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Today's Laboratory Medicine in the United Kingdom: What's New, What's Working , What's Next

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Learning outcomes

- To understand the changing political landscape
- To understand the change in attitude towards private involvement
- To understand how the new ISO 15189 is changing the landscape for laboratory medicine
- To understand how AI and digital working will change the landscape and the workforce

The purpose of this lecture

- Many of the issues discussed are global
- The UK suffers from under investment in laboratory medicine
- The workforce suffers from skill shortages
- There are not enough pathologists for anatomical pathology
- There is constant pressure to do more, better, be more focused on outcomes and do this all for less

A quick translation from English

- Pathology = clinical laboratory/ medical laboratory
- Histopathology = anatomical pathology / tissue laboratory
- Blood science laboratory = fluid laboratory
- Infection sciences / microbiology = fluid laboratory

Political considerations

- BREXIT
- COVID lessons and quality
- Get it right first time (GIRFT)
- NICE guidelines
- Professional body cooperation
- Devolved nations (This refers to devolved powers for England, Wales, Scotland, Northern Ireland)
- Inspection by the Care Quality Commission (CQC)

Brexit

- In January 2020, the United Kingdom took the decision to leave the European Union
- This resulted in increased trade barriers as free movement of goods ceased, many vendors have European wide distribution centres of which the UK market was serviced from, these are now subject to delay and increased paperwork for imports
- The regulatory framework which changed for the UK market, is in flux with the UKCA mark replacing the CE mark for quality, this is very unattractive to vendors for such a small market as the UK, talks are ongoing
- The Invitro Diagnostic Directive, is the European directive to manufacture and regulate medical devices and it is changing, the impact on the UK has the potential to be disruptive

Covid

- The pandemic hit the world and pathology had to respond with novel technology in a backdrop of uncertainty as to the risk to staff
- Laboratories had to cope with lockdown impacting the families of staff as well as staff sickness and transport issues, testing continuity plans
- Many start up testing companies for COVID testing entered the market
- COVID testing super labs were set up, with varying degrees of governance and success, some making national headiness for wrong reasons, impacting public trust
- Many, unbeknown to them, were infiltrated by undercover reporters looking for a story

Covid- unforeseen consequences for pathology

- Most of the public had access to lateral flow testing and self-collecting of swabs, including using mobile collection centres
- The public is now comfortable with what is essentially POCT for infectious disease testing
- The government spent billions on a test and trace app, with the public reporting LFT results online and being given results and healthcare information and instruction via their cell phones
- Community POCT and self-testing is now accepted and needs to be further leveraged

Covid- unforeseen consequences for Government

- The quality agenda became a political issue as the rapid growth of start-ups and government funded super COVID labs had the potential to either aid or hinder the COVID response
- The government then issued an edict, that in, order to get any funding the POCT COVID labs needed to accredit to ISO 15189:2012
- UKAS (United Kingdom Accreditation Service) had to deliver this due to intense political and commercial pressure, impacting their whole inspection schedule for the next few years
- The reality that POCT service can be accredited and now this is something that the government is looking to roll out for all POCT providers, with the laboratory professionals advising on this

GIRFT

- NHS England started a national programme designed to improve the treatment and care of patients though in-depth review of services, benchmarking and presenting a data-driven evidence base to support change.
- This covers all specialties in health, medicine, surgery and emergency medicine
- Pathology is one of the medicine work streams
- Workstreams included guidance for enhancing secondary care direct access to diagnostic tests for patients with clinical features of suspect COPD, asthma or heat failure

GIRFT

- The need for further consolation of pathology services is an objective of the GIRFT programme
- This review is clinically based and builds on the Lord Carter review of pathology from 2016
- It is looking to use data to identify good and sub optimal practice with individual services to then share perceived best practice as a model for all pathology services to adhere to
- Many networks failed to consolidate, costing the taxpayer millions, with some notable successes who formed robust public sector networks

NICE

- NICE is the National Institute for Clinical Excellence
- They produce evidence-based recommendations for the health and social care sector, developed by independent committees, including professionals and lay members, and consulted on by stakeholders
- Although termed recommendations, it is expected that they are adhered to

NICE and pathology

- NICE guidance for pathology included:
- The use of enzymic creatinine for Acute Kidney Injury calculations
- Enhanced Liver Fibrosis (ELF) testing for Non-Alcoholic Fatty Liver Disease (NAFLD)
- There are more examples, which bring additional financial pressure on many departments but are linked to patient wellbeing
- This is then bringing pressure onto vendors to help the laboratory comply via the pricing schedule, as Jaffe creatinine is much cheaper than enzymatic, as an example

Professional body cooperation

- The three major professional bodies in the UK are;
- The Royal College of Pathologists (RCPath)
- The Institute of Biomedical Science (IBMS)
- The Association for Clinical Biochemistry and Laboratory Medicine (ACB)
- Historically there was co-operation and some professional tension which over the last decade has largely disappeared and replaced by a genuine will to work to the common good in pathology, recognising that skill shortages and technology changes requires a more agile and focused workforce

Professional body cooperation- the impact

- This recognised that trying to do the same thing with the increasing workload and struggle to recruit pathologists needs to be addressed
- Scientists are now being trained in dissection, under strict medical supervision and competence sign off
- Risk based reporting to clinical protocols has also been developed by agreement between the professional bodies, with qualifications developed to support the education and training for these specialist scientists
- This frees up the Consultant workforce to focus on more clinically complex investigations and reporting
- There is pressure on turnaround times, using digital pathology and the workforce differently, including more automated reporting are methods to try and reduce this pressure

Devolved nations

- There are now health boards for the home nations which cause national variation on how pathology is funded and how the services are to be provided
- All are looking at consolidation of service, but using different mechanisms, either public sector, private sector or a hybrid model
- This is very similar to the states system in the USA
- This makes cross nation cooperation in terms of guidance and recommendations more complex in terms of agreed protocols

Inspection by the CQC

- The CQC are an independent regulator for health and social care for England, Scotland has the Care Inspectorate as does Wales, whilst Northern Ireland has the Regulation and Quality Improvement Authority
- The CQC now inspects pathology services
- They can inspect without notice and have the power to place services into special measures or in extreme cases, if felt unsafe, can shut services down
- Traditionally pathology being accredited to ISO15189 was sufficient, this is now not the case, and they actively assess services
- CQC has signed a memorandum of understanding with the RCPath to highlight any clinical concerns
- Blood Transfusion can also be inspected by the Medicines and Healthcare products Regulatory Agency (MHRA), who also can immediately close any transfusion department if deemed unsafe

Private sector involvement

- There is increasing involvement of the private sector in the UK market, with most activity being in England as the other home nations prefer a more public sector approach
- This does not mean that there are no private laboratories across all four nations, just that the government funding streams are not used to support the public hospitals to outsource pathology
- The four main service models are:
- Public funded pathology
- Private sector provided outsourced NHS pathology
- Joint ventures between the NHS and the private sector
- Pure private pathology, often linked to private sector care facilities operating on a fee per consultation basis

Traditional Public Sector

- These are publicly funded labs, normally attached to NHS hospitals
- They are increasingly forming networks as larger services for economic and service reasons
- There is a recognition that much of the real estate needs improvement and new large pathology hubs are being built, such as the new Leeds Laboratory

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Public sector, continued

- There has been a ‘rationalisation of hospitals’ with many closing or being downgraded to more specialist services
- This rationalisation has reduced the number of pathology departments
- Along with few departments, networks have often implemented hub and spoke models of service delivery, rather than offer all specialties on all sites
- This has partially been done to address staff storages, partially for economic reasons

Public sector, Agenda for change

- In 2004 the government introduced a project call agenda for change
- This was designed for all non-management NHS Staff to try and ensure equal pay for equal value
- Due to the way the pay structure was set out in the scheme, pathology staff largely did well out of this as having a degree equalled an increased score when assigning pay grades
- The local nature of how banding was agreed, led to different departments having different scores depending on local negotiation, resulting in the same job being paid differently across the country depending on how well the job descriptions were written
- The net result, however, was a significant increase in pay cost across pathology

Private Sector provided outsourced NHS services

- These are previously publicly funded laboratories, normally attached to NHS hospitals that have been outsourced via a tender process to the private sector
- This can be attractive to the NHS when attempts to form local networks within the NHS have failed, so the service is then put out to tender
- These are increasingly looked at due to the ability of the private sector to access capital and cost benefits from their purchasing power with vendors
- An example is London North West University Hospital and surrounding general practice (secondary care) who outsourced their pathology to The Doctors Laboratory (TDL), part of Sonic Healthcare UK. The contract recently being renewed.
- This gives the NHS a contract with key performance indicators to manage against as well as the benefit of private sector funding to refurbish the laboratories

Private Sector provided outsourced NHS services

- This also allows flexibility in appropriate staffing for the increase in automation, with a realisation that market forces will influence staff movement if the pay package is unattractive

- The private sector has the advantage that its business is pathology, with its own dedicated support services, such as human resources and information technology, rather than competing within a wider healthcare environment for limited support

- They are liked by the wider healthcare management, due to robust methods for providing data, such as turnaround times and the ability for the host NHS departments to manage the contract against the criteria set out in the agreed service provision, as this provides accountability

Public – private joint ventures

- These are business units formed are a joint venture between the NHS and private companies
- The NHS partners and the private company are shareholders in the business and profit share
- They then bid for new NHS business and any new additions become customers to the joint venture
- This allows a mix of NHS governance best practice with the commercial skills of the private sector
- The reputation of these joint ventures should be defined by quality and good patient outcomes, rather than just price

Public – private joint ventures – Heath Service Laboratories

- This is the company I work for, HSL, a Sonic Healthcare UK laboratory
- It is a partnership between TDL, The Royal Free Hospital (RFH) and University College London Hospital (UCLH)
- RFH and UCLH are two large teaching hospitals in central London
- There are two smaller hospitals attached to RFH, Barnet hospital and Chase Farm hospital
- The North Middlesex Hospital and Whittington Hospital are customers of HSL
- Due to the links with TDL, this opens up a significant menu of examination methods previously unavailable to the NHS due to the volumes of tests they would require, making them uneconomic
- As the methods are requested by private clients, the NHS has access to these as part of the joint venture, for example HSL offers over 600 different allergens as part of its immunology service

Public – private joint ventures – Heath Service Laboratories, laboratory real estate- The Halo

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Public – private joint ventures – Heath Service Laboratories, laboratory real estate- Automation

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Public – private joint ventures – Heath Service laboratories laboratory real estate, microbiology- new technology

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Public – private joint ventures – Heath Service Laboratories laboratory real estate, molecular laboratory

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Public – private joint ventures – Heath Service Laboratories laboratory real estate, UCLH rapid response lab and anatomical pathology

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Public – private joint ventures – Heath Service Laboratories laboratory real estate, UCLH anatomical pathology

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Public – private joint ventures – Heath Service Laboratories the unseen benefit

- HSL hosts as part of its business several national and international reference laboratories:
- Parasitology
- Renal stones
- Mycology
- All three have now been incorporated into the HSL training system and the next generation of staff are now trained and competent , ensuring service continuation as the outsourced staff have retired after long and illustrious careers
- The ability to work across disciplines in a state-of-the-art building is more attractive, had the service been left as was, they were in danger of collapse

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Pure private sector pathology

- These tend to be attached to private healthcare systems such as Circle, Spire or the Nuffield hospitals, funded by insurance or directly by patients themselves
- These treat private patients only and operate outside of the traditional NHS model, although the NHS may send patients to these systems to help manage capacity and directly pay for treatment via the taxpayer
- Some also offer walk-in high-street testing such as Randox, again outside of the NHS model
- This is the only model that requires direct patient payment, every other service delivery is free at the point of use

ISO 15189:2022

- There is an expectation for all laboratories to be accredited to ISO 15189
- When tendering for pathology services, commissioners will make this a requirement for consideration
- ISO15189 is viewed as ensuring the quality of laboratory services
- The new version is risk based and patient welfare focused
- Laboratories now need to formally view their services for its impact for the local patient populations wellbeing
- An examples is compliance to NICE guidance

AI and its impact

MyBotGP Normal Blood Filing Features

- ✓ **Configure your own Blood filing rules..**
  - File based on min-max ranges updated within MyBotGP
  - File based on keyword checks or in absence of keywords
  - File based on checking patient history
  - File based on gender – separate male & female ranges
  - File based on checking previous test results either number of test results or number of days
  - File based on age checks i.e. over 18
- ✓ **Reporting Dashboard Analytics showing total number of blood test filed by Category..**
- ✓ **Full audit trails of all Blood Tests filed – downloadable reports..**
- ✓ **Schedule MyBotGP to run anytime..**
- ✓ **Send Text messages to patients – send tailored message to patients..**
- ✓ **MyBotGP "Learning" capability to deal with all pop-ups..**

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AI and primary care

- AI is being rolled out to primary care (outreach)
- This project is being driven by NHS London and looks for AI to review pathology tests based on local protocols, clinically driven, this is to save the GP from reviewing results
- A normal result may be significant if the disease state suggests it should be abnormal

AI and anatomical pathology

- AI is also being considered as a solution for workforce issues and digital image recognition

- PubMed produced a paper in 2022 by Kim at al entitled:
- Application of Artificial Intelligence in Pathology: Trends and Challenges
- This paper suggests when AI can be used to screen large volumes of samples with algorithms
- This can apply to any discipline which looks at images, such as haematology
- It is something which pathology needs to ensure clinical utility and embrace as the technology will be introduced with or without support

NHS Long Term Plan for Genomics

- To be the first national health care system to offer whole genome sequencing as part of routine care
- To sequence 500,000 whole genomes by 2023/24 and help transform healthcare for maximum patient benefit, including for all children with cancer or children who are seriously ill with a likely genetic disorder
- Extended access to molecular diagnostics and offer genomic testing routinely to all people with cancer
- Early detection and treatment of high-risk conditions including expanding genomic testing for Familial Hypocholesterolaemia
- Linking and correlating genomic data to help provide new treatments, diagnostic approaches and help patients make informed decisions about their care

National Genomic Test Directory

- A central feature of the NHS Genomic Medicine Service (GMS) is the National Genomic Test Directory (Test Directory) which outlines the full range of genomic tests that are commissioned for the NHS in England. The Test Directory sets out the genomic tests that are available and the patients who are eligible to access a test. To keep pace with scientific and technological advances, while delivering value for money for the NHS a robust and evidence-based process and policy is in place to ensure that genomic testing continues to be available for all patients for whom it would be of clinical benefit

- NHS England is now funding eight innovative networks to develop the evidence and model of adoption for cutting edge genomic advances and technology applications that will be transformative for patients. The NHS Genomic Networks of Excellence are designed to be partnerships between the NHS, academia, the third sector and industry to leverage expertise and resources from the broader genomics ecosystem, and to ensure there is a route towards rapid informing commissioning decisions

Newborn Genomes Programme

- Every year hundreds of babies are born in the UK with rare genetic conditions. Early intervention can enhance the health and quality of life of many of these babies. But these conditions can be hard to diagnose, leading to delays in care

- The Generation Study is a groundbreaking research study which will sequence the genomes of 100,000 newborn babies. Genomics England are running our study in partnership with the NHS to understand whether we can improve our ability to diagnose and treat genetic conditions

- The study has been developed following extensive consultation with the public, parents and families affected by rare conditions as well as healthcare professionals, policy makers and scientists. It will involve babies born in a number of different hospitals in England and will run until March 2025. The results will add to evidence that will inform future decisions on using whole genome sequencing to support newborn screening. This includes using it to accelerate diagnosis and access to treatments for rare conditions

Multi-Cancer Blood Test Programme objectives

The Multi-Cancer Blood Test Programme would offer up to 1 million multi-cancer early detection (MCED) blood tests in select areas of England from summer 2024, providing first year results from the ongoing NHS-Galleri trial are promising

The pilot programme is an in-service evaluation that would generate real-world evidence to supplement what is available from the NHS-Galleri trial and provide information on how the Galleri test could be offered at scale in the NHS.

Carrying out such a pilot programme will enable the NHS to understand how it could implement a national MCED screening programme rapidly in the future.

Image courtesy of Centre for Ageing Better.

Generating evidence on multi-cancer early detection tests

The Galleri test is a multi-cancer early detection blood test that has been found to detect a signal shared by more than 50 types of cancer and predict the tissue or organ where the cancer signal originated.[1]

NHS-Galleri trial

The clinical utility of the Galleri test for population screening is being assessed in the NHS-Galleri trial,[2] a prospective randomised controlled trial in England that aims to establish whether screening with the Galleri test reduces the incidence of late-stage cancer when used in an asymptomatic population in combination with existing NHS cancer screening programmes.

Multi-Cancer Blood Test Programme

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Galleri is a screening test and does not diagnose cancer. Diagnostic testing is needed to confirm cancer.

[1]Liu MC, et al. *Ann Oncol*. 2020;31(6):745-759. DOI:10.1016/j.annonc.2020.02.011. [2]Neal R, et al. *Cancers*. 2022; 14(19):4818. DOI: 10.3390/cancers14194818.

Sonic UK approach to staffing shortfalls

- Sonic Healthcare UK has set up its own training academy
- The aim of the training academy is:
- *To develop a capable, proficient Biomedical Scientist workforce for the future in pathology*

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Sonic Training Academy - Apprenticeships

- **Students can'Earn while you learn'**
  - Work full time
  - 20% 'off-the-job training' – attending lectures, seminars etc.
  - Earn a salary as a Trainee Biomedical Scientist!
  - Degree paid for by the employer!!!

- **They will work in one of our laboratories across our network**
  - 4-year fixed term contract
  - Develop laboratory skills
  - Complete BSc (Hons) Biomedical Science degree
  - Complete IBMS Registration Portfolio and become a HCPC registered Biomedical Scientist
  - Attend the Training Academy Laboratory at the local Sonic Laboratory

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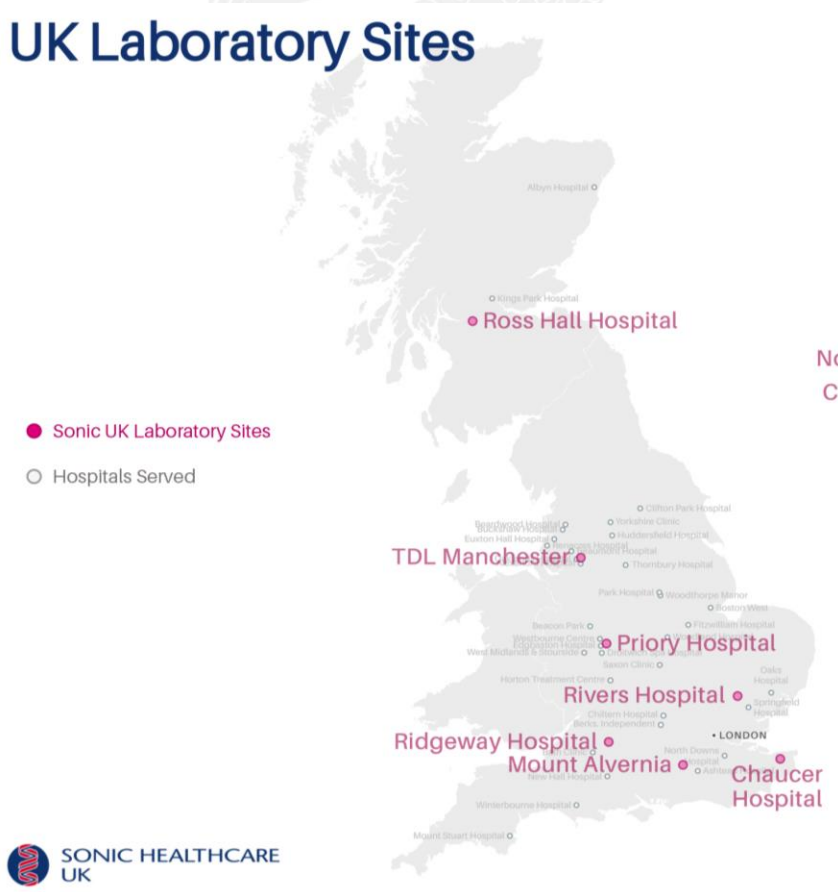
Sonic Training Academy – Locations & Departments



- ***Royal Free:*** *Haematology, Coagulation/ Blood Sciences (2)*
- ***North Middlesex :*** *Blood sciences + Blood Transfusion (BT) (1)*
- ***60 Whitfield St:*** *BT, Histology, Biochemistry (3)*
- ***Halo L3 :*** *Microbiology (1)*
- ***Barnet Hospital :*** *Blood Sciences + BT (1)*
- ***Northwick Park :*** *Haematology, BT, Microbiology, Histology (4)*
- ***Rivers:*** *Blood Sciences (1)*
- ***Blackheath :*** *Blood Sciences (1)*
- ***St John & St Elizabeth:*** *Blood Sciences (1)*
- ***Ealing Hospital:*** *Blood Sciences (1)*

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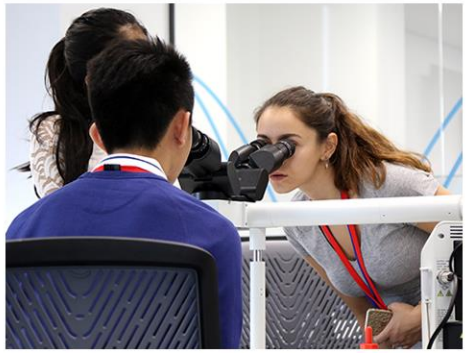
- Thank you for your time and any questions?



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