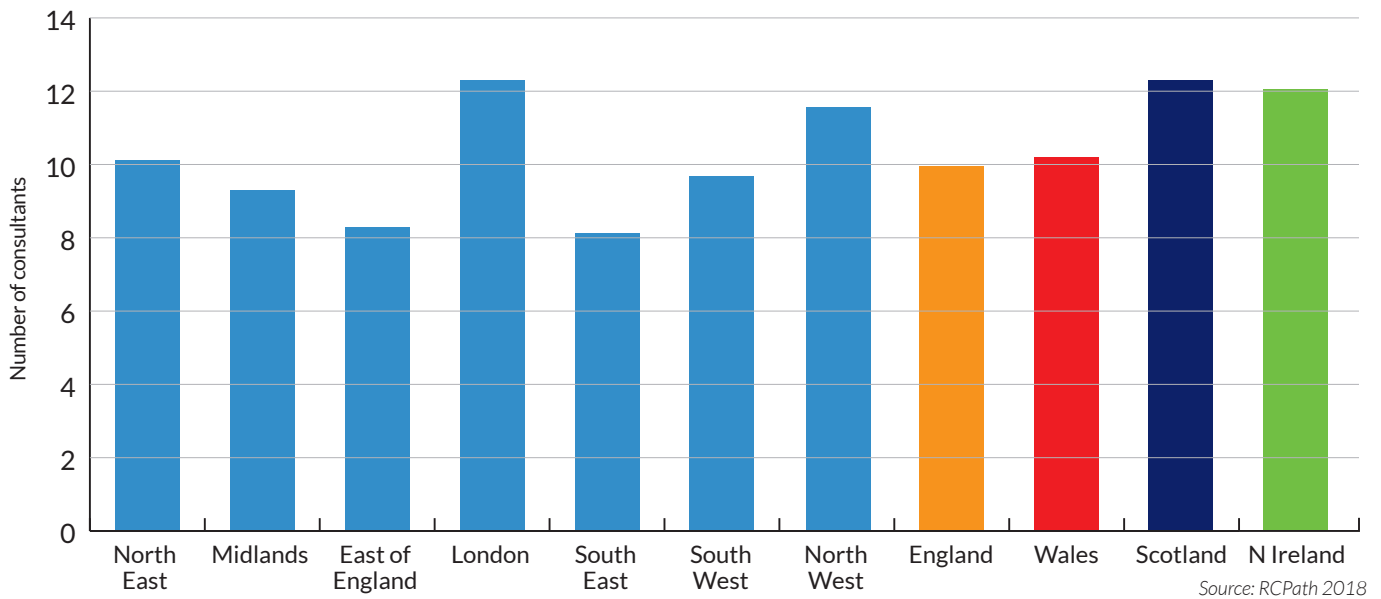


Figure 74: Number of microbiology consultants per million population



As with haematology, we recommend that the number of consultant clinical scientists is increased to meet the demands of the service, especially at consultant level within the lab.

Medical laboratory assistants and assistant practitioners

Every lab will have a number of medical laboratory assistants and assistant practitioners: it is unclear how many there are throughout England, as each lab will categorise these differently. They have varied roles, including clinical tasks, administrative and clerical duties, and assisting in the testing of samples on analysers. They may work across several lab specialties.

Medical laboratory assistants and assistant practitioners work in a support role. They are generally supervised by a biomedical scientist, and do not undertake work independently. There may be opportunities for these staff to be upskilled to take on more responsibilities, or to enter training to become biomedical scientists.

Associated staff

Pathology labs cannot run effectively without the support of many associated staff, most notably phlebotomists and porters.

Some of these staff may be managed directly by labs, but others will be managed by trusts, or work outside the hospital in a widening range of other settings. A key objective of the Community Diagnostic Hubs project is to increase access to community phlebotomy. As noted above in the section *Phlebotomy issues* on page 42, labs need to proactively seek to influence and improve standards in phlebotomy to improve the quality of blood samples they receive. Similarly, they need to seek to influence how other shared services are managed, including portering. See *Trust and network governance* on page 87 for more on this.

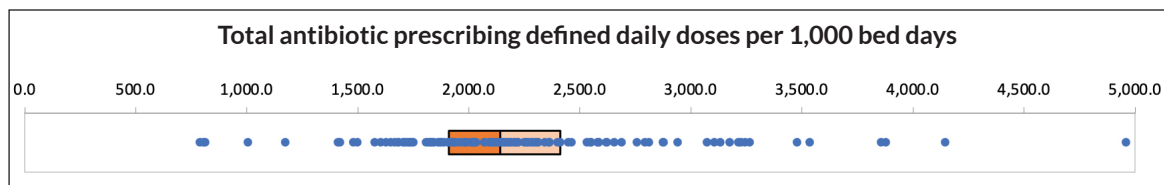
Using multidisciplinary approaches

In our deep dives, we saw successful examples of specialties working together in multidisciplinary teams (MDTs).

For example:

- Some of the highest performing trusts in terms of antibiotic stewardship had MDTs with pathology and pharmacy colleagues working closely together. These sites had been able to achieve an ideal profile of antibiotic usage, including low usage of broad spectrum antibiotics. In the charts below, trusts with proactive teams were all towards the left of each chart. We noted that these MDTs involved highly active pharmacy teams with a strong ward presence. This may be an area where trusts can proactively monitor their own antibiotic prescription data and decide whether an MDT approach could be beneficial.
- We are aware of trusts implementing a multidisciplinary approach in anticoagulation, where nurse practitioners and pharmacists with prescriber qualifications take on responsibility for anticoagulation management.
- In clinical biochemistry, we saw that successful POCT teams often combined the skills of pathologists with nurse specialists and biomedical scientists to co-ordinate care.

Figure 75: Variations in antibiotic prescribing



Source: PHE Fingertips 2017/2018



Source: PHE Fingertips 2017/2018

A workforce to match pathology as it evolves

The pathology landscape is rapidly evolving, and it is vital that the workforce is able and available to match these changing requirements.

As the technologies involved in pathology converge, and new technologies appear, it is likely that staff will benefit from broader skillsets. These will enable them to work more freely between specialties, understanding and learning from commonalities between them, and providing greater career opportunities. This will result in a team that is both more flexible and multidisciplinary. This may mean that all staff may need experience across different specialties as part of their training.

Trusts also need to consider the growing informatics requirements in pathology. The advantages of being able to access simple, real-time performance metrics was brought into very sharp focus by the COVID-19 pandemic, but will only increase in importance and utility. Many labs already use bioinformaticians, but career and skills development can be problematic. Again this is an area where pathology networks may be able to 'cross-fertilise' bioinformatician skills across trusts.

Future challenges to the pathology workforce

Pathology currently faces many of the same workforce issues as other specialties.

For example:

- The service relies on staff at all levels working additional hours, increasing the risk of staff burn-out. This is often due to insufficient staff at appropriate grades.
- There is a greater need to support part-time and flexible working patterns as the workforce evolves.
- Following recent issues such as the pensions tax concern (where higher-level staff could not work additional hours without facing prohibitively large tax bills), and the increased working hours caused by the COVID-19 pandemic, there is a risk that staff may be looking to reduce hours to restore work-life balance.
- Pathology generally provides a 24/7 service, staffed on site predominantly by biomedical scientists working shifts, including senior staff (due to staff shortages). The shift system can cause issues for staff wellbeing. Where staff are unable to access higher grades, they may remain working shifts throughout their career.
- There is a need to develop and nourish leadership roles in pathology (see *Developing leadership in networks* on page 110).

However, in addition to these existing issues, demand for pathology services is unlikely to decrease over coming years. The COVID-19 pandemic highlighted the need for agile, adaptable diagnostic services that can be scaled quickly, both to deal with future epidemics and with the NHS's evolving requirements. In particular, Community Diagnostic Hubs, as proposed in the report *Diagnostics: Recovery and Renewal*,⁴⁶ will require a rapid expansion of pathology services (see page 110).

We therefore recommend a major drive to develop the pathology workforce as outlined in recommendation 19 below. We recommend that:

- networks first take proactive steps to identify workforce gaps, seeking to manage these using the full range of skills and staff available in the network itself;
- networks measure and plan for future demand, and feed back on areas of concern to the NPB;
- the NPB uses network metrics to identify areas of national shortage, and achieves a consensus with networks on workforce strategy;
- the NPB works with training bodies, HEE, The RCPATH, the IBMS, The National School for Healthcare Science (NSHCS) and the Academy for Healthcare Science (AHCS) to ensure a wide range of intake;
- the NPB investigates effective levers to encourage network leaders and training bodies to take up training responsibilities.

The problem of unfilled vacancies is not unique to pathology. Although we can seek to recruit and to train, we must also think laterally in order to ensure a continuing quality pathology service. Indeed, if we focus on delivering value, workloads may reduce in some areas – for example if we can reduce the number of tests of limited clinical value, or reduce 'default' testing.

As pathology continues to evolve, our thinking on successful workforce solutions must evolve too. From upskilling a variety of staff, to utilising new technologies, to working in multidisciplinary teams, to embracing and developing a wider range of roles in staff with different areas of experience and expertise, we must continue to monitor and learn from what works. To continue our focus on End-to-End Pathology, delivering the **right test, at the right time, with the right answer**, we must retain an open mindset about useful solutions, rather than a fixed idea of what has worked in the past.

⁴⁶ NHS England, 2019. *Diagnostics: Recovery and Renewal – Report of the Independent Review of Diagnostic Services for NHS England*. <https://www.england.nhs.uk/publication/diagnostics-recovery-and-renewal-report-of-the-independent-review-of-diagnostic-services-for-nhs-england>

Detailed recommendation: Workforce

Recommendation	Actions	Owners	Timescale
19. Identify and close workforce gaps at a national level.	a Building on network-level metrics identifying gaps, the NPB to work with training bodies and Health Education England (HEE) to ensure a wide range of intake and increase the number of training positions available, to meet anticipated future demand.	NPB, PNs, HEE	Within 2 years of publication
	b Labs, trusts and PNs to allocate time for biomedical scientists to mentor and tutor colleagues to higher levels to fill gaps in the medical workforce in all relevant specialties.	Labs, trusts, PNs	Within 2 years of publication

Finance

During our deep dives, we found overwhelming concern that in recent years there had been a focus on improving efficiency by reducing cost per test: this tended to be the abiding memory of reports and reviews, regardless of the breadth of their recommendations. As a result of dedicated work, pathology has already delivered on opportunities for savings, and the proportion of total NHS expenditure spent on pathology has decreased from 4% to between 1.5% and 3%.

Colleagues did appreciate that pathology, like any NHS specialty, does need to continue its focus on productivity. However, focusing mainly on cost can:

- hinder innovation, even innovation that could result in longer-term savings;
- delay the introduction of new tests to improve patient care and potentially avoid downstream costs;
- result in pathology-focused rather than patient-focused initiatives and services;
- where costs per test are reduced, have the unintended consequence of more tests being requested resulting in increased expenditure.

Restoring the balance between value and productivity

Reducing cost per test by improving productivity is one strategy to reduce costs, but concentrating just on this approach risks reducing quality. Demand optimisation – reducing unnecessary testing at source – should also be a key focus in efforts to control costs. We have already presented evidence that pathology can save expenditure by (for example) removing tests of little clinical value from common testing profiles. See also other savings presented in the *Notional financial impact* section on page 132.

However, our most important aim throughout this report is to build an End-to-End Pathology service that restores the balance between cost-oriented and value-oriented approaches. A clear way to achieve this is to focus on developing network standards, and (where appropriate) achieving national consensus on these (see *Establishing network-wide standards and standardised national diagnostic pathways* on page 82). These standards will include demand optimisation, and will balance value with cost by:

- focusing clinicians on sufficient tests to answer their clinical question, meaning they can remove redundant tests case by case;
- identifying tests of limited value overall, and removing them from default testing profiles;
- speeding up adoption of new technology that adds value and may reduce costs in the longer term;
- increasing governance of, and compliance with, agreed pathways, to reduce unwarranted variation;
- agreeing processes and other standards (such as reference intervals), removing burden from local labs and increasing best-practice consistency;
- reducing downstream costs and potential iatrogenic harm caused by unnecessary investigations, including resulting litigation costs;
- encourage investment in knowledge and skills – such as in IT infrastructure – that are necessary to build a robust service.

In each case, it is clear that the measure increases value to the patient and requesting clinician, as well as delivering savings for pathology. Once network standards are implemented and (where possible) built into accreditation, variation will be reduced and both value and savings will result. Indeed, we strongly believe the savings achieved from a value-based approach are likely to dwarf savings from cost-cutting measures.

Looking at funding for pathology departments

During our deep dives, we saw evidence of variation in quality. While we cannot explicitly link this with variable funding, it was clear that many pathology departments were under pressure to reduce expenditure – with, often, a knock-on effect on quality.

The finance model for the NHS overall is changing to a blended payment approach, ending the previous system of Best Practice Tariffs (BPTs). The new system needs to be designed thoughtfully for pathology, to ensure that effectiveness and quality are incentivised alongside continuing the drive for necessary efficiency.

Detailed recommendation: Finance

Recommendation	Actions	Owners	Timescale
20. Review funding models for pathology.	a NHS England and NHS Improvement to explore ways to incentivise effectiveness in pathology alongside continuing the drive for efficiency.	NHS England and NHS Improvement	Discussions to begin immediately

Litigation

Reducing the impact of litigation

Each of the GIRFT programme teams has been asked to examine the impact and causes of litigation in their field – with a view to reducing the frequency of litigation and, more importantly, reducing the incidents that lead to it. It is important that clinical staff have the opportunity to learn from claims. In conjunction with learning from complaints, patient safety incidents and inquests, this will lead to improved patient care and reduced costs, both in terms of litigation itself and the management of the resulting complications of potential incidents.

It was clear during GIRFT visits across workstreams that many providers had little knowledge of the claims against them. This included some with high litigation costs per admission as well as those at the low end. As a consequence, there is an opportunity to learn from the claims to inform future practice. Further work is needed at both a local and national level to analyse claims to maximise this opportunity to improve patient care.

Pathology clinical negligence claims volume and costs

Data obtained from the NHS Resolution (detailed in **Table 2**) shows clinical negligence claim costs in pathology related claims. There has been no significant change on the numbers of claims and there has not been a significant change in claims costs.

Table 2: Volume and cost of medical negligence claims related to pathology notified to NHS Resolution 2013/14 to 2017/18

Notification year	No. of cases	Sum of Total Claim costs (£million)
2013/14	135	27.2 million
2014/15	116	14.3 million
2015/16	140	23.7 million
2016/17	130	17.3 million
2017/18	124	25.0 million
Grand Total	645	107.5 million

Source: NHS Resolution

Pathology specialties

The pathology specialty with the highest volume of claims and total claims costs was haematology (**Table 3**). This is unsurprising, as this specialty has the most direct patient contact and claims can overlap with other specialties, especially when anti-coagulation for life-threatening conditions such as a stroke or pulmonary embolism is involved. Additionally, there is an overlap in claims that involve major haemorrhage management in surgical specialties. This is most apparent in obstetrics.

However, this data emphasises the importance for robust, agreed anticoagulation pathways and blood transfusion teams to be in place and for consultant haematologists, consultant clinical scientists and consultant or equivalent level biomedical scientists in haematology to take an active role in the laboratory service.

Histopathology is the second highest in both claims volume and cost. Of the 240 claims, 228 were involving cancer diagnosis (missed or delayed diagnosis) including 43 specifically due to misdiagnosis of cervical smear. Misinterpretation of cervical cytology samples has featured as a frequent cause for pathology related clinical negligence claims in the USA.⁴⁷ Sub-specialisation, second reporting and MDTs contribute to improved cancer diagnosis, and it is important that small histopathology departments embrace the creation of pathology networks to ensure that a critical mass of experienced and appropriately qualified staff is available to undertake these working practices.

⁴⁷ Fable, W.J., 2007. *Error reduction and risk management in cytopathology*.

There are fewer microbiology/virology claims, but there have been individual potentially high cost claims involving diagnosis, management and contact tracing of tuberculosis.

Over half of the chemical pathology clinical negligence claims are due to wrong diagnosis (30 of 58). This emphasises the importance of robust reporting and assurance mechanisms to ensure accurate diagnoses and results are produced. The low number of claims generally compared to the huge volume of chemical pathology analyses performed annually is a testament to the quality of the processes already in place.

Table 3: Volume and cost of medical negligence claims related to pathology specialties notified to NHS Resolution 2013/14 to 2017/18

Specialty	No. of claims	Sum of Total Claim costs (£million)
Haematology	299	51.0m
Histopathology	240	35.5m
Chemical pathology	58	9.4m
Microbiology/virology	48	11.5m

Source: NHS Resolution

Detailed recommendations: Litigation

Recommendation	Actions	Owners	Timescale
21. Reduce litigation costs by application of the GIRFT programme's five-point plan.	a Clinicians and trust management to assess their litigation claims covered under Clinical Negligence Scheme for Trust (CNST) notified to the trust over the last five years.	Trusts	For immediate action
	b Clinicians and trust management to discuss with the legal department or claims handler the claims submitted to NHS Resolution to confirm correct coding to that department. Inform NHS Resolution of any claims which are not coded correctly to the appropriate specialty via CNST.Helpline@resolution.nhs.uk	Trusts	Upon completion of action a
	c Once claims have been verified, clinicians and trust management to further review claims in detail including expert witness statements, panel firm reports and counsel advice as well as medical records to determine where patient care or documentation could be improved. If the legal department or claims handler needs additional assistance with this, each trusts panel firm should be able to provide support.	Trusts	Upon completion of action b
	d Claims should be triangulated with learning themes from complaints, inquests and serious untoward incidents (SUI)/serious incidents (SI)/Patient Safety Incidents (PSI) and where a claim has not already been reviewed as SUI/SI/PSI we would recommend that this is carried out to ensure no opportunity for learning is missed. The findings from this learning should be shared with all staff in a structured format at departmental/directorate meetings (including multidisciplinary team meetings, Morbidity and Mortality meetings where appropriate).	Trusts	Upon completion of action c
	e GIRFT clinical leads and regional teams to share with trusts examples of good practice where it would be of benefit.	Trusts	For continual action throughout GIRFT programme

Notional financial impact

Throughout this national report there is a clear message that the influence and impact of pathology extends outside the lab: 'good' pathology should not be defined by the number of tests performed or results. It is about answers – getting the **right answer, at the right time, in the right place**. Recommendations therefore reach far beyond a lab's walls: into primary care, transport logistics, accreditation services, and to regional and national bodies.

There are some areas, however, where there are tangible opportunities for costs to be reduced. The table below is illustrative and focuses on areas of the national report where there is potential to make the changes discussed above, which could contribute to an overall reduction in pathology costs.

For example, *Using Care Sets* (see page 33) discusses the need to establish robust Care Sets to ensure only necessary tests are requested. *Minimising error and wastage in blood transfusion* on page 112 discusses the use and waste of blood products. A notional financial opportunity has been attached to some of these recommendations.

Note: the calculated financial opportunity in this section is for illustration purposes only, as much of the underlying data is based on numbers self-reported by providers in the GIRFT pathology questionnaire.

In addition, the potential for savings elsewhere in the healthcare system which could arise from – among other things – more informed and focused use of pathology investigations, is difficult to quantify and not included here, but could be highly significant. For example:

- reducing repeat investigations required because of poor quality samples (for example, samples that are delayed or haemolysed);
- impact and cost to patient care and productivity (clinical and lab) arising from delayed results (for example, ED delays);
- unnecessary further investigation (including imaging and endoscopy) arranged in response to unexpected results, for example, overly cautious interpretation linked to a locally set reference range, or a result for a test carried out as part of a common test profile that did not have any bearing on the clinical question under investigation.

To try to quantify this financially, one trust with a population of approximately 160,000 used case studies and estimated potential savings to be in the region of £160,000 in a single year, related to downstream costs of further investigations, incurred after unnecessary liver function tests.

We have also highlighted in our report the current variation in expenditure on equipment and suggest that this is another area where significant savings could be made by streamlining the approach to purchasing in networks; one report⁴⁸ estimated savings of around £200m per year through improved approaches to procurement.

In addition to the specific areas outlined in the table, the report has identified a total spend of £107.4m on litigation over a five-year period. Implementation of the GIRFT programme's five point plan should improve patient safety and reduce litigation costs for patients.

Table 4: Gross notional financial opportunities

Improvement	Standard			Target		
	Target	Notional activity opportunity*	Gross notional financial opportunity**	Target	Notional activity opportunity*	Gross notional financial opportunity**
<p>Creating Care Sets that link the symptoms that the patient presents with to the tests that are required (Recommendation 1)</p> <p>Opportunity = Reduce test rates (note: only a selection of tests are covered below)</p> <p>Data: Apr 18 to Mar 19 (pathology questionnaire - self-reported by providers)</p> <p>Cost estimated based on relevant pathology direct access cost (18/19 ref costs uplifted to 20/21).</p>						
<p>Primary care: liver function tests (LFTs) Note: calculation includes bilirubin and transaminase (ALT only) - other tests may be included in LFTs</p>	National average			Best Quartile		
Bilirubin	798 GP bilirubin tests per 1,000 GP Potassium requests	820,900 tests	£0.94m	772 GP bilirubin tests per 1,000 GP Potassium requests	1,280,600 tests	£1.46m
Alanine transaminase (ALT)	805 GP ALT tests per 1,000 GP Potassium requests	686,200 tests	£0.78m	774 GP ALT tests per 1,000 GP Potassium requests	1,154,400 tests	£1.32m
<p>Primary care: other tests</p>	National average			Best Quartile		
C-reactive protein (CRP)	139 GP CRP tests per 1,000 GP list size	1,218,900 tests	£1.39m	101 GP CRP tests per 1,000 GP list size	2,235,600 tests	£2.56m
Haemoglobin	432 GP haemoglobin tests per 1,000 GP list size	2,807,100 tests	£3.21m	378 GP haemoglobin tests per 1,000 GP list size	4,271,900 tests	£4.88m
Vitamin D	54 GP vit D tests per 1,000 GP list size	757,700 tests	£0.87m	27 GP vit D tests per 1,000 GP list size	1,533,100 tests	£1.75m
Urine samples	105 urine specimens from primary care per 1,000 list size	682,500 tests	£5.38m	88 urine specimens from primary care per 1,000 list size	1,191,800 tests	£9.4m
Erythrocyte sedimentation rate (ESR)	682 GP ESR tests per 1,000 GP CRP requests	1,094,000 tests	£3.17m	412 GP ESR tests per 1,000 GP CRP requests	2,189,400 tests	£6.35m

Table 4: Gross notional financial opportunities (continued)

Improvement	Standard			Target		
	Target	Notional activity opportunity*	Gross notional financial opportunity**	Target	Notional activity opportunity*	Gross notional financial opportunity**
Primary care: other tests	<i>National average</i>			<i>Best Quartile</i>		
Ferritin	120 GP ferritin tests per 1,000 GP list size	994,600 tests	£2.88m	94 GP ferritin tests per 1,000 GP list size	1,779,500 tests	£5.16m
Rheumatoid factor	13 GP rheumatoid factor tests per 1,000 GP list size	135,600 tests	£0.92m	9 GP rheumatoid factor tests per 1,000 GP list size	233,600 tests	£1.59m
Urea***	<i>Clinical view</i>			<i>Clinical view</i>		
	85% reduction in GP urea tests	18,568,300 tests	£2.12m	90% reduction in GP urea tests	19,660,600 tests	£2.25m
Primary care: free thyroxine (FT4)	75% reduction in GP free thyroxine (FT4) tests	4,358,800 tests	£4.98m	80% reduction in GP free thyroxine (FT4) tests	4,649,400 tests	£5.32m
Emergency Department: Liver function tests (LFTs)	<i>National average</i>			<i>Best Quartile</i>		
<i>Note: calculation includes bilirubin and transaminase (ALT only) - other tests may be included in LFTs</i>						
Bilirubin	290 ED Bilirubin tests per 1,000 ED attendances	738,300 tests	£0.84m	226 ED bilirubin tests per 1,000 ED attendances	1,446,400 tests	£1.65m
Alanine transaminase (ALT)	282 ED ALT tests per 1,000 ED attendances	675,400 tests	£0.77m	223 GP ALT tests per 1,000 ED attendances	1,269,300 tests	£1.45m
Joint working with primary care to tackle stabilisation problems	<i>National average</i>			<i>Best Quartile</i>		
<i>(Mainly recommendation 7, and recommendation 2 as the overarching principle.)</i>						
Opportunity = reduce unnecessary admissions from ED	80% reduction in hyperkalaemia ED (zero LOS) admissions	3,800 emergency admissions	£1.72m	90% reduction in hyperkalaemia ED (zero LOS) admissions	4,200 emergency admissions	£1.9m
<i>(Note: this calculation looks at ED admitted hyperkalaemia patients only, with zero LOS, which is known to be poorly coded. This calculation is therefore likely to be a significant underestimate of the actual opportunity)</i>						
<i>Base data: HES 2018/19</i>						
<i>Cost estimated based on HRG KCO5 (hyperkalaemia) non-elective short stay (18/19 ref costs uplifted to 20/21).</i>						

Table 4: Gross notional financial opportunities (continued)

Improvement	Standard			Target		
	Target	Notional activity opportunity*	Gross notional financial opportunity**	Target	Notional activity opportunity*	Gross notional financial opportunity**
Minimise error and wastage in blood transfusion (Recommendation 18)	National average			Best Quartile		
Opportunity = minimise waste of blood products Base data: Jan to Dec 2018 (NHS Blood Stocks Management Scheme - BSMS. An arm of NHSBT) (Note: The calculation is based on self-reported blood product waste data provided to BSMS (which is historically poorly reported) Cost estimated based on NHSBT blood and component price list 20/21****						
Red blood cells (RBC)	2.1 % RBC waste	6,500 RBC units	£0.9m	1.4 % RBC waste	11,800 RBC units	£1.64m
Fresh frozen plasma (FFP)	14.3 % FFP waste	6,500 FFP units	£0.22m	9.2 % FFP waste	10,400 FFP units	£0.36m
Total			£31.09m			£49.04m

* Activity opportunities are annual figures, based on one year of activity data. The majority of activity used in the calculations above has been self-reported by providers within the GIRFT pathology questionnaire (April 2019). Any extreme outliers have been excluded. Unless specified, activity that could be avoided is shown

** Costing of financial opportunity: unless otherwise stated, cost estimates are based on published national average 18/19 reference costs <https://www.england.nhs.uk/national-cost-collection/>, uplifted to 20/21 pay and prices using tariff inflation. The cost of individual pathology tests identified in the table above may be less than this

*** 10% of the published biochemistry reference cost (18/19) has been used in the calculation of financial opportunity related to urea, based on clinical judgement

**** The NHS blood component price list can be found at <https://hospital.blood.co.uk/components/portfolio-and-prices>

About the GIRFT programme

Getting It Right First Time (GIRFT) is a national programme designed to improve treatment and care by reviewing health services. It undertakes clinically-led reviews of specialties, combining wide-ranging data analysis with the input and professional knowledge of senior clinicians to examine how things are currently being done and how they could be improved.

Working to the principle that a patient should expect to receive equally timely and effective investigations, treatment and outcomes wherever care is delivered, irrespective of who delivers that care, GIRFT aims to identify approaches from across the NHS that improve outcomes and patient experience, without the need for radical change or additional investment. While the gains for each patient or procedure may appear marginal, they can, when multiplied across an entire trust – and even more so across the NHS as a whole – deliver substantial cumulative benefits.

The programme was first conceived and developed by Professor Tim Briggs to review elective orthopaedic surgery to address a range of observed and undesirable variations in orthopaedics. In the 12 months after the pilot programme, it delivered an estimated £30m-£50m savings in orthopaedic care – predominantly through changes that reduced average length of stay and improved procurement.

The same model has been applied in more than 40 different areas of clinical practice. It consists of four key strands:

- a broad data gathering and analysis exercise, performed by health data analysts, which generates a detailed picture of current national practice, outcomes and other related factors;
- a series of discussions between clinical specialists and individual hospital trusts, which are based on the data – providing an unprecedented opportunity to examine individual trust behaviour and performance in the relevant area of practice, in the context of the national picture. This then enables the trust to understand where it is performing well and what it could do better – drawing on the input of senior clinicians;
- a national report, that draws on both the data analysis and the discussions with the hospital trusts to identify opportunities for improvement across the relevant services;
- an implementation phase where the GIRFT team supports providers to deliver the improvements recommended.

GIRFT and other improvement initiatives

GIRFT is part of an aligned set of workstreams within NHS England and NHS Improvement. It is the delivery vehicle for one of several recommendations made by Lord Carter in his February 2016 review of operational efficiency in acute trusts across England.

The programme has the backing of the Royal Colleges and professional associations and has a significant and growing presence on the Model Hospital portal, with its data-rich approach providing the evidence for hospitals to benchmark against expected standards of service and efficiency. The programme also works with a number of wider NHS programmes and initiatives which are seeking to improve standards while delivering savings and efficiencies.

Implementation

GIRFT has developed an implementation programme designed to help trusts and their local partners to address the issues raised in trust data packs and the national specialty reports to improve quality. The GIRFT team provides support at a local level through the NHS England regional teams, advising on how to reflect the national recommendations into local practice and supporting efforts to deliver any trust specific recommendations emerging from the GIRFT visits. GIRFT also helps to disseminate best practice across the country, matching up trusts who might benefit from collaborating in selected areas of clinical practice. Through all its efforts, local or national, the GIRFT programme strives to embody the ‘shoulder to shoulder’ ethos that has become GIRFT’s hallmark, supporting clinicians nationwide to deliver continuous quality improvement for the benefit of their patients.

Glossary

Clinical and NHS terms

For further information on tests used in pathology, see <https://www.labtestsonline.org.uk>

Accreditation

A quality checking process that results in formal recognition that an organisation is competent to perform specific processes.

Action limit

When reading results of a test, the action limit is the decision point for taking further action, such as phoning results through to clinical teams. Also known as the 'phoning limit'.

Advice and Guidance (A&G)

A service that enables primary care clinicians to ask a consultant or other secondary care clinician for advice on referral or further investigation of their patient.

Alanine transaminase (ALT)

An enzyme found in the liver. Testing for this can help clinicians to diagnose liver conditions.

Analyser

Machines used in labs to perform a variety of tests.

Analyte

A substance which is being tested for. Sometimes called a measurand.

Anticoagulant

Medication to help prevent blood from clotting.

Anti-neutrophil cytoplasmic antibody (ANCA)

Testing for this can help clinicians diagnose certain kidney and other inflammatory conditions.

Artefact, artefactual

An abnormality or inaccurate finding due to some form of systemic error introduced by the processing of a sample.

Atlas of Variation

A tool for analysing NHS diagnostic data.

<https://www.england.nhs.uk/rightcare/products/atlas>

Best Practice Tariff (BPT)

A payment model designed to provide a financial incentive to promote improved and consistent standards across services.

Bilirubin

A substance made by the liver as part of the process of breaking down red blood cells. Testing for this can help clinicians to diagnose liver conditions.

Bimodal distribution

A spread of data showing two centres, or peaks.

Biopsy

A biopsy involves taking a small sample of tissue for further examination.

Block contract

A system of payment for NHS trusts where the trust is paid for a providing a service, as opposed to Payment by Results (see below).

CA125

A protein made by certain types of cancer cells. Testing for this can help clinicians diagnose and monitor ovarian cancer.

Care bundle

A set of investigations or follow-up actions recommended in response to a particular patient condition.

Care Set

A set of tests grouped to match a clinical question, which can usually be selected on an electronic referral system by clicking one button.

Category Towers

The procurement function of the NHS Supply Chain operating model. There are 11 category towers, with each one specialising in a particular area of products or services, for example medical equipment.

www.supplychain.nhs.uk/sccl

Centrifugation

A lab process where a liquid sample is spun at high speed to separate out elements. Often used in blood samples to separate out blood cells from serum or plasma.

The Clean Framework

A quality framework that ensures a focus on quality at all stages of the diagnostic pathway: Clean in (pre-analytic), Clean through (analytic), and Clean out (post-analytic).

See *The Clean Framework* on page 27.

Clinical Commissioning Groups (CCGs)

Clinically-led statutory NHS bodies responsible for planning and commissioning healthcare services for their local area. There are 207 CCGs in England.

www.nhscc.org/ccgs

Clinical decision tools

Guidance on when to order tests, usually part of an electronic requesting system.

Coagulometer

An analyser used to test how quickly blood clots.

Commissioning

The process through which the health needs of the local population are identified and the services purchased and reviewed to meet those needs.

Common testing profile, testing profile

A group of tests that are frequently ordered together, for example Urea and Electrolytes (U&E), which usually includes tests for sodium, potassium, urea and sometimes chloride.

Community Diagnostic Hubs (CDHs)

Centres offering diagnostic tests outside the hospital setting, proposed in Professor Sir Mike Richards' report *Diagnostics: Recovery and Renewal*.⁴⁹

Computerised requesting

See Intelligent requesting below.

COVID-19

A pandemic disease in 2020, caused by a new strain of coronavirus first identified in 2019.

C-reactive protein (CRP)

A protein produced by the liver. Testing for this can help clinicians check for inflammation.

Creatinine

A waste substance that kidneys usually filter from blood. Testing for this can help clinicians check for kidney conditions.

Cross-matching

Matching a donated unit of blood to the patient's blood type.

Cut up

Dissection of a tissue sample ready for analysis.

D-dimer

A test that looks for a protein fragment made as a blood clot dissolves.

Deep vein thrombosis (DVT)

A blood clot in a deep vein, usually in the leg. See Venous thromboembolism below.

Demand optimisation

Actively seeking to reduce demand for tests by careful selection of appropriate tests, minimising redundancy.

Diagnostic pathway

Guidance on which tests, investigations and referrals clinicians need to carry out for a particular condition, including guidance on when to take further action and what action to take.

Elective (surgery or care)

Surgery or care that is planned rather than carried out as an emergency (non-elective).

Electronic referral system

An electronic system for transferring pathology results between labs. Please note this is different to how the term may be used in other GIRFT reports.

Electronic requesting

Computerised system for a clinician to request tests.

End-to-End Pathology

An approach to pathology that focuses on considering all stages of the diagnostic pathway, including the pre-analytical and post-analytical stages.

Erythrocyte sedimentation rate (ESR)

A test used to check for inflammation.

Faecal immunochemical test (FIT)

A test to detect blood in a patient's stool, which may be an early sign of bowel cancer.

Ferritin

A blood protein that helps the body to store iron. Testing for this can help clinicians diagnose iron deficiency.

⁴⁹ NHS England, 2019. *Diagnostics: Recovery and Renewal – Report of the Independent Review of Diagnostic Services for NHS England*. <https://www.england.nhs.uk/publication/diagnostics-recovery-and-renewal-report-of-the-independent-review-of-diagnostic-services-for-nhs-england>

Free thyroxine (fT4)

A hormone made by the thyroid gland. Testing for thyroxine can help clinicians to diagnose some thyroid conditions.

Gamma-glutamyl transferase (GGT)

An enzyme found mostly in the liver. Testing for this can help clinicians to diagnose types of liver conditions.

Haemoglobin (Hb)

A component of blood, usually in the red cells, that helps to transport oxygen around the body.

Haemolysed, haemolysis

A problem in blood samples where red blood cells have ruptured and leaked out their contents.

Healthcare Resource Group (HRG)

Standard groupings of clinically-similar treatments that use common levels of healthcare resource. HRGs help organisations to understand their activity in terms of the types of patients they care for and the treatments they undertake.

Heparin

An anticoagulant medicine used by injection to treat various conditions including venous thromboembolism.

Hospital Episode Statistics (HES)

Data on all admissions, outpatient appointments and ED attendances at NHS hospitals in England. HES data aims to collect a detailed record for each 'episode' of admitted patient care commissioned by the NHS and delivered in England, by either an NHS hospital or the independent sector. HES data is used in calculating what hospitals are paid for the care they deliver.

Hub and spoke

A network arrangement between larger and smaller service providers in a geographic area. Hub and spoke networks can be either formal or informal:

- formal means there is a contractual agreement in place;
- informal means there is a shared understanding of how the network will operate, but no contractual agreement.

Hyperkalaemia

Elevated potassium level.

Hyperlipidaemia

High cholesterol level.

Hypertension

The clinical name for high blood pressure.

Hypokalaemia

Low potassium level.

Immunofluorescence

An imaging technique where antibodies are chemically labelled with fluorescent dyes and then used to view tissues that they attach to under a microscope.

Integrated care systems (ICS)

NHS organisations, in partnership with local councils and others, taking collective responsibility for managing resources, delivering NHS standards, and improving the health of the population they serve.

<https://www.england.nhs.uk/integratedcare/what-is-integrated-care>

Intelligent requesting

Electronic requesting with a level of decision support built in, for example advice on when a test is not needed, or Care Set groupings.

Otherwise known as computerised requesting.

See also Care Sets and Electronic requesting above.

Interoperability

The ability to access and use data across settings and platforms – wherever it is needed.

International normalised ratio (INR)

A test that measures how long it takes for blood to clot, usually to monitor patients taking the anticoagulant drug warfarin.

ISO15189:2012

An international standard, created by the International Standards Organization, used in accreditation of pathology labs.

Knowledge Management System (KMS)

Searchable online system allowing useful information (such as policies, guidelines, audit tools and presentations) to be uploaded, shared and downloaded.

Lateral flow device

Test that displays results on the device itself, using coloured lines, similar to commonly used pregnancy tests.

Length of stay (LoS)

The length of an inpatient episode of care, calculated from the day of admission to day of discharge, and based on the number of nights spent in hospital.

Liver function tests (LFTs)

A common testing profile combining tests used to check liver function.

Mini-lab

A small unit within another department or other clinical setting that can carry out some pathology tests needed urgently by that department.

Minimum retest interval

The recommended minimum time interval before requesting a repeat test for a patient. For example, if the minimum retest interval is six months, clinicians should wait six months before requesting the same test for that patient.

Model Hospital

A free digital tool provided by NHS Improvement to enable trusts to compare their productivity and identify opportunities to improve. The tool is designed to support NHS provider trusts to deliver the best patient care in the most efficient way.

<https://model.nhs.uk>

mmol/L (millimoles per litre)

A unit of measurement used in many blood tests.

Multidisciplinary team (MDT)

A team of healthcare professionals from different disciplines.

National Institute for Health and Care Excellence (NICE)

Provides evidence-based guidance, advice, quality standards, performance metrics and information services for health, public health and social care.

www.nice.org.uk

National Pathology Exchange (NPEx)

A national service to connect all pathology labs together electronically, so that test requests and pathology results can be transferred between labs quickly and easily.

NHS Long Term Plan (NHS LTP)

A long term programme designed to prepare the NHS for the future, published in 2019.

www.longtermplan.nhs.uk

NHS Resolution (formerly NHS Litigation Authority)

Provides expertise to the NHS to resolve negligence concerns, share learning for improvement and preserve resources for patient care. NHS Resolution is an 'arm's length' body of the Department of Health and Social Care. This means it is an independent body, but can be subject to ministerial direction.

www.resolution.nhs.uk

NHS Supply Chain

An organisation that provides healthcare products and supply chain logistics to the NHS, including procurement, logistics, e-commerce, and customer and supplier support.

www.supplychain.nhs.uk

Non-numeric result

A result generated by an analyser when a sample has 'failed', for example due to haemolysis (see above).

OpenPathology

A team developing free, open tools to analyse real-time pathology data in the NHS.

www.openpathology.net

OpenPrescribing

A platform for analysing medicine prescription data.

www.openprescribing.net

OpenSAFELY

OpenSAFELY is a secure analytics platform for electronic primary care health records in the NHS, created to quickly deliver urgent results during the global COVID-19 pandemic.

www.opensafely.org

Pathology Quality Assurance Dashboard (PQAD)

A set of metrics that labs can use to monitor and analyse performance. See Data in action: PQAD on page 96.

Payment by Results (PbR)

The payment system in England used by healthcare commissioners to pay healthcare providers for each patient seen or treated. The system takes account of the complexity of the patient's healthcare needs. This is also known as the National Tariff.

Phlebotomist; phlebotomy

Someone trained to take blood from a patient; the process of taking blood.

Pulmonary embolism

A blood clot in the lungs. See Venous thromboembolism below.

Pre-analytical stage

The stage of the diagnostic pathway from collection to when the sample reaches the lab.

Point of Care Testing (POCT)

Testing using a method or device that delivers results where the sample is collected from the patient, often using a testing device, or an analyser at the location.

Polymerase chain reaction (PCR)

A test used to check for viral infections, including COVID-19.

Post-analytical stage

The stage of the diagnostic pathway after lab analysis, when results are delivered to a requesting clinician.

Prostate-Specific Antigen (PSA)

A protein produced by the prostate gland. High levels of this can help a clinician diagnose prostate cancer.

Quality Outcomes Framework (QOF)

A quality dashboard used to measure outcomes in primary care.

Reagent

A substance used in testing.

Reference intervals, reference ranges, reference limits

Definitions of high and low levels for any test results, which help clinicians to decide whether to take further action.

Reference lab

A lab that tests samples that have been referred to it, usually more complex or specialised investigations which the referring lab does not perform.

Specialist Services National Definitions Set

A proposed list of which pathology are 'specialist'.

Specialty doctors and Associate Specialists (SAS)

Hospital medical doctors with at least four years of postgraduate experience, two of which are in their chosen specialty.

Temporal artery biopsy

A biopsy taken from the temporal artery, located at the 'temple' at the side of the head. Used to test for conditions including giant cell arteritis, a potentially sight-threatening condition.

Testing profile

See Common testing profile above.

Thyroid stimulating hormone (TSH)

A hormone produced by the pituitary gland, which helps to control the thyroid gland. Testing for this can help clinicians to diagnose various conditions, including thyroid disease.

UK Conformity Assessed (UKCA)

A product marking scheme introduced to replace European Union CE-marking.

Urea and electrolytes (U&E)

A common testing profile, often used to check kidney function.

Venous thromboembolism (VTE)

A condition where a patient has developed a clot in a deep leg vein – a deep vein thrombosis or DVT. This can move to the lungs, where it is known as a pulmonary embolism or PE.

Warfarin

An anticoagulant medicine, taken by mouth and used to treat various conditions including venous thromboembolism.

Wells score

A clinical scoring used to assess probable venous thromboembolism.

Abbreviations

See above for explanations of terms.

AAC

Accelerated Access Collaborative

ACB

Association for Clinical Biochemistry and Laboratory Medicine

A&G

Advice and Guidance

AHCS

Academy for Healthcare Science

AHSN

Academic Health Science Networks

AKI

Acute kidney injury

AST

Aspartate transaminase

ALT

Alanine transaminase

ANCA

Anti-neutrophil cytoplasmic antibody

AP

Advanced Practitioner

BPT

Best Practice Tariff

BSMS

Blood Stocks Management Scheme

BSH

British Society for Haematology

CaPA

Clinical and Product Assurance

CCG

Clinical Commissioning Group

CDH

Community Diagnostic Hub

CQC

Care Quality Commission

DOACs

Direct Oral Anticoagulants

DVT

Deep vein thrombosis

ED

Emergency department

EQA

External Quality Assurance

FIT

Faecal immunochemical test

FRCPath

Fellow of the Royal College of Pathologists

ft4

Free thyroxine

GGT

Gamma-glutamyl transferase

Hb

Haemoglobin

HCPC

Health and Care Professions Council

HEE

Health Education England

HES

Hospital Episode Statistics

HRG

Healthcare Resource Group

HSSR

Higher Specialist Scientist Register

HSST

Higher Specialist Scientist Training

IBMS

Institute of Biomedical Science

ICS

Integrated care system

INR

International normalised ratio

IQA

Internal quality assurance

IQC

Internal quality control

K

Chemical symbol for potassium

KMS

Knowledge management system

KPI	Key Performance Indicator	PHE	Public Health England
LFD	Lateral flow device	POCT	Point of Care Testing
LFT	Liver function test	PQAD	Pathology Quality Assurance Dashboard
LIMS	Laboratory Information Management Systems	PSA	Prostate-specific antigen
MDT	Multidisciplinary team	PSI	Patient Safety Incident
MHRA	Medicines and Healthcare products Regulatory Agency	QOF	Quality Outcomes Framework
mmol/L	Millimoles per litre	RCPATH	Royal College of Pathologists
MSU	Mid-stream urine sample	SAS	Specialty and Associate Specialist doctors (see above)
NEQAS	National External Quality Assessment Service	SCS	Spend Comparison Service
NHSBT	NHS Blood and Transplant	SHOT	Serious Hazards of Transfusion
NHS LTP	NHS Long Term Plan	SI	Serious Incident
NICE	National Institute for Health and Care Excellence	SUI	Serious Untoward Incident
NIHR	National Institute for Health Research	TFT	Thyroid function test
NPB	National Pathology Board	TSH	Thyroid stimulating hormone
NPEX	National Pathology Exchange	TVG	Technology Validation Group
NSHCS	National School for Healthcare Science	U&E	Urea and electrolytes
PAS	Patient Administration System	UKAS	United Kingdom Accreditation Service
PbR	Payment by Results	UKCA	United Kingdom Conformity Assessed
PCN	Primary care network	VTE	Venous thromboembolism
PCR	Polymerase chain reaction	WBIT	Wrong Blood in Tube (incident)
PE	Pulmonary embolism	WHO	World Health Organisation

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Tom Lewis, Marion Wood and Martin Myers

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Appendix 1: The coronavirus pandemic and lessons for pathology services

The COVID-19 pandemic of early 2020 arrived towards the end of our initial phase of hospital deep dives, and has provided a powerful lens through which to view our emerging thinking.

The pandemic produced an extraordinary acceleration in innovation, and the GIRFT team was able to fast-track some recommendations to help labs deal with the twin pressures of increased testing and loss of workforce time to COVID-19 infection or quarantine.

At the time of writing, in early 2021, it is impossible to predict in detail how COVID-19 will continue to impact pathology. However, what is already clear is that the changes necessitated by the pandemic – from prioritising tests, to quickly establishing a quality framework, to improving digital interoperability – were an archetype of the wider changes that we recommend across all of pathology. Our patients' questions: **Am I ok?** and **Can I trust your answer?** were never more relevant, nor more central to how the nation dealt with the pandemic. And the importance of delivering the **right test, at the right time, with the right answer** meant that testing hit the headlines every day. In this section, we have given an overview of how labs performed during the pandemic, and learnings for the future, with an outline of changes made.

Clean in: prioritising tests

During the pandemic, the question of which tests were appropriate was especially urgent and relevant. At an early stage, there was a national requirement for the rapid introduction of COVID-19 testing. The GIRFT team worked with the RCPATH in the production of their document *COVID-19 testing: a national strategy*,⁵⁰ which outlined the quality framework that new testing should adhere to.

The first two principles of the strategy were as follows:

1. The test is the right one, at the right time, and with the correct result. This result includes the appropriate clinical interpretation and, where not specifically designed and validated for home use, a test carried out by skilled trained laboratory professionals to recognised and accredited quality and service standards.
2. Testing must be carried out for a purpose: for diagnosis, for screening or for gathering data to understand the spread, or level, of disease in a population. Any testing programme must be clear as to its purpose, and the tests chosen appropriate for that purpose.

The national testing programme was most successful where it adhered closely to these founding principles, with a close attention to which tests were most appropriate, and why they were being carried out – for example, for diagnosis, monitoring or surveillance. These principles are an archetype of establishing appropriate tests as part of the Clean Framework.

Clean in: stabilising and transporting tests

During mass testing, the importance of the pre-analytic stage was especially evident.

- While home kit samples were stabilised by using a preservative liquid, there were issues when swab tubes leaked in transit, contaminating packaging and invalidating tests.
- It quickly became apparent that simple issues such as the time taken to open envelopes, and the disposal of potentially contaminated packaging, were highly significant when carrying out such high numbers of tests.

These issues highlight how even more important the pre-analytic stage is when large numbers of tests need to be carried out. These challenges will continue to be significant as more testing is done at home, and in the event of a further epidemic requiring mass testing.

It is vital that quality assurance is in place to ensure contamination is minimised throughout the pathway, and to detect when it is occurring, as contamination can cause false positives alongside risk to staff handling the tests.

Data and digital delivery: highlighting the need for data interoperability

Beyond the rapid increase in the use of NPEX (see *Increasing use of electronic referral systems and messaging* on page 94) – which was a significant achievement – the pandemic highlighted the necessity of developing true data interoperability across pathology.

⁵⁰ The Royal College of Pathologists, 2020. *COVID-19 testing: a national strategy*. <https://www.rcpath.org/uploads/assets/2e8d8771-f85a-408a-b5c8e68969cd21d5/5293a4bb-cd96-42ff-8de231d47e637aab/RCPATH-COVID-19-testing-a-national-strategy.pdf>

Had true data interoperability been in place before the pandemic:

- transfer of results between labs would have been even faster and more seamless;
- it would have been easier to integrate results with patient records;
- patients might have been able to access and understand their own results more easily;
- public health officials would have been able to visualise key healthcare data, such as case numbers, testing numbers, and vaccination rates, faster and without the need for new dashboards to be created;
- it would have been easier to open up the data for other organisations to create new analysis tools.

These considerations lend even greater urgency to the need to establish true interoperability as part of a national initiative.

Quality: rapid test validation

During the pandemic the Department of Health and Social Care and the NHS set up a Technology Validation Group (TVG), which identified, validated and advised on tests for COVID-19, including where the test would be most usefully deployed, based on the performance of the test. Using this information, appropriate tests were then sent to hospitals. This rapid validation and mobilisation significantly improved patient care, particularly with rapid testing. The TVG model worked extremely well, and should be seen as an exemplar on how tests could be deployed in the NHS.

Service delivery during the COVID-19 pandemic

During the pandemic, there was a real opportunity for pathology networks to support the national testing programme.

The COVID-19 pandemic also sped up the diversification of test settings, and will continue to do so as Community Diagnostic Hubs (see page 110) are established as part of the recovery process. This again highlights the importance of flexibility, and an ability to evolve, in the creation of pathology networks. COVID-19 taught us that such fast adaptation is not only possible, but a true strength of pathology, and this resilience must be built into the networks we build.

CASE STUDY

Drive-through phlebotomy

Sheffield Teaching Hospitals NHS Foundation Trust

The trust successfully developed an outdoor phlebotomy site to continue service during the COVID-19 pandemic.

Social distancing made it difficult to maintain a traditional phlebotomy service within a hospital or GP setting. Instead, the trust erected a large marquee in the car park of a local arena.

Orders placed by GPs and trust clinicians were printed on demand using the surgery's electronic requesting system. If this was not possible, patients were sent a paper form. When directed, patients passed the phlebotomist their test order out of their car window, then put their arm out of the window to be bled.

Once the patient and phlebotomist were confident that the patient was fit to drive, they were allowed to go. If the patient experienced any side effects, they were monitored by a site steward until they felt well enough to leave.

Samples were transported to the Northern General Hospital labs every hour.

Results

Between April and December 2020, the service regularly saw over 350 vehicles a day, with over 50,000 patients in total. Turnaround times for many tests improved, because the service had more control over the logistics of the samples.

Over 90% of patients stated they would use the service again, and nearly 70% said they would like it to continue post-pandemic. Some reasons patients gave for this were that:

- they could bring family members with them;
- it was easier for those with mobility issues;
- they did not have to find and pay for parking.

How labs performed during the COVID-19 pandemic: a snapshot

During the pandemic, pathology labs had to adapt incredibly quickly to new requirements coming from every side – from the obvious need to provide rapid testing for COVID-19 itself, to prioritising other types of test to help specialties deal with their referrals.

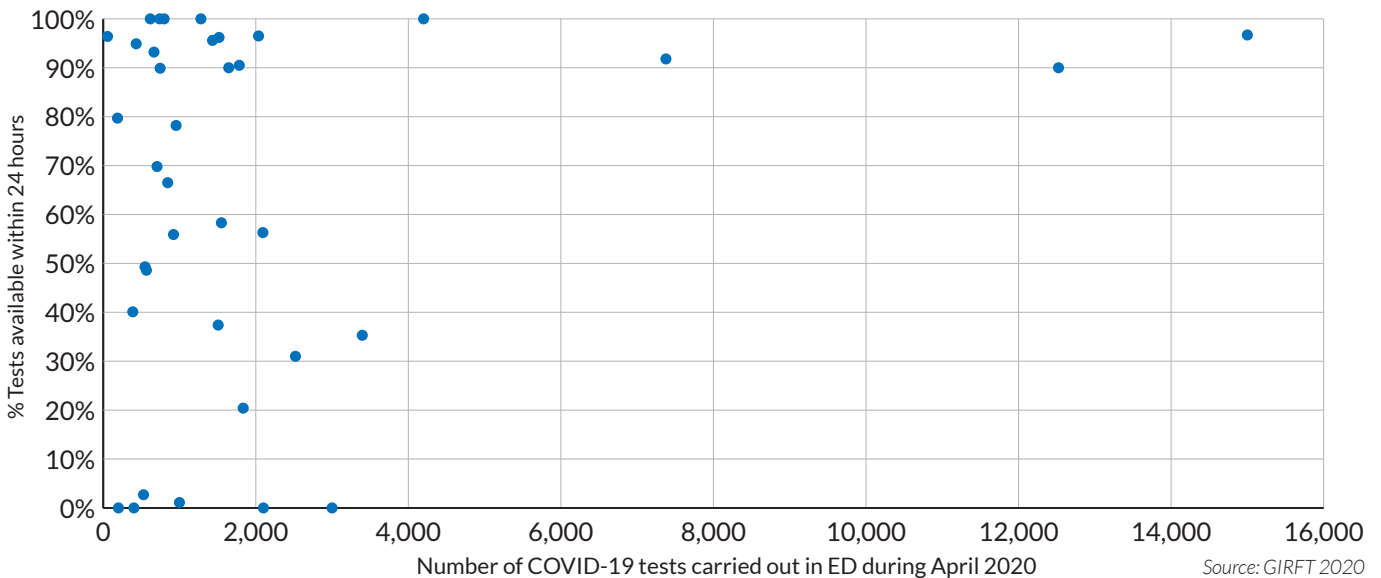
We used our questionnaires and discussions to gain a snapshot of how labs had adapted to match these new requirements.

COVID-19 testing itself

At the very beginning of the pandemic, labs rapidly developed new testing capability at pace. In April 2020, we sent out a supplementary questionnaire to NHS labs asking about their ability to perform polymerase chain reaction (PCR) tests for active COVID-19 infection (the SARS-Cov2 RT-PCR ‘swab’ test) within short time frames, as shown in **Figure 76** below.

This research showed the incredible acceleration of lab response: within just one month some labs were able to meet 100% of tests within 24 hours; 15 out of 29 labs that responded to our questionnaire were getting more than 90% of results from their ED back to clinicians within 24 hours. In fact, four smaller labs managed to get more than 90% of results back within 12 hours.

Figure 76: Percentage of COVID-19 PCR tests from the ED with result available within 24 hours



However, some labs did struggle to meet this sudden and massive increase in demand. Labs that were not able to perform to this level tended to have:

- poor communication between clinical teams and labs;
- a lack of IT connectivity;
- poor systems for transporting samples to labs;
- problems with local logistics (for example portering);
- poorly developed regional networks;
- a reliance on reference labs (external labs performing part of a test, or checking results) that were not able to prioritise;
- a lack of clarity on delivery responsibilities between local, Public Health England (PHE) and national testing options;
- difficulty obtaining accurate patient identifiers, particularly with offsite testing;
- a lack of molecular experience, meaning they needed to rely on external reference labs.

In contrast, labs that were able to deliver a faster turnaround tended to have:

- effective regional networking;
- networking supported by logistics and IT connectivity (mainly NPEx);
- strong local clinical engagement (the labs felt they were ‘kept in the loop’);
- empowerment to solve problems and to innovate.

Overall, we found that an integrated pathology service had clear benefits in the response and delivery of the COVID-19 service. These points reflect our findings throughout this report.

Changing pathology to reflect new priorities

As well as delivering PCR swab tests and antibody testing for COVID-19 at pace, pathology labs also adapted their services to support rapidly changing patient pathways. In many cases, specialties needed to alter diagnostic pathways in order to minimise the use of invasive procedures that carried a higher risk of COVID-19 transmission and/or reduce the number of patients attending hospital – to minimise community-to-hospital transmission, protect shielding patients, and follow social distancing requirements in hospital facilities.

There were multiple examples of how pathology labs adapted. For example, they:

- rapidly expanded delivery of the Faecal Immunochemical Test (FIT) to detect faecal occult blood as part of the diagnostic pathway for colorectal cancer, enabling gastroenterology departments to prioritise referrals for endoscopy to manage escalating waiting lists;
- supported drive-through clinics that allowed shielded patients on anticoagulants to have blood tests safely (see case study above);
- provided more testing to support treatment of patients with COVID-19, such as interleukin-6 and procalcitonin testing;
- adapted to the health and safety implications of carrying out SARS-CoV2 testing, such as the safe processing of swabs;
- supported acute hospitals and the new Nightingale hospitals with an unprecedented mobilisation of pathology-based diagnostics, such as blood gas analysers.

Lessons for the future: how the pandemic response encapsulated and reinforced our recommendations

Every one of the key requirements for pathology during the pandemic reflected the priorities highlighted in the rest of our report:

- taking samples correctly;
- labelling samples correctly so that the patient can be correctly identified;
- delivering results within a clinically meaningful timeframe;
- controlling quality, in an appropriate and visible way;
- making results visible to all those who need to see them – for example: frontline clinicians, GPs, occupational health services, and public health services – by integrating all results (including POCT, for example from blood gas analysers) into the patient’s records;
- providing advice and support on interpretation and appropriate responses to the results.

In other words, what worked best in the pandemic was, unsurprisingly, what will work best for pathology in general after the pandemic.

More generally, it has been interesting to reflect on what can be achieved when those involved in diagnostic medicine are released from the constraints of financial contracts to design and deliver services that are necessary to keep patients and clinicians safe. It was notable that there was no significant uplift in expenditure, and labs continued to follow good financial management practices, while transforming their services to meet fast-evolving requirements.

There is still much to be learned from the pandemic, including how pathology will need to adapt to the post-COVID landscape. Key to this will be how to verify and adopt technology at pace – for example the use of POCT in rapid diagnosis of respiratory diseases – to maintain pathology capacity and also to continue to meet turnaround requirements for all tests, not only COVID-19 testing.

Appendix 2: CA125 testing: a candidate for network standard development

The existing NICE guidance on diagnosis of ovarian cancer can be used as an archetype of a network standard:

- it clearly defines which patients should have a particular diagnostic test (CA125);
- it builds the lab test into a wider diagnostic pathway;
- it includes clearly specified action limits for the test, and what should happen in different situations.

We can think of this as having the following stages, with each triage stage representing a node on a clinical decision tree:

Diagnostic pathway		Example for suspected ovarian cancer	
Step 1	Patient attends GP (or ED, or community care etc)	Clinical triage 1: <ul style="list-style-type: none"> • Appropriate clinical question; • Examination; • Care Set requested. 	Patient attends GP with persistent bloating and abdominal pain. GP checks that patient is over 50 and has had symptoms persistently. GP gives consent guidance, including information on false negatives/positives. GP follows pathway: orders nationally set Gynaecological cancer Care Set (including CA125).
Step 2	Lab tests	Clinical triage 2: <ul style="list-style-type: none"> • Lab runs tests according to Care Set; • Lab uses set reference intervals; • Lab follows set action limits, for example in communicating urgent results or flagging concerning results; • Results delivered to requestor and/or next stage of pathway within set time, with interpretation. 	Lab flags that CA125 is over reference interval. Issues interpretation to GP along with potential other causes. GP refers to consultant / ultrasound.
Step 3	Imaging tests	Clinical triage 3: <ul style="list-style-type: none"> • Radiology runs appropriate imaging test • Results delivered to requestor and/or next stage of pathway within set time, with interpretation. 	Ultrasound carried out and identifies potential malignancy. Results returned to consultant and GP.
Step 4	Further investigations, such as biopsy, endoscopy	Clinical triage 4: <ul style="list-style-type: none"> • Further investigations carried out (with radiology involvement as needed) • Results delivered to requestor and/or next stage of pathway within set time, with interpretation. 	Laparoscopy performed to obtain biopsy. Biopsy confirms ovarian cancer. Results returned to consultant and GP with interpretation.
Diagnosis made: proceeds to treatment pathway			

Appendix 3: PSA testing: another candidate for network standard development

Prostate-specific antigen (PSA), a test used to identify cases of possible prostate cancer, is an example of a consensus-based reference interval, where the limits are based on a consensus about which results may indicate pathology.

Since levels of PSA increase naturally as men age, there are age-based reference intervals for PSA. The upper limit for men in their 50s is up to 3 nanograms per millilitre of blood (3ng/mL), while for men in their 60s, the upper limit is 4ng/mL. This is defined in NICE's *Suspected cancer: recognition and referral guideline* (National Guidance 12, 2015).⁵¹

However, these reference intervals are different to the 'action limits', the limit at which the clinician needs to take action. For men aged between 50 and 69, the action limit defined in a different NICE guideline (Clinical Knowledge Summary, 2017)⁵² is 3ng/mL.

The NICE clinical knowledge summary on prostate cancer also advises on situations where men should not have a PSA test, for example if they have exercised vigorously in the last 48 hours.

These different definitions increase clinician and patient confusion. Establishing a consistent diagnostic pathway could reduce this, increase consistency, and allow patients to have confidence in the approach. The pathway would need to be:

- established by discussion and consensus between the different clinicians involved, including primary care, pathology, and radiology colleagues, and preferably in consultation with support groups such as Prostate Cancer UK;
- consistent, and consistently communicated, across all network decision support materials, including patient information, with clear explanation of risks;
- consistent with intervals used and communicated by PHE and NICE and other national bodies – when applied nationally this will enable charities and other support groups to reference consistent levels.

This approach has been successfully implemented by Lancashire and South Cumbria Cancer Alliance Network, and is being used as a paradigm for other cancer pathways.

Different groups have different risk levels for developing prostate cancer. In particular, Afro-Caribbean men are at significantly higher risk of developing the condition,⁵³ and family history of prostate, breast or ovarian cancer is also a known risk factor. Networks may wish to consider whether they wish to recommend a lower action limit for patients with these risk factors.

However we handle reference intervals, these considerations highlight the need for standards to be consistent, and to contribute to a wider clinical conversation, rather than a 'normal' or 'abnormal' result being the sole focus of the test.

⁵¹ <https://www.nice.org.uk/guidance/ng12>

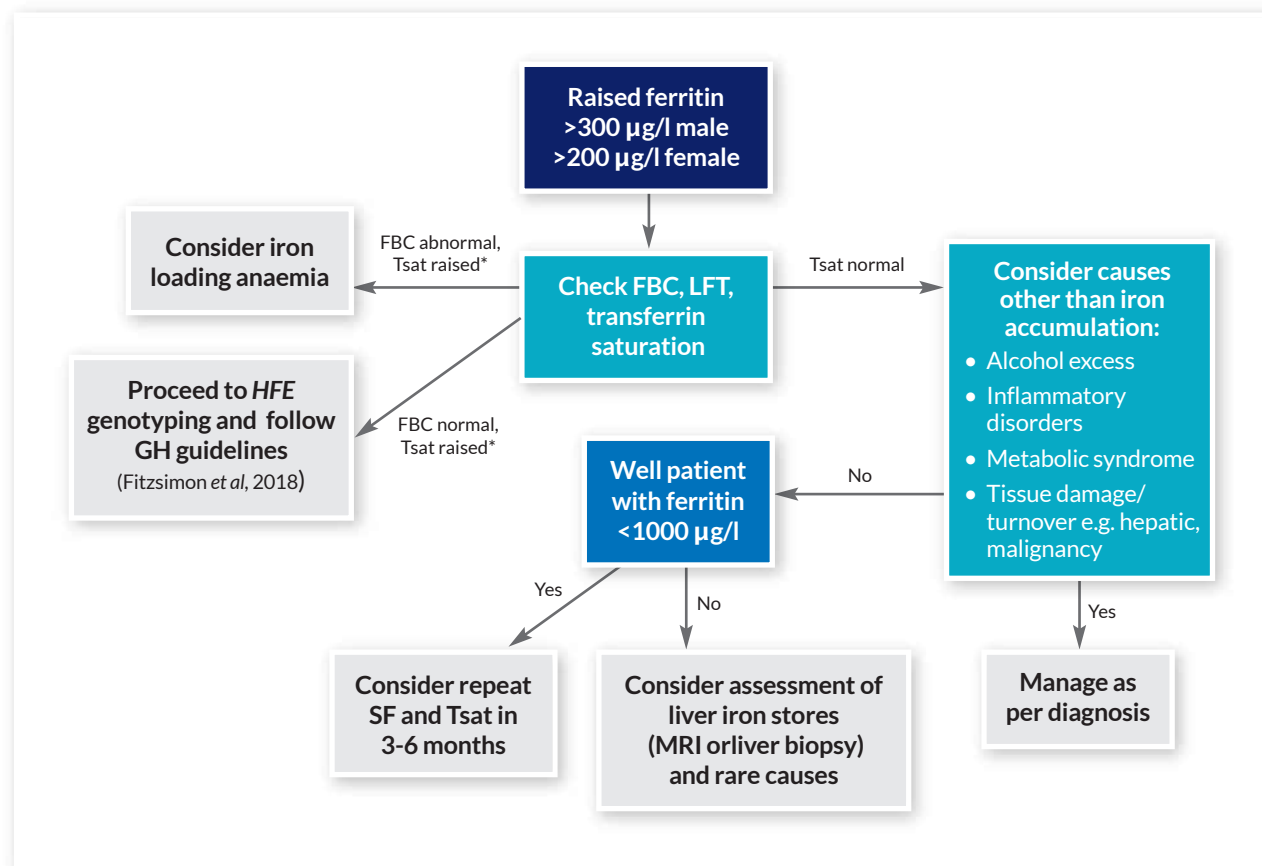
⁵² <https://cks.nice.org.uk/topics/prostate-cancer>

⁵³ Ben-Shlomo, Y., Evans, S., Ibrahim, F. et al, 2007. *The risk of prostate cancer amongst black men in the United Kingdom: the PROCESS cohort study.* <https://www.pubmed.ncbi.nlm.nih.gov/17368710/>

Appendix 4: Example of decision aid to help clinicians interpret results

An example of how simple decision support can help clinicians interpret results and guide them on next steps.

Figure 77: Flowchart to help clinicians interpret ferritin results (created by the BSH)⁵⁴



*>50% male, >40% female

Source: British Society for Haematology

The tests in this diagram will be familiar to haematologists. For an explanation, see <https://www.labtestsonline.org.uk>

⁵⁴ Cullis, J. O., Fitzsimons, E. J., Griffiths, W. J. H., Tsochatzis, E., Thomas, D. W., 2018. Investigation and management of a raised serum ferritin.

National specialist network

Some highly specialised tests should be referred to national centres of excellence.

In our deep dives, we heard that there is a risk that the infrastructure to deliver highly specialist tests is fragile in part. We therefore suggest that the NPB will also need to take a strategic overview to ensure there is adequate national infrastructure. These centres of excellence will be needed to develop a service fit for the future.

The basis of this structure is already present in some areas within the pathology community. For example, national genomic hubs, paediatric metabolic medicine, antenatal screening, neonatal screening and colorectal screening have formed national networks to deliver the service from a limited number of sites. We suggest that this model be developed for all specialist testing.

In 2006, the NHS created the Specialist Services National Definitions Set. This outlined which tests within pathology were 'specialist', and proposed a specialist testing infrastructure based on geography, expertise, quality and efficiency. This document resulted in changes in the way some specialist services were delivered, and we recommend that the document is updated.

Community Diagnostic Hubs

In Professor Sir Mike Richards' report *Diagnostics: Recovery and Renewal*,⁴² Community Diagnostic Hubs (CDHs) are proposed for cancer, cardiac and respiratory, and other conditions. These recommendations have become particularly urgent post-COVID-19.

The CDHs are likely to develop further and may have a significant effect on the evolution of local pathology networks. They can be used to support better access to quality phlebotomy – lack of quality community phlebotomy was an issue we encountered on our deep dives. CDHs can also support community diagnosis services for:

- conditions such as diabetes;
- patients on anticoagulants (INR clinics);
- health checks (especially for vulnerable patients, such as those with learning disabilities etc).

To support CDHs effectively:

- Diagnostic pathology testing using both POCT and the lab will need to be available and supported by the local pathology network, ensuring appropriate ISO15189:2012 accreditation.
- The diagnostics devices used will need to have full IT connectivity to ensure that the test is requested electronically, and that results are added to the patient's record. Finances are being made available through the Diagnostics Recovery Group to upgrade network LIMS systems. It is essential that this ensures integration of pathology requests and results across all sites, including the CDHs.

Developing leadership in networks

In our deep-dive discussions, we were often told – and it was frequently clear – how critical proactive clinical leadership was in the establishment, development and ongoing success of networks. Networks with strong leadership had been able to galvanise labs towards shared goals, establish new collaborative methods, and find innovative solutions to network-wide issues, such as transport.

Developing leadership in healthcare organisations brings unique challenges. Leadership in pathology requires both clinical expertise and expertise in running large organisations – whether that is a hospital lab or a regional network – with a clear vision of future improvements, the knowledge to guide colleagues towards achieving them, the drive to push change forward, and the time to oversee these changes.

NHS England and NHS Improvement have created a *Clinical leadership framework*,⁴³ which includes pathology exemplars. We recommend that networks use this to develop leadership skills throughout their network, and to ensure resilient succession and continuity plans.

⁴² NHS England, 2019. *Diagnostics: Recovery and Renewal – Report of the Independent Review of Diagnostic Services for NHS England*. <https://www.england.nhs.uk/publication/diagnostics-recovery-and-renewal-report-of-the-independent-review-of-diagnostic-services-for-nhs-england>

⁴³ https://webarchive.nationalarchives.gov.uk/20200327164837/https://improvement.nhs.uk/documents/3702/Clinical_leadership_-_framework_Jan2019.pdf

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