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**REGULATION****THE NEW STANDARD**

With its publication nearly here, we look at ISO 15189: *p.32*

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Practical advice on managing mental and physical health: *p.35*

# THE BIOMEDICAL SCIENTIST

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JULY 2022

## EMERGING THREAT?

THE RAPID SPREAD OF A ZOONOTIC DISEASE



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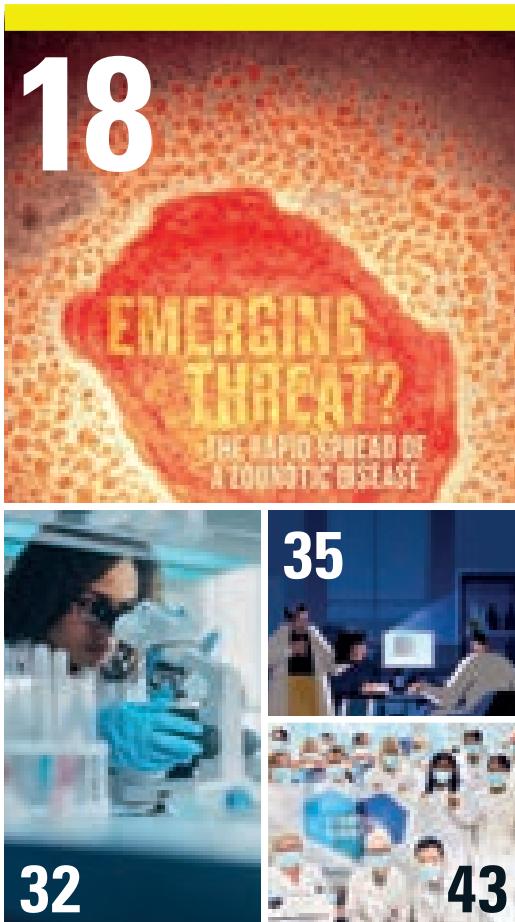
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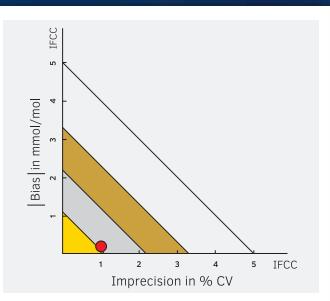
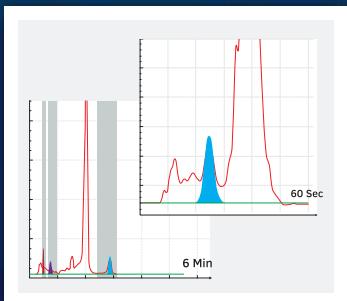


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I am writing this shortly after Biomedical Science Day – and what a great celebration it was this year. IBMS members and their colleagues were finally back in hospital foyers across the UK spreading the word about the profession and its expertise face to face.

On social media, there was lots of support across major government and healthcare accounts – with #BiomedicalScienceDay2022 trending in the UK top 5 on Twitter for most of the day. I think we can honestly say that the profession has reached a point where the importance of our work is recognised, and increasingly understood.

In the run up, I attended Northern Ireland's ACM and visited laboratories across Belfast. It was my first official visit anywhere as IBMS Chief Executive and it was great to be doing something in person. I was impressed by the dedication of the teams, how resilient they were, and the ways in which they collaborated. There was sense of a new dawn, of positivity, and of having come through the worst of times stronger.

In this month's magazine, our new Head of Education Sue Jones sets out her vision for the future of IBMS Education and Training in our "Here To Help" article and I'm very excited to work with her. I think she's going to be a huge asset to the profession and will really help us move our qualifications forward.

This month also sees the IBMS achieving some great new things in our

# A BRIGHTER FUTURE



IBMS Chief Executive **David Wells** feels a new dawn for the profession and a brighter future awaiting us all.

commitment to equality, diversity and inclusion. By the time you read this, our members will have just marched in our first Pride in London, donning lab coats with rainbow IBMS logos and showing the world just how proud we are of ALL of our members.

With the help of national Council member Tahmina Hussain, we are also launching the IBMS' Equality, Diversity and Inclusion Working Group – aiming to make our professional body a fairer and more representative organisation. I'm looking forward to seeing how the group will enhance and empower the careers of the IBMS members who need it most.

Maybe it's because I enjoyed the visit

to Belfast so much, or coming off the back of Biomedical Science Day when I've seen so many of our members' smiling faces and positive messages on social media, but with everything the IBMS is doing and has in the pipeline, I feel like we are at the beginning of a new dawn for the profession, and that a brighter future awaits us all.



**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

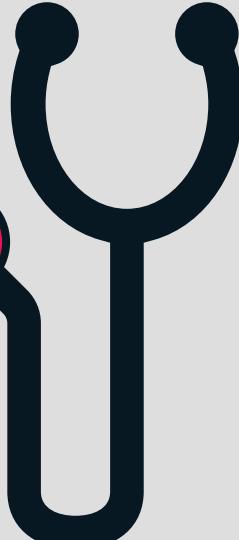


## BIGGER VIOLENCE IN SURGERIES

Violent incidents at surgeries have doubled in less than five years, according to the figures.

Police forces recorded a total of 1068 violent incidents at surgeries between 2021 and 2022. This is an increase from 586 from between 2017 and 2018.

The Royal College of GPs Chair called the findings "unacceptable".



NHS absence rates

# 6.7%

The NHS absence rate for England in January 2022 was 6.7%.

This is higher than December 2021 (6.2%) and higher than January 2021 (5.7%).

The North West region reported the highest rate in January 2022 at 7.9%; this is higher than the rate in December 2021 (7.3%). The South East of England region reported the lowest sickness absence rate in January 2022 at 5.9%; this is higher than the rate in December 2021 (5.5%).

Ambulance trusts had the highest sickness absence rate at 9.9% in January 2022; this is higher than the rate in December 2021 (9.3%).

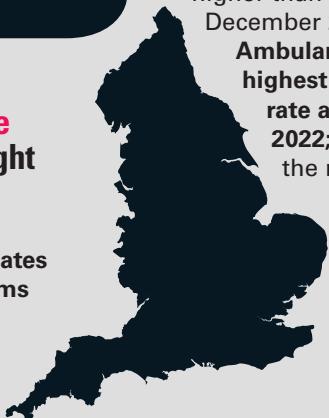
Commissioning support units had the lowest sickness absence rate at 3.0%.



## LONG COVID

**Two million people in the UK are thought to be living with long COVID, Office for National Statistics data have revealed.**

It is the highest figure since official surveys began, and equates to 3.1% of the population. A total of 71% said their symptoms had a negative impact on their day-to-day activities.

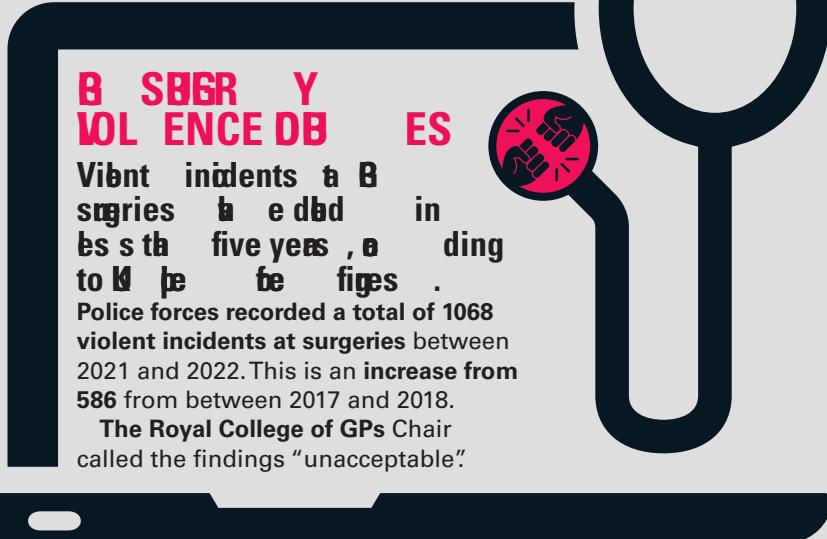


# 3 DAYS

A successfully transplanted donor liver was kept warm and alive outside the body for three days, it is reported.

The team used "normothermic perfusion" to give the organ a continuous blood supply, which experts say is better than the traditional way of putting it on ice.

It might even be possible to stretch viability to 10 days, the Swiss team said. Cooled livers only keep for up to 12 hours.



# 25,000

The NHS has lost almost 25,000 beds across the UK in the last decade, according to a report.

The Royal College of Emergency Medicine publication says this has led to a sharp rise in waiting times for A&E, ambulances and operations.

There are currently 162,000 beds in the NHS across the UK, according to the college.

The UK has the second lowest number of beds per 1000 people in Europe at 2.42, the report said.



## BIOMARKERS

## Early disease detection using DNA droplets

A group of scientists has developed a computational DNA droplet with the ability to recognise specific combinations of chemically synthesised microRNAs (miRNAs) that act as biomarkers of tumours.

Using these miRNAs as molecular input, the droplets can give a DNA logic computing output through physical DNA droplet phase separation.

Professor Masahiro Takinoue from Tokyo University of Technology said: "Even though biological systems regulate their functions by combining biosensing with molecular logical computation, no literature is available on integration of DNA droplet with molecular computing."

Developing this DNA droplet

required a series of experiments. First, they designed three Y-shaped DNA nanostructures called Y-motifs A, B, and C with three sticky ends to make A, B, and C DNA droplets.

The team used linker molecules to join the A droplet with B and C droplets. They evaluated the "AND" operation in the AB droplet mixture by introducing two input DNAs.

They then introduce breast cancer tumour markers, miRNA-1 and miRNA-2, to the AC droplet mixture as inputs for the AND operation. The AND operation was successful, implying that the computational DNA droplet identified the miRNAs.

→ [bit.ly/3Q5IJnq](https://bit.ly/3Q5IJnq)



# SCIENCE NEWS

## PROTEIN INTERACTION

## MINIPROTEINS THAT LAUNCH TWO-PRONGED ATTACKS

A new approach developed by researchers at the Indian Institute of Science (IISc) provides an alternative mechanism to vaccines, which renders viruses such as SARS-CoV-2 inactive.

The researchers report the design of a new class of artificial peptides or miniproteins that can not only block virus entry into our cells but also clump virus particles together, reducing their ability to infect.

A protein–protein interaction is often like that of a lock and a key. This interaction can be hampered by a lab-made miniprotein that mimics, competes with, and prevents the "key" from binding to the "lock", or vice versa.

In the new study, the team has exploited this approach to design miniproteins that can bind to, and block the spike protein on the surface of the SARS-CoV-2 virus.

This binding was further characterised extensively by cryo-electron microscopy (cryo-EM) and other biophysical methods.

→ [go.nature.com/3mgVgqi](https://go.nature.com/3mgVgqi)



## IMMUNOLOGY

## GENETIC TEST CAN DIAGNOSE IMMUNE SYSTEM DISORDERS

Investigators have used next-generation sequencing to test a DNA panel of 130 different immune system genes from 22 study participants.

They found that many patients had inherited a genetic defect that caused a disorder in their immune system.

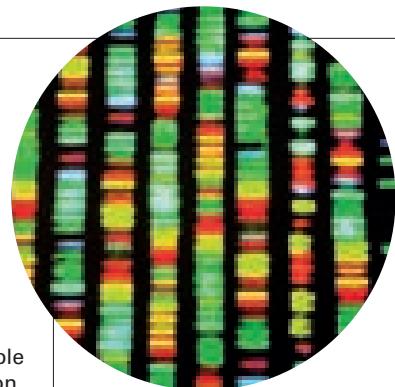
These findings are hoped to help facilitate better treatment options and earlier diagnosis in family members who may have inherited the same genetic abnormality.

Lead investigator Loyd D'Orsogna said: "Genetic testing was costly to perform and was mostly targeted to DNA sequencing of a single or very small number of genes. Therefore, a genetic diagnosis was limited for many patients with primary immunodeficiency disorders. Recent advances in genetic technology allow affordable testing of multiple genes from the same individual. We can therefore identify a specific gene that

may lead to frequent infections in patients. An earlier and more accurate diagnosis may improve the patient outcome and prevent complications."

Twenty-two unrelated patients with common variable immunodeficiency, a common type of B-cell disorder, and a previously unknown genetic diagnosis, were recruited for the study.

DNA samples were tested and processed with a next-generation sequencing panel



containing 120 different immune genes.

A total of 130 genetic variants were identified for analysis.

→ [bit.ly/3tlDvd1](https://bit.ly/3tlDvd1)

## DERMATOLOGY

## CHARACTERISTICS OF STABLE VITILIGO SKIN DISEASE

A new study reveals the unique cell-to-cell communication networks that can perpetuate inflammation and prevent repigmentation in patients with vitiligo disease.

Professor of Dermatology Anand K Ganeshan said: "In this study, we couple advanced imaging with transcriptomics and bioinformatics to discover the cell-to-cell communication networks between keratinocytes, immune cells and melanocytes that drive inflammation and prevent repigmentation caused by vitiligo."

"This discovery will enable us to determine why white patches continue to persist in stable vitiligo disease, which could lead to new therapeutics to treat this disease."

Vitiligo is an autoimmune skin disease that is characterised by the progressive destruction of melanocytes, which are mature melanin-forming cells in the skin, by immune cells called autoreactive CD8+ T cells that result in disfiguring patches of white depigmented skin. This disease has been shown to cause significant psychological distress among patients.

Melanocyte destruction in active vitiligo is mediated by CD8+ T cells, but, until now, why the white patches in stable disease persist was poorly understood.

The authors identified distinct subpopulations of keratinocytes in lesional skin of stable vitiligo patients, along with the changes in cellular compositions in stable vitiligo skin that drive disease persistence.

In patients that responded to punch grafting treatment, these changes were reversed, highlighting their role in disease persistence.

The findings of this study raise the possibility of targeting keratinocyte metabolism in vitiligo treatment.

Further studies are needed to improve the understanding of how keratinocyte states affect the tissue microenvironment and contribute to disease pathogenesis.

→ [bit.ly/3zmZV1Q](https://bit.ly/3zmZV1Q)



### WHAT'S HOT AND WHAT'S NOT



#### HOT CATS

A fluffy ginger cat has a following of more than 4500 on Facebook after making Addenbrooke's Hospital, in Cambridge, his second home. Patients said they had been soothed by Henry's presence.



#### HOT SLEEP

Australian teens had improvements in sleep and dietary choices during lockdown. However, these were offset by increases in screen time and alcohol use, a new study reveals.



#### HOT BLOOD BIKES

Serv Herts & Beds, a group of bikers who deliver blood, medical samples and breast milk for the NHS, has been honoured with the Queen's Award for Voluntary Service.

#### NOT BREAST CANCER

A study saw women with a genetic abnormality in their cancer given a new drug combined with hormone therapy. It found they could expect to survive almost twice as long compared with standard treatment.



#### NOT VOLES

Researchers from the Zoonosis Science Centre at Uppsala University have identified a new coronavirus. Their study of 260 bank voles shows that the virus is well established in Sweden's red-backed voles.

#### NOT POLLUTION

Long-term exposure to air pollution is linked to a greater risk of severe COVID-19, according to research presented at the annual meeting of the European Society of Anaesthesiology and Intensive Care.



## COMPUTATIONAL BIOLOGY

**LARGE-SCALE DATA INTEGRATION**

A Chinese research team has proposed a new algorithm (NetMoss) for efficient integration of large-scale microbiome data and biomarker identification.

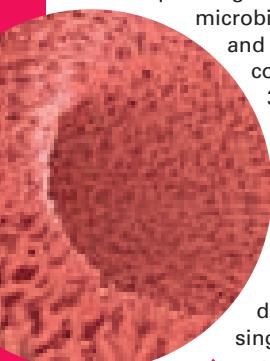
The algorithm uses microbial interaction networks to effectively integrate data from different populations. It can quantify the topological differences between different network modules by comparing the perturbations of microbial networks in different states, thus enabling the identification of disease-associated biomarkers.

Compared with previous methods, NetMoss can unbiasedly integrate different batches of microbial data more efficiently, mine disease-associated biomarkers, and identify microbial dysbiosis covariation patterns that drive the occurrence of multiple diseases.

The study is based on 11,377 sequencing samples of gut microbiome from diseased and healthy controls, covering 78 studies, 37 diseases, and 13 countries or regions.

The algorithm was applied to simulated and real datasets. It was highly accurate and robust both in the integrated dataset and in the single dataset.

→ [go.nature.com/3MqfFnq](https://go.nature.com/3MqfFnq)



## BIOCHEMISTRY

**COVID-19 ANTIBODY TREATMENTS AND NEW VARIANTS**

A new paper provides the physical basis for why approved antibody therapeutics are not working in neutralising the recent variants of concern, such as Omicron and its subvariants.

The study found that certain mutations appear repeatedly in emerging variants showing convergent evolution.

One such evolution occurs at three amino acid positions K417, E484 and N501 in the spike protein's receptor binding domain (RBD).

Nearly half of the 4.3 million variant sequences in GISAID database that contain any of these three mutations have all three occurring together.

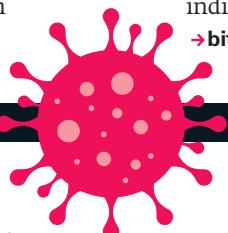
Although individual mutations have both beneficial and deleterious/adverse effects, when they come together, deleterious/adverse effects get cancelled out, leading to improved selection of the mutations together.

The researchers found the three RBD mutations perform very distinct and specific roles that contribute toward improving the virus fitness and build the case for their positive selection, even though individual mutations have deleterious effects that make them prone to negative selection.

Compared to the wild-type, K417T escapes Class 1 antibodies and has increased stability and expression; however, it has decreased ACE2 receptor binding. E484K escapes Class 2 antibodies; however, it has decreased receptor binding, stability and expression. N501Y increases receptor binding; however, it has decreased stability and expression.

The authors conclude the collective effect of these mutations is far more advantageous for virus fitness than the individual mutations.

→ [bit.ly/3O2sEwZ](https://bit.ly/3O2sEwZ)

**UNDER THE MICROSCOPE*****This month:*  
*Conspiracy theories***

**OK, conspiracy theories... are we talking about whether the 1969 moon landing was faked?**  
No, we are not (and no, they were not, although as recently as 2019 polls were reported that showed as many as 6% of Americans still believe the Apollo 11 astronauts never landed on the moon).

**So which conspiracy theories are we looking at?**

Rather predictably, I'm afraid it's COVID-19 conspiracy theories.

**Why now? They've been doing the rounds for quite some time.**

New work was presented at the European Congress of Psychiatry that looks at the link between COVID-19 conspiracy theories, depression and anxiety.

**Tell me about the study.**

The research group, from several Polish universities,

recruited nearly 700 volunteers (585 female, 110 male, 5 other, average age 24.8) and asked them about their beliefs. They developed and validated a new way of measuring belief in COVID-19 conspiracy theories, the COVID-19 Conspiratorial Beliefs Scale.

**What did they do next?**

They used this, along with other questionnaires, such as the Generic Conspiracist Beliefs Scale and the Hospital Anxiety and Depression Scale, and analysed the data.

**What did they find out?**

Severity of anxiety can be increased in those who express a belief in conspiracy theories and there is a significant increase in the severity of depression symptoms. However, they are unable to say whether a belief in conspiracy theories causes more anxiety and depression, or whether people who are more anxious and depressed are more attracted to these theories.

**Where can I read more?**

You can read a paper about the project by visiting [bit.ly/3MshUqp](https://bit.ly/3MshUqp)

## CELL BIOLOGY

# An autoimmune cause of schizophrenia?

Researchers from Tokyo Medical and Dental University (TMDU) have identified an autoantibody – a protein that is produced by the immune system to attach to a specific substance from the individual's own body, rather than to a foreign substance, such as a virus or bacteria – in some patients with schizophrenia.

Notably, they also found that this autoantibody caused schizophrenia-like behaviours and changes in the brain when they injected it into mice.

When considering possible autoantibodies that might cause schizophrenia, the research team had a specific protein in mind.

Previous research has suggested that

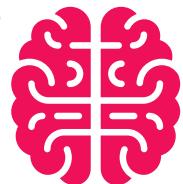


neural cell adhesion molecule (NCAM1), which helps cells in the brain talk to one another via specialised connections known as synapses, may have a role in the development of schizophrenia.

Lead author of the study, Hiroki Shiwaku, said: "We decided to look for autoantibodies against NCAM1 in around 200 healthy controls and 200 patients with schizophrenia.

"We only found these autoantibodies in 12 patients, suggesting that they may be associated with the disorder in just a small subset of schizophrenia cases."

→ [bit.ly/3NqgtKk](https://bit.ly/3NqgtKk)



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# TECH NEWS

LUMIRADX LIMITED

## DIABETES

LumiraDx Limited, a next-generation point-of-care diagnostics company, announced its HbA<sub>1c</sub> test has achieved CE marking.

Used with the LumiraDx Platform, the test provides results in under seven minutes from sample application for the monitoring of individuals with diabetes, and as an aid in screening and identifying patients who may be at risk for developing diabetes, all at the point of care.

→ [lumiradx.com](http://lumiradx.com)



→ [bio-rad.com](http://bio-rad.com)

BIO-RAD

## PCR SYSTEM

Bio-Rad Laboratories, a global leader of life science research and clinical diagnostic products, has launched the C<sub>R</sub> Duet Real-Time PCR System to support researchers in developing singleplex and duplex quantitative PCR assays.

The C<sub>R</sub> Duet System offers the robust thermal performance and proprietary, accurate optical shuttle system of Bio-Rad's C<sub>R</sub> Opus System, with thermal gradient functionality to enable optimisation in fewer runs.

→ [bio-rad.com](http://bio-rad.com)



EKF DIAGNOSTICS

## POC ANALYSERS

EKF Diagnostics, the global *in vitro* diagnostics company, announced the launch of its new EKFlink digital connectivity solution for the secure management of point-of-care POC analyser s and associated data on one centralised platform. An open, flexible solution, EKFlink middleware can be interfaced to all vendors' POC analysers, including EKF's own portfolio, to enable real-time remote management of data, such as patient test results, Q results, operator management and analyser configuration.

EKF's portfolio of POC devices includes Hemo Control and DiaSpect™ hemoglobin analyser ranges, as well as Qo-lab and Qo-Test HbA<sub>1c</sub> analysers.

→ [ekfdiagnostics.com](http://ekfdiagnostics.com)

# NUDT15 Nudix Hydrolase 15

- Mutations in NUDT15 are associated with poor metabolism of thiopurines and increased risk of myelosuppression
- c.415C>T mutation associated with NUDT15\*2 and NUDT15\*3 haplotypes
- Increased prevalence of c.415C>T mutation in Asian populations
- Recommended that NUDT15 genotyping is performed prior to initiation of thiopurine drugs (ALLtogether guidelines)
- Analysis performed by real-time polymerase chain reaction (RT-PCR)

**NHS**  
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✉ [rajvinder.garcha@nhs.net](mailto:rajvinder.garcha@nhs.net)

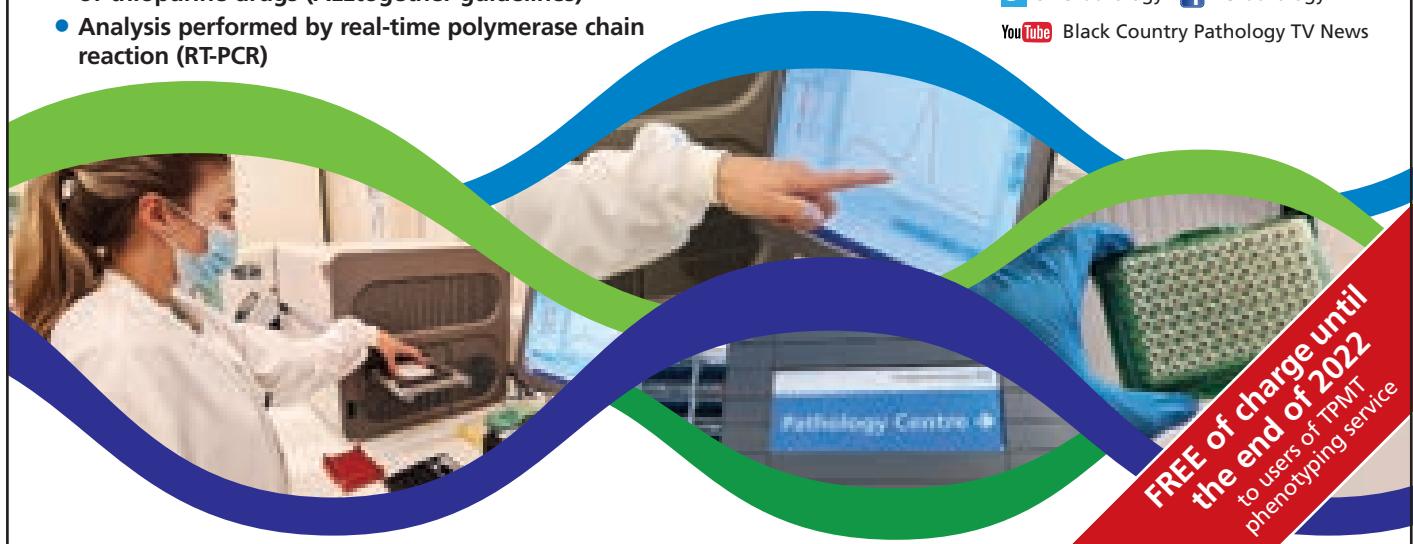
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Delaying immunisation against COVID-19 in children is an important step in offering a more suitable vaccine, argues **Dr Hamid Merchant.**

In February 2022 the government's Joint Committee on Vaccination and Immunisation (JCVI) advised that COVID-19 vaccines in 5- to 11-year-old children not in a clinical risk group are not essential, and shouldn't displace the delivery of other paediatric immunisation programmes. Some non-COVID-19 paediatric vaccination programmes had fallen behind as a result of the pandemic, resulting in health inequalities.

The statement drew criticism from some in the healthcare community who argued that a mandatory mass immunisation programme against the virus is necessary for children. "As a pharmaceutical scientist with extensive experience in pharmaceutical product development, like many, I had been following COVID-19 therapeutics and vaccines very closely," says Dr Hamid Merchant, Subject Leader in Pharmacy at the University of Huddersfield. "I decided to write an article in response to the controversy as to why COVID-19 vaccines for young children hadn't been approved in the UK but had in the US, and why the UK was so slow to respond."

In *Why COVID vaccines for young children are not essential at this moment in time?*, Merchant suggests that a public health policy should not "rush mass-immunising young children". He argues that delayed immunisation can be beneficial in offering a more suitable formulation for children,

# OPEN DIALOGUE

such as the nasal COVID vaccine that will provide protection against infection and transmission.

## Vaccine differences

During the initial phase of rollout, most healthcare professionals feared that discussing openly the necessity of the vaccine in special populations such as children would undermine vaccine uptake, Merchant says. This meant open dialogue and personalised vaccine recommendations, such as taking into consideration each patient's medical history, comorbidities, current and past medication history, were avoided.

"The later acknowledgement of COVID vaccine-induced thrombotic thrombocytopenia, Guillain-Barré Syndrome and myocarditis/pericarditis by the Medicines and Healthcare products Regulatory Agency,

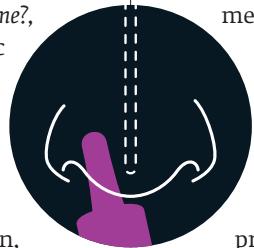
European Medicines Agency and the Food and Drug Administration [in the US] was a major step change among the public health community," Merchant says.

"It encouraged open discussions about potential rare side effects and the need for individualising risks and benefits for special populations, including children."

Merchant says that it's time the scientific community discusses the vaccine science and differences between various formulations that have been approved by the regulatory agencies. "We shouldn't rush for a one-size-fits-all approach, particularly when there is a product out there which would be of greater benefit to children," he adds.

## Vaccine efficacy

In the paper, Merchant points out that current COVID-19 vaccines were designed using the variant of the virus that was prevalent in early 2020, and since then





the virus has significantly mutated. While they may still provide protection against severe COVID-19, risk of hospitalisation and admission to intensive care, and death – all rarely seen in children – they will not provide children with protection from catching the virus in the first instance. Nor will they prevent minor illness or reduce the risk of the virus spreading around the community.

"Moreover, JCVI noted that over 85% of children aged 5–11 years contracted COVID-19 in January 2022 during the Omicron outbreak in UK and, therefore, have already acquired natural immunity that will still provide protection in healthy children against severe disease on future reinfection," he adds.

As current vaccines are injected intramuscularly, they cannot protect against catching the respiratory virus in the first place, nor do they produce the mucosal antibodies that provide the

protection at the point of entry for the virus, Merchant explains. "This is normally the case with all respiratory pathogens and corresponding injectable vaccines, for instance, flu," he writes. "Injectable flu vaccines, therefore, were not very successful historically in offering the level of protection sought from the mass children immunisation campaign."

The nasal flu spray – given to school-going 2 to 17 year olds in England – does, however, prevent children catching the infection in the first place and blocks community transmission, Merchant explains. "The annual flu immunisation campaign was a great example that every healthcare professional can easily relate to, so I tried in this article to highlight the significant benefits that we have seen by moving away from conventional injectable flu jabs to modern nasal vaccines for mass immunisation in children," he adds.

Another consideration is the significant variation in children aged 5 to 11 years of deltoid muscle mass, meaning it's not easy to standardise the dose and administration technique of the vaccine. For this reason very young children with minimal deltoid mass are often contraindicated for intramuscular injections in the arm.

### Next-generation vaccines

As someone who started his career in investigational pharmaceuticals in one of the biggest pharmaceutical companies, Merchant is trained in establishing pharmaceutical causes of mysterious adverse drug reactions, to better formulate products. He has also developed expertise in clinical pharmaceuticals, understanding the biological interactions of pharmaceutical formulations and their components, and their effects on product efficacy and safety.

"Not all products are made the same and can therefore not behave exactly the same; there may always be a better choice for a particular patient," he says. "Pharmacists are a key player in the healthcare system

## DR HAMID MERCHANT

- ✓ Subject Leader in Pharmacy at the University of Huddersfield
- ✓ Adjunct Professor at the Health Services Academy, Government of Pakistan
- ✓ Extensive experience working for and with pharmaceutical industries
- ✓ Completed PhD in pharmaceutics, University College London
- ✓ Received a Bachelors and a Masters in Pharmacy from University of Karachi, Pakistan.



and should always be a fundamental part of the healthcare team."

He believes the paper has made a significant difference in explaining the science behind vaccine formulations and how not all formulated vaccine products behave or work the same way, albeit made for same purpose. "If we had a choice, a formulation may well be more suitable for an individual than others," he adds.

"I think it has made an important contribution to initiate a thought process among healthcare professionals and did manage to start a scientific dialogue and discussion among scientists and public health professionals across the world in reevaluating their position on child vaccine mandates within their communities. We still need to do more in disseminating this information to public health authorities and policymakers around the world."

As the vaccines have done their job of enabling COVID-19 to become endemic, it's imperative to continue investigating the next generation of COVID vaccines for all those who remain at high risk from emerging variants of concern, Merchant concludes. 



# THE BIG QUESTION

THIS MONTH

Following on from Pride month, we ask: “Could the sector do more to be LGBTQ+ friendly?”



## Colin Mudd

**Higher Specialist Biomedical Scientist**  
Nottingham University Hospitals NHS Trust

**O**f course our sector could do more to be LGBTQ+ friendly, so what should we do?

First, a little context: in the last few months people in the LGBTQ+ community were described as “insane or perverted” by a member of our profession. This is 2022 not 1982. The problem has not gone away and is still gravely concerning.

Such poor behaviour must be challenged. Those of us who identify as LGBTQ+ must be able to challenge this and feel confident that they will be supported. So the responsibility here is that senior management must embrace the LGBTQ+ community, support people and be aware of the prejudices that still exist.

A very positive step is that the IBMS is setting up an Equality, Diversity and Inclusion Working Group. This involves volunteers from our membership together with Council members and is fully endorsed by our President Debra Padgett.

Those of us in the LGBTQ+ community should help to show everyone else what our contribution is to society and our profession. After all, our motto is “Learn and Improve”, so by education we can hope to improve the situation.

Being a member of the LGBTQ+ community is not always about being on *RuPaul's Drag Race*. Often it is about being actually rather ordinary and part of the absolutely invaluable care team for the nation that we are.

Also, we don't always have to understand everything; we can't possibly do that, but how much effort does being accepting take?



## Francis Yongblah

**Laboratory Manager and HSST**  
**Clinical Scientist**  
Great Ormond Street Hospital for Children

I feel that over the last 13 years, during my career as a healthcare scientist, I have witnessed significant changes and support in promoting equality and diversity in the workplace for the LGBTQ+ members of the IBMS. The work that hospital trusts have done to date to promote Pride month has been incredible. I feel that it has come a long way. As an IBMS Fellow, it has been nice to see how the institute has worked to promote its engagement and support for LGBTQ+ members, such as promoting Pride month and sharing members' stories.

This will be the first year that the IBMS will be marching in Pride in London, and it is great to have this support from the Institute. I feel that the Institute is LGBTQ+ friendly for its members, however, I feel there are further things that can be done. Recently I went to an international conference where I was given the opportunity to attend an after-conference LGBTQIA reception. It was such a nice experience to meet fellow scientists from different backgrounds who were able to share their career stories and personal stories with other members of the conference, which included friends and allies of the LGBTQ+ community. Something else that I got to see at this conference was teaching sessions for promoting equality in the workplace and I feel this would be a future benefit, particularly by making this part of leadership and management training.



## Abi Giles

**Specialist Biomedical Scientist**  
**Biochemistry**  
Royal Bolton Hospital

**A** lot of progress has been made in recent years for the LGBTQ+ community in healthcare, but there is still more that is needed.

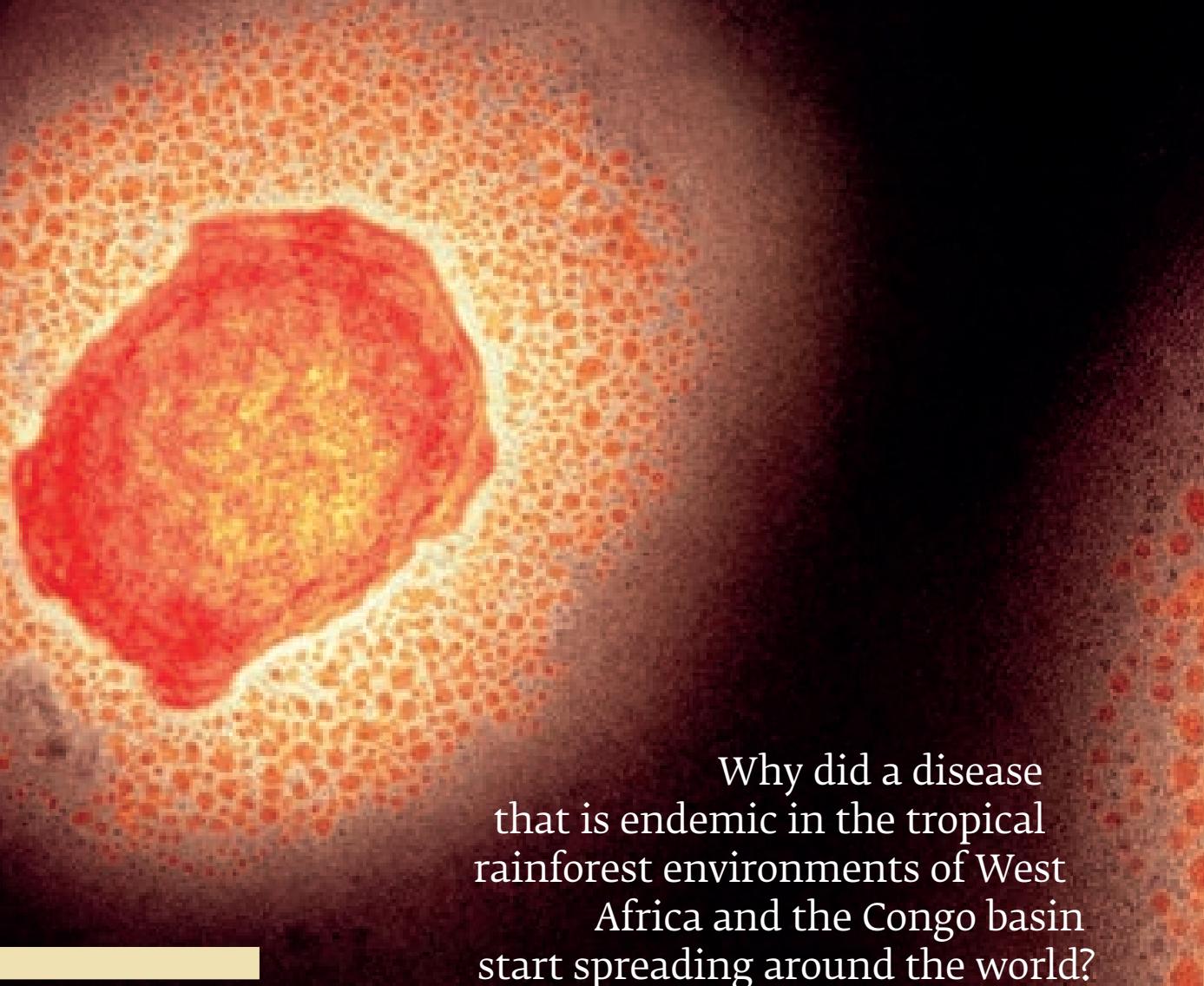
My own personal experience has highlighted to me areas such as how trans and non-binary patients are treated by the current systems in place. Reference ranges and gender markers can struggle to reflect a patient's current physiological state, but also satisfy equality and data quality legislation.

Indeed, a lot of the research is lacking in this area, especially as this can have critical effects on how an individual patient is treated. This is especially so in cases of emergency, where what course of action is taken can make the difference between life and death.

Another area that could make vast improvements is awareness training. Current healthcare is very much oriented towards a norm based on cis-heterosexual society. The needs of the LGBTQ+ community differ greatly and knowledge is key to be able to improve the services we offer as laboratory professionals.

Incremental improvements from individuals can all add up to make a huge difference in the end, especially considering the current relentlessly hostile environment in the media.

In conclusion, I am proud to be a biomedical scientist as well as a member of the LGBTQ+ community. I feel my experiences have been immensely positive as a worker in this sector. I look forward to a bright future.



## Why did a disease that is endemic in the tropical rainforest environments of West Africa and the Congo basin start spreading around the world?

### WHY RENAME MONKEYPOX?

WHO said: "Human monkeypox was given its name before current best practices in naming diseases: names should be given with the aim to minimise unnecessary negative impact of disease names on trade, travel, tourism or animal welfare, and avoid causing offence to any cultural, social, national, regional, professional or ethnic groups."

"WHO is considering the name of monkeypox and whether to rename it. For a disease that already exists, the process would include consideration of the international classification of diseases (ICD-11)."

"Naming of viruses is the responsibility of the International Committee on the Taxonomy of Viruses (ICTV). There was already a process underway to reconsider the naming of all orthopoxvirus species. This will continue under ICTV leadership."

Monkeypox has made headlines over recent weeks not just for a rapid rise in numbers around the world, but for the very nature of its name. Just as this magazine was going to press, the Director-General of the World Health Organization (WHO) announced urgent efforts were underway to rename the disease. The WHO told *the Biomedical Scientist* it is "in discussion with experts and technical advisory groups in poxvirology and viral evolution on the possible renaming of monkeypox virus clades". A spokesman said: "We will make announcements about the new names as soon as possible." However, as the magazine went to the printers, the official name remained monkeypox (see box, left).

This latest outbreak of the zoonotic virus, an orthopoxvirus closely related to smallpox, is especially alarming, coming as it does so swiftly on the heels of COVID-19. Just as we are enjoying returning to the old certainties, the worldwide infectious disease response may be set to ramp up once again.

### First identified

Monkeypox was first identified in 1958 following an outbreak among laboratory monkeys in Denmark. It turned out that the monkeys were not the reservoir for the virus, but the name stuck all the same. The actual reservoir remains something of a mystery, though the principal hosts are thought to be indigenous African rodents. While the disease is endemic in the tropical rainforest environments of West Africa

# EMERGING THREAT?

THE RAPID SPREAD OF  
A ZOONOTIC DISEASE

and the Congo basin, it escaped that environment in 2003, when an outbreak in Wisconsin in the US that affected more than 70 people was traced back to imported Gambian pouched rats.

Several other outbreaks of monkeypox have occurred since then but have mostly been limited and short-lived. This latest episode is somewhat more significant in reach and scale. The first case was confirmed on 6 May in the UK – traced back to a patient who had recently travelled from Nigeria – though the virus' often long incubation period means it may have been spreading for several weeks before that point. Since then, cases have been diagnosed across Europe, and in North and South America, and Australia. As at 17 June, they totalled more than 1880, with nearly 600 of those here in the UK.

### Symptoms

The symptoms of monkeypox are similar to those of its cousin virus, smallpox. It can incubate for anywhere between five days and 21 days, but most usually between six and 13 days, and the first

symptoms are a fever, headache, muscular pain and fatigue. Though these are fairly general signs of illness, the more specific indication of monkeypox at this stage is swollen lymph nodes in the neck. After a few days of this comes the vesicular rash, usually starting on the face and then spreading to the rest of the body, particularly the palms of the hands and the soles of the feet, inside the mouth, on the genitals and even in the eyes. This rash, like that seen with smallpox, is composed of clusters of blisters or lesions filled with fluid that often burst before drying up and then scabbing over.

Though it sounds nasty, monkeypox is, in most cases, fairly mild and self-limiting, with symptoms clearing up after two to four weeks. However, for some people the disease can be a far more dangerous prospect. For the young and the old, people with compromised immune systems and pregnant women, it can cause lasting damage, such as birth defects and loss of vision, and

complications from secondary infections, such as pneumonia, sepsis and encephalitis. The fatality rate for this current strain, which is believed to be the weaker West African variety, is expected to be around 3%.

### The leap

Originally the disease would have been transmitted to humans when they came into contact with infected animals or, on occasion, ate infected meat. But now the virus has made that leap across the species, it's spreading from human to human, though infection requires close, even intimate, contact. That means direct exposure to an infected person's lesions, body fluids, coughs or sneezes. Contaminated surfaces are a typical route for infection, especially bedclothes, towels and other material that may have soaked up the virus-laden fluid released when the lesions rupture.

In the UK, many of the early cases have been among young homosexual and bisexual men in London. While



## MONKEYPOX – A TIMELINE



**1958**

**1958**

Monkeypox is first identified after an outbreak among laboratory macaques in Copenhagen.

**1970**

The first human case of monkeypox is recorded: a baby boy in the Democratic Republic of the Congo (DRC) Central Africa.

**1970  
ONWARDS**

Human cases are reported in 11 countries across Central and Western Africa.

**1981–86**

More than 300 human cases are reported in the DRC, most a result



of contact with animals. The fatality rate is around 10%.

**1996–97**

Another DRC outbreak, this time most cases are a result of human-to-human contact.

**2003**

The first outbreak outside of Africa occurs in the US. Around 70 people are infected, with no fatalities.

monkeypox is not in itself a sexually transmitted disease, it does suggest that the intimacy of sexual activity may be a significant factor in the current spread of the infection. People who have everyday contact with these infected people, such as family members and healthcare workers, will also be at risk.

But at this early stage much of the recent outbreak remains a puzzle simply because it is so unprecedented. For a disease that was predictably restricted in the main to parts of Western and Central Africa, it has suddenly become very unpredictable. Why an outbreak now and why in so many different countries?

### The outbreak

"In terms of why it's spreading, I think several things may be going on here," says Dr Sarah Pitt, principal lecturer in the School of Applied Sciences at the University of Brighton. "One of them is that outside of Africa, you just wouldn't have been prepared for it. The public health authorities weren't expecting an outbreak and it has taken them a while to start dealing with it."

**"It's now possible to go on a flight without having pre and post COVID tests, it's logically much easier"**



Something else that may have helped the spread is that, as with many infections, there is great variation in the severity of the symptoms. Some people develop a rash with lesions all over their body and some have only a few lesions. "It might be that some infected people had a couple of spots in areas where they weren't aware of them and could have passed it on to others without really knowing about it," says Pitt. Even if they were aware of a lesion they won't necessarily have realised that it was monkeypox, given the disease's relatively low profile up to this point.

Another potential factor is the restart of international travel, which noticeably took off again this spring. "It's now possible to go on a flight without having pre and post COVID tests, it's logically much easier," says Pitt. Along with the freedom of movement restored after the travel restrictions of COVID, other pandemic-imposed barriers may also have fallen. People have started having fun again and are perhaps throwing caution to the wind in the process. One theory suggests this outbreak is linked to sexual contact at recent European festivals.

Could COVID also have assisted this outbreak of monkeypox after so many immune system challenges during the past two years, leaving large numbers of people vulnerable to infections they might have otherwise shaken off? "Some 70% of people in the UK are expected to have had COVID," says Pitt, "and we know that does potentially affect your immune system, even if you think you've fully recovered. It's possible this outbreak might be linked to COVID in that way but it's a moot point".

IMAGES: SCIENCE PHOTO LIBRARY/ALAMY/ISTOCK/SHUTTERSTOCK

## 2017–19

Nigeria experiences an outbreak, with over 500 suspected cases and fatality rate of around 3%.

## 2018

The UK records its first case, a Nigerian national who travelled to the country.

## 2019

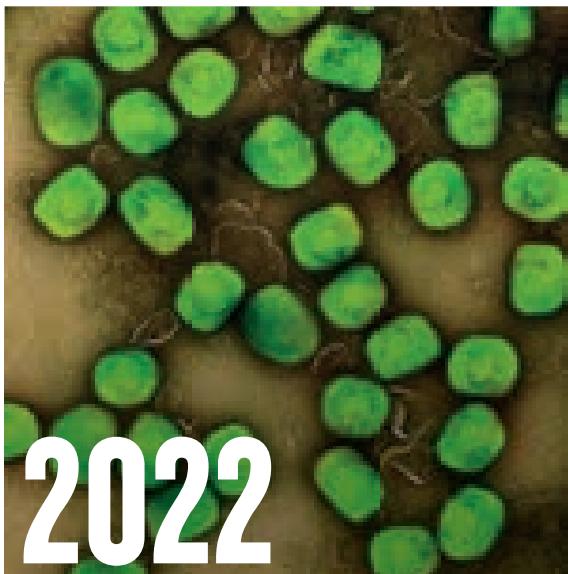
A case emerges in Singapore – another traveller from Nigeria.

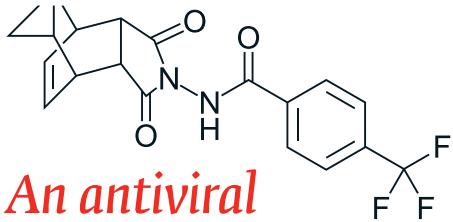


## MAY–JUNE 2022

A new case emerges in the UK. Multiple cases follow in more than 20 non-endemic countries. Studies are launched to understand infection and transmission. WHO warns the disease may become endemic outside Africa. The question of the true burden of the disease is unanswered.

## 2022





## An antiviral agent, tecovirimat, developed to treat smallpox, has also been licensed to treat monkeypox

### The new COVID?

With WHO and all the relevant national infectious disease agencies launching investigations, along with containment and treatment programmes, the real drivers behind this outbreak should become clear soon enough. For the time being, though, there is little need to worry that this is the new COVID, that pandemic restrictions are about to come slamming down again. “With COVID, flu and colds, the virus is largely airborne,” says Pitt. “An infected person can cough and sneeze and the virus hangs around in the air and then you can go to a supermarket or travel on a train and pick it up. Monkeypox is different because it requires that really close contact.”

The other key difference is that COVID was a novel virus, whereas monkeypox, related so closely to smallpox, which has plagued humanity for thousands of years, is well established. “We haven’t had any smallpox cases since 1980, but our immune systems, our genetic makeup, will still have something to work with against monkeypox,” says Pitt. “But the key problem with a lot of zoonotic diseases is that they are brand new in the human population. That’s part of what we saw early on with COVID, that massive overreaction of the immune system. It just didn’t know what to do with this new virus.”

### Zoonotic threats

This points to the underlying and ever-growing threat from new zoonotic



### OUTBREAK RESPONSE

**Sequencing of virus isolates from the current outbreak of monkeypox indicates it's the milder West African strain rather than the stronger Central African version.**

Vaccines used to eradicate smallpox have also provided protection against monkeypox. A new smallpox vaccine was licensed in 2019 and has been approved to prevent monkeypox.

An antiviral agent, tecovirimat, developed to treat smallpox, has also been licensed to treat monkeypox. This drug inhibits the activity of the VP37 viral envelope protein, preventing the production of progeny virus from an infected cell.

diseases. While monkeypox is not necessarily that threat, others certainly are lurking around the corner.

The ongoing depletion of natural habitats, putting humans in closer contact with wild animal populations, is a clear factor in raising the risk of novel zoonotic pathogens, whether viral, bacterial or parasitic. So too is the burgeoning global agricultural sector, where industrial quantities of livestock are giving rise to antimicrobial resistance, affording pathogens new opportunities to exploit and flourish, and to make the jump over to human hosts. Mass-scale food production processes also pose a risk, as do the more traditional and less-ordered meat markets that trade in wild animals – though the investigation into the spillover event for COVID remains inconclusive, a key venue for that pivotal moment remains such a market in Wuhan, China.

As COVID has amply demonstrated

over the past few years, any novel zoonosis brings with it the potential for an epidemic, exacerbated by a lack of effective treatment and prevention, triggering enormous social, economic and political consequences, and causing millions of deaths.

“I think all this just goes to show how important surveillance is,” says Pitt. Pre-COVID, there may have been a sense that infectious diseases wreaking havoc on a global scale were a shrinking problem, that public health and vaccine programmes had effectively dealt with them, and that the true challenge for medical science, and the best investment for precious resources, was now the burden of non-infectious genetic and lifestyle disease, such as cancer, diabetes and cardiovascular conditions. “And so we took our eye off the ball,” says Pitt.

### Keep vigilant

The emergence of monkeypox at this time simply reinforces the point, as if it were needed, that infectious diseases have not gone away and are highly unlikely to do so in the foreseeable future.

“We’ve been rather good at controlling viruses and bacteria with vaccines and antibiotics and so on,” says Pitt. “A lot of lives have been saved over the past 100 years and people’s quality of life has also improved as a result of these measures. But we have to keep vigilant. COVID and this latest outbreak of monkeypox have highlighted just how important that vigilance is. Governments cannot afford to think the job is done. They have to invest in training scientists, in equipment, in sequencing capacity, in laboratory space and facilities, in everything that helps us deal with these diseases.” 

# A vital leap forward in cardiac testing

Speed meets accuracy where it matters most – the wait is over for hs-cTnI at the point of care.



When ruling out a potential myocardial infarction (MI), every minute spent waiting on test results comes at a cost. Patients and their families are anxious, and clinicians and laboratory professionals are pressured to identify the problem quickly and accurately. Increased time to results adds congestion to an already busy emergency department. But what if ED staff had access to high-sensitivity troponin right at the point of care?

Consider the value of adding a new tool at the clinician's disposal that can provide high-sensitivity troponin I (hs-cTnI) results in just 8 minutes from a single fingerstick and patient interaction. The solution is intuitive, easily integrates into the existing workflow, and gives laboratory partners centralised control over decentralised testing, so ED throughput can be improved for efficiency and confidence.

The Atellica® VT Li Patient-side Immunoassay Analyser, powered by Magnotech® Technology, will transform your chest pain assessment process to benefit patients, clinicians, and your operational workflow. Because when it comes to assessing patients with symptoms of an MI in the ED, trust, time, and resources aren't just valuable – they're vital.

[siemens-healthineers.co.uk/vtli](http://siemens-healthineers.co.uk/vtli)

# ACUTE LYMPHOBLASTIC LEUKAEMIA

Lecturer in Biomedical Science at the University of Salford **Tahmina Hussain** looks at leukaemia and presents a case study.

**L**eukaemia is a cancer of the blood that involves the proliferation of white blood cells and can be categorised into two types: acute or chronic leukaemia. The rapid progression of immature white blood cells and blasts is classified as acute leukaemia, whereas chronic leukaemia develops slowly over a period of time and involves an excess of mature white blood cells that are malignant. Leucocytes originate from either the lymphoid series (T and B cells) or from the myeloid series (neutrophils, monocytes, basophils, eosinophils, erythrocytes and megakaryocytes). These two types of leukaemia can be further classified depending on whether the blasts are lymphoblasts or myeloblasts or if the mature white blood cells are lymphocytes or myelocytes:

- Acute lymphoblastic leukaemia (lymphoblasts)
- Acute myeloid leukaemia (myeloblasts)
- Chronic lymphocytic leukaemia (lymphocytes)
- Chronic myeloid leukaemia (myelocytes).

The subtypes of acute lymphoblastic leukaemia (ALL) are B-cell ALL and T-cell ALL and they can be distinguished by

immunophenotyping. ALL can be separated into three groups depending on their cellular morphology, blast size and nucleus to cytoplasm ratio. The three groups are L<sub>1</sub>, L<sub>2</sub> and L<sub>3</sub>. The L<sub>1</sub> and L<sub>2</sub> subtypes include the B and T lineage whilst L<sub>3</sub> includes only the B lineage.

The lineage in T-cell ALL can also be subdivided into three types:

- Early thymic precursor T-cell ALL
- Cortical/thymic ALL
- Medullary/mature ALL.

Cortical/thymic T-ALL is the most common subtype of T-ALL and is known to have a better prognosis. Identification of the subtype is important in the diagnosis of leukaemia particularly because some types have a poorer outcome than others as well as variable therapies, prognostic factors and higher risk of relapse.

## Abnormal proliferation

When the bone marrow produces the abnormal proliferation of white blood cells, this results in leukaemia, which can be classified into acute or chronic leukaemia, depending on whether the white blood cells are mature or immature. Although the number of white blood cells is increased, they cannot fight infections and the large numbers begin to interfere





*“The white blood cells cannot fight infections and the large numbers begin to interfere with the production of healthy blood cells”*

## TABLES 1-2: HIGH LACTATE DEHYDROGENASE AND WHITE CELL COUNT

**Table 1: Urea and electrolytes results**

Sodium	143	mmol/L	(135–145)
Potassium	4.0	mmol/L	(3.5–5.0)
Urea	3.9	mmol/L	(2.7–7.5)
Serum creatinine	69	µmol/L	(62–115)
Calcium	2.17	mmol/L	(2.10–2.65)
Phosphate	1.18	mmol/L	(0.70–1.40)
Total protein	66	g/L	(60–80)
Albumin	42	g/L	(33–49)
Globulin	24	mmol/L	(21–37)
Adjusted calcium	2.13	µmol/L	(2.10–2.65)
Total bilirubin	12	IU/L	(1–20)
Alkaline phosphatase	83	IU/L	(25–110)
AST	31	IU/L	(5–45)
LDH	<b>2594</b>	IU/L	(200–550)
GGT	16	IU/L	(0–65)
Glucose	5.8	mmol/L	(3.2–6.0)
Magnesium	0.90	mmol/L	(0.60–1.00)
CRP	10	mg/L	(0–10)
Uric acid	0.19	mmol/L	(0.00–0.42)

**Table 2: Full blood count results (H: high, L: low, pink: abnormal)**

White cell count	H	<b>76.1</b>	X10 <sup>9</sup> /L	(4.0–11.0)
Haemoglobin	L	<b>73</b>	g/L	(130–180)
Platelet count	L	<b>32</b>	X10 <sup>9</sup> /L	(150–400)
Red cell count	L	<b>2.18</b>	X10 <sup>12</sup> /L	(4.50–6.50)
MCV		93.0	fL	(76.0–96.0)
HCT	L	<b>0.203</b>	L/L	(0.400–0.540)
MCH	H	<b>33.5</b>	pg	(27.0–32.0)
MCHC		360	g/L	(320–360)
RDW	H	<b>25.0</b>	%	(12.0–16.0)
Atypical lymphs	H	<b>3</b>		(1–2)
Neutrophils	L	<b>0.76</b>	X10 <sup>9</sup> /L	(2.00–7.50)
Lymphocytes		3.04	X10 <sup>9</sup> /L	(1.50–4.00)
Blasts	H	<b>72.29</b>	X10 <sup>9</sup> /L	(0.00–0.00)



with the production of healthy blood cells. This results in changes in the functioning of vital organs leading to the reduction of platelets and red blood cells. Consequently, there is a reduced supply of oxygen and abnormalities in blood clotting. As a result, the leukaemic patient develops anaemia and is at risk of infections and excessive bleeding.

### Risk factors

Although the incidence of leukaemia in most cases is random, risk factors have been identified in epidemiological studies. A number of viral and bacterial infections have been associated with leukaemia. Epstein–Barr virus (EBV) causes the infection of B and T lymphocytes and has been linked with B-cell ALL, whilst there is an association

between Human T-lymphotrophic virus-1 (HTLV-1) and T-cell ALL. HTLV-1 causes the proliferation of T cells and failure of apoptosis resulting in an increased risk of mutations occurring.

T-ALL is a disease of thymocytes and several processes are involved in the pathogenesis of T-ALL. The combination of various genetic mutations leads to the alteration of the normal mechanisms during thymocyte development that influence “cell growth, proliferation, survival and differentiation of cells”. The NOTCH signalling pathway controls the normal regulation of T-cell development and NOTCH1 is a significant receptor in the process of thymocyte development and is involved in the chromosomal translocation found in cases of T-ALL. The most common oncogene that has been

found in more than 60% of T-ALL cases is NOTCH1, where mutations cause the abnormal activation of the signalling pathway. Over 70% of T-ALL cases involve chromosomal deletions of the CDKN2A locus, resulting in the loss of suppressor genes p16/INK4A and p14/ARF. Both the activation of the NOTCH1 signalling pathway and the loss of the suppressor genes act together resulting in T cell transformation and ultimately contribute towards the pathogenesis of T-ALL. Zhu *et al.* carried out a study in 2006 to investigate the NOTCH1 mutation in patients with T-ALL. They found that NOTCH1 mutations were present in both paediatric and adult T-ALL cases and these mutations were limited to T-ALL as they had not been detected in patients with B-ALL. Translocation and abnormal expression of oncogenic transcription factors in T-cell progenitors are also a characteristic of T-ALL. Chromosomal translocations often trigger the

## TABLES 3-4: UREA AND ELECTROLYTES RESULTS AND FULL BLOOD COUNT

Table 3: Urea and electrolytes results			
Sodium	140	mmol/L	(135–145)
Potassium	3.6	mmol/L	(3.5–5.0)
Urea	4.1	mmol/L	(2.7–7.5)
Serum creatinine	57	µmol/L	(62–115)
Calcium	2.38	mmol/L	(2.10–2.65)
Phosphate	1.51	mmol/L	(0.70–1.40)
Total protein	65	g/L	(60–80)
Albumin	44	g/L	(33–49)
Globulin	21	mmol/L	(21–37)
Adjusted calcium	2.30	µmol/L	(2.10–2.65)
Total bilirubin	22	IU/L	(1–20)
Alkaline phosphatase	62	IU/L	(25–110)
AST	20	IU/L	(5–45)
LDH	523	IU/L	(200–550)
GGT	29	IU/L	(0–65)

Table 4: Full blood count results (H: high, L: low)			
White cell count	6.1	X10 <sup>9</sup> /L	(4.0–11.0)
Haemoglobin	L	114	g/L
Platelet count	L	91	X10 <sup>9</sup> /L
Red cell count	L	3.19	X10 <sup>12</sup> /L
MCV	H	101.6	fL
HCT	L	0.324	L/L
MCH	H	35.6	pg
MCHC		351	g/L
RDW	H	23.7	%
Neutrophils		4.80	X10 <sup>9</sup> /L
Lymphocytes	L	0.80	X10 <sup>9</sup> /L
Monocytes		0.30	X10 <sup>9</sup> /L
Eosinophils	L	0.00	X10 <sup>9</sup> /L
Basophils		0.00	X10 <sup>9</sup> /L

*“A significant recovery is evident from the full blood count and urea and electrolytes results”*

transcription factor oncogenes TLX1 and TLX3 and they play an important part in the pathogenesis of T-ALL.

### Case study

A 23-year-old male presented with pain in the mouth due to mouth ulcers and bruising on his body. On processing his blood tests, a high lactate dehydrogenase and white cell count was indicated as seen in Table 1 and 2.

A peripheral blood film and bone marrow sample was requested for morphological examination and a manual differential was performed, which revealed 95% blast cells of variable size but fairly uniform morphology, scanty cytoplasm with no visible granulation.

The diagnosis of ALL was suspected after examination of the blood and bone marrow film; immunophenotyping tests were requested for the diagnosis and classification of ALL. Immunophenotyping tests confirmed the diagnosis of T-ALL in

relation to the results obtained from all the tests including histology, cytogenetics and imaging.

The patient was treated with the following drugs:

- Dexamethasone
- Pegasparaginase
- Mercaptapurine
- Methotrexate
- Vincristine.

A significant recovery is evident from the full blood count and urea and electrolytes results seen in Table 3 and 4.

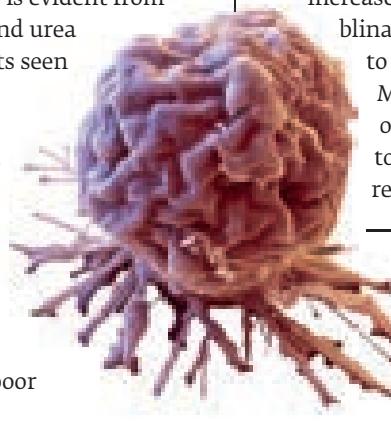
Minimal residual disease (MRD) is used as a prognostic marker in ALL, however, the treatment of MRD remains unattended and there is a higher risk of relapse and a poor

prognosis when a patient is tested MRD-positive.

Haemopoietic stem cell transplants are advised in this case; however, the prognosis remains poor. Monoclonal antibodies have been found to be effective and improve the prognosis of ALL in adults under the age of 60.

Blinatumomab is a non-glycosylated antibody and studies have demonstrated that it reduces the risk of relapse and increases survival rate. In one study,

blinatumomab was administered to patients to evaluate the MRD response. A total of 20 out of 21 patients converted to MRD negativity with a 80% response rate. 



Tahmina Hussain is a Lecturer in Biomedical Science at the University of Salford and an IBMS Council member.

# MYASTHENIA GRAVIS

## A PERSONAL JOURNEY

Rashmi Rungta gives an insight into her life with myasthenia gravis – a rare long-term condition that causes muscle weakness.



Born in 1970 in Kolkata, a sprawling city in the east of India, my family witnessed the very first symptoms of myasthenia gravis (MG) when I was just six months old. After a fall, I turned blue and eventually my eyes started to droop. I also started to get breathless during breastfeeds and was floppy. As these were unusual symptoms, it made my parents very anxious. They started to seek several medical opinions and treatments, including homeopathy. The treatments helped slightly but the symptoms persisted. I was diagnosed with MG by the end of the year and additionally cretinism and hypothyroidism two years later.

As necessity is the mother of invention, when my eyes drooped, I would use my left hand to lift my right eye and play with my right hand, which resulted in peripheral vision only in my left eye, since it remained closed.

When I turned seven, I underwent a thymectomy at the UCLA hospital in the US and at 10 years, became a research patient in NIH Bethesda as it was unknown to have autoimmune-acquired MG as a six-month-old. I was treated by renowned neurologist Dr W K Engel.

### Growing up with MG

Living with MG has not been smooth sailing and I have had my fair share of trials and tribulations. I have never known any normalcy, just “manageable” or “bad to worse”.

My condition did improve after thymectomy and being treated at NIH. Steroids caused a lot of weight gain and

excessive hair on my body. My condition was managed in India via general doctors in some consultation with the US medics, however, periodically I had bad episodes.

Due to lack of societal awareness and understanding of such a condition, I faced multiple challenges. At school, I was often bullied and excluded from joining in with other girls at play time. I was subjected to nasty pranks at an early age, which left

me feeling vulnerable and lacking in confidence. As the youngest sibling of two much older brothers, I grew up in a protected environment. All the factors combined made me into a shy and socially awkward adolescent, especially due to my droopy eyes. Because MG is such an invisible and unpredictable condition, my family struggled as well in my upbringing. If I fell ill or lost consciousness due to fits, then my family panicked. I grew up in an era and country where mental health awareness was

totally absent and any form of disability was a curse.

Despite the odds, I aspired to become an engineer from a young age, to follow in the footsteps of my father and brothers. I decided to take a leap of faith and went to a university away from home, but due to my condition and lack of support and public awareness, I struggled to adjust. I decided to drop out after trying for two years and returned home. The adverse impact of my condition was not only on my physical and mental wellbeing but cemented a misconception at home that I was incompetent. This was going to have lasting impact on my self-esteem.

### A new chapter

I had a few relapses of MG and, at one point, it resulted in a collar bone fracture from falling down the stairs. Crash diets to lose weight resulted in blood transfusions. I persevered to put the challenges behind me and, at the age of 25, I embarked on a new chapter with my first corporate job offer in my hand. I started to focus on my career and soon enjoyed the successes. My career took me to different parts of the world – UK, Europe, and the US.

I worked hard to transform my weaknesses into strengths and equipped myself with the right tools to further my career and take on new challenges. I have been on the senior management teams and have built and led teams of over 50, for large

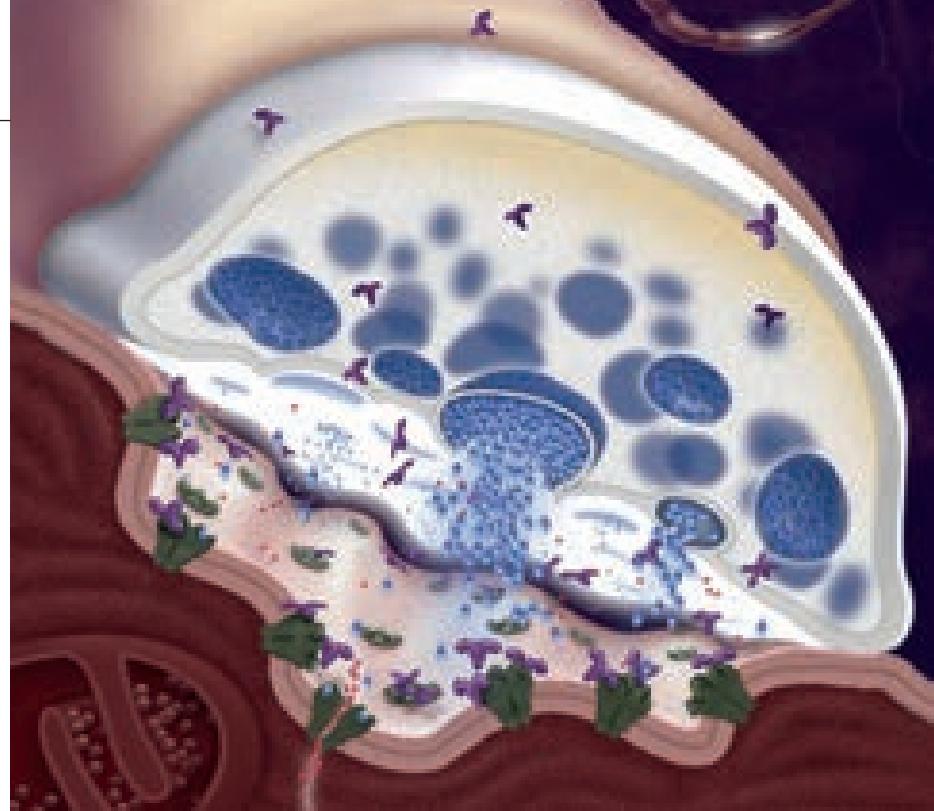
*“As necessity is the mother of invention, when my eyes drooped, I would use my left hand to lift my right eye and play with my right hand”*

multi-national corporations, such as Fujitsu Consulting, ITC Infotech and Deloitte. My clients have included FTSE 100 industry leaders Telia Sonera and IBM.

I did face medical issues from time to time and sought treatment in the respective country I was living in at the time. The only visible sign of my condition was my droopy eyes, but I learnt to ignore unwarranted stares and answered the questions honestly and the progress in my career helped. I moved cities within India as well and started living independently.

On a family trip to the US in 1996 and while working in the UK in 1998, I went back to Dr Engel, whereby he prescribed me prednisolone and Vit B12. While I was in Germany from 1999 to 2001, I was the subject of research at the Max Planck Institute, where I was prescribed pyridostigmine and azathioprine, although I did not start the medications due to a difficult personal situation.

In 2008 during my late thirties, my condition started flaring up again and an anti-allergic medication aggravated it further. As a result, I was unable to hold my hands up, walk and talk for more than five minutes, comb my hair, wear clothes, climb or descend stairs. A neurologist



started me on Mestinon every four to five hours, which helped immensely.

On my next upcoming trip to the US, I went back to Dr Engel in the University of Southern California in early 2009. After extensive examination, I was prescribed azathioprine with steroids, but I refused to take any steroids after having experienced severe side effects as a child. I continued to take Mestinon for temporary relief of my muscle weaknesses. Back in India, the Indian neurologist increased the dosage of azathioprine, which landed me in intensive care due to severe viral infection, high fever and difficulty in breathing and swallowing. With IV immunoglobulin, I came out of intensive care. I was able to stop Mestinon and just take it on an emergency basis eventually.

### Ready for challenges

In 2011, I decided to join London Business School on a Master's programme and decided to make London my permanent home. I am currently under the care of a specialist neurologist. As she was not convinced

about my acquired MG at such a young age of 6 months, my bloods were tested at the University of Oxford. All the results came back negative for congenital MG and she confirmed that it is indeed acquired.

Professionally, I worked at Deloitte Consulting and then became responsible as Country Head for an overseas SME. I have engaged with the likes of industry-leading clients Unilever, Harley Davidson, USAID and so on.

Being on immunosuppressants makes me vulnerable to infections and I have been admitted to the A&E due to viral infections (norovirus and rotavirus) and once due to an episode of vertigo.

I was shielding during the pandemic and have now taken four vaccinations, although not sure how protected I am.

Within three years of being in London, I joined Myaware, a charity supporting people with myasthenia, as a member. It has been extremely helpful to meet and learn from others living with the same condition and contribute as well. I am now also a Trustee of this organisation, with an aim to contribute and support everyone who experiences similar or even tougher challenges owing to MG. I am a Trustee of two charities, including Myaware, and a governor of two schools as well. I am always ready for new challenges and have always believed that where there is a will, there is a way. I have not let MG conquer me but rather conquered MG to the greatest extent possible. 

**“I was unable to hold my hands up, walk and talk for more than five minutes, comb my hair, wear clothes, climb or descend stairs”**



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# THE NEW STANDARD

## ISO 15189: AN INTRODUCTION

ISO 15189:2012 has undergone a review by the international community over the last few years. With its publication nearly here, we look at the standard.

**T**here were two key reasons for the review. Firstly, because the parent standard – ISO/IEC 17025:2017 – had been updated to comply with the structure of the normative ISO 9001:2015, and secondly, as ISO/IEC 17025:2017 is a normative reference of ISO 15189, there was a requirement for the documents to be aligned. Also ISO 15189:2012 had reached its periodic review date.

A vote was taken by the international community, and it was agreed that the standard required review and update to reflect the changing demands of the medical laboratory community. The standard has undergone several draft revisions, some of which have been publicly available on the British Standards Institution website ([bsigoup.com](http://bsigoup.com)), and is due to go for a vote on the final draft international standard (FDIS) within the next few weeks. This is the final voting

process required to turn the draft standard into a full ISO standard. There is no longer an option to make technical changes to the document and only editorial issues will be actioned.

### Robust process

There has been a robust process to revise the standard, with many thousands of comments received and reviewed from across the globe. The wording agreed must be translatable and applicable across many different and diverse health systems and medical disciplines. Legal and regulatory requirements in each country always take precedent over international standards.

Standards are written as guidance documents that may be used by accreditation services to assess laboratories. The standard is written as a minimum requirement and not a maximum; there is often a misconception that if the standard does not specifically

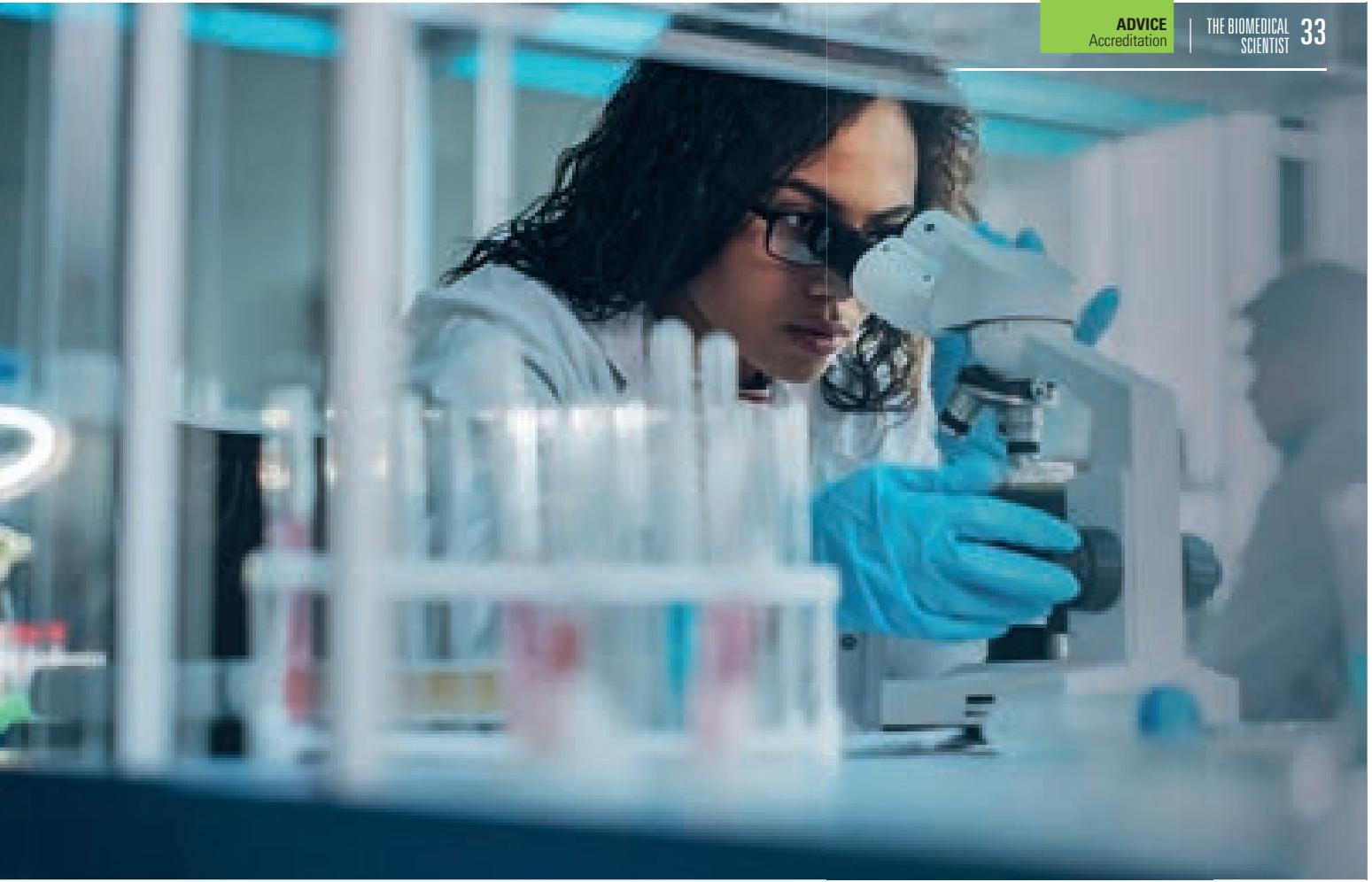


require or reference a process/activity, then it cannot be offered by an accredited organisation. This is not the case; if there is an opportunity to improve the quality of the service offered to patients and other users, then this

inherently meets the requirements of the standard (old and new), so long as adequate justification and documentation is available.

A decision was made very early in the revision that the updated version needed to be patient-focused and risk-based as this is a clinical standard for a service that is key to the patient pathway. There was an understanding that, as effective as the current version is, there is a high degree of prescription and over-reliance on interpretation of the standard in terms of perceived accreditation requirements.

There are several useful reference standards quoted in the updated ISO 15189, none of which are compulsory, but



all of which add value to any quality system. These include:

**ISO 15190:2020:** Medical laboratories — Requirements for safety

**ISO/IEC 17043:2010:** Conformity assessment — General requirements for proficiency testing

**ISO 22367:2020:** Medical laboratories – Application of risk management to medical laboratories.

### Risk management

The concept of risk, and the requirement of the laboratory to be able to articulate this, will be one of the key requirements that accredited organisations will need to consider when demonstrating compliance with the updated ISO 15189. ISO 22367:2020 “Medical laboratories – Application of risk management to medical laboratories” is a useful document to support this, as it covers concepts including risk analysis, risk control, risk acceptability and risk monitoring. The intention of including a strong emphasis on risk management in the updated ISO 15189 is to understand and think about areas of risk that can

impact patient care, put the patient at the heart of any decision, and weigh up any impact to the patient of decisions made in the laboratory.

During an accreditation assessment, we anticipate that there will be significant discussion between the laboratory representatives and the UKAS assessment team regarding how the accredited organisation has considered

their management of risk. It is important to acknowledge that every accredited service will have service-specific risks, and that there is no “one-size-fits-all” approach to risk management.

### Service agreement

The concept of service agreements is another area that needs careful review and understanding. Service agreements are the cornerstone of any service. For example, should a laboratory wish to bring its point-of-care testing (POCT) service into its accredited scope, this will need to be managed by specific agreements with the service being supported. Examples could be an agreement with the accident and emergency department for blood gas, or blood gas and urinalysis.

Requirements for a POCT service are now incorporated into the body of the new ISO 15189 standard, to replace the current ISO 22870:2016, although there is a POCT-specific annex in the updated ISO 15189, to provide additional clarity and guidance. There is no longer a specific requirement for a

*There has been a robust process to revise the standard*

multidisciplinary POCT team, however, this does not mean that an accredited organisation can't have one. If an organisation continues with a multidisciplinary POCT team, this group could be used, for example, to agree and monitor the service agreements.

Once the updated version of ISO 15189 is released, ISO 22870:2016 will be retired and any new POCT assessments will be added to ISO 15189. There will be a transition period, allowing customers currently accredited to ISO 22870:2016 time to move to being accredited against the new ISO 15189.

Technology has moved on since the 2012 standard. The standard no longer uses the term "request form" but "examination request". This can be in any format agreed by the service user and the laboratory, for example electronic requesting systems or paper-based systems. Of course, there will need to be evidence of how the format was agreed, which takes us back to the importance of service agreements. There is still clear guidance in the new standard on what information is required when examinations are requested, regardless of the format of the examination request.

There has been some consideration for more local decision making. There are some "shall" statements followed by terms such as "as appropriate". "Shall" statements indicate mandatory requirements, as opposed to "should" statements, which are recommendations.

Where a "shall" statement is followed by "as appropriate", each organisation will need to consider, and provide evidence of what is and is not appropriate to their service. An example of this can be found in the requirements relating to information for patients and



## *"Each lab is different and will need to make different information available"*

users; each laboratory is different and will need to make different information available to users. Consider an andrology lab, where samples may be produced by patients on site, with very specific timing and sample handling/transport requirements, compared to a histology department, which may only process formalin-fixed samples, where delivery is less time critical, and the lab has no patient contact.

### Decision making

There is a greater emphasis on risk to the patient and clinical decision making in the updated standard. For example, there is no longer a prescriptive requirement on how samples are labelled, however, these still need to be traceable to the patient. Also, the decision to process or not to process a potentially compromised sample should be linked to the risk to the patient before deciding on how to action the request. Consider the risk of not processing an inadequately labelled, potentially cancerous, skin biopsy vs. not processing an inadequately labelled urine sample.

There has been an update to the quality control (QC) section of the standard; there is no longer a requirement for the laboratory to follow the manufacturer's minimum testing intervals, but to look at the stability of the assay and the risk to the patient of a QC fail. There is also updated advice on QC covering the range of the assay.

The definitions of verification and validation remain unchanged, and the requirement for verification data to show how the

laboratory can demonstrate that a validated method is acceptable in their hands is still in place. However, the requirements for method validation and verification have been updated, to ensure a focus on the clinical question being asked and assurance that the methods are fit for that purpose.

More information will become available over the next few months, both about the content of the updated standard and about the UKAS process of transitioning from accreditation to ISO 15189:2012 to the new standard.

### What now?

The International Laboratory Accreditation Cooperation (ILAC), will set a timescale in which all organisations accredited to ISO 15189:2012 worldwide must transition to accreditation to the new standard. This is likely to be a three-year transition period but will not be confirmed until publication.

The British Standards Institution (BSI) and UKAS are working closely together, and taking advice from professional bodies, including the IBMS and RCPPath, to ensure that everyone impacted by the new standard, including accredited organisations, UKAS assessment managers and technical assessors, and equipment/assay manufacturers, are aware of the updated requirements and understand how the changes affect them. UKAS will be delivering training sessions and writing a number of articles for *the Biomedical Scientist* throughout the rest of 2022 and beyond, to support this work. 



**Dr David Ricketts** is the Head of Laboratory Process at Health Service Laboratory, **Alyson Bryant** is Healthcare Accreditation Specialist at UKAS and **John Ringrow** is Senior Assessment Manager at UKAS.

# ON THE NIGHT SHIFT

Senior Lecturer **Sheri Scott**  
with practical advice for  
employers and employees  
on how to best manage  
mental and physical health  
while undertaking shift work.

In the April issue of *the Biomedical Scientist*, I took a look at the potential health effects of night shifts and the disruption of our circadian rhythms. In this article I explore preventative measures that employer and employee can take to mitigate those risks. By following the recommendations of the Health and Safety Executive (HSE) in combination with findings of the recent literature on shift-work risk we can adopt a mix of existing best practices, common-sense lifestyle changes and practical measures from the employer to the working environment, the serious health risks of shift work can be significantly reduced.

## Helping ourselves: travel

In total, 20% of accidents are caused by fatigue. Driving can be risky after a long shift, a night shift or before an early start.



The HSE provides several strategies to help make driving safer (see below).

### Food and drink

It comes as little surprise that consuming stimulants, such as caffeine and nicotine, before going to sleep is not recommended. Caffeine is a drug that acts as both a mental and physical stimulant. We should try to avoid consumption of caffeine for at least four hours prior to going to bed.

The HSE also recommend that we restrict our energy intake between midnight and 6am. We should try to eat at the beginning and end of the shift and, although a small bedtime snack is fine, it is recommended that you should allow two to three hours between the last main meal of the day and heading off to bed. You should avoid sugary foods as these provide a short-term energy boost followed by a dip in energy levels. Alcohol should be avoided for at least four hours before going to bed, as this will also disrupt your sleep during the day.

It is recommended that employees stick as closely as possible to a

normal day and night pattern of food intake, with the dividing of daily food into three main meals, with each contributing about a third to the overall intake.

The more energy demanding the tasks, the more frequent any meals and snacks should be. However, where possible, sugar-rich products should be avoided and employees should choose vegetables, salads, fruit, lean meat, poultry, fish, dairy products, grains, vegetable soups, wholegrain bread, boiled nuts and green tea, which are more easily digested.

Eating and drinking patterns should be adapted according to the shift pattern. Afternoon/evening shift workers should consider having their main meal in the middle of the day, rather than during their shift, and night workers should eat lightly throughout the shift, with a moderate breakfast. Sufficient time is needed for digestion and it is important that plenty of water/fluids are consumed to avoid dehydration. Other foods to avoid

are those with high fat and salt content.

It is important to avoid the excessive use of antacids, tranquilisers and sleeping pills to try to combat some of the ill effects of shift work, as these will have a negative effect on health.

### Activities and environment

Before we settle down for the day, we need to make sure that family and friends are aware and considerate of our sleep hours and needs. You can put a notice in your window to alert potential callers, unplug the doorbell and change your phone to settings that are less likely to disrupt your sleep. Try to ensure your environment is comfortable and quiet and at an appropriate temperature. Voicemail, foam earplugs, eye masks and good blinds or curtains are all worthwhile investments.

### Preparation

Preparing for a day rest should follow the same principles as preparing for bed at

## TOP TIPS FOR TRAVEL

### Driving to and from work:

- ✓ Use public transport or taxis rather than driving.
- ✓ Exercise briefly before your journey.
- ✓ Share driving, if possible.
- ✓ Drive carefully and defensively and try not to hurry.
- ✓ Stop if you feel sleepy and take a short nap if it is safe to do so.
- ✓ Make occasional use of caffeine or "energy" drinks.



night – you need to make time for quiet relaxation. It is best to try to establish a pattern to facilitate sleeping during the day.

The HSE and others recommend avoiding activities such as strenuous exercise before sleeping as this elevates the body's metabolism, which can remain elevated for several hours.

Age can also be a factor, with studies showing that sleep problems become more exaggerated from the age of 40.

Employees need to try to avoid doing 10 consecutive years of shift work and maintain a healthy lifestyle with exercise, regular mealtimes and good sleeping habits when not working.

## Alertness at work

On nights and very early mornings employees often find it difficult to remain alert, which can affect their performance. It can increase the risk of errors, injury and accidents. Tips to increase alertness include:

- Moderate exercise before the start of work and keeping the light bright.
- Regular short breaks during the shift, if possible.
- Moving and walking during breaks.
- Conducting more stimulating work at the times you feel most drowsy.
- Communication with co-workers.

## Employer steps

There are several steps employers can take to mitigate the health risks and these should be considered when implementing a shift pattern. When planning the shift rota, this should be considered as far in advance as possible. Schedules need to be flexible to allow workers to trade shifts, allowing for time off as required. Firstly, there needs to be an evaluation of the shift schedule design – does the duration of the shift contain sufficient number and length of break? Do the start and finish times allow adequate time between the shifts for sufficient sleep and meal

preparation? Quick returns need to be avoided (<11 hours) and the schedule of work should consider that the most demanding work is early into the shift when workers are most alert. Ideally, no more than five to seven shifts should be scheduled in a row, and it is recommended that no more than two nights in a row.

In addition to the night shifts, excessive overtime, split shifts and excessive 12-hour shifts should be avoided. If a shift pattern includes rotation, this rotation should rotate forward (morning – afternoon – night) wherever possible and there should be at least 48 hours between shift changes to allow the body to adjust.

It is important for the employer to consider individual differences and needs. It is important that day employment for workers who can't work shifts for medical reasons is available. Employees suffering with shift work disorder often experience a reduction of symptoms if they move back to a more traditional work schedule. If this is not the case, it is important they are encouraged to seek medical help, especially if symptoms persist for two weeks or longer. It is also important that the evaluation of sleep problems is considered during regular health checks, and that employees are educated to ensure that these health checks become more frequent from age 40 and in those who have been shift workers for 10 years or more. It is considered good practice to provide workshops and information sessions on stress management and healthy living.

Employers need to make sure the demands on the workers are reasonable. Mental and physical health need to be considered and employers should consider offering facilities for social activities, such as recreation and relaxation.

## TOP TIPS FOR SLEEP

- ✓ Identify a suitable sleep schedule.
- ✓ Most adults need 7–8 hours sleep a day, although this may decrease with age. If you cannot do this, try to rest, as this is still beneficial.
- ✓ Have a short sleep before your first night shift.
- ✓ If coming off night shifts, have a short sleep and go to bed earlier.
- ✓ Once you have identified a suitable sleep schedule, try to keep to it.

It is recommended that a 24-hour cafeteria where night workers can obtain a hot, nutritious meal and appropriate dining facilities are available and that allow a meal to be eaten away from the workplace, with colleagues, in as pleasant a surrounding as possible, with the inclusion of regular meal breaks factored into the shift schedule.

## Conclusion

Although many of these suggestions are considered best practice and/or essential requirements, in reality they are not always adopted. Staffing levels, facilities and financial implications all play a part in what is feasible.

However, it is hoped that increasing awareness of the implications on health and the NHS working towards sustainability development goals (which include SDG3, Good Health and Well-being), means there will be a move towards supporting these recommendations and requirements in the future. 

**Sheri Scott** is a Senior Lecturer in Biomedical Science at Nottingham Trent University



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# MY IBMS NEWS



## ANNUAL GENERAL MEETING

The 80th Annual General Meeting of the Institute of Biomedical Science was held on Saturday 11 June. Tim Sutherland, an archaeological consultant who lectures and advises on historic battlefield-related issues to government, developers, students and the media, gave a presentation to those present.

It was titled: "Investigating the dead: human remains from the Battle of Towton, AD1461, and what they can tell us."

The AGM heard one nomination for a national member was received by the due date from Mrs Sheri Scott, who took office from the conclusion of the meeting.

Mr McDowell, Dr Walsh, Mr Usher, Mr Coles and Mrs Andrew were deemed duly elected regional members of Council, without the requirement for a ballot.

To reduce the cost of sending

publications, it was proposed to amend Article 16 so that members' entitlement to receive journals and other publications will cease as soon as their subscriptions are overdue.

There were a number of awards handed out at the meeting, including the Higher Specialist Diploma Company Members' Prizes, which went to:



Meerani Munasinghe from Colchester General Hospital for the Higher Specialist Diploma Company Members' Prize in Medical Microbiology.

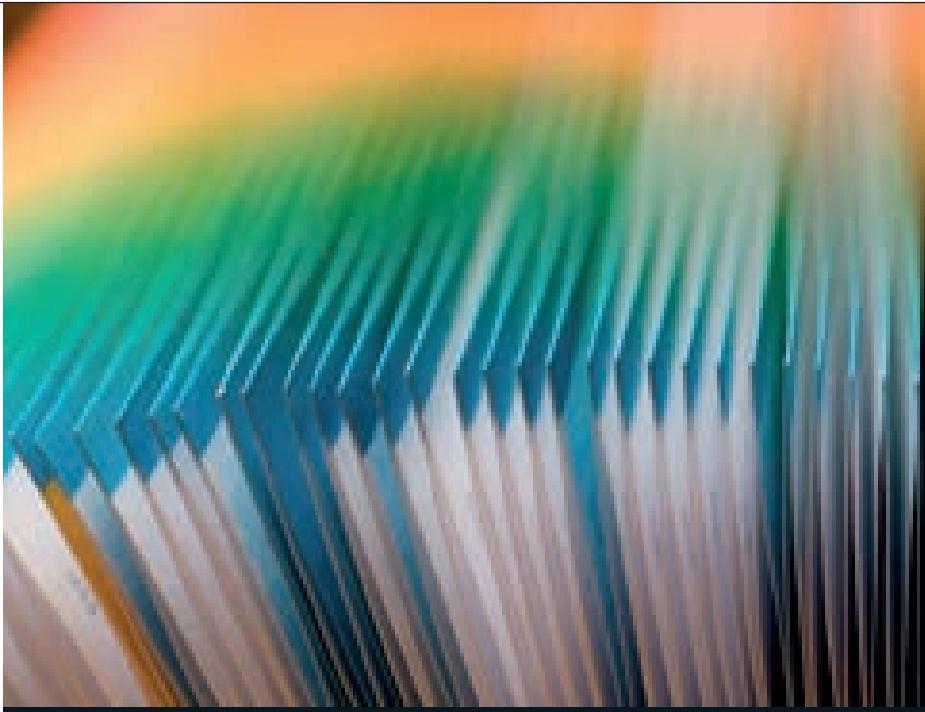
Emily McNeill from Royal Lancaster Infirmary for the Higher Specialist Diploma Company Members' Prize in Transfusion Science.

Rachel Doherty from Glasgow Royal Infirmary was awarded the Higher Specialist Diploma Company Members' Prize in Clinical Chemistry.

The IBMS also awards a Company Members' Prize for the candidate who achieved the highest mark across all the Diploma of Expert Practice qualifications. This year this was awarded to Rudi Schmigylski for her marks in the Diploma of Expert Practice in Histological Dissection - DEP in Histological Dissection.

Also awarded was the R J Lavington prize, which was established in 1977 in memory of the man who was General Secretary of the Institute for 22 years, from 1948 to 1970. Richard Lavington, who took the post after 28 years at the laboratory bench, was already a member of the Executive Committee at the age of 26. He had exceptional ability and character and was described as having "the finest art of a secretary concealing notable efficiency behind a sunshine of consideration, kindness and infectious happiness".

Since 2003, this prize, which consists of a payment of £500 and a silver medal, has been awarded annually to the candidate who, at the first attempt, receives the highest mark in the Higher Specialist Diploma examination across all disciplines. This year it was presented to Emily McNeill who undertook the Higher Specialist Diploma in Transfusion Science.



## PANDEMIC RESPONSE

## COVID-19 INQUIRY: NEW TERMS OF REFERENCE

After giving extensive feedback on the initial Terms of Reference for the UK COVID-19 Inquiry, the IBMS is pleased to see some of its recommendations taken on by the Inquiry's Chair Baroness Hallett. After the public consultation, the new scope of the Inquiry's investigation makes clear reference in the "workforce testing in the social care sector" section to "infection prevention and control". Most importantly for our profession, the IBMS and the rest of the public were heard with regard to the need to analyse the government's use of the available pool of experts and data when planning the COVID-19 response.

A new bullet point has been added to address "the role of experts, advisers, science and data in informing the government's pandemic response". IBMS Chief Executive David Wells said: "The COVID-19 Inquiry will be far-reaching so it was important that we sought to ensure that the experience of our members was a central part. "I am pleased that we have been listened to on this point and that changes have been made to the Inquiry's scope. The scope still does not go far enough to answer all the questions we might have and we will continue to push for our members' voice to be heard."

## PROFESSIONAL PROMOTION

## MEDIA FELLOWSHIP AWARDED

The IBMS-sponsored Association of British Science Writers (ABSW) Media Fellowship for 2022 has been awarded to Dr Sarah Pitt.



The IBMS wants members to be in the media – promoting the profession, standards and expertise.

That's why the institute sponsors a place on the ABSW Media Fellowship scheme for one IBMS member.

The ABSW Fellowship provides an opportunity for practising scientists, clinicians and engineers to spend two to six weeks working at the heart of a media outlet, such as *The Guardian*, *BBC Breakfast* or *Sky News*.

The chosen Fellow gains the chance to work within the media, understand why and how stories are selected and then collaborate with journalists.

Sarah said: "I am very pleased to have been awarded a place on the Association of British Science Writers Media Fellowship scheme.

"I have done quite a few media interviews and have contributed to short articles over the last couple of years. I am looking forward to finding out more about what it is like to prepare and produce programmes and understand more about the journalists' perspective on science news stories."

Over the course of the pandemic, Sarah has been a very active IBMS member – interviewing in the media on behalf of our members and the public in order to spread fact-checked, professional information.

## PROFESSIONAL DEVELOPMENT

## CPD awards open for nominations

The Science Council's CPD Awards are back to continue the celebration of outstanding CPD, with nominations open until 17 July.

The CPD Awards are designed to celebrate outstanding professional development in science, showcasing examples of good practice and continuous improvement.

They celebrate the professional development efforts and achievements of registrants across the four Science Council registers: Registered Science Technician, Registered Scientist, Chartered Scientist and

Chartered Science Teacher.

Christian Burt, Professional Support Services Manager at the IBMS, said: "The Science Council CPD awards are a unique opportunity for IBMS registrants to demonstrate their commitment to lifelong learning. I strongly recommend a self-nomination to showcase to the wider scientific and technical community, the dedication to CPD from biomedical scientists."

→ For more information visit [bit.ly/3HFcYxP](https://bit.ly/3HFcYxP)



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Institute of Technology Sligo (part-time)

- Biomedical Science (Life Sciences)
- Biomedical and Bio-Industrial Sciences
- Applied Medical Sciences

### Full-time courses:

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MSc Personalised Medicine (eLearning, part-time)





# TRENDING BIOMEDICAL SCIENCE DAY

A round-up of all the activity on the sixth annual Biomedical Science Day.

The biggest ever Biomedical Science Day saw thousands of members celebrating the profession and millions of people reached online.

The day was held on 9 June with members promoting their vital work to the public and colleagues in healthcare, as well as NHS decision-makers.

The hashtags #AtTheHeartOfHealthcare

and #BiomedicalScienceDay2022 trended in the top five on social media and are estimated to have reached more than four million people.

Prominent politicians (see box, overleaf) and influential organisations and individuals tweeted their support, while thousands of IBMS members took part both virtually and face to face.

Public engagement events and laboratory tours took place across the UK

and hundreds of members set up stands for the public and medical colleagues in hospital foyers.

The celebrations continued online, with members following and engaging with the IBMS social media channels.

## Social media

As ever, participation and enthusiasm was high on social media, as the IBMS encouraged members to use the hashtags #BiomedicalScienceDay2022 and #AtTheHeartOfHealthcare.

On Twitter, #BiomedicalScienceDay2022 was trending for most of the day and was used in posts 4212 times, with a total



of 1467 accounts sharing the posts.

Some of the top accounts that posted and used the hashtag included the UKHSA, Lord Bethall and the best-selling author Dr Amir Khan.

On the day, more than 65,000 people viewed the IBMS Facebook gallery, where pictures were posted from labs around the UK, while on Instagram and TikTok members and NHS trusts shared creative photos and videos of their celebrations, hosted live streams explaining their roles and held virtual tours of their labs.

Members who tagged @IBMScience were included in the IBMS Instagram and Facebook story, chronicling the highlights of the day. These posts can still be viewed on the IBMS Instagram account under "highlights".

### Public engagement,

Communications teams in hospitals, trusts and university laboratories once again handed their social media accounts over to their pathology staff and allowed them to celebrate and inform their followers about the skills and expertise involved in biomedical science.

The IBMS had over 700 entries to its competitions – with members sharing





## POLITICAL SUPPORT

The following politicians tweeted their support for the profession on Biomedical Science Day:

[Caroline Dinenage MP](#) – Conservative MP for Gosport

[Rachel Hopkins MP](#) – Labour MP for Luton South

[Ben Everitt MP](#) – Conservative MP for Milton Keynes North

[Stuart Anderson MP](#) – Conservative MP for Wolverhampton South West

[Liz Twist MP](#) – Labour MP for Blaydon

[Karen Bradley MP](#) – Conservative MP for Staffordshire Moorlands

[Martyn Day MP](#) – SNP MP for Linlithgow and East Falkirk

[David Duguid MP](#) – Conservative and Unionist MP for Banff and Buchan

[Colm Gildernew MLA](#) – Sinn Féin MLA for Fermanagh South Tyrone

[Lord Bethell](#) – Conservative politician in the House of Lords

## FAST FACTS: SOCIAL MEDIA

**42120**

Biomedical Science Day tweets

**4m** potential audience reached on Twitter

**65,000**

people viewed the IBMS Facebook gallery of images on the day



photo and video submissions, including hundreds for the popular “Biomedical Bake” and “Biomedical Meme” contests.

Members also set up their own public engagement events, with 264 event packs distributed for members’ events across the UK and 32 members’ activities were given IBMS funding, totalling over £14,000 in grants.

IBMS Council member and Lecturer in Biomedical Science Tahmina Hussain hosted a popular “Here to Help” webinar, providing career advice and tips for students on the day, with the webinar receiving very positive feedback from attendees.

# JOURNAL-BASED LEARNING EXERCISES



Please select your choice of correct answers and complete the exercises online at: [www.ibms.org/cpd/jbl](http://www.ibms.org/cpd/jbl)

**DEADLINE WEDNESDAY 5 OCTOBER 2022**

**Approach to interpreting common laboratory pathology tests in transgender individuals.** Cheung AS, Lim HY, Cook T *et al.*

*J Clin Endocrinol Metab* 2021; **106** (3): 893–901. doi: 10.1210/clinem/dgaa546. Assessment No: 070322

01	CKD-Es the Chronic Kidney Disease Epidemiology Calculation.	11	No studies have evaluated the optimal estradiol concentration for feminisation in people presumed male at birth.
02	Many common laboratory tests such as haemoglobin, iron studies, cardiac troponin and creatinine are affected by sex steroids or body size.	12	In trans people who have been on established and full-dose feminising hormone therapy (estradiol and anti-androgen) for at least six months, there is a significant increase in haemoglobin, haematocrit, and red blood cell count to the female reference range.
03	Trans people are individuals whose gender is different than that presumed for them at birth and includes people with a binary and/or nonbinary gender identity.	13	Reference ranges for serum ferritin, a common indicator of body iron status, vary depending on age and sex.
04	Masculinising hormone therapy is not typically testosterone alone.	14	In clinical pathology laboratories eGFR is calculated based upon an individual's serum urea, creatinine level, age and sex.
05	Feminising hormone therapy is usually estradiol and an androgen.	15	For those receiving masculinising hormone therapy with testosterone, given higher muscle mass and lower fat mass compared to females, the female CKD-E formula would be more appropriate.
06	Spirostanolactone or cyproterone acetate will induce body fat redistribution to a more gynoid pattern, with increases in fat mass and decreases in muscle mass.	16	Lower reference limits based on sex-specific 95th percentile centiles for hs-cTn are subtly higher for people recorded as males than those recorded as females in population studies.
07	Target sex-steroid reference ranges on gender-affirming hormone therapy are generally the normal reference ranges of an individual's affirmed gender.	17	There is currently insufficient data to draw an inference regarding the appropriate reference range in people using gender-affirming hormone therapy.
08	Using a former pronoun, gender marker, or name, even if still listed on identity documents, can cause intense distress and lead to, or exacerbate, dysphoria for an individual.	18	No "one size fits all" interpretation ideally should be individualised by the treating clinician based on the clinical information.
09	There is a lack of long-term outcome data on the safety of using a particular reference range.	19	For urea and electrolytes there is no sex-specific reference ranges.
10	It is clear that trans-specific reference ranges are required for a period after gender-affirming hormones are commenced to monitor analytes that are gradually affected by sex hormone.	20	Dual reporting of both male and female reference ranges is another potential option; however, current laboratory information system barriers exist.

## REFLECTIVE LEARNING

01	What test results are influenced by hormone therapy and what are the biological reasons for these influences?	02	What do you consider to be a way forward to tackle potential incorrect interpretation of results in this group of patients?
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**DEADLINE WEDNESDAY 5 OCTOBER 2022**

**Updated diagnostic criteria for paraneoplastic neurologic syndromes.** Graus F, Vogrig A, Muñiz-Castrillo S *et al.* *Neurol Neuroimmunol Neuroinflamm* 2021; 8 (4): e1014. (<https://nn.neurology.org/content/8/4/e1014>). Assessment No: 070522

01	Patients with breast cancer and paraneoplastic opsoclonus-myoclonus syndrome (OMS) usually have Hu antibodies (also known as ANNA-1).	11	Positive results of antibody panels that are incongruent with the patient's neurologic phenotype and/or cancer (eg positive Yo antibodies in a male patient with seizures) should be critically evaluated and seek additional expert testing.
02	The definition of definite paraneoplastic neurologic syndrome (PNS) solely based on the presence of onco-neural antibodies is no longer adequate.	12	Paraneoplastic OMS in children accounts for 60% of cases and is closely associated with neuroblastoma.
03	Limbic encephalitis (LE) usually presents with short-term memory loss, seizures, and psychiatric manifestations progressing slowly over more than three months.	13	The term encephalomyelitis (EM) should be used only in patients with clinical dysfunction at multiple sites of the nervous system.
04	Positive results by commercial line blots or cell-based assay (CBAs) should be confirmed by brain immunohistochemistry; this is important if only serum is tested, the antibody titre is low, and/or the result is discordant with the clinical phenotype.	14	Paraneoplastic neurologic syndromes stated incidence varies from 1.6 to 8.9 per million person-years, suggesting that under diagnosis and under reporting are still relevant issues.
05	There are no absolute pathognomonic neurologic presentations associated with PNS.	15	Antibodies against surface antigens positive in serum but negative in the CSF should be reassessed in reference laboratories, particularly if the patient has high- or intermediate-risk phenotypes.
06	Paraneoplastic neurologic syndromes are remote effects of cancer with an immune-mediated pathogenesis.	16	Paraneoplastic neurologic syndromes develop in approximately one of 3000 patients with cancer.
07	Antibodies against P/Q type voltage-gated calcium channels (VGCCs) are present in nearly 90% of LEMS patients, and their detection is required for the diagnosis.	17	EM almost always associates with small cell lung cancer (SCLC) with Ri (also called ANNA-2) or CV2/CRMP5 antibodies.
08	Rapidly progressive cerebellar syndrome was previously known as subacute cerebellar degeneration.	18	GFAP may occur as an immunologic accompaniment in anti-NMDAR encephalitis with ovarian teratomas.
09	Neuronal IgG, IgM or IgA antibodies as diagnostic biomarkers all have diagnostic significance.	19	Indiscriminate and unfocused testing increases the chances of false-positive and false-negative results.
10	Brainstem encephalitis may co-occur with LE and is strongly associated with Ma2 antibodies, usually with underlying testicular tumours or non-small cell lung cancer (NSCLC).	20	About 10% of Lambert-Eaton myasthenic syndrome (LEMS) patients have symptoms of autonomic dysfunction (eg dry mouth, erectile dysfunction, and constipation).

**REFLECTIVE LEARNING**

01	Compare your testing algorithm for paraneoplastic disease and its compliance with the recommendations in this paper.	02	Compare and contrast the relative sensitivities and specificities of both indirect immunofluorescence and line blot assays for paraneoplastic disease.
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**IBMS RESOURCES****CONTINUING PROFESSIONAL DEVELOPMENT****My CPD**

Members can enhance their professional practice and development with the IBMS CPD scheme. The scheme offers members a flexible system of recording CPD that

is easy to use and meets the requirements for achieving and maintaining professional registration. The scheme is now electronic, so recording, amending and validating are all carried out online.

**Journal-Based Learning (JBL)**

IBMS JBL involves reading and answering questions based on articles in scientific journals. It is an excellent way to learn about scientific

advances and techniques as part of CPD.

**Reading resources**

IBMS reading lists, textbooks and journals support learning and development.

I am hugely excited to take on the role of IBMS Executive Head of Education and am looking forward to working closely with colleagues in practice and academia to build on the current IBMS education and training offer. I am keen to design, create and deliver education and training enhancements by working in partnership with you all on six key areas:

## Communication

The improved IBMS website is almost complete, giving us the opportunity to create updated content for students, academic staff, practitioners, trainees and the public. We are also using social media more to share news and stories about who we are and what we do. We can take this opportunity to be clearer about the benefits of Membership / Fellowship and IBMS qualifications and training.

## Consultation

I am keen to work with trainers, verifiers, specialist advisory panel members and universities to map the new HCPC standards to the registration training portfolio and IBMS-accredited degree programme documentation. I am also planning to work with IBMS colleagues, national education leads and our current membership to discuss and enhance our existing education and training provision, informing updates to the content and delivery of qualifications.

## Clarity of information

There are several routes to registration for biomedical scientists and clinical scientists. This offers flexibility but can also cause confusion. How students and employees can train



# HERE TO HELP ENHANCED EDUCATION

**Dr Sue Jones, the new IBMS Executive Head of Education, outlines the priorities in her new role.**

to become biomedical scientists then use IBMS qualifications to progress in their careers needs clarification. As Deputy Chair of the QAA Subject Benchmark Statement for Biomedical Science and Biomedical Sciences, I have co-created content to clarify the similarities and differences between the IBMS accredited and non-accredited degree programmes available.

## Consistency

I would like to enhance and develop robust quality

assurance processes, to underpin consistent decisions and outcomes. This includes expanding training for degree assessors, accreditation panel members, portfolio verifiers and module leaders or examiners of IBMS qualifications. The content and workload across post-registration qualifications in different subject areas needs to be more consistent. The assessment strategies and types used in both pre- and

post-registration qualifications need to clearly align with the required learning outcomes and roles in the laboratory.

## Collaboration

Core to our ongoing work is a united voice to support and promote the profession. I will work closely with IBMS colleagues, IBMS Council, universities and local practitioners to support strong and ongoing relationships. We can work together to ensure current and relevant technical skills and data analysis and interpretation are embedded for our students and trainees. The new IBMS digital platform offers a great opportunity to provide excellent online digital resources for all our members.

## Community

The IBMS “Support Hub”, peer-mentoring network and other activities can be used to create nationwide and regional communities of practice for laboratory trainers to raise the profile of this crucial role. We need to increase outreach work using hospital and university locations to raise the profile of the profession. This is important in order to create a talent pipeline for the future of our profession by promoting IBMS-accredited programmes and NHS placements as the route to registration. 





**SONIC HEALTHCARE  
UK**

## It Keeps Growing!

### Infection Sciences at the Halo Building

Sonic Healthcare UK's flagship Halo building in London contains the very best laboratory facilities, reflecting its ambition to provide an outstanding and transformational pathology service. One of these services is the Infection Sciences department.

This is a consultant-led service with regular clinical case studies and seminars presented by the clinical staff, who bring with them specialist knowledge and academic interests. There are several specialist centres in the user group, including the National Hospital of Neurology and Neurosurgery, the Royal National Throat, Nose and Ear Hospital, and Moorfields Eye Hospital. The department also operates the High-Level Isolation Unit Pathology Laboratory at the Royal Free Hospital, where patients with Hazard Group 4 pathogens, such as the recent viral haemorrhagic fever cases and monkeypox, are cared for.

The department receives more than 1.2 million samples per year, making it one of the largest and most complex pathology laboratories in the country. It has several specialist sections, including a Mycology suite, utilising a variety of molecular techniques; a dedicated Enterics laboratory, which is also home to the Hospital for Tropical Diseases, and a dual Containment Level 3 laboratory housing Mycobacteriology and a Tissues and Fluids laboratory. Technology ensures staff can concentrate on using their

scientific skills to interpret results, and includes MALDI-TOF, BD Kiestra, APAS analysers, EntericBio and extensive specialised IT solutions. The team are rapidly expanding molecular testing repertoires to add to the various RT PCR methods currently employed.

Quality is key to ensuring our patients and clients receive the best care as efficiently as possible. The departmental quality managers, who are supported by Sonic Healthcare UK's Quality Management Group and a separate QC bench, are dedicated to safeguarding procedures and results.

The department's dedicated Research and Development team investigates, validates and verifies the latest technology available to ensure we remain at the forefront of diagnostics, offering staff opportunities to work with this group on new developments where possible.

In a department of over 150 people, training and development is key to supporting staff engagement and progression. Sonic Healthcare UK's award-winning clinical training programme and established robust IBMS portfolio training programme for Certificate of Competence and Specialist Diplomas enables them to offer career opportunities and invest in growing their own scientific team. The department has STP training approval, several apprentices and staff completing various professional qualifications, including MSc and IBMS portfolios at varying levels.



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Working as part of a team, this is an excellent opportunity to develop skills, knowledge and experience in a unique busy laboratory. With diverse clinical requesters and high number of samples, our Infection Science team isolate the rarest of organisms, guaranteeing an interesting day!

Further information about the vacancies currently available at Sonic Healthcare UK can be found by scanning this Q-Code or visiting

[www.sonichealthcareuk.com/careers](http://www.sonichealthcareuk.com/careers)



## MY LAB

# ENCOURAGING AND SUPPORTING RESEARCH

**Professor Stephen Fôn Hughes** gives a guided tour of his laboratory in Wrexham, North Wales.

The Maelor Academic Unit of Medical and Surgical Sciences (MAUMSS) is a novel initiative by Betsi Cadwaladr University Health Board (BCUHB), co-established in 2021 by Professor Iqbal Shergill, Professor Stephen Fôn Hughes and Professor Arvind Arya. MAUMSS is designed to encourage and support research within the health board and to promote academic activity, basic science, and clinical research across North Wales and beyond.

MAUMSS is located in Wrexham (North Wales) and staffed by an interdisciplinary team of academics, clinicians, scientists and postgraduate students who are available to lead on, and help other healthcare professionals develop and run, all kinds of clinical research projects. It has several laboratories containing state-of-the-art molecular, analytical and diagnostic equipment. There are also meeting rooms, video-conferencing and hot-desk facilities. All of this is available for use to encourage new researchers, help maximise research impact and ultimately provide better outcomes for patients and the public.

The main aims and objectives of MAUMSS are to:

- Enhance the health board's profile by promoting MAUMSS as a Centre of Excellence for supporting staff development and continuing education and training, which is central to all healthcare professionals practice, with the emphasis



based on lifelong learning.

- Promote and develop expertise in academia (programme development), healthcare education (teaching and learning), and to encourage staff, affiliated colleagues and students within the region and beyond to undertake and participate in research activities.
- Develop a pan-Wales collaborative approach to academia and research scholarly activity.
- Develop and sustain long-term collaborative partnerships with local, national, and international higher education institutions and commercial organisations.

To achieve these aims, collaboration within the NHS and with academic and commercial organisations is essential.

MAUMSS has established collaborations with Wrexham Glyndwr, Aberystwyth, Staffordshire, Keele, Bangor, Warwick, Oxford, Swansea, Cardiff and Birmingham universities, along with the MRC Laboratory of Molecular Biology in Cambridge. Via BCUHB,



MAUMSS is an official partner with Wales Cancer Research Centre and Wales Kidney Research Unit. It is also affiliated with the Celtic Advanced Life Science Network and the Life Sciences Hub Wales.

Examples of feasibility or basic science research studies currently underway at MAUMSS include using artificial intelligence (AI) to monitor patients before and after surgery to identify those who will develop complications.

Several studies are looking to develop novel urological biomarkers to aid in the prediction of patients with post-operative complications and cancer recurrence. Changes to microRNA expression in head and neck tumours and epigenetic changes in triple negative breast cancer are being investigated. A molecular diagnostic technique is also being developed for the rapid diagnosis of bacterial meningitis in newborn babies, as is a project looking at hearing loss in elderly patients with dementia.

As part of its formal collaborative partnership with its local university, namely Wrexham Glyndwr University (WGU), MAUMSS has been instrumental in conceiving, developing and subsequently delivering IBMS-accredited BSc (Hons) Biomedical Science, an MSc in Biomedical Science and two IBMS-approved MRes programmes in Applied Biomedical Sciences Research and Applied Clinical Research. MAUMSS, in collaboration with WGU, also delivers successful MPhil and PhD programmes. 

For more information, visit [maumss.com](http://maumss.com) and follow @BCU\_MAUMSS on Twitter.

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