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OCTOBER 2022

NHS

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DELIVERING EXCELLENCE

IBMS Chief Executive **David Wells** on why we need to meet the new HCPC standards.

In August, the HCPC updated their standards of proficiency for the first time since 2015. The changes, which will come into effect on 1 September 2023, have been made following an extensive period of engagement with a wide range of stakeholders – including the IBMS.

The revised standards set clear expectations of a registrant's knowledge and ability in a healthcare service that has changed dramatically in the wake of the pandemic. They have also expanded to have more focus on the registrant's mental health and their understanding of equality, diversity and inclusion.

Given what we have undergone over the past few years, I think updating the standards at this juncture is crucial. It will help us as HCPC registrants to continue delivering excellence in our profession and, in turn, enable us to ensure that the public can access high-quality care safely and with confidence.

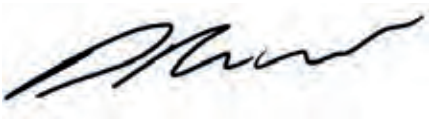
As the changes approach, we must remember that we cannot assume fitness to practice just because we have been working in the profession for "x" number of years, or because we are intelligent people with plenty of common sense. The new standards are the new requirements for practice – and if we are not familiar with them then we are not fit to practice.

It is not enough to assume that we are inclusive or that we know how far we can venture into our own stress or tiredness before it results in a mistake. The new standards are there to keep us practising at the highest level of professionalism and to keep our patients safe. We will all need to read, understand and reflect on them.

To hold our heads up as professionals, we have to walk the walk. A colleague of mine who encountered an allegation of malpractice comes to mind when I say this. A resolute professional, they took the appropriate action and reported the allegation to the HCPC – which resulted in a fitness-to-practice hearing. After the evidence was reviewed, it was clear that they were in no way responsible for any malpractice and, on the contrary, were an exemplary professional.

However, they did not risk their career and position because they knew they would be absolved. They did it because they knew the standards of proficiency. They acted as a true biomedical scientist – they reflected, understood the process, applied their knowledge and then let the evidence speak for itself.

Now it is time for us all to act with that same professionalism and make sure that we review and meet the new standards ahead of time. As biomedical scientists, we will soon be confirming that we have reflected, understood and applied them to our practice.



David Wells
Chief Executive

Institute of Biomedical Science is the professional body for the biomedical science profession.

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SCIENCE NEWS IN NUMBERS

6 MODULAR HOUSES

An NHS trust is putting a three-storey block of temporary units in a car park for staff relocating to the area to live in.

Cornwall Partnership NHS Foundation Trust is adding the **six modular units in a car park** beside one of its properties in Redruth.

1 in 70

COVID infections in the UK fell to their lowest level since October last year, the Office for National Statistics (ONS) announced in September.

Fewer than a **million people had the disease** in the last week of August – **about one in 70, down from one in 15 in mid-July.** The statistics show **COVID was decreasing** in England and Wales, but **staying constant** in Northern Ireland and Scotland.

A&E visit: rich vs poor

Patients in the poorest parts of England attend A&E at double the rate of those in the richest parts, new NHS data show.

There were a total of

3,013,316

A&E attendances in the **top 10% of deprived populations** compared to

1,546,722

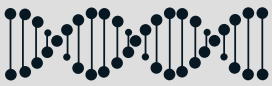
in the **least deprived**, according to the figures. Last year the rates in the **poorest areas increased by 829,963** compared to 2020–21.

39% INCREASE

Personally funded treatments increased by 39% across the UK in 2019–2021 as NHS backlogs continued to grow.

Demand for such treatments **rose by 90% in Wales** and **84% in Scotland**. In England, the **increase** was highest in the **East Midlands (75%)**. In **London the increase was 20%**, but it already had the highest rate nationally.

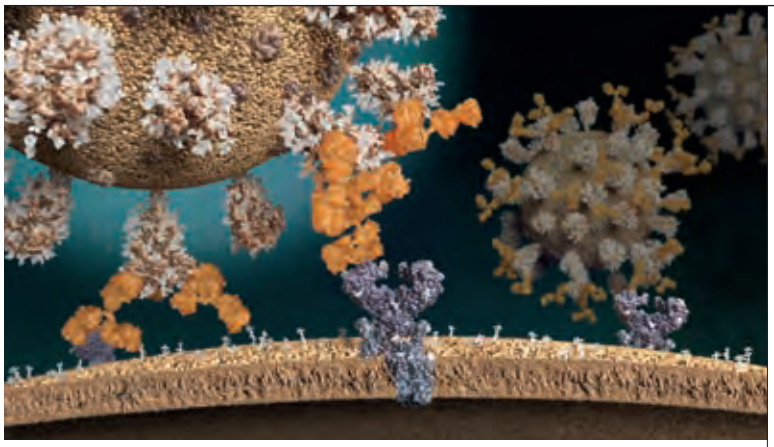
20,000 PEOPLE



The biggest ever genetic study of myalgic encephalomyelitis (ME) is being launched.

DecodeME aims to better understand the causes and symptoms of the condition to find treatments. Those behind the research are **looking for 20,000 people to take part**.

More than **250,000 people in the UK are affected by ME**, but the causes of the disease are unknown and there is **no diagnostic test or effective treatment**.



SCIENCE NEWS

IMMUNOLOGY

"Hybrid immunity is robust and long-lasting"

One in three infected but unvaccinated people no longer have detectable COVID antibodies one year after the infection, according to a prospective seroprevalence study.

The research team performed a second measurement in a population-based cohort from Catalonia six months after the start of the vaccination campaign (the first one was just after the first confinement), to monitor the level and type of antibodies against five viral antigens (the whole spike (S) protein, the RBD receptor-binding domain, the S2 fragment, the full nucleocaspid (N) protein, or the N-terminal fragment).

A total of 1076 people, aged 43 to 72 years, were included in the analysis.

They found in 36% of infected but unvaccinated people antibodies were no longer detectable almost a year after the infection.

Also, vaccination induced significantly higher antibody levels in people who had a prior infection, as compared to those without prior infection.

The research team also found that Moderna's Spikevax generated the highest levels of antibodies.

→ **bit.ly/3Lgl68x**

VACCINE DEVELOPMENT

TRIGGERING HUMAN IMMUNE RESPONSE

Researchers have found that disruption of a cellular structure, known as the actin cytoskeleton, is a "priming signal" for the body to respond to a virus.

These findings could potentially lay the groundwork for development of new antiviral vaccines and treatments, they claim.

Previously, viral genetic material, such as RNA, was considered the sole requirement for certain sensor molecules that live in cells to trigger an immune response – an "alarm system" for many types of cells.

RNA also serves as a basis for vaccines through training a patient's immune system to recognise a virus. This new study showed that the signalling process also requires disrupting the actin cytoskeleton inside cells, which occurs when a virus infects cells.

"It's a new way of considering how the immune system can be activated, and the implications are that this could lead to broad antiviral therapeutics," said author Michaela Gack. "Our data show this process is common across different types of RNA viruses."

→ **bit.ly/3LIlgLD**

IMAGES: ISTOCK/SHUTTERSTOCK/SCIENCE PHOTO LIBRARY

ALZHEIMER'S

LINK BETWEEN REPEATED INFECTIONS AND NEURODEGENERATIVE DISEASES

Infections treated with specialty hospital care in early- and mid-life are associated with an increased subsequent risk of Alzheimer's (AD) and Parkinson's diseases (PD), but not amyotrophic lateral sclerosis (ALS), it is claimed.

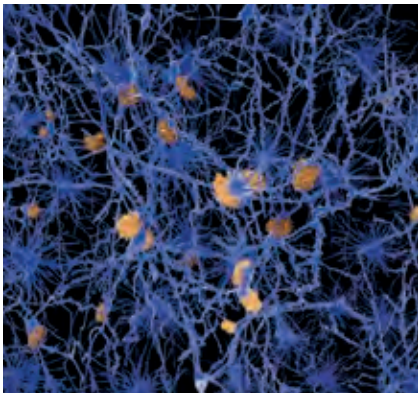
Experimental studies in animals have suggested that infection plays a role in the development of some neurodegenerative diseases, but supporting evidence in humans is limited.

Scientists used data from people diagnosed with AD, PD or ALS from 1970 to 2016 in Sweden, with five controls per case, all identified from the Swedish National Patient Register. The analysis included 291,941 AD cases, 103,919 PD cases and 10,161 ALS cases.

A hospital-treated infection five or more years before diagnosis was associated with a 16% higher risk of AD (95% CI: 1.15–1.18, P < 0.001) and a 4% higher risk of PD (95% CI: 1.02–1.06, P < 0.001), with similar risks seen for bacterial, viral and other infections and for different sites of infection.

The highest risk of disease was seen in people with multiple hospital-treated infections before the age of 40, with more than double the risk of AD (OR=2.62, 95% CI: 2.52–2.72, P < 0.001) and more than 40% increase in the risk of PD (OR=1.41, 95% CI: 1.29–1.53, P < 0.001).

→ **bit.ly/3LhWoWm**



CARDIOVASCULAR DISORDERS

GECKOS AND BLOOD MONITORING

Geckos can stick to just about anything, and their feet are inspiring researchers to change how medical professionals can monitor blood pressure.

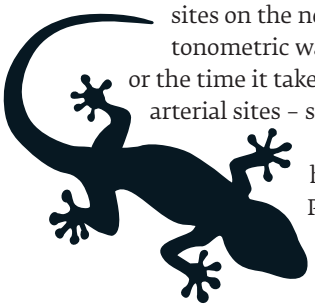
The small reptilians' toe pads are covered in thin hairs called setae, which is what adheres to surfaces.

Researchers are using gecko feet to improve the adhesion of cuff-less 24-hour ambulatory blood pressure monitoring.

Cuff-based devices are most commonly used to track changes in blood pressure, as well as diagnose hypertension, but the devices come with their own set of limitations. The cuff periodically inflates and deflates every 15 minutes or so, even when the patient is trying to sleep. Monitoring blood pressure during sleep is crucial for medical professionals, but interrupting patients' sleep can cause misreadings during clinical observation.

Cuffless blood pressure monitoring devices would not only improve patient sleep, but provide medical professionals with a more effective clinical approach to diagnosing hypertension, the researchers claim.

The team will design wearable tonometric sensors at arterial sites on the neck and ankle, which will collect tonometric waveforms and pulse transit time (PTT) – or the time it takes for the pulse to travel between two arterial sites – simultaneously.



Ultimately, the team plans to combine high-fidelity arterial tonometry and PTT principles to achieve cuffless 24-hour blood pressure monitoring.

→ **bit.ly/3eTVNxY**

WHAT'S HOT AND WHAT'S NOT

HOT

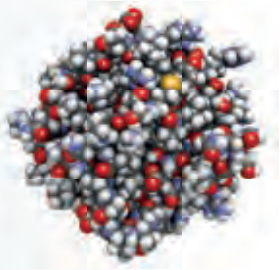
VIDEO TECHNOLOGY

Children and adolescents with obesity lost weight and showed improvements in metabolic health following a 12-month, video-based weight loss programme.

HOT

IMMUNOTHERAPY

An international research team led by the University of Zurich has developed a new immunotherapy strategy to eliminate fibroblasts in a targeted manner.



HOT

GUT MICROBIOMES

Research in *Nature Medicine* used data from over 300 human faecal microbiota transplants to gain an ecological understanding of what happens when two gut microbiomes clash.

NOT

SMARTPHONES

Exposure to blue light, via regular use of tablets and smartphones, may alter hormone levels and increase the risk of earlier puberty, according to data from a rat study.

NOT

ANTIBODY DRUGS

The antibody drugs sotrovimab and casirivimab-imdevimab are not recommended for patients with COVID-19, says a WHO Guideline Development Group.

NOT

ECZEMA

The first study to treat moderate-to-severe eczema in infants and with a biological drug (monoclonal antibody) rather than immune-suppressing medications shows the drug was highly effective.

STDS

MUCUS-BASED LUBRICANT FOR HIV AND HERPES

Cow mucus provides the basis for a synthetic prophylactic gel that has been developed at KTH Royal Institute of Technology to protect against HIV and herpes transmission.

The lubricating gel proved 70% effective in lab tests against HIV, and 80% effective against herpes.

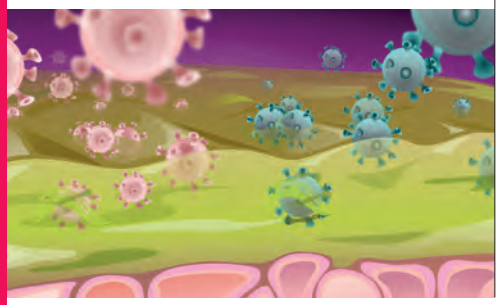
Hongji Yan, a Biomaterials Researcher at KTH, says the promising results raise hope that when it becomes available as a product, the gel could help reverse troubling trends in the spread of sexually transmitted infections.

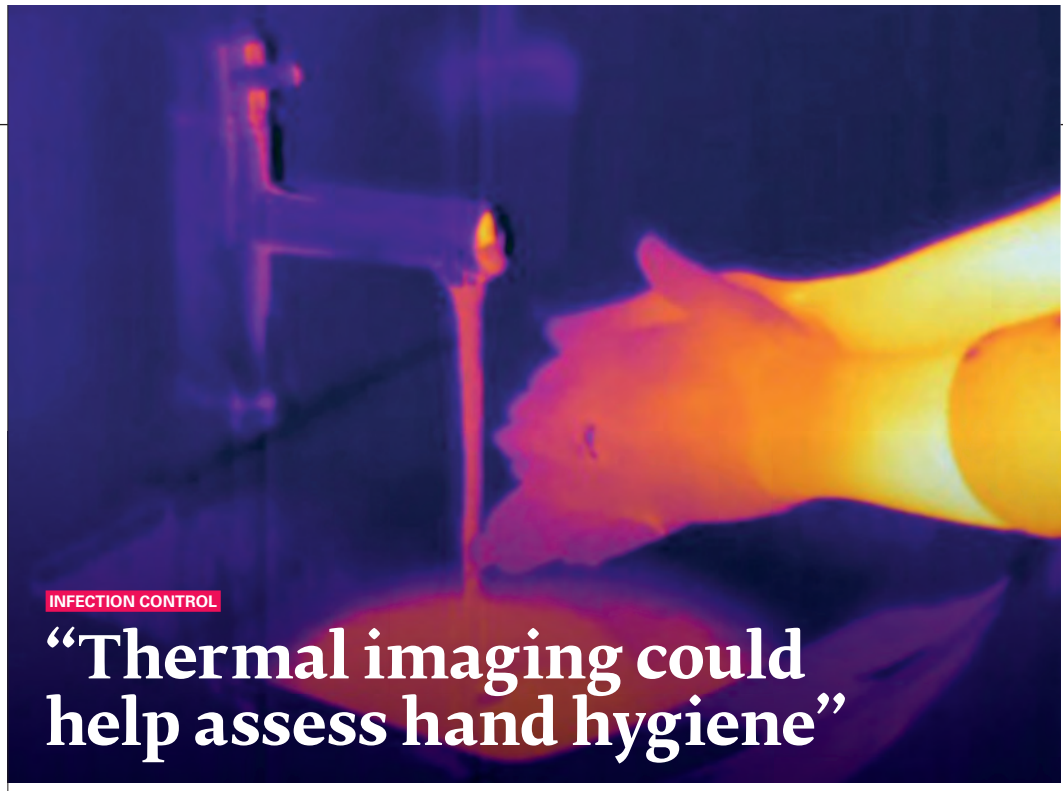
The lubricant is derived from mucin, which is a main component of mucus that is produced in the human body, though suppliers provide the bovine type in purified form for fabrication of hydrogels.

Hongji said the natural complexity of the mucin molecules is the reason the synthetic gel is so effective at stopping the HIV and herpes.

→ **bit.ly/3LjURPy**

IMAGES: ©KTH ROYAL INSTITUTE OF TECHNOLOGY





INFECTION CONTROL

"Thermal imaging could help assess hand hygiene"

Findings from a pilot study suggest that portable thermal imaging cameras might provide a new approach to assessing and improving hand-hygiene practices among healthcare professionals (HCPs).

"Effective hand hygiene is recognised as the single most important act to prevent the transmission of potentially pathogenic microbes in the healthcare setting, but there is no widely adopted method for assessing the effectiveness of healthcare professionals' hand hygiene technique," said John Boyce, a study author. "Our study shows that thermal imaging shows promise as an approach that warrants additional research to determine if it can be used for routine monitoring of hand hygiene technique to improve patient care."

Using an infrared camera attached to an iPhone, they obtained thermal images of 12 HCPs' dominant hands, recording baseline readings of the mid-palm area, the tips of the third finger and thumb before and then at multiple time points after the study participants performed hand hygiene with alcohol-based hand sanitiser (ABHS) .

The images revealed significant decreases in mid-palm, finger and thumb temperatures after the hand hygiene was performed ($P < 0.01$ for all sites), confirming that the infrared camera was capable of detecting colour changes that reflected drops in temperature. The researchers also found that when participants performed ABHS without including their thumbs, a lack of colorimetric change in the thumbs was visible in the resulting thermal images.

→ **bit.ly/3S7yY8d**

IMAGES: ISTOCK/SHUTTERSTOCK/SCIENCE PHOTO LIBRARY

UNDER THE MICROSCOPE

This month: Digital masks

What is a digital mask?
It is a creation of scientists from the University of Cambridge that will allow facial images to be stored in medical records while preventing potentially sensitive personal biometric information from being extracted and shared.

How does it work?
The scientists used 3D reconstruction and deep learning algorithms to erase identifiable features from facial images while retaining disease-relevant features.

Is this a big issue?
With the increasing digitalisation of medical records comes the risk of data breaches. While most patient data can be anonymised, facial data is more difficult to anonymise while retaining essential information.

How is this currently done?
Common methods include blurring and cropping identifiable areas. But this may lose important disease-relevant information.

What can we learn from looking at someone's face?
Facial images can be useful for identifying signs of disease. For example, features such as deep forehead wrinkles and wrinkles around the eyes are significantly associated with coronary heart disease, while abnormal changes in eye movement can indicate visual cognitive developmental problems.

What do patients think?
The team surveyed randomly selected patients attending clinics to test their attitudes towards digital masks. Over 80% believed the digital mask would alleviate their privacy concerns and said they would have increased willingness to share their personal information.

Where can I read more?
Visit **go.nature.com/3dnHxwX**

CANCER

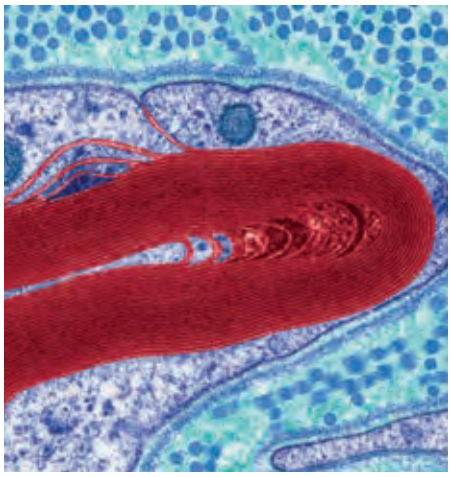
"Neighbouring cells could make tumours benign"

Schwann cells are known to protect and repair nerve cells. Until now, however, it was not known that they themselves take over functions of certain immune cells during nerve healing.

For example, they produce signalling molecules that can activate other immune cells.

They are able to stop inflammatory reactions in order to prevent excessive tissue damage and allow the nerve to regenerate.

"This is essential, because inflammation releases free radicals against which nerve fibres cannot protect themselves. Therefore, the inflammation must be cleared quickly, which is precisely what Schwann cells do," explains Dr Sabine Taschner-Mandl, who designed the study.



After nerve injury, Schwann cells adopt a "repair" mode that is also found in benign infantile nerve tumours. There, it causes the tumour cells to mature and thus reach a stage where they lose their aggressive properties and no longer divide unchecked, stated the authors.

The study shows Schwann cells can influence T cells, which play an important role in the defence against cancer.

Schwann cells – both those in nerve regeneration and those in benign tumours – carry MHC-I and MHC-II molecules on their surface that are important for T-cell regulation.

→ **bit.ly/3BdYT7y**

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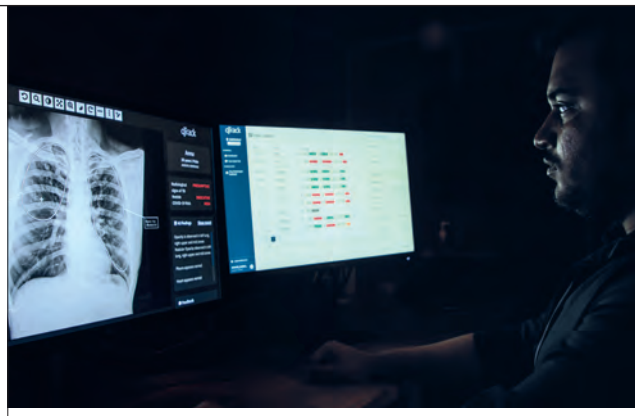


IMAGE: ©QURE

MAST GROUP

MISSION HOSPITAL

The Khristiya Seva Niketan (KSN) is a mission hospital in Sarenga, West Bengal, India, which is two hours from the nearest city with modern facilities. Ivor Mitchelmore, a retired Chief Biomedical Scientist, has been visiting KSN since 2014 with colleagues to try to establish a microbiology service. Several companies have supported this effort, including the Mast Group, by providing equipment and consumables. The next visit is planned to KSN is January/February 2023.

→ **mast-group.com**

IMAGE: ©QLUCORE

QLUCORE

BLOOD CANCER

Qlucore is expanding its collaboration in precision diagnostics with Lund University with the aim of developing solutions for improved blood cancer diagnostics. Combining the software expertise of Qlucore with the cancer diagnostics expertise of Lund University, the collaboration aims to develop and evaluate classification models for improved diagnostics of two different forms of blood cancer – acute lymphoblastic and acute myeloid leukemia.

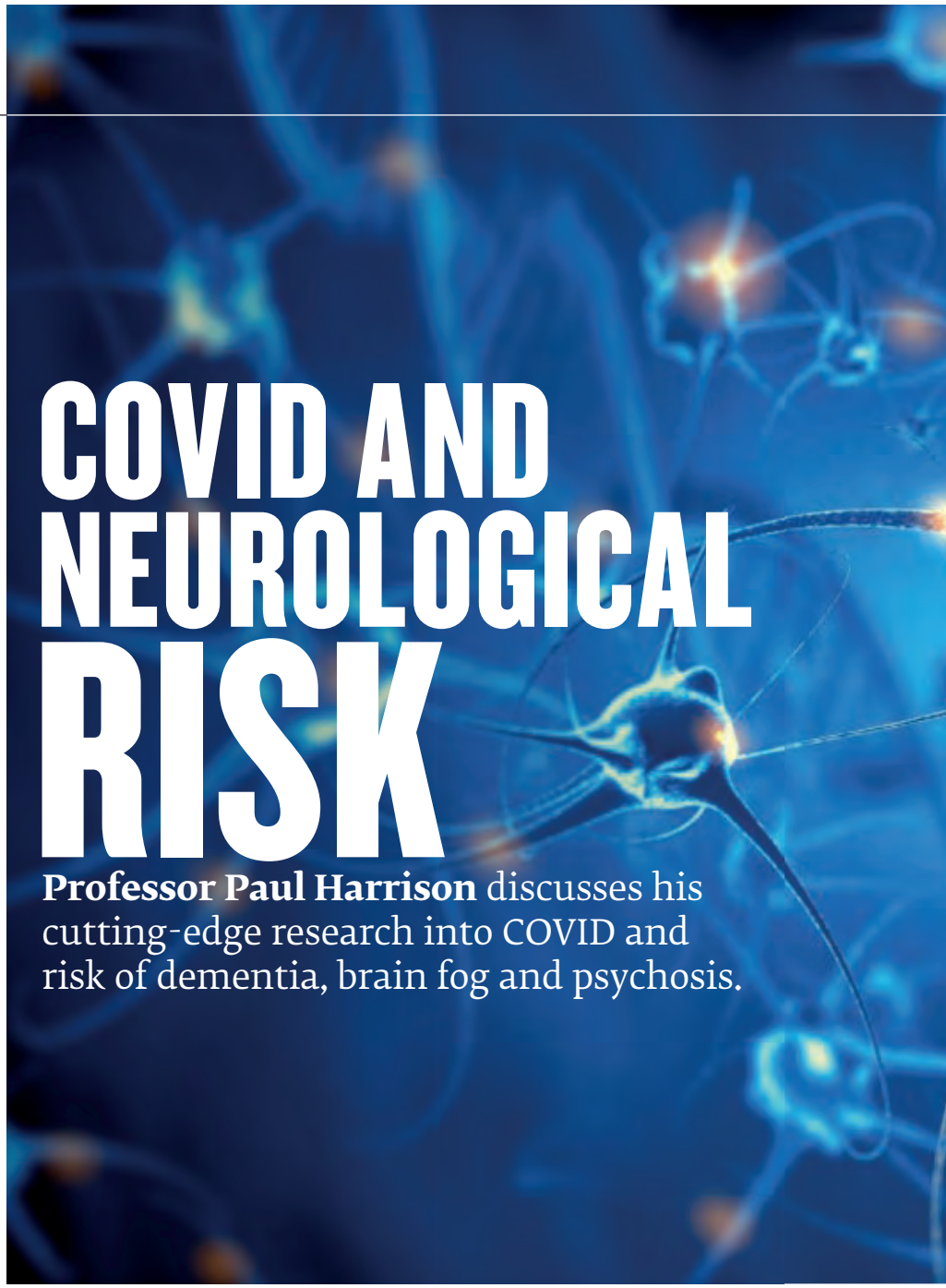
→ **qlucore.com**

QURE.AI

AI IMAGING

Health tech firm Qure.ai has partnered with Erasmus MC, University Medical Centre Rotterdam, to launch the AI Innovation Lab for Medical Imaging. The initial programme will run for three years and will include research into the detection of abnormalities by artificial intelligence (AI) algorithms for infectious and non-infectious disease conditions. The goal will be to understand the potential use cases for AI in Europe and provide guidance to clinicians on best practices for the adoption of the technology specifically for their requirements. Erasmus MC is a leading innovator in healthcare, pursuing excellence through research and teaching. It will run the Lab, conducting research projects using Qure's AI technology.

→ **qure.ai**



COVID AND NEUROLOGICAL RISK

Professor Paul Harrison discusses his cutting-edge research into COVID and risk of dementia, brain fog and psychosis.

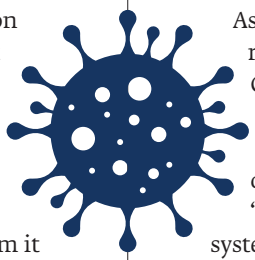
The long-term physical effects of a COVID infection have been investigated, analysed and discussed at length, but not quite so much has been said about the psychiatric and neurological repercussions of the viral infection. What lasting impact might the virus have had on people's levels of depression and anxiety, and on diagnoses of conditions such as dementia, epilepsy and psychosis?

This imbalance has been redressed, in part, by the publication in August's *The Lancet Psychiatry* of "Neurological and psychiatric risk trajectories after SARS-CoV-2 infection: an analysis of two-year retrospective cohort studies including 1,284,437 patients". Conducted by a team from the University of Oxford, the study found that some conditions were more common two years after the onset of a COVID infection, but others were not.

Roots of the research

Lead author Professor Paul Harrison, from the university's department of psychiatry, says the roots of the research were laid down in the early days of the pandemic, amid concerns, based on evidence from previous viral outbreaks, that this new virus would bring an increased risk of a range of mental problems.

"There was a theoretical reason to think that SARS-CoV-2 might produce similar problems. Then, fairly early in the pandemic, we began to hear anecdotal reports of people who had developed COVID and didn't seem to be recovering from it as quickly as one might have hoped. As an academic psychiatrist I'm interested in these sorts of questions, so we took the opportunity to do research in the area to try and put some robust numbers on the scale and the nature of the association between having had a COVID infection and then developing a range of psychiatric and neurological diagnoses."



As with so much of the other research that has centred around COVID, this study took full advantage of the recent trend for healthcare systems to move over to electronic health records. "There are a number of different systems in different parts of the world, and we happened to have access to TriNetX," says Harrison. This particular network consists of around 89 million de-identified records collected from hospitals and other healthcare providers mostly in the US but also in the UK, Spain, Bulgaria, India, Malaysia, Taiwan and Australia. "It is a big sample size, which gives us a lot of power to identify what the risks might be and the factors associated with different people."

Risk trajectory

Harrison's team have been delving into this gigantic block of data to identify everybody who had a confirmed diagnosis of COVID infection and then to compare them with otherwise matched patients who'd had been diagnosed with other infections – all with the goal of getting a sense of what, if anything, might be different, in terms of the psychiatric and neurological effects, between a COVID infection and those other infections. This latest paper from the team represents the biggest and the longest follow-up

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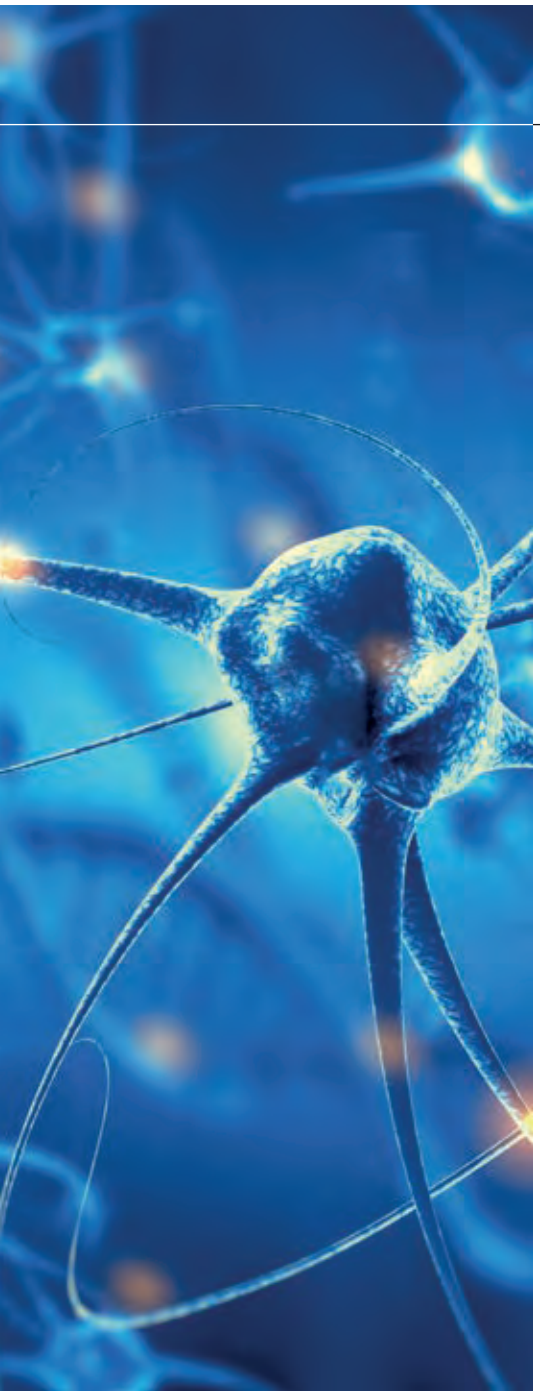


of the outcomes for those patients.

"Previous studies have suggested that in the first few months after a COVID infection, people were at greater risk of a range of mental and neurological disorders. But we also wanted to see how long those risks last and whether the trajectory of risk is the same for all the different disorders. So we simply measured up to two years after COVID infection the risk of being given a new diagnosis."

The paper sets out the data in all their richness, but, in essence, the team found two categories of risk trajectory. "One was actually very transient," says Harrison. "The common mental health problems that we had been concerned about – those greater risks had disappeared within a few months, at the most, compared to other infections. It appeared that COVID was maybe having a short-lived effect as a stressor, precipitating diagnoses of depression and anxiety. But taking a two-year perspective, there was no greater risk of getting depression or anxiety after COVID than other infections."

However, the picture changed when looking at the more neurological-based conditions. "These are things such as dementia and brain fog, but also psychosis, which is a psychiatric problem. For these conditions, the risks didn't seem to go away. Even two years after COVID infection, people were still more likely to get a diagnosis than with other infections. This suggest there are two clusters of risk and that there might be different mechanisms at play."

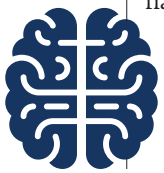
Emerging theories

Since the start of the pandemic, a number of theories have emerged to explain the association between a COVID infection and mental health issues. A direct viral or persistent viral infection of the nervous system is one theory. A second is that it is collateral damage from the body's immune response. A third is the propensity of COVID to cause blood clots, or microthrombi. "This is the theory where the most evidence is beginning to accumulate. Other researchers are using brain scanning of different sorts, particularly MRI, to identify potential changes in brain structures or connectivity, which may be part of the underlying mechanisms causing these problems to develop."

The team is now involved in PHOSP-COVID, a large study looking at the long-term health of patients in the UK who had been hospitalised with COVID. "Some of those patients are approaching the two-year follow-up, and we are looking at their risks of these mental health issues and what, if anything, are the biomarkers that predict their persistence two years later."

For Harrison, one of the key lessons of the TriNetX-based research is just how quickly results can be extracted from electronic health records. "We can't underestimate the value of that. My normal research is lab-based, and all that stopped overnight during the first lockdown. But I was able to switch with some of my team immediately to doing this research from home perfectly happily. We have produced good data on the scale and nature of the association between this particular virus and subsequent mental and brain health, and there's a real sense that this is important public health research." BMS

"We wanted to see how long those risks last and whether the trajectory is the same for all the different disorders"



PAUL HARRISON

- ✔ Professor of Psychiatry, Department of Psychiatry, University of Oxford
- ✔ Trained in medicine and psychiatry in Oxford and London
- ✔ Was a Wellcome Trust Senior Research Fellow
- ✔ Appointed to present post in 1997
- ✔ Awarded a Chair in 2000.

WINTER IS COMING

HOW WILL PATHOLOGY AND HEALTHCARE SERVICES COPE OVER THE COMING MONTHS?

This time last year, COVID cases were about to soar. Driven by the arrival of the Omicron variant, which was first identified in the UK at the end of November, cases recorded peaked in England at 234,873 on 4 January– the highest since the pandemic began.

For context, the seven-day average at the end of August this year was 3554 – nearly one hundred times lower than last winter's peak.

The NHS was under intense pressure. Ambulance emergency response times were nearly double that of previous winters, as were long waits at A&E departments, while staff sickness absence levels were also higher than usual.

Thankfully, the vaccination campaign meant that last winter fewer English NHS hospital beds were occupied by patients with a confirmed case of COVID-19 than the previous winter (although they still occupied up to 15% of acute beds). This year's booster campaign is underway across the UK (see box on p.19), but what will happen in the coming months is unknown.

As we face an uncertain winter, we asked a range of scientists how pathology and healthcare services will cope. Here's what they said.

PHOTOGRAPHY: RICHARD GLEED


NHS

DR ELAINE CLOUTMAN-GREEN

Consultant Clinical Scientist, Great Ormond Street Hospital

"As *Game of Thrones* says, 'Winter is coming' and, sadly, I see winter with the same amount of dread as that series presents. The data from Australia indicate that we might have a difficult time with the number of influenza cases we might see and the jury is still out about whether 'COVID information fatigue' will impact vaccination uptake for flu, SARS-CoV-2 or both. Combined with the level of waiting list catch-up activity needed, I think we need to brace for a difficult time, in terms of an over-stretched diagnostic and healthcare system. That said, the sun is still shining and we should use this time to recharge our batteries and prepare for when the days shorten and the outlook may not be so cheerful."

SHERI SCOTT

Senior Lecturer in Biomedical Science, Nottingham Trent University

"The winter months are going to be challenging. Apprenticeship student numbers are high and my sustainability advocacy (see p.34) has grown legs. I feel the training burden for pathology will be demanding with workload increases and the uncertainty of staff wellbeing. This said, it has never been more important to shore up the skills of the workforce of tomorrow and consider sustainability in current practice."

NICKY HOLLOWOOD

POCT Manager, Harrogate and District NHS Foundation Trust

"POCT will no doubt be busy over the winter, but the big question is whether we will see a flu season materialise and if there will be a clinical need to establish rapid flu testing. Hopefully we will continue to see COVID-19 playing a less dominant role in healthcare and start to see growth and development of diagnostics services, particularly in the community."

CAROLINE FILLMORE

Biomedical scientist, Regional Virology Laboratory, Belfast

"In virology, there is a bit of uncertainty as although the COVID pandemic seems over for everyone else, we are now wondering what will happen next. Will there be much flu this year and will COVID have a resurgence? Our hospitals are still feeling the pressures so there is a worry that a bad winter with flu will be difficult to cope with. With so much change in the government, things are very unsure in the NHS, but pathology services will still strive to meet the top standards, as the staff are amazing."

MALCOLM ROBINSON

Founder, Harvey's Gang

"I believe that this winter may hold our greatest challenge to date. Why? The pathology morale is so low that we may have run out of goodwill. Our phenomenal teams responded beyond expectations through COVID times, but without recognition, pay increases and with the energy/fuel crisis, the staffing crisis and retirement, I fear for our teams. However, I have noted that Harvey's Gang tours are restarting and that is helping our teams, but won't solve the pay issues."

AZUMA KALU

Laboratory Manager (Specialised Clinical Chemistry & Toxicology), Sheffield Teaching Hospitals NHS Foundation Trust

"The toxicology service at Sheffield Teaching Hospitals NHS Foundation Trust receives and analyses the highest number of cases during the

"We should use this time to recharge our batteries and prepare for the days when the outlook may not be so cheerful"

winter. Some of the cases are elderly people, homeless people and drug users who may have been found dead and these cases are referred to us by the coroners. With the energy crisis, this winter is forecasted to be difficult, so we are preparing for a potential increase in cases. We are hopeful that the combination of winter seasonal flu and COVID will have minimal effect on our workforce to enable us manage the forecasted increase in workload this winter."

DR DAVID RICKETTS

Head of Laboratory Process Improvement, Health Services Laboratories

"ISO 22367 has a section on staff wellbeing as a risk to be managed. Given the pressures on the service, the emotional drain caused by inflation and fuel costs and the risk of a spike in viral cases, this aspect of risk management needs careful consideration, as well as managing the potential of increased sickness absence. Winter is coming and we have more potential challenges than last winter, which was tough enough."

MARTYN HICKS

Regional Pathology Apprenticeship and Educational Lead (South West England), NHS England South West

"Ensuring timely turnaround of laboratory diagnostic results is key to ensure biomedical scientists do their bit. But many labs are struggling with recruitment and retention, as has been widely reported. Laboratories are increasingly looking at new ways of working to ease these pressures and the STP route is one way to ease the strain on clinical staff and has been successful where implemented. Apprenticeship routes, which are also to expand and provide a continued source of workforce to help assist with the shortfall from degree routes into the profession and

COVID BOOSTER JABS

Millions of people across the UK are being invited for their autumn COVID booster jabs, with care-home residents among the first to receive them.

Those who are eligible are being urged to protect themselves from serious illness by getting vaccines.

Moderna's recently approved "bivalent" vaccine will be used, however, there is not enough of this vaccine for everyone invited.

Those who are eligible for the booster are adults aged 50 and over; people aged five to 49 with health conditions that put them at higher risk (including pregnant women), care-home staff, frontline health and social care workers, carers aged 16 to 49 and household contacts of people with weakened immune systems. The most vulnerable are being prioritised first.

Wales started offering COVID boosters in August, while Northern Ireland followed in mid-September.

In Scotland, care-home residents were offered COVID boosters in early September, followed by health and social care workers.

England's autumn booster campaign also started in September, with 1.6 million care-home residents, staff and housebound people the first to receive their top-up COVID jab.

From this month, the NHS is also rolling out this year's flu vaccine, with eligible people able to get their flu and COVID jab at the same time, depending on local system arrangements.

appeal to a wider demographic, are increasingly popular. It's important to ensure new models of workforce delivery are continually explored to guarantee a sustainable flow of people into the profession. There are a lot of positives from the many initiatives seen across the laboratory networks, but it is currently not enough to expand and bolster what is really needed. I've asked many labs the same question: 'What is the major issue holding back training?' The answer is always the same – 'backfilling trainer time'. It requires financial input to support those in post delivering the training as laboratories are struggling to cover all the bases with the current financial thresholds."

ABI GILES

Specialist Biomedical Scientist, Royal Bolton Hospital

"I think this will be another challenging year for the health service as a whole. We don't know what the new government's direction is for the health service and the increased physical and mental stresses from the cost-of-living situation will no doubt impact service users. As a biomedical scientist within a hospital in an area that already suffers from economic disadvantage, the impact could be quite severe."

NIGEL BROWN

Consultant Clinical Scientist, Toxicology, Wansbeck General Hospital

"I fear increased hospital admissions due to hypothermia and malnutrition, particularly in the elderly. The effects of this will be compounded by lack of space in resources in care homes and respite care. I hope I'm wrong. On the lab side, I expect at least one more new illicit drug to appear – there is never a dull moment in toxicology! I hope the new prime minister will announce major funding for training in the NHS over a

10-year period to get a new generation into all the professions. But I'm not holding my breath."

EILEEN KELLY

Medical Scientist, Royal Children's Hospital, Melbourne, Australia

"In Australia, as we leave winter behind us, I will not miss the respiratory syncytial virus, which took a toll on the children who had not met the virus during lockdown. We will get back the ICU beds we need for all the delayed surgeries – delays made worse by staff having to isolate due to COVID. Now maybe we can recover and make pathology even better... with a little help from extra funding and contingency planning for the future."

PROFESSOR ADRIAN ESTERMAN

Chair, Biostatistics and Epidemiology, University of South Australia

"A recent editorial from the *BMJ* pointed out that 'the NHS is not living with COVID, it's dying from it'. Unfortunately, politicians no longer listen to public health advice, and with winter approaching for the UK, I am expecting case numbers, hospitalisations and deaths from COVID-19 to go up, even without a new subvariant or variant. Sad to say, Australia is going the UK route and removing all public health measures. At least we have summer to look forward to."

TAHMINA HUSSAIN

Lecturer in Biomedical Science, University of Salford

"The cost-of-living crisis is going to be a worry and the winter months will be difficult, especially for those patients whose conditions might be exacerbated from a cold or viral infection, which could then potentially result in a surge of hospital admissions. This will have an impact on the healthcare facilities and pathology services."

BAMIDELE FARINRE

Lead Biomedical Scientist, Halogene, I-HUB,

"There is a need for urgent preparation to mitigate the risks of a particularly challenging winter. This will include developing effective policies to maximise population participation in essential control measures, such as physical distancing, wearing face coverings in settings where physical distancing is not possible and regular hand and respiratory hygiene, among others."

RICK LOVIE

Network Deputy Quality Manager, York Teaching Hospital NHS Foundation Trust

"Recently I have had the privilege of working with the microbiology team. The challenges the team are experiencing can seem daunting, especially with COVID, winter flu and relocation of services. I have learnt a lot i n my time with the team and have been inspired by the dedication they display. Therefore, I hope, regardless of where we all find ourselves over the winter months, that we can work with their same resilience and professionalism."

DR CHRIS MOORE

Programme Leader, BSc Biomedical Science, UWE, Bristol

"An issue the service faces in the coming winter months is simply capacity. It is already deeply embroiled in

"I hope the new prime minister will announce major funding for training in the NHS over a 10-year period to get a new generation into all the professions. But I'm not holding my breath."

trying to keep up with the backlog from the last few years and will now have the 'usual' winter escalation to cope with. But labs have finite equipment, and finite space within which to have the people doing the work to operate in. You can't simply employ 10 more biomedical scientists to help because they won't have the kit to process the specimens or the physical space to move about in. On top of that, the workforce remains understaffed due to the severe limitation on portfolio training roles for undergraduate and graduate students on accredited courses. It's going to be tough in the coming months. The service will need major influxes of finances and resource to cope and to grow. I think the public often forgets the crucial role that middle piece plays – without effective and efficient diagnostics, people will remain untreated at home or in hospital beds."

IAN DAVIES

Healthcare Science Course Leader, Staffordshire University

"I've no doubt that this winter will bring many challenges to pathology teams, with unprecedented demand together with seasonal clinical and workforce pressures. That said, I'm sure that the agility and resolve that the workforce demonstrated during COVID will provide the drive to tackle these challenges in ways we haven't seen before, for example through wider integration with clinical teams, developing innovative solutions and driving system changes to improve workflow. Most importantly, especially with concerns related to the cost of living and current events, we need to remember the lessons learnt during COVID – looking after ourselves, our colleagues and our teams, placing wellbeing at the top of our agenda, and remembering that our care for our patients is dependent upon our care for each other and ourselves."

"The health service, and particularly pathology, innovates constantly – we are short of time, people, and resources, but we manage and we thrive"

MARTIN MALEY

Senior Lecturer in Biomedical Science University of Sunderland

"From a university perspective, we continue to see evidence of a squeeze on staffing in the NHS, which impacts student and trainee grades. There are fewer placements available, mainly because NHS pathology labs need to have the staff available to mentor the students. This means there will be fewer graduates with lab placement experience. Applied biomedical placements remain unpaid, which also means that we did struggle somewhat to get students to apply for these in a time when there is a cost-of-living crisis. When talking to NHS colleagues about supporting university lab days, there is also ongoing evidence of problems sourcing equipment and reagents in a timely fashion."

MATT GRIFFITHS

Principal Lecturer in Cellular Pathology, Nottingham Trent University

"The health service, and particularly pathology, innovates constantly – we are short of time, people, and resources, but we manage and we thrive. We find new ways of working: faster, better, cheaper; we change our processes; we react to the research. We work as a team, supporting each and we know how many procedures depend on our results – we are integral to the health service. As a team, we step up to these challenges to give patients the best care."

ZOE ANDREWS

Trainee Biomedical Scientist, Microbiology, States of Guernsey

"I think the winter months hold uncertainty for pathology. We know

flu season is upon us, so our microbiology department will have a larger workload, but we also need to be present for staff at a human level throughout the winter months to ensure their wellbeing."

JONATHAN M EVANS

Lead Biomedical Scientist/Operational Manager, Wales Specialist Virology Centre

"This winter could easily be the most challenging the NHS has ever faced. With numerous vacancies across the service and staff still recovering from the pandemic, it is going to be a tough winter. From a virology viewpoint, Australia has just had its worst flu season in five years, which could foreshadow what we're about to experience. Also, COVID is definitely still here, so it's going to be busy in our labs. I wish everyone in the NHS the strength to get through it."

"As a team, we step up to these challenges to give patients the best care"

RICHARD WARDLE

Pathology Manager, South Yorkshire and Bassetlaw Pathology

"With COVID still a real threat, not only to patients but to our staff, we will have to dig deep to ensure we maintain the quality services the NHS has become accustomed to from pathology. Whilst we should never take it for granted, one thing the last couple of years have shown everybody outside pathology, something we already knew from the inside, is that our services are renowned for their resilience. Pathology personnel are something else and that is what will see us through to the Spring."

CARMELA DUFFY

Virology Discipline Manager, Royal Victoria Hospital, Belfast

"I believe the laboratory workload will continue to grow and evolve over winter. Diagnostic planning for winter 2022–23 must take into account concurrent SARS-CoV-2 and influenza activity. Normal epidemiological cycles of winter viruses continue to be disrupted with RSV circulating in July. Many of the skills we developed through COVID will be tested again. These skills of adaptability, responsiveness and resourcefulness will allow us to meet the needs of our patients even in the challenging winter ahead."

EMMA VICTORY

Team Lead, UKHSA Malaria Reference Lab & LSHTM Diagnostic Parasitology Lab

"I expect we will see the same challenges as last year – more COVID infections, more stress, more staff shortages... One of the positive outcomes from the pandemic has been increased compassion and greater connection between teams and colleagues. It is important to acknowledge workplace stress and offer practical solutions to support staff wellbeing – not just

NHS ACTION

NHS England's core objectives and actions are to increase capacity and resilience.

1. **Prepare for variants of COVID-19 and respiratory challenges**, including an integrated COVID-19 and flu vaccination programme
2. **Increase capacity outside acute trusts**, including the scaling up of additional roles in primary care and releasing annual funding to support mental health through the winter
3. **Increase resilience in NHS 111 and 999 services**, through increasing the number of call handlers
4. **Target Category 2 response times and ambulance handover delays**, including improved utilisation of urgent community response and rapid response services, the new digital intelligent routing platform, and direct support to the most challenged trusts
5. **Reduce crowding in A&E departments** and target the longest waits in ED by improving use of the NHS directory of services, and increasing provision of same day emergency care and acute frailty services
6. **Reduce hospital occupancy**, through increasing capacity by the equivalent of at least 7000 general and acute beds
7. **Ensure timely discharge**, across acute, mental health, and community settings
8. **Provide better support for people at home**, including the scaling up of virtual wards and support for High Intensity Users with complex needs.

resilience training. We need to lean into the positive changes and continue to care for each other as well as service users."

CHERIE BECKETT

Acting Senior Biomedical Scientist, Microbiology, The Princess Alexandra Hospital NHS Trust

"The demands on the healthcare service are traditionally amplified during the winter months, but this year, as in recent years, what one typical time of year used to indicate, is less so the case. 'Seasonal' viruses such as influenza, RSV and norovirus, have been seen throughout the year, but I would still imagine will peak in the winter months and perhaps COVID-19 too. With the cost of living and energy prices rocketing, it is saddening to think that the healthcare system may see more cases of illnesses associated with a reduced food intake and hypothermia. Pathology sample numbers will increase, but the foundation on which COVID-19 high-throughput laboratory testing and point-of-care testing has been stepped up hopefully means that for some tests (notably respiratory viruses), workload might be more manageable in some ways."

MARTINE JENSEN

Higher Specialist Biomedical Scientist, Hull University Teaching Hospitals NHS Trust

"The upcoming winter months will be challenging, as being post-COVID the winter viruses may be difficult to predict. But what COVID has taught us is that pathology can handle anything and I am sure that whatever is coming our teams have the ability to overcome it."

DR MARK HAJJAWI

Head Biomedical Scientist (Specialist Services), SHYPS

"The summer of 2022 has been a mixed period for the specialist diagnostics service I lead. The post-COVID-19 catch-up has led to a record high workload as the NHS strives to clear the backlog. Even with this high workload, we have had a sense of normality we have not seen for a couple of years: grant applications have been written, clinical audits conducted, and improvement projects completed. Summer is now over and once again the dark spectre of winter respiratory viruses is upon us. The cancer catch-up must continue despite the predicted spread of respiratory viruses through the population and the workforce; this will result in significant strain on the service. NHS staff will also face an unprecedented assault from inflation and the increasing cost of living. We will all be squeezed at work, and at home, to do more with less. As biomedical scientists, we will deliver excellent clinical care for patients, as we always do, with creativity and tenacity, perhaps doing our brightest work of the year in the darkness of winter."

DR GUY ORCHARD

Consultant Biomedical Scientist, Operations Manager, Tissue Sciences Head of Education, St. John's Dermatopathology, Viapath

"We are going through a bumpy time, and it looks set to continue for the next few months. We have supply chain issues, partly as a result of the ongoing fallout from Brexit, but also the effects of the war in Ukraine. A case in point is the ongoing national shortage of paraffin wax, which is causing severe headaches for histopathology managers. Coupled with this is the ongoing catch up with our cancer work that we're still working through as a consequence of the COVID pandemic. There is also a national shortage of qualified biomedical scientists that are now required to engage in more complex working environments. All of these factors have developed and expanded quite swiftly making the

process of providing services difficult to deliver. I would predict that pathology services will be working under even greater winter pressures than normal this year. I would love to offer some positive words, but the next few months look pretty challenging to me. In effect, most of these changes are not easy to control or predict and as such the focus should be on managing what we can control."

ASHLEY BALLARD

Senior Biomedical Scientist, Cellular Pathology, University Hospitals Dorset NHS Foundation Trust

"With a background of high energy prices eroding budgets, ongoing staff shortages, record waiting lists and the looming possibility of strike action, this winter looks like it could be one of the most challenging in recent memory for the NHS. Traditionally, cellular pathology would not be significantly impacted by the normal winter pressures. Although more staff would be sick during this period, there would not be huge seasonal variations in workload. However, with the drive to reduce elective waiting lists post-COVID, cellular pathology is now facing a huge surge in workload. Combined with normal winter sickness and increasing levels of staff burnout in what is still a very manual discipline, we potentially face a perfect storm this winter in cellular pathology. We are already starting to see the first signs of this with laboratory backlogs becoming more frequent and turnaround times increasingly more protracted. However, despite all the doom and gloom there is hope on the horizon. There are ongoing projects to improve cellular pathology services, with initiatives such as digital pathology, advanced roles for staff, and equipment modernisation hopefully helping to boost productivity. So, while winter could be dark and desperate, we are hopefully facing a brighter spring."

DAN SMITH

Haematology Manager, Oxford University Hospitals

This winter will be a difficult one for pathology. While hoping COVID levels do not approach those seen in 2020 and 2021, there is an expectation of an increase in COVID and other respiratory infections leading to an increase in testing. The traditional pressures of increased winter illness will happen. Haematology and chemistry colleagues will be supporting very busy services in A&E and other acute access areas. Initiatives to expand access to primary care will create increased demand at non-traditional times with phlebotomy increasingly available at weekends. A network of community diagnostic centres is coming online and, while the main focus is radiology, most will provide more open-access phlebotomy to support additional access after the last two years of disruption. Elective waiting lists are at record levels and the NHS nationally is signed up to try to eliminate all waits of more than 18 months by March 2023 (a long way from the previous 18-week standard). This is going to lead to competing priorities between elective and acute cases and pathology under pressure to support both simultaneously."

MADIHAH ABBAS

Specialist Biochemistry Team Manager, The Christie Pathology Partnership

"The biggest challenge in winter for the NHS will be maintaining a

"We will deliver excellent clinical care for patients, as we always do, with creativity and tenacity, perhaps doing our brightest work of the year in the darkness of winter"

"As a workforce we will need to adapt by strengthening compassion and the inclusive culture and looking at new ways of working"

robust service that can cater to demanding turnaround times within emergency departments in health and social care trusts, with an expected rise of potential COVID/flu A/B cases and increased general activity. There is also a lack of experienced biomedical scientist staff who can fulfil advanced roles. As a workforce we will need to adapt by strengthening the compassionate and inclusive culture and looking at new ways of working alongside investing more within our immediate workforce to ensure they are equipped with the necessary skills to facilitate our journey through winter."

DAVID WESTRIP

Senior Biomedical Scientist and Training Manager, Microbiology, East Kent University Hospitals NHS Foundation Trust

"Microbiology departments this winter bring a degree of uncertainty as we adapt to fluctuating demands whilst continuing to provide an effective, patient-focused service. The legacy of SARS-CoV-2 and the pandemic response means we are still reacting to changing patterns of traditionally seasonal pathogens; winter pressures seem to come earlier each year and who knows what new demands flu will make on already very busy laboratories. All this on a pretence of returning to business as usual. Staff originally taken on in fixed-term positions to support the COVID testing, having acquired useful skills and training, are now reaching the end of these contracts. Losing these staff now as additional funding dries up may prove to be short-sighted in the long term."

NICKI LAWRENCE

Principal Biomedical Scientist Advanced Practitioner in Morphology, Haematology, University Hospital of North Midlands NHS Trust

"The winter months ahead will continue to be a challenging time for pathology and the NHS as we continue to face winter pressures from seasonal flu and the lasting effects of COVID-19. From a personal perspective, my winter will be spent continuing to provide our usual high-quality service in haematology, whilst also focusing on service development again, which I feel took a hit while we battled through the pandemic."

COLIN MUDD

Higher Specialist Biomedical Scientist, Nottingham University Hospitals NHS Trust

"From a personal perspective, I feel rather uneasy, and certainly apprehensive. It is one of those occasions when I would prefer to be wrong and the wisdom of hindsight shows that my fears were unfounded. That is to say I am concerned that staffing will not markedly improve and that the pressures on our hospitals and all those businesses that provide us with vital supplies will not ease. That's on the negative side. On a positive side, we have shown what we are capable of doing – being a tremendous contributor to the health of the nation, and, by working effectively together, if needs be... we can do it again..." BMS

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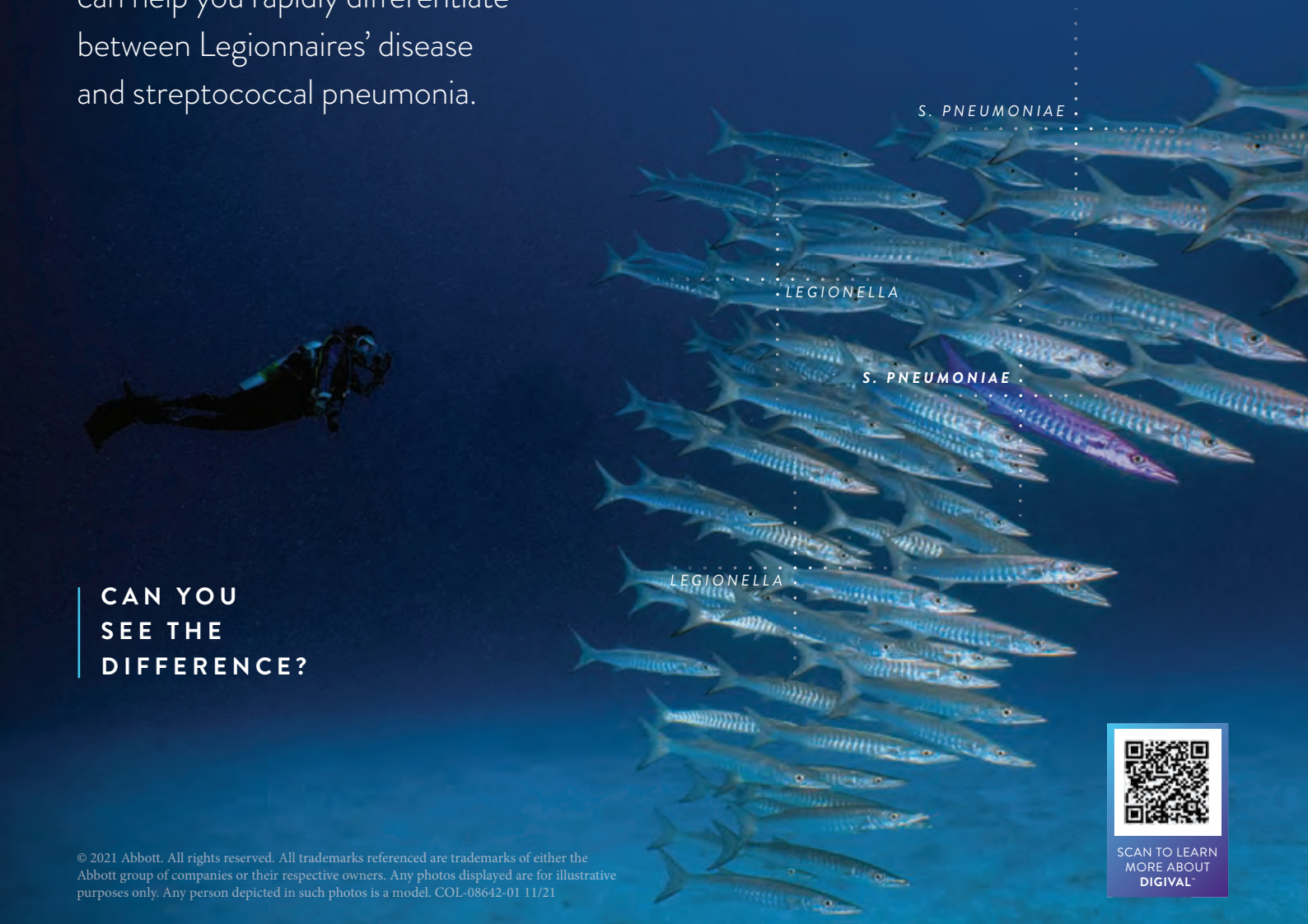

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A RARE DIAGNOSTIC ENTITY CASE STUDY

Cheyanne Box and **Tim Farren** present a blastic plasmacytoid dendritic cell neoplasm case study.

Leukaemia at its simplest can be described as a malignant proliferation of white blood cells, which can be categorised into acute and chronic subtypes, from myeloid or lymphoid lineage. Acute leukaemia is defined as a rapid uncontrolled progression of immature white blood cells, whereas chronic leukaemia is a slower progression of more mature and functionally competent white blood cells.

Diagnosis is based on the World Health Organization (WHO) classification of haematopoietic and lymphoid tissues, which provides an integrated scientific and clinical approach for these complex neoplasms. One such entity, which is somewhat challenging to diagnose due to its overlapping features with other malignancies, is blastic plasmacytoid dendritic cell neoplasm (BPDCN). This neoplasm has historically been underdiagnosed and confused with several other haematological malignancies, including acute myeloid leukaemia (AML), but also misdiagnosed as infectious diseases for which patients may receive ineffective antibiotic therapy.

What is BPDCN?

BPDCN is an aggressive and extremely rare haematological malignancy derived from precursor plasmacytoid dendritic cells (pDCs) that overexpress CD123, known as interleukin-3 receptor subunit alpha (IL3Rα). It is postulated that these cells have defective type 1 interferon signalling, which may be related to E-cadherin expression. BPDCN was historically termed "Natural Killer cell leukaemia" or " Blastic natural killer lymphoma", but, as of 2016, the WHO listed BPDCN as its own distinct entity.

BPDCN is extremely rare with a poor prognosis and is suggested to account for <1% of all haematological malignancies. Patients often present with widespread disease involving multiple anatomic sites, primarily the skin, lymph nodes, bone marrow and peripheral blood, although the latter can be minimal at presentation.

Approximately 80% of patients present with cutaneous involvement, with skin lesions described as plaques or purplish pustules that can disseminate systemically rapidly and aggressively. Patients also commonly present with cytopenias (especially thrombocytopenia), lymphadenopathy and splenomegaly.

It is estimated that the incidence of central nervous system (CNS) involvement in BPDCN may be 10% or more, and many chemotherapy regimens used in BPDCN have included intrathecal chemotherapy.

Although there is no known aetiology, there is a common association with other myeloid malignancies, such as myelodysplastic syndrome (MDS) and chronic myelomonocytic leukaemia (CMML).

BPDCN predominantly affects men with a 4:1 ratio, with the mean incidence occurring in patients aged 60–70 years, but can occur at any age with a bimodal age distribution; survival rates usually range between 9–24 months, irrespective of the initial presentation of the disease.

BPDCN is notoriously challenging to diagnose due to disease heterogeneity that overlaps with other malignancies, such as CMML. In these conditions, mature plasmacytoid dendritic cells lack CD56, but in BPDCN, they do not.

Upon laboratory testing, cell morphology can be misleading. Morphologically cells are medium sized, pseudopodia with an agranular appearance; they appear strongly basophilic with abundant cytoplasm with a low nuclear to cytoplasmic ratio often

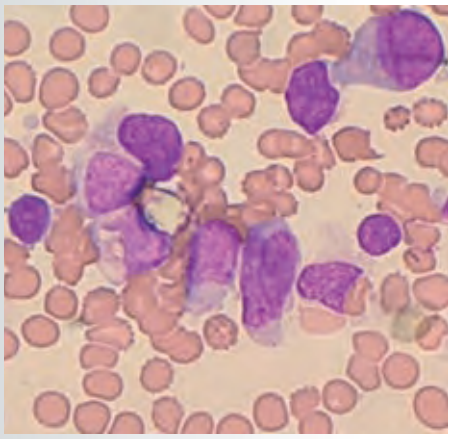


Figure 1. BMA showing BPDCN blasts with abundant cytoplasm, open chromatin, pleomorphic appearance with a proportion of cells resembling a hand mirror.

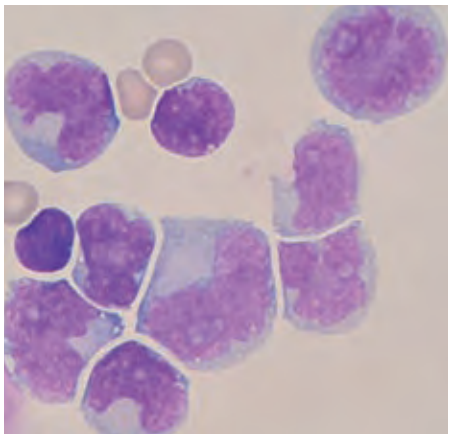


Figure 2. CSF infiltration of BPDCN showing large BPDCN blasts with a low nuclear: cytoplasmic ratio, abundant basophilic cytoplasm, pleomorphic appearance, and visible nucleoli.

containing microvacuoles. BPDCN diagnoses are based on a combination of morphological features and characteristic immunophenotype by either flow cytometry or immunohistochemistry.

Diagnosing BPDCN

Immunohistochemical (IHC) staining is an important diagnostic tool used to diagnose BPDCN and commonly shows positive staining for markers such as CD4, CD56, CD123, HLA-DR and TCL-1, and can be considered pathogenomic of BPDCN.

There are only a few recurrent genetic abnormalities that have been discovered in BPDCN, such as *TET2* and *ASXL1*; however, no single cytogenetic change is specific or diagnostic, although monoallelic and biallelic *12p13/ETV* deletions have been reported, and complex karyotypes are common.

Despite various therapeutic options, there is a lack of approved therapies and no centralised approach to these treating patients. AML, ALL and lymphoma treatment regimens that have been used have had minimal success, which highlights the significance of an early and accurate diagnosis.

Case report

A 76-year-old male presented with reduced appetite, weight loss, splenomegaly, thrombocytopenia, and skin lesions. He was subsequently referred for investigation to initially rule out MDS syndrome (MDS). The bone marrow aspirate (BMA) was sent for immunophenotyping, cytogenetic and molecular analysis.

Histological investigations on a skin biopsy discovered a population of blast cells with round to oval nuclei with irregular nuclear margins. Immunohistochemistry (cytology) found a blast infiltrate that exhibited aberrant coexpression of CD4, CD56, TdT and CD123.

Immunophenotyping found a population of cells that expressed CD123, HLA-DR, CD56 and CD7. Upon morphological examination, a heavy infiltration by large blasts with open chromatin with many elongated hand mirror forms made up 71% of total nuclear cells (TNC) with very little background granulopoiesis. This infiltrate was found in both the BMA and CSF.

Several genetic mutations were detected, including *ASXL1*, *KRAS* and *PTPN11*, and *TET2*, with the latter being the most commonly mutated gene in BPDCN.

This patient was treated with tagraxofusp, a CD123-directed cytotoxin made up of interleukin-3 bound to truncated diphtheria toxin under compassionate use. Tagraxofusp was approved by the FDA in 2018 but is still awaiting NICE approval. The response was inadequate, and the patient was moved on to the UKALL60+ regimen. This regimen follows successive phases to try and elicit a response; treatment starts with phase 1 induction, followed by phase 2 induction, then consolidation and finally maintenance. This regimen includes the drugs:

- Dexamethasone
- Idarubicin
- Vincristine
- Cyclophosphamide
- Cytarabine.

Conclusion

BPDCN is an extremely rare haematological malignancy comprising immature cells with plasmacytoid dendritic cell differentiation, which diagnostically can be challenging and requires differentiation from acute leukaemia.

The recent introduction of newer targeted therapies has seen promising results and novel toxicities that are important to understand and recognise. Targeted therapy with tagraxofusp has been beneficial showing improved overall response rates and overall survival, but this therapy is usually reserved with the mainstay therapy based on cytotoxic chemotherapy. Stem cell transplantation after achieving remission is the mainstay of treatment among the younger and fitter eligible patients, regardless of therapeutic options used. However, the median age of onset for BPDCN is between the sixth and seventh decade of life and this is often not an option.

This case study highlights the need for integrated diagnostics within multiple laboratories to ensure a complete and proper investigation and correct and timely diagnosis. It also demonstrates collaborative working between dermatopathology and haematopathology. BMS

Cheyanne Box, Senior Biomedical Scientist in haematology at The Royal Marsden Hospital. Thanks to co-author **Tim Farren**, Head of Immunophenotyping and Scientific Lead for SIHMDS at NHS East and South East London Pathology Partnership. To see flow plots that accompany this case study, visit thebiomedicalscientist.net and type "BPDCN" into the search bar.

LABORATORY ERRORS IN TRANSFUSION

Anne Lockhart and **Nicola Swarbrick** explain the results in the latest annual Serious Hazards of Transfusion report.

Serious Hazards of Transfusion (SHOT) is the United Kingdom's independent, professionally led haemovigilance scheme. Since 1996, SHOT has collected and analysed anonymised information reported in the UK about serious adverse reactions and other serious adverse events related to blood transfusion. For the first time in 2021, SHOT saw 100% of UK NHS trusts/health boards that are registered to report to SHOT submit reports. In addition to this, there were 19 non-NHS organisations that submitted 49 reports in 2021.

The total number of reports analysed and included in the *Annual SHOT Report 2021* is 3161. This is a decrease of 53 from the 3214 reports analysed in the *Annual SHOT Report 2020*. The continuing high level of participation in haemovigilance reporting is a sign of a good reporting culture and reflects that an open and fair culture largely exists in the NHS where staff learn from things that have gone wrong. Organisations with a culture of high reporting are more likely to have developed proactive reporting and learning to ensure the services they provide are safe. Participation has continued despite the pandemic-related challenges and benchmarking of this data helps identify areas for improvement.

Excerpts from the laboratory errors chapter in the *Annual SHOT*

IMAGES: SHUTTERSTOCK

Report 2021 are highlighted in this article and should be cited as Narayan *et al.*, 2022.

Reduction in errors reported

Laboratory errors accounted for 573/3161 (18.1%) of all SHOT reports in 2021, a reduction from 639/3214 (19.9%) in 2020. This reduction is possibly due to improvement in practices, or continued pressures on laboratory staffing due to the COVID-19 pandemic, leading to reduced reporting.

The highest proportion of errors occurred within the component labelling, availability, handling, and storage (122/389), closely followed by the testing category (114/389) and component selection (91/389). These categories are similar to previous years. In total, 41% of laboratory errors occur out of routine hours, where additional pressures are often placed upon lone workers. A total of 126/184 of laboratory near-miss error reports stated that the event occurred due to failure to follow policy, confirming previous findings that policies must be clear, concise, and easy to follow. Figure 1 shows the pattern of laboratory reporting by step over the past five years.

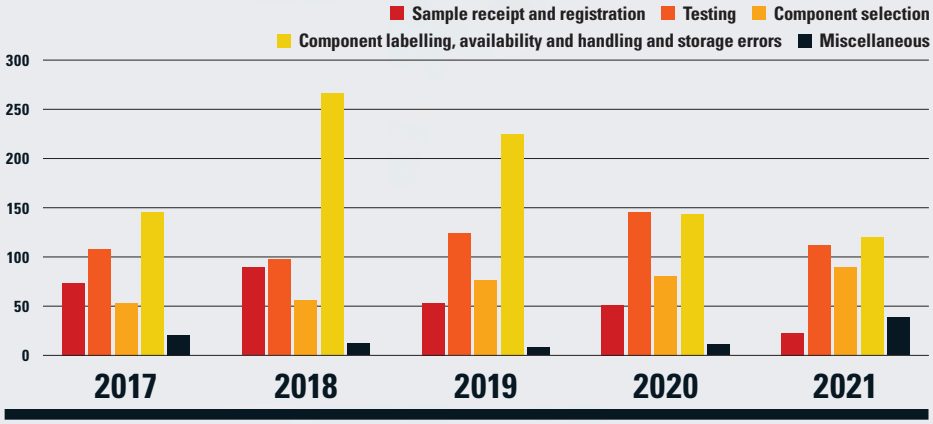
Messages and recommendations

Key SHOT messages and recommendations for the laboratory have been generated through the analysis of the laboratory errors in 2021.

Key SHOT messages

- Final checking of the unit before issuing is important. The use of label verification in LIMS or electronic blood-tracking systems helps to optimise safety
- LIMS alerts should be relevant, appropriate, not easily overridden and have an audit trail
- Communication between clinical teams and the laboratory, and between clinical teams in shared-care patients is vital to ensure provision of appropriate blood components
- Manual input of patient information and blood grouping results is prone to error. Independent checking processes should be in place where IT solutions are not available
- Release of red cells in a major haemorrhage situation should not be delayed whilst awaiting Hb results, or where recent Hb is within normal limits.

FIGURE 1: LABORATORY ERRORS 2017–2021 CATEGORISED BY STEP WHEN THE ERROR OCCURRED



Organisations with a culture of high reporting are more likely to have developed proactive reporting and learning to ensure the services they provide are safe.

Recommendations

- Laboratories should have training programmes and regular competency assessments that ensure staff have the appropriate knowledge and skills commensurate to their role
- Laboratories should have a schedule for regular LIMS upgrades in accordance with manufacturers' recommendations and contractual requirements. The operational LIMS should include all available functionality to support safe practice. Where deficiencies are noted, a roadmap for upgrade and/ or development should be in place and regularly reviewed by the laboratory management and the LIMS supplier
- The LIMS should be used to its full potential to support transfusion safety; transfusion service managers should work with the LIMS supplier to ensure that all functionality is available and operational to support safe laboratory transfusion practice
- Laboratories should have capacity plans in place that

include all aspects of transfusion practice. These should be reviewed regularly and have appropriate escalation processes when safe staffing levels are not met

- Interoperability between patient administration systems and LIMS reduces the risk of errors in manual registration of patient information. Transfusion service managers should work with the LIMS supplier and IT departments to explore options for interfacing.

Information technology

IT has become an integral part of the transfusion laboratory and is a recurring theme, highlighted again in this year's report. There is evidence that laboratory staff can get overwhelmed by multiple IT alerts, resulting in alert fatigue. Between 2016 and 2019, over 10% of SHOT reports stated the source of error was overriding alerts. This results in staff tendency to ignore notifications when they become too frequent with the potential for errors and impact on transfusion safety.

It has been identified that LIMS alerts should be driven by evidence, ensuring that an alert will only be triggered if appropriate and will inform a decision by the laboratory staff at the time required.

Analysis of the data submitted in relation to laboratory errors highlights the importance of performing the final checks on units before issuing to prevent errors. SHOT is introducing the PAUSE concept, encouraging laboratory staff to pause and recheck at this final critical step before the component is released for transfusion. This final check will ensure that all steps carried out prior to this have been performed correctly and that the unit is safe and suitable for transfusion. The key steps that staff should ask themselves at the point of component issue are detailed in Figure 2.

P ATIENT IDENTIFICATION
Are the details correct and do they match on sample/form/label/LIMS?

A UTHORISED
Have all required tests been completed and authorised, including antibody investigation?

U NIT NUMBER
Does the unit number match the compatibility label?

S ELECTION OF COMPONENT
Is it as requested?
Is it ABO AND D compatible?
Does it meet all specific requirements?

E XPIRY
Will the unit expire before required date/time? Will sample expire before required date/time?

Conclusion

Transfusion laboratories have a crucial role in ensuring safe and timely provision of suitable blood components for patients. A recurring theme over the last few years of SHOT reporting is that laboratory staff are working under increased pressure. This is reflected in this year's summary from NEQAS, which has seen errors in EQA reporting that can be attributed to pressures such as transcription errors and lack of individual knowledge.

"It has been identified that LIMS alerts should be driven by evidence, ensuring an alert will only be triggered if appropriate"

The United Kingdom Transfusion Laboratory Collaborative (UKTLC) surveys have highlighted staffing challenges, lack of appropriately trained scientists and increasing out-of-hours workload, which need to be addressed urgently to ensure transfusion safety, all of which have been worsened by the COVID-19 pandemic. The UKTLC standards from 2014 are being updated and a 2022 revision is due to be released to provide laboratories with guidance for staffing, education, culture and IT.

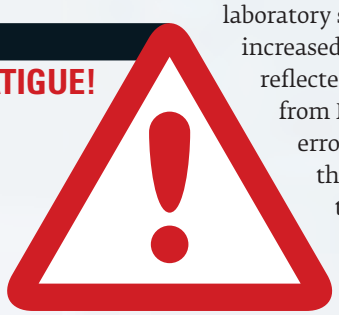
In order to improve transfusion safety, laboratory staff (and all staff involved in the transfusion process) should take heed of the key SHOT messages and recommendations. A strong learning culture that continually adapts and transforms will ensure that learning is optimised from all experiences, adverse events, and instances of excellent care.

The Annual SHOT Report 2021 for incidents reported in 2021 was published in July and is available, along with previous reports, on the SHOT website. IBMS

Anne Lockhart is the SHOT IBMS Steering Group Representative and **Nicola Swarbrick** is a SHOT Laboratory Incident Specialist.

BEWARE OF ALERT FATIGUE!
ALERTS SHOULD BE

- **Relevant**
- **Understandable**
- **Actionable**
- **Not easily overridden**
- **Auditable.**



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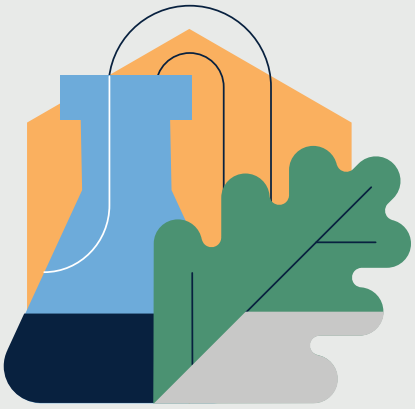

CLINICAL LABORATORY SUSTAINABILITY
AN EVOLVING PICTURE

Sheri Scott, a Senior Lecturer in Biomedical Science at Nottingham Trent University, looks at the latest developments.

The climate and ecological crisis represent the most important threat to human health and wellbeing of the century. Climate change is in the news, in our politics and sustainability is consequently appearing on every organisation's agenda.

The Health and Care Act 2022, which came into effect this July, has placed specific duties on the NHS in England, to ensure that climate change is considered when making key decisions. This legislation ensures that NHS organisations are compliant with the UK's Climate Change Act 2008 and includes targets to reduce greenhouse gas emissions and improve the natural environment, including air quality. The Health and Care Act also mandates that the NHS "must adapt to any reported current or predicted impacts of climate change". These requirements correspond closely to the European Green Deal (EGD), which aims to make Europe the world's first climate-neutral continent by 2050. The EGD has a vision of overcoming climate change and environmental degradation challenges, transforming the EU into a resource-efficient and competitive economy.

What is clear is that the climate health emergency is real, and we all have a responsibility in enabling positive change. More than ever there is the need for a collaborative approach for these ambitions to be realised.

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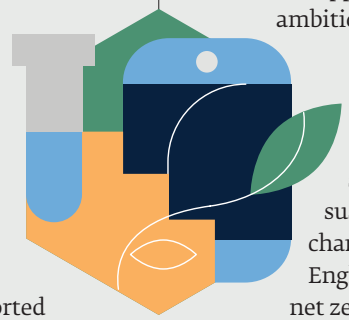
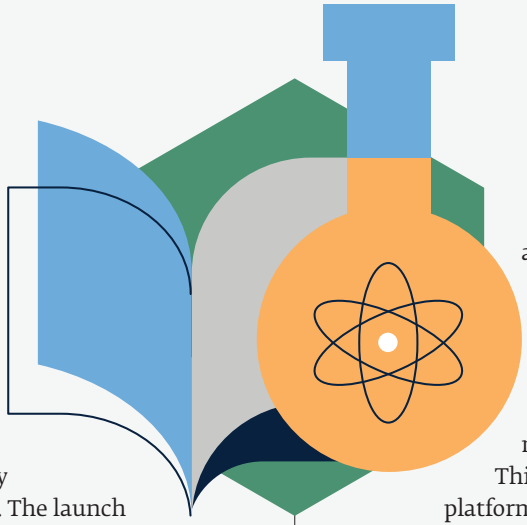


Play a part

During the past 24 months, the NHS has stepped up its game on sustainability and climate change. Every trust in England now has its own net zero strategy, and all NHS



procurements include a minimum 10% net zero and social value weighting. But how many of the green plans consider pathology?

It has become imperative that clinical laboratories play their own part in supporting these ambitions. Clinical laboratories are high energy and water consumers, and they generate huge amounts of hazardous and non-hazardous waste. Labs consume more energy per square metre than most other industries. A total of 40% of global CO_2 emissions come from generating electricity and, as such, labs contribute to the largest percentage of carbon emissions. When we consider that a typical new ultra-low temperature (ULT) freezer will consume as much electricity in a year as an average UK household – not to mention fume cupboards, laboratory automation and IT equipment – it is not surprising that laboratories typically consume 5–10 times more energy than office buildings. In addition to this, if we consider the use and disposal of single-use plastics, and the use of hazardous materials, the environmental impact of clinical labs is substantial (in 2014, lab plastics were estimated to contribute 1.8% to the total global plastic waste).

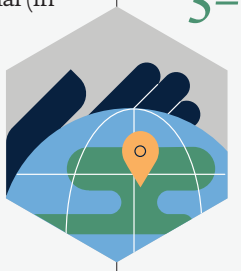
Green certification in the academic and research sector in the form of LEAF and My Green Lab programmes is well established, but how adaptable are these certifications to the tightly regulated clinical lab? Both these organisations are now branching into clinical lab sustainability but when it comes to patient safety and quality drivers, UKAS-accredited laboratories have limited leeway on making changes in the same way an academic or research laboratory can. However, there are changes that can be made that will not impact patient safety.

Key initiatives

I am fortunate enough to be involved in two key initiatives that will help clinical laboratories embrace more environmentally sound practices. The launch of the Centres for Sustainable Healthcare Clinical Labs Susnet network and the European Federation of Clinical Chemistry and Laboratory Medicine Green Labs (EFLM GL) Taskforce, pave the way for more sustainable practice.

The Centre for Sustainable Healthcare (CSH) is "an organisation that offers strategic input and consultancy on sustainable healthcare research and practice". This organisation works with Greener NHS and NHS England in sustainability education.

"It is not surprising that laboratories typically consume 5–10 times more energy than office buildings"



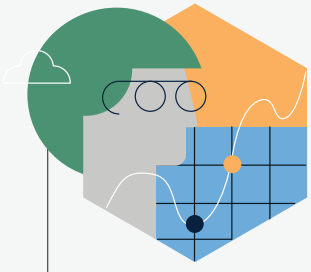
The CSH has a Sustainable Specialties networking programme, which mainstreams sustainability within different clinical specialities, so that sustainability becomes integral to the planning of health systems and healthcare practice in all aspects of healthcare. The Clinical Labs Susnet network is one of their newer specialities. Launched in June, Clinical Labs Susnet provides clinical laboratory professionals, the *in vitro* diagnostics industry, educators and students across biomedical and healthcare science with their own online sustainability networking space. This space provides a platform for like-minded individuals with a passion for sustainability to come together, share ideas, resources and collaborate to embed sustainable practice into pathology and associated healthcare laboratories.

Membership of this network is growing and conversations around projects, ideas and best practices are already taking place. As the membership and resource list grow, connections are being made that will foster collaborative research and promote service improvements. As lead for this network, our next objective is to offer panel discussions and training in collaboration with professional bodies and the EFLM GL Taskforce. The EFLM GL Taskforce aims to transform clinical laboratories into safe and sustainable spaces by reducing their environmental impact. It is hoped that collaboration and teamwork will bridge the gap in knowledge and skills among healthcare lab professionals, helping to deliver more sustainable practice.

The main aim of the taskforce is to facilitate the implementation of efficient and more environmentally sound everyday actions within laboratories at an international level. This aims to minimise energy, water, and hazardous chemical use, as well as reduce waste generation within the lab environment, without compromising the quality of healthcare we have come to expect. The hope is for EFLM to lead the laboratory medicine community in the shift to carbon neutrality and it recognises good collaboration among the EU healthcare systems is needed to ensure environment-friendly laboratories in the future.

Clinical laboratories can limit their

environmental impact and provide sustainable services by making reductions in four key areas – energy consumption, water consumption, waste production and use of hazardous chemicals.



"It is through partnerships that collaborative change will be recognised"

Guidelines

The taskforce aims to achieve safe and sustainable space transformation, by providing guidance on ways to make these reductions and providing ways to adopt efficient actions to minimise energy, water, and hazardous chemical use.

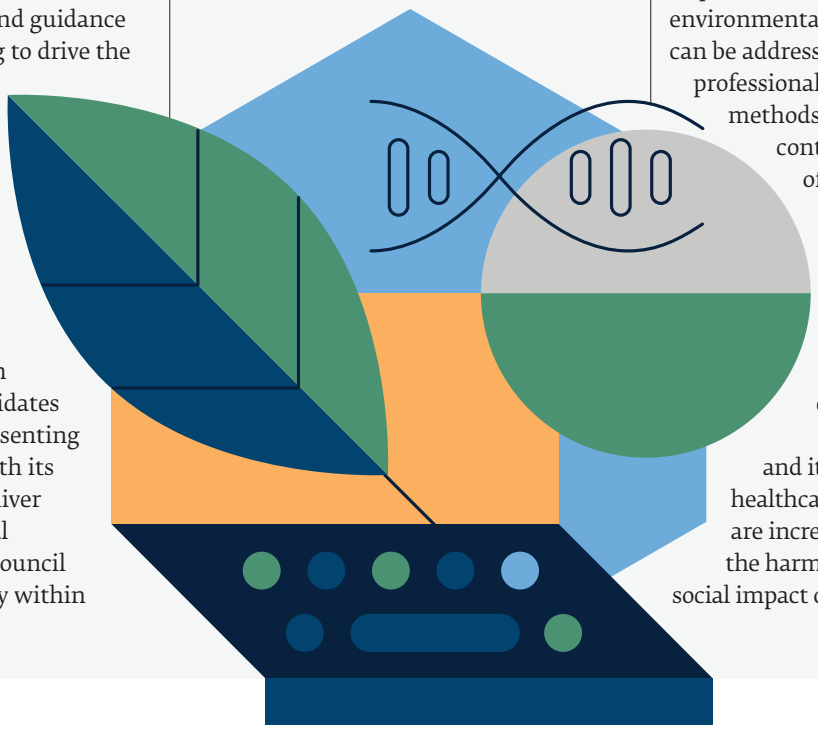
The initial objective of this new EFLM Taskforce was to create "Green Lab" guidelines, target criteria, and key recommendations for sustainable practices in clinical laboratories (a Green Lab Guide) before implementing a system of transition and annual EFLM certification.

Co-authored by the core members of the taskforce, these guidelines are now published and provide key information and justification for manageable change, and it is hoped that these changes will be embraced and adopted as part of wider sustainability agenda of the NHS and other European Healthcare institutions.

Clinical lab sustainability now has a platform for collaboration and guidance for change, but who is going to drive the changes we need to see? This question has been answered in the call for sustainability champions.

The Association for Clinical Biochemistry and Laboratory Medicine (ACB) put out a call for voluntary Sustainability Champions in Spring. The successful candidates share responsibility of representing the organisation to work with its members to develop and deliver a strategy for environmental sustainability. As an IBMS Council member, I have a role to play within the IBMS to support lab sustainability. It will be through sustainability champions that the training materials produced by the EFLM GL Taskforce will be distributed to its members, and it is through partnerships that collaborative change will be recognised. At this year's UKLABMed22 in November, we will see a sustainability workshop supported by key stakeholders including the institute and the British In Vitro Diagnostic Association (BIVDA), and through other key events in the lab professionals' calendar, we can expect to see similar opportunities to develop knowledge and skills in lab sustainability.

The Sustainability Champion role can also be found in our hospitals. Many organisations and NHS trusts have advocates for sustainable practices. It is important that we as a profession join our voice to the collective. Upon researching clinical lab sustainability this year, it was worrying how little lab sustainability had been considered in hospital sustainability plans and agendas. Going forward, we need to join in these conversations and represent our profession. One way of achieving this is for lab professionals to consider the sustainability champion role within their trust or organisation, thus ensuring that the "hidden profession" has a voice. By working across all professions, a positive sustainable impact can be achieved either through education, such as sustainability training (induction and local CPD seminars) or through projects such as reducing waste by more environmentally lean practice, embracing appropriate POCT or by the elimination of error as part of sustainability service improvement (SusQI).



Embedding sustainability

SusQI is a CSH term, which describes the embedding of sustainability into quality improvement. It is a way that social and environmental challenges in healthcare can be addressed as a core part of professional practice, using recognised methods for change in order to contribute to the improvement of healthcare services. I hope to see the implementation of SusQI into routine practice and I wish to bring the fundamentals of this and sustainability awareness into all levels of education and assessment. Positive change is coming and it is gratifying to see that healthcare laboratory professionals are increasingly motivated to reduce the harmful environmental and social impact of our health systems. IBMS

UKAS ANDROLOGY ACCREDITATION

Dave Sanders, **John Ringrow** and **Al Bryant** from UKAS give an update on the examination and processing of human semen.

In 2021, the World Health Organization published the 6th Edition of the *WHO laboratory manual for the examination and processing of human semen*. For many organisations accredited by the United Kingdom Accreditation Service (UKAS), this is the go-to reference document for diagnostic semen analysis. This document is referenced on UKAS schedules of accreditation as the methodology applied by laboratories providing accredited fertility analysis services in the UK.

UKAS is the sole national accreditation body for the UK and is recognised by government to assess, against nationally and internationally agreed standards, organisations that provide conformity assessment services, such as certification, testing, inspection, calibration and verification.

Accreditation builds public confidence in standards and quality initiatives. Assessment and accreditation by UKAS promotes the importance of quality performance requirements and verifies that they are met. This delivers an independent, impartial confirmation of technical competence.

The wide range of sectors accredited by UKAS reflects the demand from departments and policymakers across all areas of government and the public sector. Working with UKAS, they gain a trusted and experienced partner and access to an internationally recognised and well-established accreditation service.

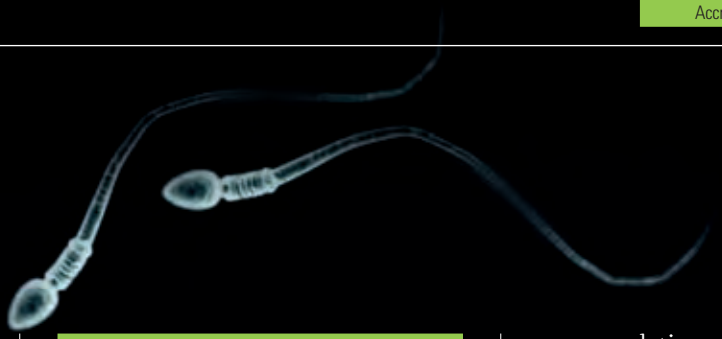
Throughout 2022, UKAS has been establishing the transition process for accredited laboratories, from WHO 2010 to WHO 2021. To manage this efficiently, and to ensure that there is not any perceived commercial advantage by being the first to transition, the transitions will take place independent of each laboratory's standard annual assessment. All laboratories will be assessed within a two-month period and all schedules of accreditation will be published on the same date (assuming any findings raised during the assessment have been cleared).

Schedule of accreditation

The schedule of accreditation is a critical document, as it defines the measurement capabilities, ranges and boundaries of the activities for which the organisation holds accreditation. Each accredited organisation's schedule is published on the UKAS website and is publicly available to view on the UKAS website. Whilst most andrology laboratories are accredited to ISO 15189:2012, there are a small number that are accredited to ISO 17025:2017. Regardless of the accreditation standard, the transition process will remain the same.

All currently accredited laboratories will shortly receive communication from UKAS confirming the transition process.

Laboratories need to perform a gap



analysis to identify the differences between the 2010 and 2021 laboratory manuals and will need to implement appropriate changes to laboratory documentation and practice.

To transition, UKAS will require all laboratories to submit requested documentation to UKAS in January 2023. During March and April 2023, the submitted documentation will be assessed by UKAS, to ensure that the laboratory's own transition activities demonstrate conformance to the requirements of the relevant ISO standard and to the new WHO 2021 laboratory manual. Subject to a positive recommendation, and clearance of any mandatory findings raised, laboratories will transition to accreditation to the 2021 laboratory manual, and the schedules of accreditation will be updated to reflect this.

Key areas of change

To transition UKAS accreditation to the 2021 laboratory manual, laboratories will need to submit to UKAS evidence of actions taken to address the changes from the 2010 manual. UKAS has identified some key areas of change (see box, right).

UKAS has produced a gap analysis template for laboratories to complete and submit their documentation, linking the evidence to the relevant clause within ISO 15189:2012 and section of the WHO 2021 manual. This template shall be provided to all accredited laboratories, and enables laboratories to embed the documentation that is relevant to each specific area. The gap analysis will also be available on the UKAS website in due course.

Laboratories will be asked to provide evidence covering at least the following requirements:

- Training and competence
- Information for users
- Pre-examination processes
- Selection, verification and validation
- Reporting of results
- Quality assurance.

IMAGES: SCIENCE PHOTO LIBRARY

KEY AREAS OF CHANGE

Sample collection: More detail has been given regarding sample collection, transportation and pre-examination.

Examination processes: Additional detail is included in the 2021 manual. Motility is now to be assessed as four grades; many experienced andrologists will remember this from earlier versions of WHO. The need for replicate dilutions or assessments of slides has been updated. This is reliant on effective sample mixing processes to attempt to achieve homogeneity in the sample. For morphology, in addition to assessing the percentage "ideal" sperm, there is also a requirement to determine the prevalence of the individual defects.

Reporting: Decision limits are now given. Whilst similar to the previous reference limits, there have been some changes.

Only documents that provide evidence directly relating to the area of the standard listed in the gap analysis should be submitted. When submitting evidence, the laboratory shall ensure that the relevant sections of any documents are referenced in the gap analysis (e.g. "see paragraph 4.3"). If large documents are submitted without guidance, there is a risk that the key evidence points could be missed, resulting in a non-conformance being raised.

Where non-conformance is identified, UKAS shall raise an improvement action, as per all UKAS assessments. Where findings are raised, there will be a four-week period for the laboratories to implement any required actions, and to submit evidence for UKAS to review. An assessment report (including a recommendation on the transition) shall be issued following the assessment.

Practical challenges

It is UKAS's experience that accredited laboratories have a good understanding of the accreditation process and employ knowledgeable and competent staff. UKAS acknowledges that there are some practical challenges associated with implementing the requirements of the updated WHO laboratory manual, but remains confident that accredited laboratories will understand and implement all required changes. We advise all affected laboratories to use this time (prior to the document submission due date) to prepare; familiarise technical and management staff with the WHO 2021 laboratory manual and identify and implement necessary changes.

Any questions about the transition process are to be directed to the laboratory's UKAS Assessment Manager in the first instance. Unaccredited laboratories interested in finding out more about accreditation can find information on the UKAS website (ukas.com) or contact info@ukas.com. BMS

Dave Sanders is an Assessment Manager, **John Ringrow** is a Senior Assessment Manager and **Al Bryant** is a Healthcare Accreditation Specialist. All are based at UKAS.

RACE & EQUALITY POSITIVE CHANGE

Aneela Arshad, Biomedical Scientist and Black, Asian and Minority Ethnic Network Co-Chair, discusses the founding of the network.

The Black Lives Matter events of 2020 that escalated globally after the tragic death of George Floyd in the US resonated deeply with so many of us in a way not seen before. Coupled with the pandemic and the impact this was having on black and minority ethnic people in the UK, it was important that frank discussions about race and equality had to take place. This forced institutions to recognise and assess unconscious bias behaviours and bring about a positive change in the workforce.

This was particularly apparent at the Queen Victoria Hospital, where I am based. When our Chief Executive sent out a poignant email acknowledging the events taking place and the personal effect on him, it deeply impacted me because it was so refreshing and honest.

He didn't claim to understand all the issues or profess to have all the solutions – instead he was open and transparent about his lack of understanding of the complex issues involved. He stated: "I do know that as someone who is empowered and white, and as a leader in the NHS, I have a responsibility to listen, to learn and to act." And this action was to set up and support the Black, Asian and Minority Ethnic Network at the trust.

Being heard

Initially, I had no intention of being part of the network – with a demanding full-time role as a Senior Biomedical Scientist and Quality and Training Lead in histopathology, as well as a busy home life, it was unfathomable to think about adding another role to my repertoire at this point. After much deliberation, discussion and research I decided to apply because it was the right thing to do. I wanted to initiate change and be part of that change. I wanted to help create support systems where black, Asian and minority ethnic staff could truly be heard.

Setting up the network was very important and what could be a better time to try and facilitate this than now, when these hard-hitting issues were being discussed on public platforms across the country? It is difficult to diagnose systemic racism, especially within the NHS, which is why the role and network was so essential.

Network role

The role is shared between me and a colleague who is the theatre nurse lead. This has been extremely advantageous as we have been able to cover a wide staff demographic. It has also been an excellent personal development opportunity – learning how to set up a network from the ground up, project manage the objectives and deal with senior and executive-level staff to ensure goals are realised and delivered. This has been particularly valuable as it means being able to influence at all levels across the trust and develop ties with key operational areas.

The role has allowed us to have a visible presence within the trust and input our objectives and feedback into the wider staff priorities.

The most vital aspect for me as the Network Co-Chair has been to ensure minority ethnic staff are heard and supported. Initially, issues were raised about the need for a network and there was possibly some resentment. By presenting trust data and holding interactive sessions with all staff, those feelings were soon resolved. The NHS

"Staff could feel a change in culture, felt better supported and wanted to help build the network to provide further support for others"

needs to take a strategic approach to instil a culture of inclusion, which then links to better healthcare.

Embedding accountability

We are part of the education and development board meetings to ensure that not only are equal opportunities in place but to provide additional opportunities where needed and set up a protected talent pool. Furthermore, for all senior band 8 and above positions within the trust there is a designated network representative on the interview panel. This has enabled us to embed accountability within core policies and allow the comfortable discussion of race equality to make positive changes. The most rewarding side has been the feedback from staff. Minority staff feel heard and more protected knowing that there is now a system in place with staff who understand their concerns, vulnerabilities and fears. We can guide our colleagues to the appropriate avenues, such as liaising with the Freedom to Speak Up guardian and HR support, while providing additional support if needed.

Although the network has faced challenges, the fact that we are being supported by the trust demonstrates that the organisation is trying to make positive changes. Anonymous feedback from questionnaires showed that staff could feel a change in culture, felt better supported and wanted to help build the network to provide further support for others.

We have also set up an Ally Mentoring Scheme – where white colleagues want to learn how to provide support and appreciate the issues black, Asian and minority ethnic staff face. This could be in the form of mentoring, counselling and/or training. A key aspect of the training is understanding unconscious bias and white privilege. We have been able to provide courses on this and tackling racism within the NHS.

The support is out there and we have liaised with other trusts, had critical conversations on podcasts and ensured our intranet has the latest information for staff. New-starter welcome packs have detailed information about the network and we have been able to provide extensive pastoral care for staff recruited from abroad.

Conclusion

There are significant cultural challenges within the NHS that prevent staff with an ethnic minority background access to equal career opportunities and fair treatment. We must continue to delve beyond our comfort zones and have difficult conversations to ensure racial equality remains a top priority for the NHS and the diversity of our workforce is valued. BMS

IMAGES: ISTOCK

SOURCING INFORMATION FOR ASSIGNMENTS

The third instalment of an occasional column by Biomedical Science Programme Leader **Dr Lynne Lawrance**, for training officers and others supporting students undertaking degrees.

The first step in creating a good assignment is to select good sources: as the saying goes "garbage in: garbage out". Your students will have been given guidance on this, but how well they have engaged with it is variable; any support you can give to help them make good choices will be valuable.

The appropriateness of a source depends on the stage of their studies – what is appropriate for a first-year undergraduate is often of too low a level for a Masters student, though to complicate things it depends on the role the source is playing.

Taking information in a textbook as an example, this would be appropriate for most first-year assessments, where acquisition of core knowledge is the priority. By their third year, students should be using journal articles more (the second year is a transition phase), and by Masters, sourcing should be primarily from journal articles. However, use of textbook material could be appropriate for "deep background" in an introductory paragraph, though a review article from a peer-reviewed journal would be a better choice.

Using material from the internet needs to be carefully considered, but there are times when it is the most appropriate source. There are well-curated reliable sources, e.g. the WHO website, and epidemiological data will always be more up to date on the internet then in papers due to the publication process. Of course, most journals these days are housed online but are recognised as journals

when it comes to academic work. Online encyclopaedias can be a good starting point, but where they are user edited they can have factual errors. They should rarely be referenced but sourcing of the primary papers that the encyclopaedia cites should be encouraged.

Please, help your students understand source bias. Bias is not something to avoid, especially in the later years of study, it is something that students need to tackle. Some bias is really clear, e.g. opinion pieces and commentaries. Other biases are subtle, and even highly regarded sources such as the WHO have a bias – a pro-health one. Even lab documents such as SOPs will have bias or a rationale for a choice made (e.g. using CLED over MacConkey or vice versa, revealing my bias towards microbiology).

Always encourage your students to read widely for their essays. Over-reliance on a single source raises the risk of an assessment offence, and of over-simplifying a topic. There is also the risk of picking a source that is "wrong" or represents a minority view as "the" only view. At higher-level academic assignments you should expect students to show integration of multiple sources to form their own evidence-based view of a subject.

However, reading widely needs to be balanced against information overload. The volume of material available to students via internet search engines or journal searches is massive, especially if your memory goes back to hardcopy Index Medicus or library microfiches! Your student will need help in developing the skills to separate the wheat from the chaff. BMS

IMAGES: ISTOCK

MY IBMS NEWS

CPD EVENT

SIGN UP FOR THE BIOMEDICAL SCIENTIST LIVE

The Biomedical Scientist Live is returning this autumn and registrations are open for the virtual event.

This November, the IBMS is hosting the two-day digital event, which will feature a packed line-up of knowledge-sharing sessions, including seminars, presentations, discussions and demonstrations.

Since the global pandemic, the profession has gained increasing traction in the media spotlight, with biomedical scientists being called on to tackle a multitude of challenges presented by the COVID-19 outbreak.

The Biomedical Scientist Live will bring experts in the field together to present their research findings and to showcase cutting-edge developments across the field.

The event is free to access for IBMS members.

More information, including a full programme, will be available on the dedicated event website in due course.

→ To register, visit the website live.thebiomedicalscientist.net/registration

CPD AWARDS

IBMS members shortlisted

The Science Council has shortlisted several IBMS members for the CPD Awards 2022.

A total of eight members have made it to the second round of judging for the CPD Awards 2022.

The shortlisted members are: Jodelyn Marquez Asinas, Victoria Barnwell, Gareth Blackburn, Clare Ellis, Bamidele Farinre, Timothy Farren, Alison Muir and Sheri Scott.

Once the winners have been selected, they will be invited to the award ceremony on 21 November in London.

The awards will be part of the Science Council's Celebration of Science Event alongside the 2022 Roberts Lecture, with Professor Dame Ottoline Leyser speaking.

Last year, two IBMS members were recognised for their outstanding record of continuous professional development at the Science Council's CPD awards: IBMS Fellow Mark Cioni won the CPD award in the Chartered Scientist category and Victoria Moyse was commended in the same category.

→ For more information, visit sciencecouncil.org

REGULATION

SAFER CARE FOR ALL REPORT

The Professional Standards Authority for Health and Social Care has published its *Safer care for all – Solutions from professional regulation and beyond* report.

The report was launched in September 2022 at a Parliamentary reception in the House of Lords.

IBMS President Debra Padgett represented the IBMS at the event.

She said: "I welcome the report and the recommendations outlined. Patient safety is something that we should all hold at the centre of the work we do.

"It was heartening to hear that there was an understanding that regulation of biomedical scientists (and wider healthcare professions) keeps the public safe, supports the delivery of a workforce strategy, facilitates the continuous development of our teams and provides confidence to the public in the services we deliver."

The Professional Standards Authority for Health and Social Care was established by Parliament in 2002 to improve the regulation of healthcare professionals.

The new report examines the current state of professional health and care regulation in the UK, and identifies and proposes solutions to some of the huge challenges in health and social care today.

It considers four main themes: tackling inequalities, regulating for new risks, facing up to the workforce crisis and accountability, fear, and public safety. It also looks into "structural flaws in the safety framework".

→ **To read the report, visit bit.ly/3UnhEhz**

LEGISLATION

Coronavirus test device approval

The UK Government has issued a call for evidence on the coronavirus test device approval process.

In July 2021, legislation came into force that introduced validation for antigen and molecular coronavirus (COVID-19) detection tests.

This call for evidence aims to support the government's understanding of the impact the Coronavirus Test Device Approval (CTDA) process has had on the wider internal market, individual business and trade flow of antigen and molecular COVID-19 tests.

This will support the wider statutory review of the policy that will be reported on by 31 December 2022.

The call for evidence aims to obtain specific evidence in relation to businesses operating in the COVID-19 diagnostics market.

The UK government is seeking evidence and opinions on the following areas:

- Costs for individual businesses involved in the domestic COVID-19 test kit sector
- Scale and nature of domestic COVID-19 test kit activity, including manufacturing and trading
- Scale and nature of activities abroad that are integral to our existing domestic COVID-19 test kit supply and market
- The direction of the COVID-19 test kit market
- How the CTDA objectives have been met and if they could be met more efficiently in future.

The IBMS will be submitting evidence on our members' behalf and has forwarded details to Company Members.

IMAGES: ISTOCK/SHUTTERSTOCK

MEMBER EVENT

AGM DETAILS

The IBMS West Midlands Region and Birmingham Branch Annual General Meeting takes place on 6 October.

The event starts at 6.30pm and can be attended in person or via Zoom.

It will be followed by a presentation "Obesity – is dieting wishful shrinking?" by Consultant in Clinical Chemistry Dr Helen Ashby.

→ **For further details, please contact Kathryn Dudley at K.DUDLEY2@WLV.AC.UK**

MEMBERSHIP

OBITUARY NOTICES

When the IBMS is informed of the death of a member, their names will be included in *the Biomedical Scientist* magazine.

The IBMS is sad to report it was informed of the deaths of the following members in July and August.

- Joyce Bunting
- David John Byrne
- Brian Henry Prichard
- Dr BJ Houghton.

JOURNAL-BASED LEARNING EXERCISES

Institute of Biomedical Science
Continuing Professional Development

Please select your choice of correct answers and complete the exercises online at: **www.ibms.org/cpd/jbl**

DEADLINE WEDNESDAY 4 JANUARY 2023

Rate of D-alloimmunization in trauma does not depend on the number of RhD-positive units transfused: The BEST collaborative study.
Seheult JN, Callum J, Delaney M *et al.*; The Biomedical Excellence for Safer Transfusion Collaborative. *Transfusion* 2022; **62** (Suppl 1): S185–S192. doi: 10.1111/trf.16952. Assessment No: 100222

01	When blood is administered in the pre-hospital or early in-hospital phases of the resuscitation, group O RBCs or low titre group O whole blood are selected.	**11**	The rate of D-alloimmunisation among the males in this study was 69/204 (33.8%), and among the females the rate was 8/31 (25.8%).
02	D-alloimmunisation is of minimal clinical significance for males and females who are beyond childbearing potential.	**12**	The D-alloimmunisation rate increased significantly as the number of transfused D-positive RBC units increased.
03	A multi-national study revealed that only approximately 12% of RBC distributions to hospitals were group O-negative.	**13**	The median number of D-positive RBC units transfused in the group of patients who received >10 units was 16.
04	The study was a multicentre, retrospective study of D-positive trauma patients who received at least one D-negative unit during their resuscitation.	**14**	In this retrospective analysis of trauma patients, the overall rate of D-alloimmunisation was 32.7%.
05	Criteria for the study included patients who had been confirmed as D-negative, had received at least one D-positive RBC unit and had an antibody detection test performed ≥14 days after the index D-positive RBC unit had been transfused.	**15**	The rate of D-alloimmunisation in this study falls within the range of previously reported rates, with the lowest reported rate of 12.2% and the highest rate of 47.6%.
06	For those who became D-alloimmunised, length of serological follow-up was the number of days between the first antibody test following the index D-positive RBC transfusion, and the date anti-D was detected.	**16**	The centre with the highest D-alloimmunisation rate contributed only 21 patients to the study; however, the institution with the lowest D-alloimmunisation rate contributed 74 patients.
07	The D-alloimmunisation rate was calculated as the number of patients who became alloimmunised during the study multiplied by the total patients in the study.	**17**	There is a very high rate of fetal demise from HDFN at centres where advanced antenatal care is available.
08	Responses from nine different institutions were received; six were from the S A, and one each from Brazil, Canada and England.	**18**	The study suggested that D-negative patients exposed to at least one D-positive RBC unit could be maintained on D-positive RBC units during resuscitation.
09	For female trauma patients of unknown D-type, 2/9 (22.2%) centres would start the resuscitation with D-negative RBC products but might begin using D-positive products if the bleeding is severe or if D-negative products are unavailable.	**19**	It was possible to determine exactly when the anti-D was formed in those who seroconverted.
10	Excluding the sites that provided fewer than 10 patients, there were 235 patients from four institutions available for analysis.	**20**	The method used for antibody detection could have influenced the results, as it has been demonstrated that the solid phase method has reduced sensitivity for anti-D.

REFLECTIVE LEARNING

01	What are the main reasons for using O D-positive red cells in pre-hospital care? an you list the pros and cons for all emergency red cells to be O D-positive rather than O D-negative?	**02**	This study found that there was no significant difference in the number of patients who produced an antibody after being exposed to only one red cell unit, compared to those who were exposed to more than one red cell unit. Referring to the text, can you explain why that is?

DEADLINE WEDNESDAY 4 JANUARY 2023

Polycythemia vera: historical oversights, diagnostic details, and therapeutic views.
Tefferi A, Vannucchi AM, Barbui T. *Leukaemia* 2021; **35** (12): 3339–51. doi: 10.1038/s41375-021-01401-3. Assessment No: 100422

01	*JAK2*V617F is one of three MPN-specific driver mutations that include *CALR* and *MPL* mutations; the latter are usually not found in patients with PV but are prevalent in *JAK2*V617F-negative ET and PMF.	11	Pruritus is a particularly vexing symptom associated with PV and in a large cohort of German patients with PV, a patient-directed questionnaire revealed that 68% of the patients were affected by aquagenic pruritus.
02	Treatment-relevant risk stratification in PV is designed to estimate the likelihood of bleeding complications, which is estimated to occur in approximately 26% of patients followed for a median of 20 years.	12	In a trial of phlebotomy-dependent patients treated with idasanutlin 76% of patients who were evaluable at week 32 of treatment experienced reduction in *JAK2* mutant allele burden.
03	Heidel *et al.*, Barosi *et al.* and Podoltsev *et al.* report that aggressive phlebotomy in low-risk patients with PV might result in severe phlebotomy-induced side effects and might also not be adequate in controlling certain disease-associated symptoms such as severe pruritus.	13	Numerous treatment modalities have been introduced and utilised in the treatment of PV including busulfan (1958), uracil mustard (1964), dapsone (1966) and hydroxyurea and melphalan in 1968.
04	Reports of pregnancies in women with MPN are more common in ET than they are in PV, because PV has a male preponderance with only 15% diagnosed before age 40 years.	14	The first step in approaching the diagnosis of PV should include *JAK2* mutation screening, and upfront targeting of exon 14 and 12 should be performed.
05	Favourable perioperative outcomes were found in 80% of the cases reviewed at three months post-operative in a 2008 study of 255 patients with PV or ET when analysed for a total of 311 surgical interventions.	15	Cornerstone of treatment in PV includes scheduled phlebotomy, with a target HCT of <45%, and daily low-dose aspirin therapy.
06	Givinostat, a histone-deacetylase (HDAC) inhibitor that selectively targets *JAK2* clones, shows treatment-emergent adverse effects including QTc prolongation, thrombocytopenia, diarrhoea, dysgeusia and headache.	16	Several studies show there is an increased risk of thrombosis associated with a *JAK2*V617F allele burden >75%.
07	A wide range of treatment modalities have been utilised to treat pruritus including antihistamines, anti-psychotics, IFN-α, phlebotomy, phototherapy, iron supplements, and myelosuppressive drugs with mixed results.	17	The 2016 WHO classification system for haematopoietic tumours recognises the almost perfect association between PV and *JAK2* as well as the fact that *JAK2*V617F is also detected in 50–75% of patients with either ET or PMF.
08	In a 2013 study by Tefferi *et al.* the cumulative risk for leukaemic transformation was 2.3% at 10 years and 5.5% at 15 years; risk factors for leukaemic transformation included abnormal karyotype, older age, leukocytes ≥15 x10^9/L and treatment exposure to pipobroman and hydroxyurea but not to P32/chlorambucil or busulfan.	18	Next-generation sequencing (NGS) studies have revealed that over 45% of patients with PV harbour DNA sequence variants/mutations other than *JAK2*, with the most frequent being *TET2* (18%), *ASXL1* (15%) and *LNK* (3%).
09	There is general agreement regarding which drugs should not be used for cytoreductive therapy in high-risk patients with PV due to their well-demonstrated leukaemogenic and/or carcinogenic potential (eg chlorambucil, P32, and pipobroman).	19	In a 15-year study of patients with splanchnic vein thrombosis, the affected veins were portal in 78% of 1915 patients, hepatic in 11%, and mesenteric in 11%.
10	There are extensive data for guidance regarding optimal pre- and perioperative management of patients with PV or ET with studies dating back to 1963.	20	Rusfertide, a hepcidin mimetic, is administered by weekly subcutaneous injection at escalating doses of 10, 20, 40, 60 and 80 mg, adjusted to maintain haematocrit <45%.

REFLECTIVE LEARNING

01	Critically discuss the use of cytogenetics in the diagnosis of polycythaemia vera.	02	Discuss the risk factors that can impact on the management of polycythaemia vera patients, and how these affect treatment.

HERE TO HELP

FUNDING TO SUPPORT IBMS QUALIFICATIONS

Chris Ward, IBMS Head of Examinations, explains how employers can access grants to support staff who undertake IBMS qualifications.

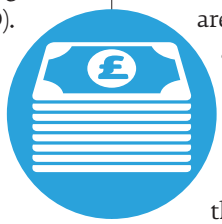
Since November 2020, the IBMS and the National School of Healthcare Science (NSHCS) in Health Education England (HEE) have been providing grants to support the training of scientists working in England to undertake histopathology qualifications run jointly by the IBMS and Royal College of Pathologists (RCPath).

The funding has a direct and positive impact on IBMS members with several employers having already accessed the grants. To help employers support the training of colleagues in their department this funding has now been extended to include other IBMS qualifications.

The funding demonstrates a tremendous mark of confidence in the IBMS's professional examinations and underlines their value in the training of scientists to undertake advanced and consultant roles. To be eligible for funding, candidates must be employed in England and undertaking any of the following qualifications:

- Diploma of Expert Practice (DEP) in Non-Gynaecological Cytology
- Advanced Specialist Diploma (ASD) in Non-Gynaecological Cytology
- ASD in Cervical Cytology
- DEP in Histological Dissection
- ASD in Histological Dissection
- ASD in Histopathology Reporting
- Higher Specialist Diploma (HSD).

Employers can claim £1000 per candidate for the dissection, cytology and HSD qualifications. The training grant is available to employers of candidates in England who have already registered on these qualifications and to the employers of all new candidates until the end of the contract the IBMS has with NSHCS in HEE (in October 2025), whilst funding is available. For the dissection qualification, funding is paid at the point the candidate applies for the training logbook. For cytology and the HSD, the funding is paid at the point the candidate applies to undertake the qualification.



Employers can claim £3000 when a candidate starts each stage of the qualification for Histopathology Reporting qualifications. Funding is available to employers of candidates who are already on the qualification and who start it during the remainder of 2022 and in 2023.

Employers will still need to pay the assessment fees to the IBMS or the RCPath at the appropriate time, but the availability of the grant should help departments plan the training of their colleagues.

Please note that it is the responsibility of the employer to agree with the candidate how the grant will be used to support their training. This might include, but is not limited to, attendance at training courses, events, seminars and IBMS Congress, providing backfill to enable other staff to support the candidate undertaking the qualification, portfolio assessment and examination fees, travel and subsistence for attending courses and the purchase of textbooks. The funding cannot be used to cover the IBMS membership fee of the candidate, and they must maintain their IBMS membership throughout the time they are undertaking this qualification.

For more information visit the IBMS website or email examinations@ibms.org

IMAGES: ISTOCK/SHUTTERSTOCK

MY LAB

A BESPOKE STATE-OF-THE-ART LAB

Alix Costello gives a guided tour of the laboratory facilities at Blackpool Victoria Hospital.

Blackpool Victoria Hospital is a district general hospital specialising in cardiothoracic care. Cellular pathology at Blackpool is a UKAS-accredited service that provides routine diagnostic investigations for a wide range of specimen types. We process over 35,000 tissue samples and around 3000 cytology samples each year. As Blackpool is a cardiothoracic centre, we receive a lot of lung work, including biopsies, resections, endobronchial ultrasound (EBUS) samples and frozen sections. In addition to diagnostic work, we also provide a lung molecular pathology service to our neighbouring trusts in the Lancashire region, which enables faster turnaround times for lung cancer patients.

We have a fantastic team of medical laboratory assistants, assistant practitioners, biomedical scientists, medical secretaries and consultant histopathologists who all work together to provide the cellular pathology service to the Blackpool region. Our team has recently expanded, and we have a lot of new staff in the department, which is helping us to manage our post COVID-19 backlogs. We are also a keen training laboratory and each year we host trainee biomedical scientists from the University of Central Lancashire and Lancaster University. In fact, my journey at Blackpool started as a placement student from Lancaster University.

In June 2022, the histology team was very fortunate to move into a new laboratory after a year-long project of architecture, design and building work. The ventilation systems in the previous histology lab were no longer fit for purpose, meaning that laboratory staff had to wear respirators when working around formalin.

Thanks to a lot of hard work from managers at the trust, we were able to commission a bespoke, state-of-the-art laboratory with new purpose-built equipment that could modernise our histology workflows and provide a safer working environment. One of the biggest and most welcome changes to the department was the addition of two extra cut-up benches. The team were all very excited to get started in the new laboratory and we have seen a boost in morale since working in the new environment. Last month, Michael Osborn, President of the Royal College of Pathologists, came to officially open the laboratory including cutting a red ribbon. I commissioned a piece of artwork to commemorate the occasion, which is now hanging outside the laboratory entrance.

Despite the excitement of the new laboratory, the last few months have not been without their challenges. Pressures on the cellular pathology department have only worsened as we try to tackle patient backlogs following the global pandemic. Also, juggling a laboratory move, training, a national wax shortage and a UKAS inspection has kept us all very busy. However, the new laboratory has provided us with the opportunity to streamline our work processes and further develop our scientists into advanced roles, including genomic biomedical scientists and dissection practitioners. Whilst there is a lot of work still to be done and despite the workload challenges, every day I am grateful to be part of the hardworking, capable and supportive cellular pathology team at Blackpool Teaching Hospitals NHS Foundation Trust. BMS

LAUNCH DIAGNOSTICS

RESPIRATORY MOLECULAR WINTER SOLUTION

Anatolia geneworks

Key points of the Anatolia assays:

- Simple workflow
- Compatible with routine extraction and real-time PCR platforms
- Same thermal profile so can be run together on the same PCR plate
- An endogeneous control is included to ensure sampling quality
- SARS-CoV-2 sequence data are reviewed monthly against emerging new variants

All products are CE marked

DETECTION OF SARS-COV-2, FLU & RSV

Triplex	✓ SARS-CoV-2: orf1ab and N gene ✓ Flu A/B ✓ RSV A/B
	✓ Endogenous control with RNAse-P ✓ Only 1 MasterMix

DETECTION OF SARS-COV-2 + MULTIPLE RESPIRATORY PATHOGENS (15 TARGETS)

SARS-CoV-2 respiratory panel	✓ SARS-CoV-2: orf1ab and N-gene ✓ Flu A/B ✓ RSV A/B ✓ Adenovirus ✓ Enterovirus	✓ Metapneumovirus ✓ Rhinovirus ✓ *Legionella pneumophila* ✓ *Mycoplasma pneumoniae* ✓ Parainfluenza 1 - 4
	✓ Endogenous control with RNAse-P ✓ Only 3 MasterMixes	

LAUNCH DIAGNOSTICS

For further information please call

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or visit our website

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Diagnostics inform the countless decisions which need to be made along every step of a person's health, wellness and disease journey.

We are committed to developing diagnostic solutions that support healthcare professionals in making critical decisions for their patients.

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