MICROBIOME

A GUT FEELING

[illegible] impact can the [illegible] have on [illegible]v? *p.24*

TRANSFUSION SCIENCE

BLOOD ON BOARD

An innovative project and collaboration with emergency services: *p.30*

SCREENING

MEASURING AMMONIA

A look at the latest on ammonia analysis and reporting: *p.34*

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CONTENTS

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MARCH 2020

EDITORIAL

5 Thoughts on the current coronavirus outbreak

NEWS

7 News in numbers

8 Research, funding, developments and clinical updates

13 Product advances and launches

OPINION

14 **The big question:** How do unions help in healthcare science?

16 **One-to-one:** Professor Simon Clark discusses a protein that is strongly linked to the most common cause of blindness in developed countries

SCIENCE

COVER FEATURE

18 **Global catastrophe?** With the coronavirus death toll continuing to rise, we ask if a virus will ever cause global catastrophe

24 **A gut feeling:** What impact can the gut microbiome have on the human body?

30 **Blood on board:** An innovative project in which a blood bank has collaborated with the emergency services

34 **Measuring ammonia:** A look at the latest on ammonia analysis and reporting

ADVICE

36 **Cervical screening in Moldova:** Introducing a project to improve the outdated cervical screening programme in Moldova

40 **Science Council CPD review:** An opportunity for members to demonstrate their excellence

MY IBMS

43 **Institute news:** The latest from the IBMS

44 **Journal-based learning:** CPD exercises based on journal articles

46 **CPD update:** Training courses, events and activities

47 **Here to help:** Advice on the revised training laboratory re-approval process

MY LAB

50 **David W Jones** gives a guided tour of Eurofins Forensic Services

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SCIENTIFICALLY PROVEN DEFENCES

Sarah May, IBMS Deputy Chief Executive, gives some of her thoughts on the coronavirus epidemic.

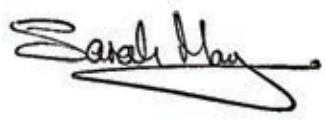
With coronavirus, or COVID-19 as it has now been officially named, the headline feature of this edition of *the Biomedical Scientist* and the hot topic of most news bulletins, I feel it would be remiss of me not to offer some thoughts of my own on this subject.

My particular area of interest has been the construction of the massive care facilities (I can't quite bring myself to call them hospitals) erected by China in a matter of days to deal with the increasing number of people infected with the virus and requiring medical care or social isolation. Coupled with this is the plight of the passengers quarantined on a cruise ship in a Japanese dock, unable to leave, watching the number of infected passengers increase exponentially.

Both of those scenarios fill me with horror; the sight of endless rows of hospital beds in a structure reminiscent of an airplane hangar, and affording about as much privacy, is the stuff of nightmares. However, the parallel prospect of incarceration in a ship's cabin, albeit a "luxury" one with private washing facilities, would feel more like punishment than privilege after a couple of weeks without access to the outside world. Both are symbols of the loss, or restrictions, of freedom that have been implemented to control the spread of an outbreak. Living as we do in the UK in a primarily urban, or suburban, environment I do wonder how we would react if movement control measures had to be implemented.

The other image that has become for me the "trademark" of this outbreak is that of the surgical face mark. This puzzles me greatly as, in terms of protection from catching the virus, a tightly knitted scarf tied around the face, particularly if coupled with a nice balaclava, would be only marginally less effective. A face mask functions as a bacterial filtration barrier protecting the environment from the wearer, but in terms of protecting the wearer from a virus, it's rather less effective. Perhaps the problem is that the messages and images circulated via the media have far greater appeal and impact than the less sensationalist facts from scientist. It is for this reason that I was so please to see the brilliant feature written by biomedical scientist Dr Sarah Pitt on COVID-19 was picked up by her local news station, leading to her being interviewed.

So, what scientifically proven defences will I employ if COVID-19 spreads in the UK? As a cold-handed individual I will continue with my trusted, but totally unscientific, defence against all the nasty bugs that daily assail the commuting public; a pair of woolly gloves.



Sarah May
Deputy Chief Executive

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

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SCIENCE NEWS IN NUMBERS

Minimum alcohol pricing

Alcohol sales in Scotland fell during the first year of minimum pricing, while sales increased south of the border.

NHS research found the **volume of pure alcohol sold per person dropped from 7.4 to 7.1 litres** – a decrease of **3.6%**.

In England and Wales, where **minimum pricing was not implemented**, the volume **increased from 6.3 to 6.5 litres**.

The only drink to show an increase in Scotland was fortified wine, which was not affected by the price increase. The sales figures are:

Cider – down 18.6%
Spirits – down 3.8%
Beer – down 1.1%
Fortified wine – up 16.4%

£6000

Some women in the UK have paid at least £6000 for a procedure to delay the onset of the menopause by over 10 years.

The procedure involves **surgically removing a small portion of one of the ovaries** – which is then formed into tiny strips and frozen.

Private doctors provide the procedure and the strips can be reinserted later in life.

49,029 CASES

Prostate cancer is now the most commonly diagnosed cancer in England.

In 2018 there were nearly **50,000 registered cases** – around **8000 more than in 2017**.

Public Health England says it is because more men are getting tested.

In **2018, there were 316,680 cancers of any kind diagnosed** – the equivalent of 868 cases a day. **Prostate was the most common type – 49,029 cases, followed by breast – 47,476 cases**.

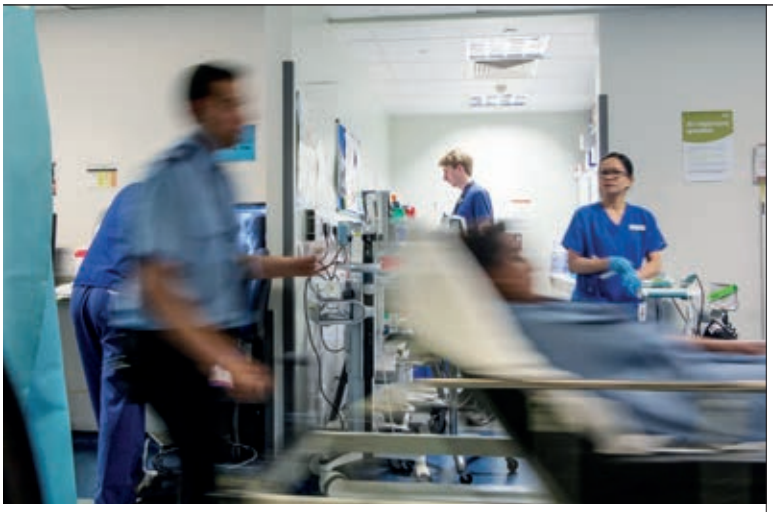
1100 CASES

The NHS is failing to detect about 1100 cases of bowel cancer a year in England, because **diagnostic services are so short-staffed**, according to **Cancer Research UK**.

£10,000

NICE has rejected a ketamine-based antidepressant for use on the NHS.

It said there is **not enough evidence** and the **£10,000+ price for the average course** is **too high**. If approved, it would have been the first antidepressant with a **new mechanism of action** to be licensed in **30 years**.



SCIENCE NEWS

ENVIRONMENT

NHS plans to cut climate change

NHS staff are being encouraged to drive to work less and bring in reusable cups and bottles to help tackle climate change.

The suggestions are part of an NHS plan to cut carbon emissions to net zero and reduce air pollution.

Hospitals will also be told to switch to less-polluting anaesthetic gases and reduce emissions from buildings.

The plan follows the launch of Climate Assembly UK, which looked at how the UK can best get to net zero.

The government has committed to the UK reaching the target – where the same volume of greenhouse gases is being emitted as is being absorbed through offsetting techniques, like forestry, by 2050.

Sir Simon Stevens, Head of the NHS, said: "With almost 700 people dying potentially avoidable deaths due to air pollution every week, we are facing a health emergency as well as a climate emergency.

"Patients and the public rightly want the NHS to deliver for them today, and to help safeguard the future health of our children and grandchildren."

FOLLOW-UP STUDY

EXAMINING PROSTATE CANCER

A five-year follow-up study of more than 2000 US men who received prostate cancer treatment is creating a road map for future patients regarding long-term bowel, bladder and sexual function to clarify expectations and enable men to make informed choices about care.

It is a multi-site research study conducting long-term follow-up on men who were diagnosed with localised prostate cancer between 2011 and 2012.

The five-year results provide evidence on outcomes with radiation, surgery or active surveillance in patients of all ages and ethnicities.

"We are providing information about the side effects of different treatments for prostate cancer that men and their providers can use to make treatment decisions," said senior author Daniel Barocas.

"However, we have only illuminated one facet of a complex decision. There is more to a treatment decision than just the side effects, the most obvious being the effectiveness of the treatment, and that is something we hope to be able to demonstrate as we are now funded to look at 10-year cancer outcomes."

→ **bit.ly/2SJrFXc**

ALZHEIMER'S DISEASE

AI PREDICTS DISEASE PROGRESSION

A new study shows artificial intelligence (AI) analysis of blood samples can predict and explain disease progression.

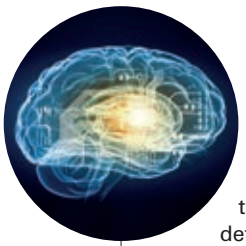
Scientists behind the work claim this could help inform more appropriate and effective treatments for patients.

An AI algorithm was used to analyse the blood and post-mortem brain samples of 1969 patients with Alzheimer's and Huntington's diseases. The goal was to find molecular patterns specific to these diseases.

The algorithm was able to detect how these patients' genes expressed themselves in unique ways over decades.

It is claimed that this offers the first long-term view of molecular changes underlying neurodegeneration – an important accomplishment because neurodegenerative diseases develop over years.

Previous studies of neurodegeneration often used static or "snapshot" data, and are therefore limited in how much they can reveal about the typically slow progression of disease.

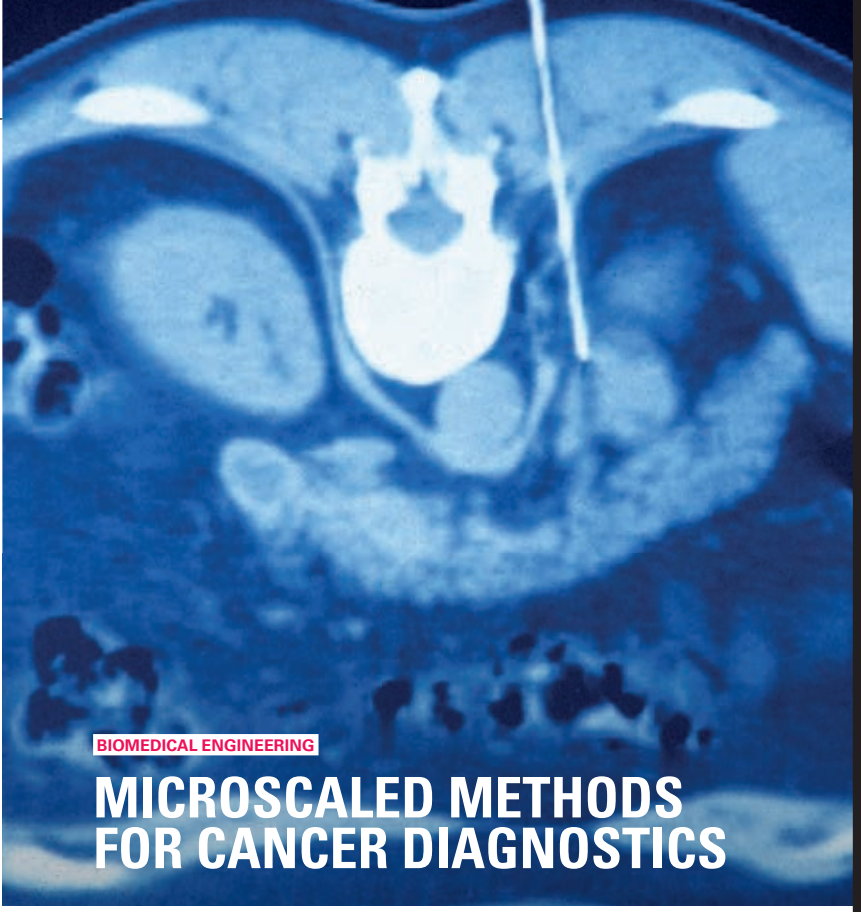


This study aimed to uncover the chronological information contained in large-scale data by covering decades of disease progression, revealing how changes in gene expression over that time are related to changes in the patient's condition.

Furthermore, the blood test detected 85-90% of the top predictive molecular pathways that the test of post-mortem brain data did, showing a striking similarity between molecular alterations in both the brain and peripheral body.

→ **bit.ly/38mDYiU**

IMAGES: ALAMY/ISTOCK/SHUTTERSTOCK



BIOMEDICAL ENGINEERING

MICROSCALED METHODS FOR CANCER DIAGNOSTICS

Using a single-needle biopsy and new technology for tumour diagnosis, researchers have been able to provide a more detailed and wider window into cancer biology, tumour type and the mechanisms of response and resistance to therapy than with conventional approaches.

The new method analyses the combination of tumour genetic material with deep protein and phosphoprotein characterisation using a single-needle core biopsy from a patient's tumour. This type of proteogenomic analysis had only been possible before with much larger tissue samples taken at surgery and shows promise for future use in clinical application.

Dr Steven Carr, co-corresponding study author, said: "Typically, patient tumour biopsies are about one-fifth the size of what is needed for proteogenomics analyses, so we invested considerable effort to identify methods to successfully 'microscale' the process to match the smaller amount of material obtained in the routine diagnostic setting and, importantly, not sacrifice depth of coverage of the proteome and phosphoproteome."

The scientists applied the methods to a pilot study designed to evaluate the feasibility of proteogenomic profiling before and 48 to 72 hours after initiating ErbB2-targeting chemotherapy.

They expected to gain insights into the variability of outcomes after treatment by assessing the ability of ErbB2 antibodies to inhibit the drug target.

The test of the micro-scaled technology provided large amounts of data from the tumours, revealing fundamental insights into the diverse elements that drive tumour responses, including those from the tumour immune microenvironment. The test served as proof of principle that these technologies have promise for precision medicine, meaning they can be used to examine individual tumours and find precise treatment plans.

→ **go.nature.com/2UNB4jb**

WHAT'S HOT AND WHAT'S NOT

HOT

WALNUTS

Eating walnuts may help slow cognitive decline in at-risk groups of the elderly population, according to a study conducted by researchers in California and Spain.

HOT

TOBACCO

A novel, second-generation malaria vaccine candidate, based on the tobacco mosaic virus, may offer protection against *Plasmodium falciparum* malaria, claim scientists.

HOT

NANOPARTICLES

Michigan State University and Stanford University scientists have invented a nanoparticle that eats away – from the inside out – portions of plaques that cause heart attacks.

NOT

VAPING

While vaping rates have increased over recent years, 86% of young people do not vape, and among the minority who do, most are not regular users.

NOT

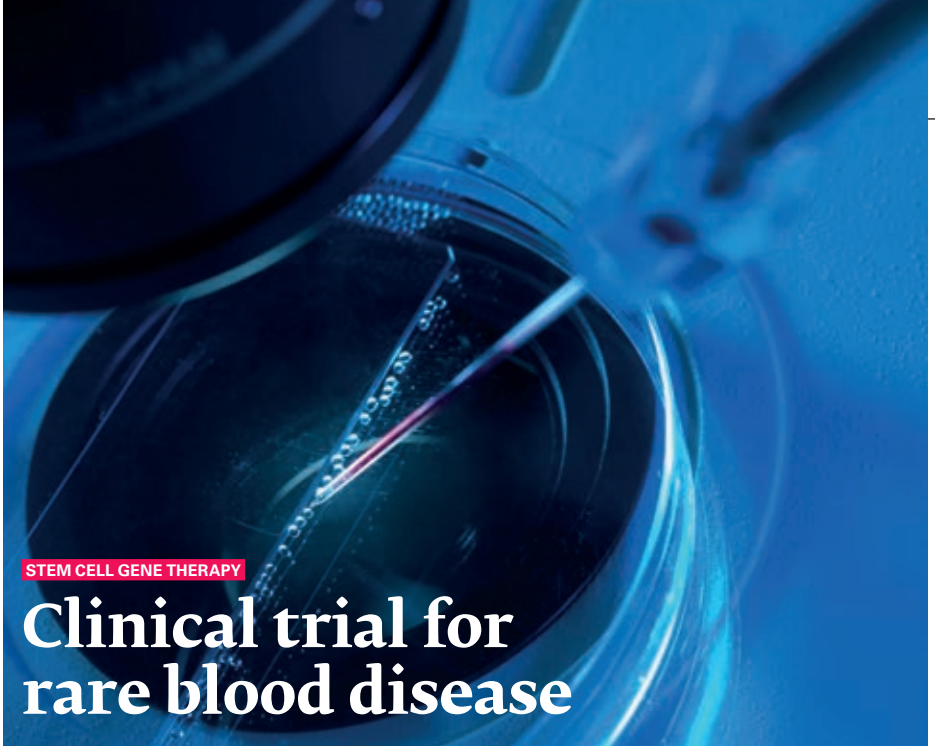
PROTEIN

People who eat high-fibre diets are more likely to experience bloating if their high-fibre diet is protein rich as compared to carbohydrate rich, a new study shows.

NOT

SHORTNESS OF BREATH

GPs are being urged to consider shortness of breath and cough as potential predictors of lung cancer, after a study found they were becoming more common as the first symptom in diagnosis.



STEM CELL GENE THERAPY

Clinical trial for rare blood disease

An international team has reported the use of a stem cell gene therapy to treat nine people with the rare, inherited blood disease known as X-linked chronic granulomatous disease (X-CGD).

Six of those patients are now in remission and have stopped other treatments. Until now, people with X-CGD – which causes recurrent infections, prolonged hospitalisations for treatment, and a shortened lifespan – had to rely on bone marrow donations for a chance at remission.

Donald Kohn, a senior author of the paper, said: "With this gene therapy, you can use a patient's own stem cells instead of donor cells for a transplant.

"This means the cells are perfectly matched to the patient and it should be a much safer transplant, without the risks of rejection."

The researchers removed haematopoietic stem cells from X-CGD patients and modified the cells in the laboratory to correct the genetic mutation. Then, the patients' own genetically modified stem cells – now healthy and able to produce white blood cells that can make the immune-boosting burst of chemicals – were transplanted back into their bodies.

Two people in the new study died within three months of receiving the treatment due to severe infections that they had already been battling before gene therapy. The seven surviving patients were followed for 12 to 36 months after receiving the stem cell gene therapy. All remained free of new CGD-related infections, and six of the seven have been able to discontinue their usual preventive antibiotics.

→ **go.nature.com/3bzpPRz**

BRIEF HISTORY

ADVANCING GENOMICS

Genetic discoveries over the past 25 years have substantially advanced understanding of both rare and common diseases, it is reported.

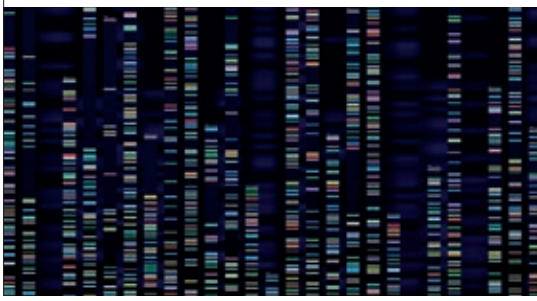
This has furthered the development of treatment and prevention for ailments ranging from inflammatory bowel diseases to diabetes.

This is outlined in a new paper entitled "A brief history of human disease genetics".

It reviews breakthroughs in the association of specific genes with particular disorders, progress mostly driven by advances in technology and analytical approaches. The study also provides a framework for medical innovation to improve clinical care in the field.

The researchers say the biggest task in the coming decade will be to optimise and broadly implement strategies that use human genetics to enhance understanding of health and disease, and maximise the benefits of treatment.

→ **go.nature.com/2SKxROM**



UNDER THE MICROSCOPE

This month: histamines

Tell me about histamines.
You probably know all about antihistamines – the medicines that inhibit the physiological effect of an excess of histamines – but we hear less about histamines, which are a biologically active substance found in a great variety of living organisms. Histamines are chemically classified as amines – organic molecules based on the structure of ammonia.

What function do they perform?
They are part of a chain reaction your immune system launches in response to an attack. It will send a chemical signal to the mast cells in your skin, lungs, nose, mouth, gut, and blood, which will then release histamines. They will boost blood flow in the affected area, causing inflammation, which lets other chemicals from your immune system step in to do repair work.

Have they been in the news?
Indeed. New research, using a mouse model, from the University of Tsukuba claims that histamines are "an unexpected defender against heart and kidney damage".

What do the scientists behind this work say?
Histamines are an important factor in various inflammatory processes, and their inhibition generally leads to better disease control. Akiyoshi Fukamizu, corresponding author on the study, said: "We found elevated levels of histamine in a mouse model of cardiorenal syndrome, which were surprisingly protective against further damage in these mice."

What happened to these mice?
In the study, mice that could not produce histamine showed worse cardiorenal damage effects, including altered cardiac contractility and poor urinary filtration. Similar effects were observed when a specific histamine receptor (H3) antagonist was administered to mice with cardiorenal damage, suggesting that this receptor may serve as a useful drug target.

IMAGES: ALAMY/SHUTTERSTOCK

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SCIENTIFIC LABORATORY SUPPLIES

TECH NEWS

EKF DIAGNOSTICS

ANAEMIA REDUCTION

EKF Diagnostics has announced that it is supporting the reduction of anaemia in developing regions of South America.

It is doing so through the use of its point-of-care haemoglobin analysers, as highlighted in a recent international symposium.

EKF's Hemo Control haemoglobin analyser has been helping the screening and monitoring of anaemia to fight chronic child malnutrition by South American public health programmes for a number of years.

→ **ekfdiagnostics.com**

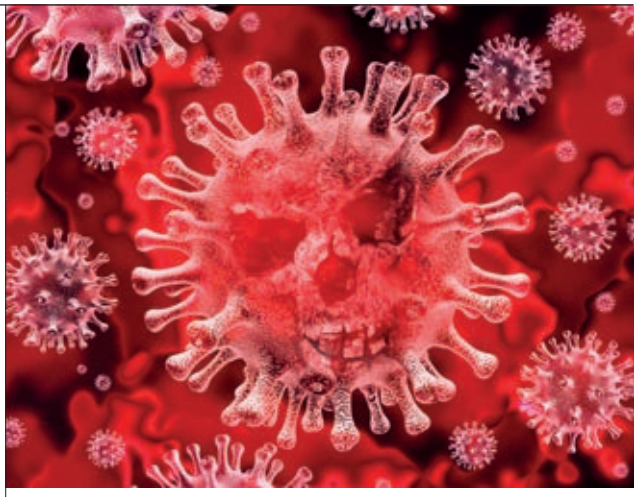
CARTERRA

ANTIBODY DISCOVERY

Carterra, the world leader in high-throughput antibody screening and characterisation, has closed a $6m round of financing led by Ballast Point Ventures with participation from current investor, Telegraph Hill Partners.

The additional funding will support the continued adoption of the innovative Carterra LSA high-throughput Surface Plasmon Resonance (HT-SPR) antibody screening platform and the development of new products and applications.

→ **carterra-bio.com**



SERACARE

CORONAVIRUS

In response to the outbreak of coronavirus strain 2019-nCoV, LGC's SeraCare Life Sciences is developing molecular reference materials for coronavirus, utilising proprietary AccuPlex recombinant technology.

The control material is being produced in collaboration with several diagnostic manufacturers to support development, evaluation, and validation of molecular test methods directed to 2019-nCoV.

LGC is a manufacturer and leading partner of global *in vitro* diagnostic manufacturers and clinical laboratories.

→ **seracare.com**

THE BIG QUESTION

THIS MONTH WE ASK

How do unions help in healthcare science?

Colenzo Jarrett-Thorpe

National Officer – Health
Unite the Union

In the ever-shifting sands of the NHS, there needs to be constructive engagement with trade union and healthcare science leaders to ensure the charge towards hub-and-spoke models of service delivery are benefiting patients, and that the scientific workforce reaches its full potential.

Too often workforce issues are an afterthought in these projects. Centralisation is an opportunity, but also a threat – some believe that pathology networks in England could see a 30% reduction in workforce.

For any change to be successful, the workforce need to buy into the change and be actively engaged. Trade unions are the premier agents in staff engagement – since through our experience and network of workplace representatives, who have expertise of the clinical and staffing issues – engagement means addressing the issues that concern staff.

Academics have shown that better staff engagement leads to better patient care, but to achieve this, trade unions need to be involved in workforce issues early on; when the ideas are only formative. Workforce plans regarding tendering processes should be produced in partnership with local trade union representatives and communication on both sides should be open and transparent. Trade unions, as the employees' voice, are a prerequisite for high-quality healthcare science service in the NHS, which will lead to better outcomes for patients.

Donna Torrance

Training Manager Blood Sciences
North West London Pathology

When I started working for the NHS, individuals doing the same job at different hospitals could have different salaries and annual leave, spine points could be negotiated and, each year, unions at each hospital would negotiate pay increases for individual groups of staff.

The most radical overhaul of the NHS pay structure was Agenda for Change (AfC) and this was driven by unions and the demand for equal pay for equal work. Whether you agree or not with the final implementation, AfC standardised pay structure, career progression and terms and conditions of all NHS staff, and created a system that attempted to provide equal pay for equal work.

All of the working conditions we have, including equality in the workplace, working time directive and flexible working, are in place because of union involvement. Unions have representation at national, regional and local level and this allows staff concerns to be addressed and negotiations to be conducted at all levels. These negotiations may not always feel like NHS staff have received the best deal, however, I fear without unions the conditions would be worse.

Unions help in healthcare as they protect working conditions, raise public awareness of issues relevant to the NHS, allow a national voice and negotiating power to the staff and help maintain quality of patient care by supporting staff to raise concerns over service provision, health and safety and quality issues. But a union is only as strong as its members.

Joanna Andrew

Laboratory Medicine Manager (designate)
York and Scarborough Hospital

I have been a member of a union since starting in the profession back in 1993. I was simply handed a form – there was no discussion or explanation, it was just assumed that everyone would join. I didn't really know what it meant, or how it would benefit me as an individual.

As my career has developed, I have been involved with unions for many reasons, not all positive, but, overall, my response is: "Yes, unions do help and they are a vital support for the workforce."

The current process of consolidating pathology services is leading to workforce changes, challenges and uncertainty. The unions are able to ensure negotiations are fair and members feel supported.

The reduction in cytology laboratories due to the centralisation of screening services with the introduction of human papillomavirus (HPV) screening led to 14 members of staff at my trust being made redundant. This was the first time, as a manager, I had faced dealing with the devastating impact of job losses. I really valued the support from the union during the redundancy consultations.

The union representative was vital in ensuring that staff understood the process. Their expertise and understanding of processes, such as the Transfer of Undertakings (Protection of Employment) Regulations 2006, known colloquially as TUPE, and their knowledge of NHS terms and conditions under AfC were invaluable in being able to negotiate the best possible outcome for all the staff in very difficult and sad circumstances.

BREAKTHROUGH FOR LEADING CAUSE OF BLINDNESS

Professor Simon Clark discusses how his international team of scientists identified a protein that is strongly linked to the most common cause of blindness in developed countries.

Age-related macular degeneration (AMD) is one of the main causes of impaired sight and blindness in adults, affecting around 600,000 people in the UK alone. There are two distinct types of the disease: the first is "wet" AMD, which is caused by the growth of abnormal blood vessels in the eyes, though the progression of this growth can be slowed when treatment drugs are injected into the eye. The second is "dry" AMD, which occurs when a fatty substance called drusen slowly builds up at the back of the eye. This type accounts for the vast majority of AMD cases and, unlike its less common sibling, is completely untreatable. However, that might be about to change.

New treatment?

In a major international study published in *Nature Communications* in February, a team drawn from the universities in Manchester, Cardiff, London and Nijmegen, along with Manchester Foundation NHS Trust, has detected a link between the onset of dry AMD and raised blood levels of a protein called FHR4 (factor H-related protein 4). If researchers can confirm their results, it could prompt a treatment for the disease that wouldn't even involve touching the eye.

One of the supervising authors of the work is Professor Simon Clark from the Institute of Ophthalmic Research at the University of Tübingen in Germany. He says the drive to find a suitable therapy for dry AMD has gradually been gathering momentum, laying the foundations for the research.

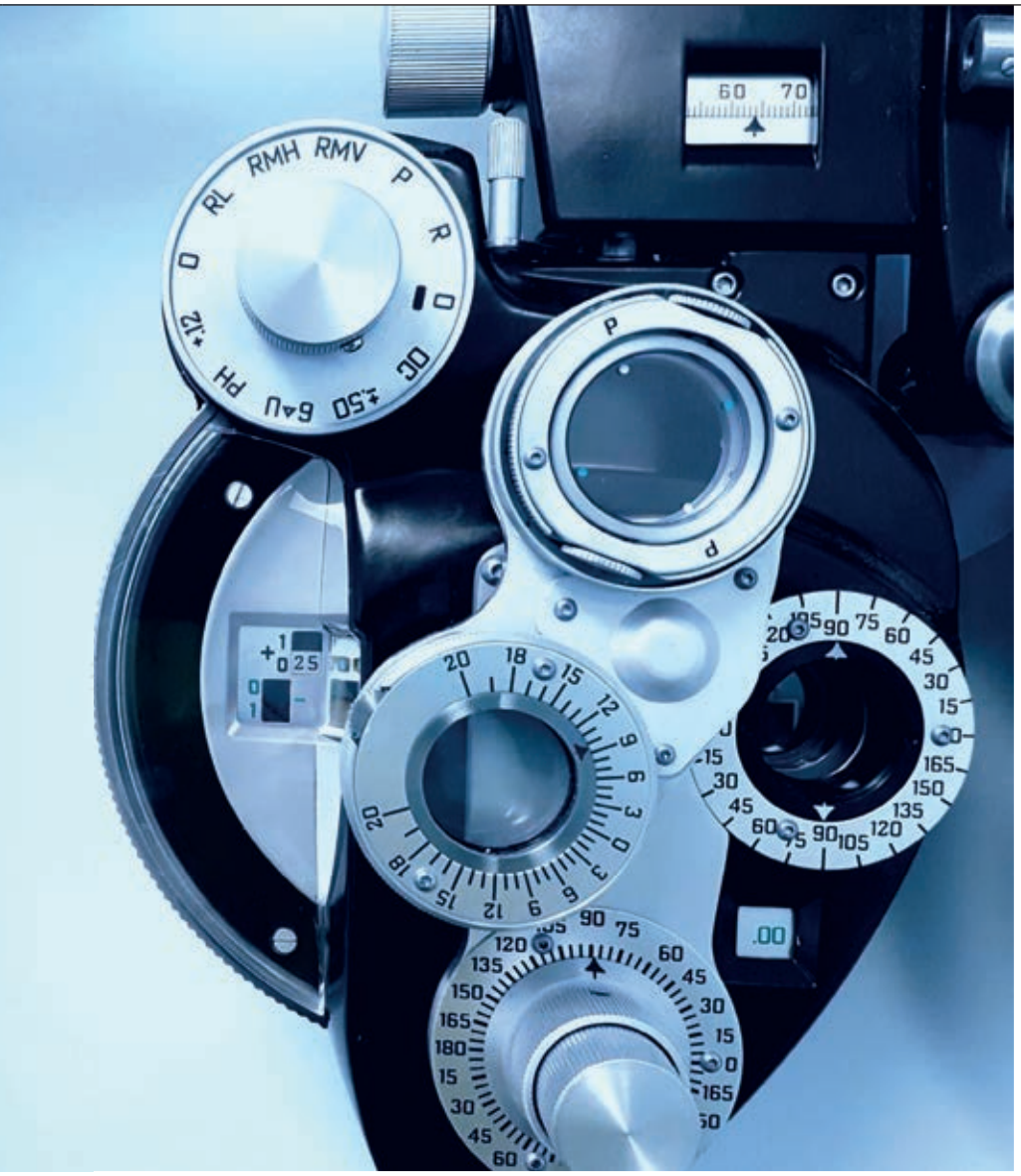
"At the back of the eye there is an immune process involving something called the complement system, and we know that there is a genetic link between this becoming overactive and an increased risk of AMD, but nobody was sure of the biochemistry behind that. Even less was known about these mystical factor H-related proteins, which are on chromosome one. Most of the genetic risk for AMD is in the factor H gene, which is also on chromosome one. But it turns out that the mutation in this factor H gene doesn't affect the factor H protein, but instead affects a protein a couple of genes downstream on the chromosome."

Stumbled across it

This initial work was groundbreaking, he says, because it blew open the door for other possible mechanisms. "Everybody assumed that the mutation would affect the gene it was found in, but no. What our work has shown is that the consequence of this mutation is increased circulating levels of this protein called FHR-4, which in itself is not particularly harmful but for some reason accumulates at the back of the eye, and there it helps to drive an inflammatory response, which then leads to the formation of drusen and the other associated phenotypes of dry AMD."

The irony is that the research initially had no real intentions of going down the AMD route. "My laboratory studies the regulation of the complement system in every disease," says Clark. "It just so happened we were historically interested

"We noticed that for some bizarre reason there was more FHR-4 in AMD patients"



IMAGES: SHUTTERSTOCK

in FHR-4. We got our hands on some blood samples and noticed that for some bizarre reason there was more FHR-4 in AMD patients than in non-AMD patients. Then we spoke with the people from Nijmegen who had independently tested another batch of patients and came up with the same results. The next step was to get hold of human eye tissue and take a look at that. In this way, the work has been going on for six years. It wasn't initially targeted; we literally stumbled across it. After that we got in contact with Valentina Cipriani, the lead author of the paper, who is a leading medical geneticist. She's the one who pulled together all the genetic links associated with the disease."

As a result of this work, it is now understood how FHR-4 causes the inflammation. "It knocks off another inhibitor called FHL-1. So, FHL-1 is happily doing its job, then along comes FHR-4 and kicks it off and the whole thing activates." The other FHR proteins are also being scrutinised. "There are five of them and it is entirely possible that the others are somehow involved. If it is just FHR-4, that's great, but if it's only half FHR-4 and half, say, another FHR protein, we need to know that."

What next

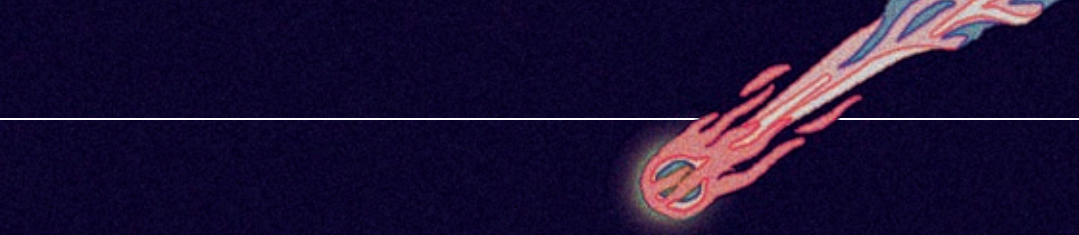
In the meantime, Clark expects other teams will start targeting FHR-4 as a way of slowing down the progression of AMD. This approach could also make treating the disease easier in more ways than one. "The problem we had was not just identifying the correct mechanism, but also the delivery of therapeutics to the back of the eye, which is quite specific about what it lets in and what it keeps out. Here, however, we have a candidate target that is systemic. We can target it in the blood. We don't have to stick needles in people's eyeballs at all. Even better, it looks like it is made exclusively in the human liver. So lower transcription levels of FHR-4 in the liver could result in less circulating protein, which means less accumulation at the back of the eye and less inflammation."

Another boon for any potential treatment regimen will be the blood tests that can detect the circulating levels of FHR-4. "We could stratify susceptible patients easily. Not all AMD is caused by elevated levels of FHR-4, so this is a subset of dry AMD that could be identified for a therapeutic approach. If we can devise that treatment, we also have a ready-made target population." If a company with FDA approval to deliver therapeutics to the liver chose to target FHR-4, all they would have to do is design the delivery mechanism. "That initial lead time could be quick," says Clark. "Then it would be off to clinical trials." BMS

PROFESSOR SIMON CLARK

- ✔ **2002:** BSc in biochemistry with immunology, University of Aberdeen
- ✔ **2006:** DPhil in biochemistry, University of Oxford
- ✔ **2006:** Postdoctoral researcher, Faculty of Life Sciences, University of Manchester
- ✔ **2013:** MRC career development fellowship, Faculty of Medicine and Human Sciences, University of Manchester
- ✔ **2015:** Co-founded the Manchester Eye Tissue Repository
- ✔ **2019:** Helmut Ecker Endowed Professorship in AMD at Tübingen University


GLOBAL CATASTROPHE?



With the **coronavirus** making daily headlines around the world and the death toll continuing to rise, we ask if a **virus will ever cause global catastrophe**.

"The test results come out positive today. Everything is settled. It is confirmed." These are the bleak, final words Doctor Li Wenliang posted on social media before his death in the early hours of 7 February.

In December last year, Dr Li had sent a message to fellow medics warning of a virus he thought looked like severe acute respiratory syndrome (SARS) – the epidemic that caused a severe socio-political crisis in China and led to a "worldwide health threat" in 2002.

The SARS outbreak claimed 774 lives – a number that by early February the coronavirus had surpassed. Among the dead was Dr Li, who had been warned by police to "stop making false comments" and was being investigated for "spreading rumours".

Ignoring his early warnings not only led to the virus claiming his life, but hundreds of others, with no indication of when, or how, the outbreak will be contained.

Epidemics

The exact number of deaths in China due to the current epidemic is probably not known (and is likely underestimated), as the testing facilities are under such strain.

But with Chinese cities on lockdown, planes grounded, quarantined cruise ships stranded at sea and shops selling out of face masks, plastic gloves and antibacterial hand gels, the crisis shows no sign of abating.

At the time of writing, coronavirus remains an epidemic, as there have been only two confirmed deaths outside mainland China: one in Hong Kong and one in the Philippines. For the virus to reach pandemic status, it should occur "worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people".

Previous pandemics

While the current outbreak has not reached this point, we do not have to look back far in our history to see a number of pandemics that shook the world.

Hitting its devastating peak from 2005 to 2012, the HIV/AIDS pandemic is believed to have claimed more than 36 million lives since 1981.

Going back just over 100 years from the present day, Spanish influenza was responsible for at least 40 million deaths – more than double those recorded for military personnel and civilians due to World War I.

Between these pandemics was Asian flu. This was an outbreak of Influenza A (H2N2 subtype) that originated in China in 1956 and lasted until 1958. In these

ILLUSTRATION: THOMAS HAYMAN/AGENCYRUSH.COM

two-years, Asian flu travelled from the Chinese province of Guizhou to Singapore, Hong Kong, and the United States. Estimates for the death toll vary widely, depending on the source, but the World Health Organization places the final tally at approximately two million deaths, 69,800 of those in the United States.

Future predictions

We asked four virology experts to draw on the past, consider the present and decide whether in the future they believe a virus can cause global catastrophe. Here are their answers.

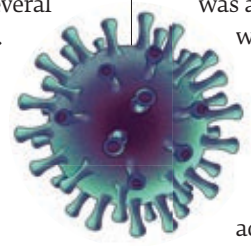
IT IS THEORETICALLY POSSIBLE

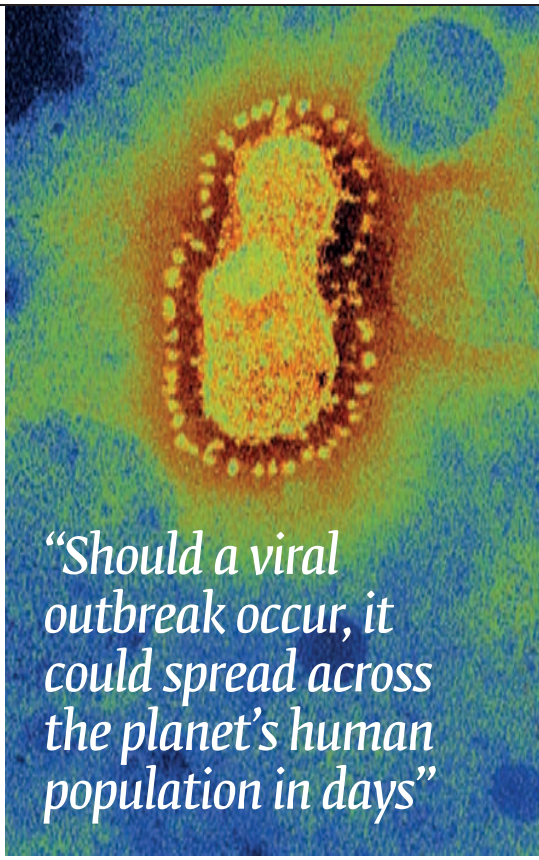
Mohamed Ahmed
Associate Lecturer and Clinical Researcher in Biosciences
London Metropolitan University

History has proven that viruses can arise and cause global pandemics, resulting in an increase in morbidity and mortality greater than any other global catastrophe. Although our scientific and medical understanding of infectious outbreaks continues to advance, there is a real risk that humanity could experience an outbreak that would cause a major global catastrophe. Importantly, to cause a global catastrophe the virus doesn't need to kill its host. This could occur via the mutation of a known pathogen or a new virus not previously encountered. Furthermore, it could also arise via an existent or new cross-species transmission route infecting humans. However, for such a global catastrophe scenario to occur, several factors are likely to be necessary.

The primary factor could be a previously encountered virus that is significantly antigenically different, or a completely new virus to which human populations have no pre-existing immunity. The world is much more connected than ever before. Every day millions of people travel across continents and countries within short timeframes and with relative ease. Should a viral outbreak occur, it could spread across the planet's human population in a matter of days. The outbreak of the COVID-19 coronavirus is a prime example – 25 countries have confirmed cases of the virus (at the time of writing). Such a virus is of greater threat to populations considered to be immunocompromised, such as the elderly, infants and people with underlying health conditions, such as diabetes, asthma and other chronic conditions. Globally, the elderly and infant population is increasing, as people are living longer and population numbers are growing. In addition, chronic diseases, such as type 2 diabetes, are increasing.

The replicative rate and ability of the virus to transmit easily between people would also be another factor that would influence the potential global catastrophic effect. This would clearly have a dramatic impact in urban areas. Therefore, the impact of climate change on vector species (e.g. mosquitoes) and in relation to predicted coastal and rural populations moving to urban areas are important factors to consider. Importantly, for a viral pandemic to have a catastrophic effect, it would need to cause significant pathology in an estimated one-third of the population, and be able to disable their daily activities of living, causing a significant impact on the functioning of society. It would also need to breach our medical services. If hospitals and physicians failed to manage the number of infected people, or there was a lack of medical supplies, it would compromise our ability to control the spread of infection. Given such a scenario, another important factor would be the effect on the supply chain for food and water. Lack of adequate food would further impact on a new viral pandemic, as the effects of poor nutrition on immunity and infectious disease are well documented. All the above could significantly impact the global economy – the current outbreak of COVID-19 is already beginning to affect economies.





"Should a viral outbreak occur, it could spread across the planet's human population in days"

A viral pandemic could, therefore, have a wider, large-scale impact on society, affecting industry, the labour force and the economy. This type of scenario could affect every aspect of day-to-day life and could impact how society itself operates, leading to a potential breakdown within communities and social structures in some parts of the world.

It is theoretically possible that a virus could cause a global catastrophe. The virus would need to be new or a variation of an existing human or animal virus that could transmit easily between species and people, as well as having a high replicative rate. Another factor would be a lack of pre-existing immunity in the human population, such as a new pathogen or one significantly different antigenically. Furthermore, the virus would need to cause significant pathology that would affect a relatively high proportion of the human population and

IMAGES: GETTY

therefore impact societies globally.

The author would like to thank Dr Laurence S Harbige, Senior Lecturer in Biosciences, and Professor Gary McLean, Reader in molecular immunology, both at London Metropolitan University, for their input into this article.

THE HUMAN-ANIMAL INTERFACE

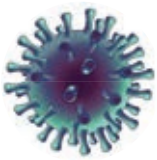
Alistair Gammie
ValuMetrix Global Senior Director
Ortho Clinical Diagnostics

Before one considers whether there are any circumstances, one should look back at those viruses that have created global pandemics, or epidemics that create global fear. The influenza A virus has created pandemics through antigenic shift, which arises from the viral reassortment of two different influenza viruses that co-infect the same host, creating a new virus.

If the novel virus can infect humans and achieve human-to-human transmission, and possesses virulence for humans, a pandemic may arise, as humans are unlikely to have appreciable immunity to the novel strain. Within the past hundred years, four pandemics have resulted from the emergence of a novel influenza strain for which humans possessed little or no immunity: the H1N1 Spanish flu (1918), the H2N2 Asian flu (1957), the H3N2 Hong Kong flu (1968), and the H1N1 swine flu (2009). The outbreak of SARS was created through a similar facilitation in China. SARS coronavirus (SARS-CoV) was identified in 2003. It is thought to be an animal virus from an as-yet-uncertain animal reservoir, perhaps bats, that spread to other animals (civet cats) and first infected humans in the Guangdong province of southern China in 2002.

The risks intensify when human beings have facilitated the bringing together of different species and have created a human-animal interface.

The Ebola virus has been shown to be associated with humans eating bush meat with the primary vector thought to be fruit bats. The multimammate mouse (*Mastomys natalensis*) is the reservoir for Lassa virus (LASV). Zoonotic transmission occurs when humans are directly or indirectly exposed to fluids of the multimammate mouse, such as urine, saliva, and blood. Housing characteristics and domestic organisation affect rodent density in and around households and villages and are likely to be a risk factor for Lassa fever in humans where the reservoir exists.



There are many more examples of viruses that have either mutated to cross from animals into humans, or have directly infected humans with a virus that is more harmful to humans.

The simple fact is that they almost always occur where humans live in unsanitary conditions, share their homes with multiple animals, prepare and eat animals in non-hygienic conditions and have poor personal habits, such as spitting and hawking. Not every one of these conditions needs to be met to create a global catastrophe. The recent coronavirus outbreak (COVID-19) started in Wuhan due to some of these conditions being met. The unfortunate confounder in this outbreak was the timing just prior to the Chinese New Year, a time that sees the greatest migration of people to or from one country. In 2018, it was estimated that Chinese travellers made around three billion trips during the 40-day Spring festival period.

This means that people who would not normally encounter each other were crowded into bus terminals, train stations and airport terminals. In Wuhan province, although the outbreak had already started, the local officials allowed the Lunar festival to take place.

So, are there any circumstances in which another virus can cause a global pandemic? The answer is clearly "yes". Is the circumstance preventable? Yes, but it is not about vaccines or surveillance, it is about education and changing the behaviour of people.

Is this possible to do? Consider two practices, one legal and one illegal, that have changed dramatically in the UK over the last 25 years. Smoking (legal) was banned from public places in July 2007 and now this has become the accepted

norm. Drink driving (illegal) has now become socially unacceptable. In fact, a recent government survey stated that people who take drugs before getting behind the wheel of a car believe it is a "much more acceptable" thing to do than driving while drunk.

Does one believe that the Chinese authorities will consider that this epidemic is grounds for major social change that could prevent further virus outbreaks? In this case, the financial cost to manufacturing and export, as well as the effect on the middle-income Chinese who are mainly working from home, may possibly become the driver for change, not the virus itself.

ADVANCES MINIMISE RISK

Zara Josephs
Independent researcher
Clinical biochemistry and molecular pathology

Yes, but only under very extreme circumstances, such as a major solar flare or meteorite strike. Pandemics are a significant cause for concern, their potential for causing widespread fatalities and socioeconomic chaos are incalculable: the 1918 influenza outbreak, which killed an estimated 50 million people globally (3% of the world's population), caused more deaths than any pandemic disease before or since, including the sixth-century Plague of Justinian; the mediaeval Black Death; or swine flu in 2009. However, 100 years on, developments in epidemiology and technology have considerably minimised the risk of such catastrophes.

Risk factors for viral pandemics include contact with wildlife or livestock (from which all human viruses originate); the activities of super-spreaders (i.e. those able to spread disease to an unusually large number of people); crowded conditions, which bring super-spreaders into close proximity with one another; malnutrition on a large scale (as during wars and natural disasters), which increases susceptibility to infection; and increasing global travel, which increases the range of viral spread.

"Our understanding of the drivers and dynamics of emerging infectious diseases can only improve"

The plethora of organisations monitoring potential sites of disease outbreaks includes the Global Public Health Intelligence Network (GPHIN), which scans informal news sources for unusual disease events and rumours of outbreaks; Global Viral Forecasting, which monitors global medical intelligence in order to catch pandemic signs early; and Global Outbreak Alert and Response Network, a World Health Organization-sponsored collaboration of institutions working on the rapid confirmation of, and response to, disease outbreaks of international importance.

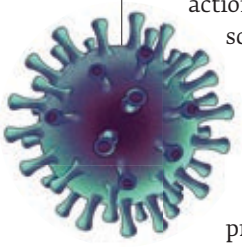
Information from these monitoring organisations is complemented by advanced molecular biology tools that enable rapid identification of pathogens; and epidemiological tools to monitor "digital signals" of potential infections, with the goal of predicting pandemics, as well as rapidly identifying hotspots and super-spreaders.

A primary focus of these investigations is the group that constitutes "sentinels": people (including blood transfusion recipients, health care workers and flight attendants) most at risk of infection from newly emerging pathogen strains. The success of these combined efforts is highlighted by a notably increased efficiency of disease containment: it was GPHIN that issued the first alert of unusual respiratory illness in China to WHO, which helped to limit deaths from that outbreak of SARS coronavirus to 774.

While deaths from the more recent outbreak of the related coronavirus COVID-19 have surpassed those from SARS-CoV, the tools are in place to combat its pandemic potential and they seem robust enough to avert a global catastrophe.

Our understanding of the drivers and dynamics of emerging infectious diseases can only improve. Evolving technology, improving search engine algorithms and increasing computational speed will lead to increasingly sophisticated surveillance methods and more accurate predictive models to help rein in an incipient pandemic. However, the international collaboration of governments, NGOs, public health networks and scientists is vital for the timely detection of, and response to, novel threats of pandemic disaster.

Given the number of safeguards in place, therefore, a catastrophic pandemic is by no means inevitable. The combined action of medical, veterinary, health, science and environmental personnel is needed to direct educational and research toward developing integrated global disease surveillance systems, diagnostic tools and preventive interventions.



GLOBALISATION HAS INCREASED RISK

Bamidele Farinre
Senior Executive Officer
National Infection Service,
Public Health England

Viruses can cause global catastrophes, if the appropriate measures are not put in place to contain them. A global catastrophe is a future event in which biological agents, such as viruses, could lead to an abrupt widespread disaster beyond the immediate control of combined capability of national and international governments and the private sector.

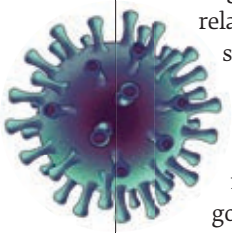
There is a unanimous value in developing a full understanding of the scope of the viral world and to be able to develop better situational awareness – an accurate, up-to-date view of potential or ongoing infectious disease threats. This includes through traditional surveillance in humans and animals and the resources available to manage those pressures in preparedness of any imminent global catastrophe.

Disease-causing viruses exhibit certain characteristics that elevate their prominence above those microbes that are capable of causing only sporadic or limited human infections.

Most worrying is the ability of the virus to transmit during incubation periods, coupled with the occurrence of mild illnesses furthering the augmentation of disease spread. Broad-spectrum antivirals are not effective in the treatment of viral infections, compared with bacteria, fungi, and parasites, which are susceptible to antimicrobials; making viruses a more likely cause of a global catastrophe.

The respiratory route is the most feared mechanism that is likely to lead to epidemic spread. This is primarily due to the fact that interventions to interrupt this method of spread are more challenging to implement, when the natural act of breathing can spread a pathogen. The prolific spread of viruses such as influenza, measles, and coronaviruses authenticates this fact.

Viruses have a high affinity for genetic mutability, due to the structure of their genomes and the generation time for viral replication. Conversely, the RNA viral class poses the greatest health concern, compared to the DNA viral class, due to their high mutability. This fact is supported by the evidence that the stability of RNA as a genomic material is less than that of DNA, giving more genomic flexibility to the RNA viruses.



Additionally, RNA viruses that are spread via the respiratory route have been shown to have the characteristics that are most concerning, in terms of their ability to cause global catastrophic uncertainties. Based on these concerns, surveillance, science, and countermeasure development programmes, efforts must be strategic in logically allocating significant resources. Presently, there is no consensus methodology for estimating the economic impacts of global catastrophe.

The likelihood of a viral cause of a global catastrophe has increased greatly due to increased global travel and integration, urbanisation, changes in land use, and greater exploitation of the natural environment. The recent outbreak of coronavirus is an excellent example of how viruses can cause catastrophe. Without strategic contingency preparedness in place, a virus outbreak could lead to abrupt, unexpected, widespread disaster beyond the cooperative capability of national and international governments and the private sector to control. If unconstrained, the aftermath would lead to great suffering, loss of life, and sustained damage to national governments, international relationships, economies, societal stability and global security.

Furthermore, all sectors of the economy face disruption, potentially leading to shortages, rapid price increases for staple goods, and economic stresses for households, private firms, and governments. Accordingly, situational preparedness will necessitate the health care workforce to recognise the illness and to have the technical and laboratory capacity to identify the pathogen or rule out known pathogens and respond to the influx of clinical specimens in a timely manner. Rapid identification reduces risk by enabling infected persons to be isolated and given appropriate clinical care.

There is only one Food and Drug Administration-approved antiviral for the treatment of respiratory-spread RNA viruses (ribavirin) aside from anti-influenza antivirals. There are currently no approved antivirals for any other respiratory-spread RNA viruses in the world.

There's no one-size-fits-all response to a public health emergency; stratagems must be tailored to the local context and to the severity and type of event. In safeguarding against the threat of a virus causing a global catastrophe, more work needs to be done to improve surveillance of respiratory-borne RNA viruses. Despite improved preparedness to mitigate the impact of global catastrophe through refined standards and funding for building health capacity, substantial gaps exist in pandemic preparedness. BMS

A GUT FEELING

What impact can the gut microbiome have on the human body? **AD Diwan** and **SN Harke** dive down the oesophagus to find out.

The human body contains a large number of bacteria, viruses and fungi, collectively known as the microbiome community. While some bacteria are associated with disease, others are important for strengthening of our immune system, the proper functioning of organs, maintenance of body weight and many other aspects of our health. Trillions of these microbes exist in our bodies, particularly in the intestines and skin. Most of the microbes are located in the large intestine and they are referred to as the gut microbiome.

Although many different types of microbes are present in our bodies, most studies have been carried on bacterial composition of the digestive gut system. In fact, there are several reports that the human body contains more bacterial cells than actual human cells. It has been estimated that roughly 40 trillion bacterial cells are present in our bodies, whereas, human cell counts are around 30 trillion. Scientists all over the world have reported about 1000 species of bacteria in the human gut microbiome, each of which plays a different role in the body.

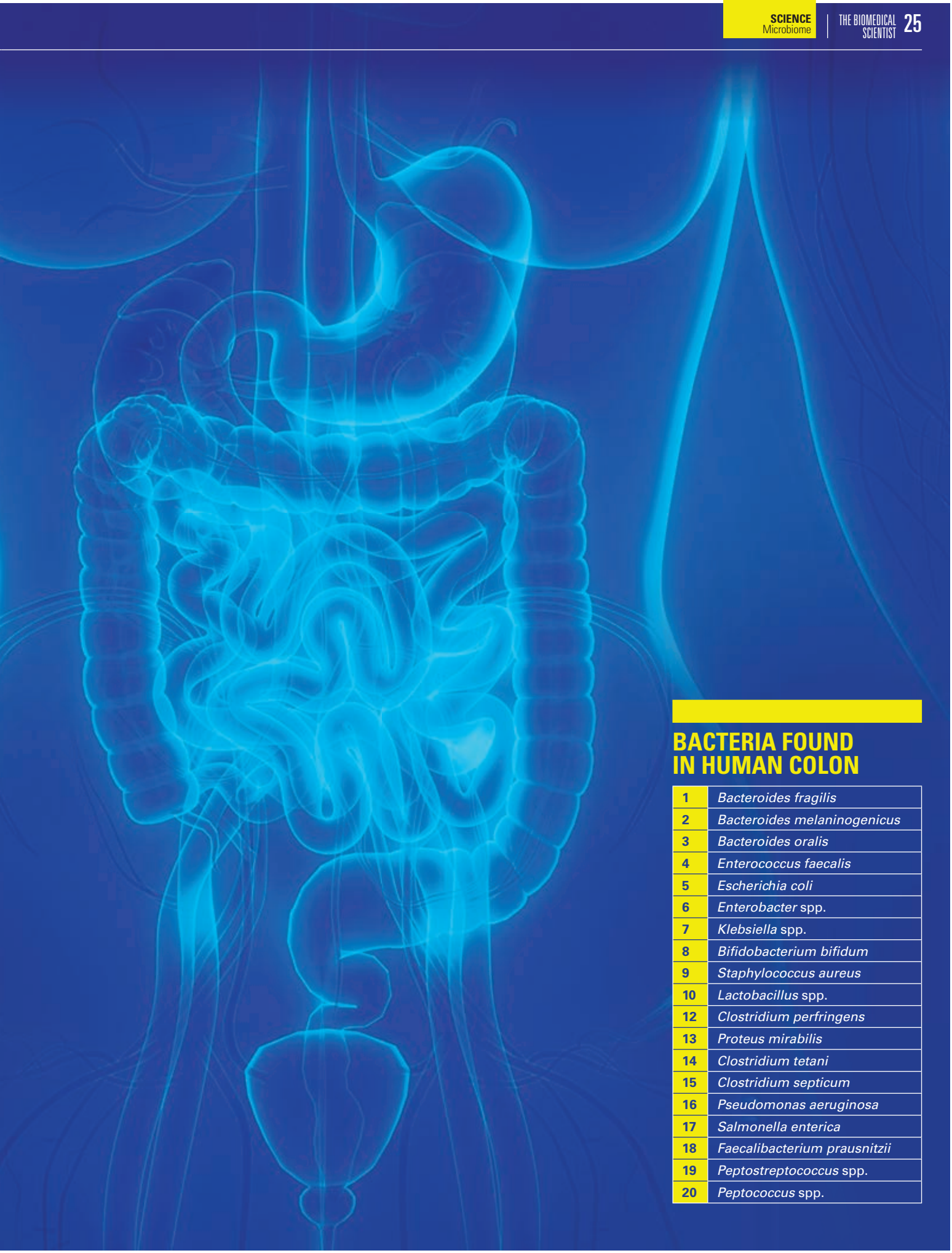
Most of them are extremely important for maintaining our body health, while a few may be harmful in creating diseases. Altogether, these microbes may weigh up to five pounds – roughly the weight of a brain.

Gut microbiome composition

The human microbiome consists of microorganisms like bacteria, archea, fungi, protozoans, and viruses. Among all microbiome microorganisms, bacteria are the most predominant. The bacterial population has been estimated between 75 and 200 trillion in a single person. The first bacterium that was noticed in the intestinal region was *Escherichia coli*. Other bacterial species observed were *Veillonella parvula* in the digestive tract and bifidobacteria in intestinal fluid. It has been estimated that human microbiota consists of more than 1000 different species of microorganisms. It is reported that the human gut microbiome contains more than 160 species of bacteria. Besides healthy bacteria, there are a number of unhealthy and pathogenic bacteria such as *Staphylococcus, Streptococcus, Enterococcus, Klebsiella, Enterobacter* and *Neisseria* species causing various types of intestinal disorders. *Clostridioides difficile,* a pathogenic bacterium most commonly found in the human gut microbiome, causes severe recurrent diarrhoea. *Prevotella* and *Firmicutes* bacteria and their abundant presence in the gut system have been associated with obesity.

Microbiome benefits

From the moment we are born, the microbiome plays an important role in carrying out various physiological functions. There is also new evidence that suggests babies may come in contact with some microbes while inside the womb. As the baby grows, its gut microbiome begins



BACTERIA FOUND IN HUMAN COLON

1	*Bacteroides fragilis*
2	*Bacteroides melaninogenicus*
3	*Bacteroides oralis*
4	*Enterococcus faecalis*
5	*Escherichia coli*
6	*Enterobacter* spp.
7	*Klebsiella* spp.
8	*Bifidobacterium bifidum*
9	*Staphylococcus aureus*
10	*Lactobacillus* spp.
12	*Clostridium perfringens*
13	*Proteus mirabilis*
14	*Clostridium tetani*
15	*Clostridium septicum*
16	*Pseudomonas aeruginosa*
17	*Salmonella enterica*
18	*Faecalibacterium prausnitzii*
19	*Peptostreptococcus* spp.
20	*Peptococcus* spp.

to diversify, indicating that different types of microbial species start accumulating and it is assumed that diversification is good for the health. Later, depending on the food we eat, the composition, quality and diversity of the gut microbiome will be affected. Dietary food habits always influence the diversity of the gut microbiome, which in turn affects body functions. For example, bifidobacteria begin to grow in the newborn baby's intestine because they are essential for the digestion of healthy sugars in the breast milk and these are important for growth. There are certain bacteria that digest the fibre, producing short chain fatty acids and these fatty acids are most essential for the maintenance of gut health. Fibre may also help to prevent weight gain, diabetes, heart disease and the risk of cancer.

There are several reports indicating that the gut microbiome helps to improve the immune system. By communicating with immune cells, the microbiome can control our body and help develop resistance to infectious bacteria. In recent years, several researchers have reported the microbiome plays an important role in controlling neurodegenerative disorders, such as Alzheimer's and Parkinson's diseases. Therefore, there are a number of different ways in which the gut microbiome can affect key bodily functions and influence our health. There are several other benefits, a few of which are summarised below.

Body weight

Several studies on the composition of the microbiome present in our intestinal portion have shown that there are thousands of types of different bacteria involved with our body system. The composition analysis indicates the presence of both good and unhealthy bacteria. When unhealthy microbes are dominant, which is also called gut dysbiosis, there is a possibility of an increase in body weight. Several confirmed studies have shown that the gut microbiome differed completely between identical twins, one of who was obese and one of who was healthy. In one study, when the microbiome from the obese twin was transferred to mice, they gained more weight than those that had received the microbiome of the lean twin, despite both groups eating the same diet. These studies indicated that microbiome dysbiosis may play a role in weight gain.

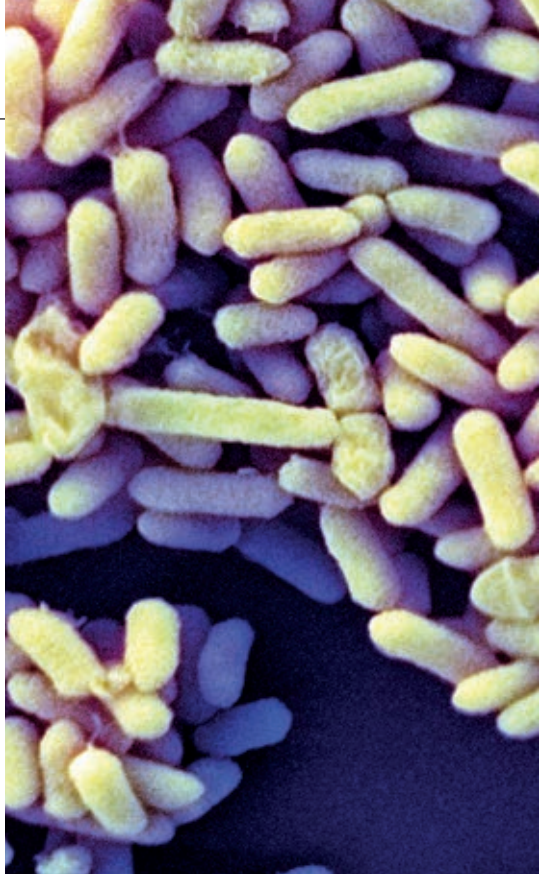
Maintenance of gut health

The microbiome present in the gut also plays a vital role in maintaining the health of the gut system. This has been confirmed by a number of research studies on intestinal microbiome analysis. An unhealthy microbiome creates a number of intestinal disorders, including irritable bowel syndrome (IBS) and inflammatory bowel diseases – the bloating, cramps and abdominal pain that occur due to the presence of IBS. This is because the microbes produce a lot of gas and chemicals, which contribute to the symptoms of intestinal discomfort. However, certain healthy bacteria in the microbiome can also improve gut health. Certain bifidobacteria and lactobacilli, which are found in probiotics and yogurt, can help seal gaps between intestinal cells and prevent leaky gut syndrome.

These species can also prevent disease-causing bacteria from sticking to the intestinal wall. In fact, taking certain probiotics that contain bifidobacteria and lactobacilli can reduce symptoms of IBS.

Heart health

Several researchers have reported that the gut microbiome plays a vital role in maintaining heart health. Developing a healthy microbiome in the gut has been correlated with production of HDL cholesterol. Unhealthy species of microbes present in the gut have been correlated with heart disease by producing trimethylamine N-oxide (TMAO). This is a chemical that contributes to blocked arteries, which may lead to a heart attack or stroke. Certain bacteria within the microbiome convert choline and L-carnitine, both of which are nutrients found in red meat and other animal-based food sources, to TMAO, potentially increasing risk factors for heart disease. However, other bacteria within the gut microbiome, particularly lactobacilli, may help to reduce cholesterol when taken as a probiotic.



"The microbiome plays a vital role in maintaining the health of the gut"

Diabetes

The quality of gut microbiome and its influence on controlling blood sugar levels has also been reported. Both types 1 and 2 diabetes can be controlled by developing an appropriate and healthy gut microbiome. A recent study reported a number of infants who had a genetically high risk of developing type 1 diabetes showed less diversity in gut microbiome composition and the available microbes in the gut system were found to be unhealthy.

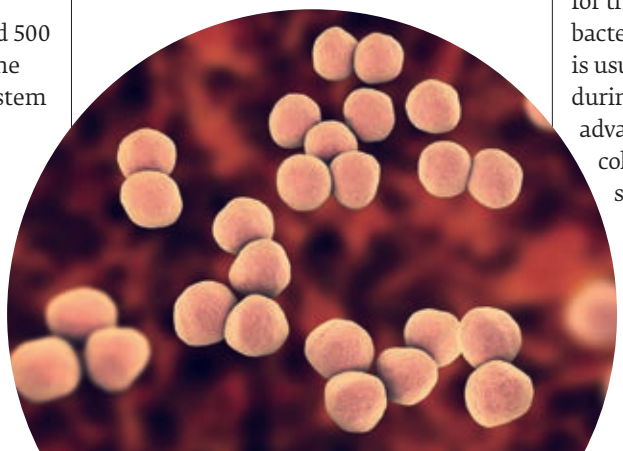
In another observation study, it was noticed that people who have unhealthy microbiome communities have great variation in their blood sugar levels. To confirm this finding, more research is needed, not only on microbiome composition, but also on the microbial ingredients and their chemical identity.

Brain health

Correlation of functioning of the brain and neurodisorders with the gut microbiome has been carried out by a number of investigators. For example, certain species of bacteria present in the gut system help to produce chemicals in the brain called neurotransmitters, such as serotonin, which is an antidepressant. Morphologically, the gut is connected to the brain through millions of nerves. Therefore, the gut microbiome may also influence brain health by controlling the messages that are sent to the brain through these nerves. It has been reported that the gut contains around 500 million neurons. The interaction of the gut, which influences the nervous system and vice versa, is known as the "gut-brain axis" and recent evidence suggests this may be implicated in a range of neurological disorders, including multiple sclerosis (MS), Parkinson's disease and dementia. It has been observed that there were alterations in the composition of gut bacteria in patients with Alzheimer's disease compared to healthy controls. For example, *Clostridium* and *Bifidobacterium* species were less abundant in Alzheimer's disease patients, whereas *Bacterioides* and *Gemella* were more abundant. Furthermore, cerebrospinal fluid markers for Alzheimer's pathology, such as the levels of amyloid-β-protein, could be correlated with a change in the number of certain bacteria in the gut.

The fact that a decrease in the number of *Bifidobacterium*, which is known to be reduced in Alzheimer's, could directly be correlated with high levels of amyloid-β-protein in the cerebrospinal fluid of patients with Alzheimer's. It is mentioned that bacteria that secrete lipopolysaccharides (LPS) and amyloid can trigger profound inflammatory changes within the gut and, therefore, within the brain. Inflammation within the gut can cause the gut to become "leaky" as well as causing the blood-brain barrier (BBB) to become more permeable.

As such, inflammatory molecules can enter the brain through a compromised BBB to trigger brain inflammation, which could trigger or exacerbate Alzheimer's pathogenesis. One bacterium that may induce neuroinflammation and initiate neurodegeneration through the gut is *Bacterioides fragilis*. An accumulation of recent evidence suggests that an imbalanced gut microbiome (dysbiosis) could lead to Alzheimer's disease and wider neuroinflammation through the gut-brain axis. Promoting "good bacteria" relative to "bad bacteria" in the gut may be important in maintaining good digestive, immune and neurological health. Our understanding of how certain gut bacteria can influence brain health is a developing field and more research is needed so that new drug discoveries can be made for effective therapies.



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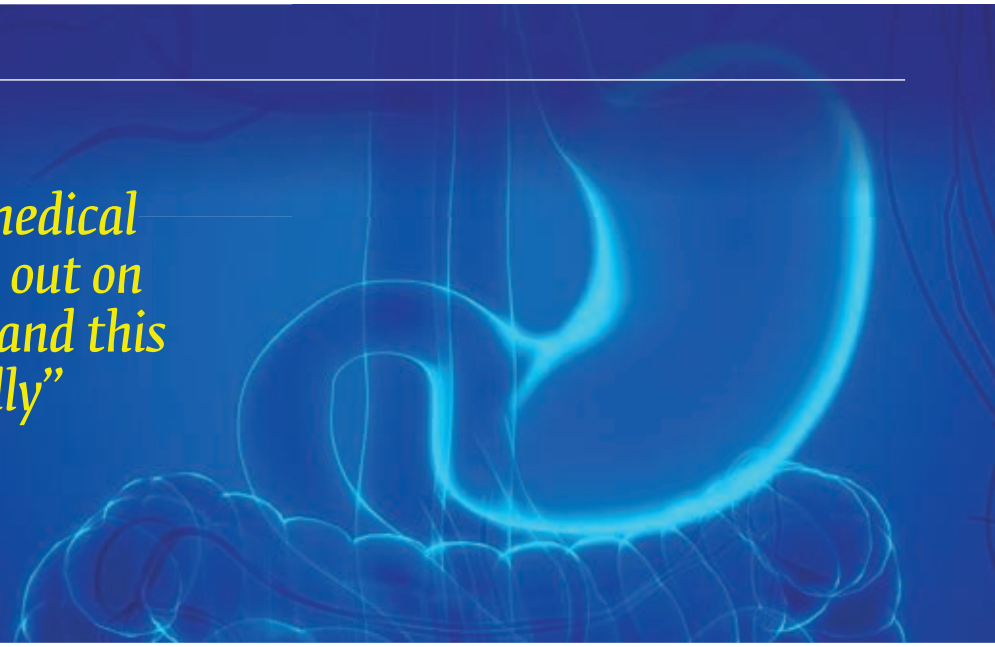
Faecal transplants

Faecal microbial transplantation is an innovative microbial therapy for the treatment of those who are infected with pathogenic bacteria, such as *Clostridioides difficile*, with the symptoms of diarrhoea, abdominal cramping and sometimes fever. This particular infection is very much prevalent in elderly people. Diagnosis is based on a stool DNA test that detects the organism. The antibiotic drugs used for the treatment of this infection include metronidazole, vancomycin and fidaxomycin and these drugs very often have side effects and may aggravate the health condition of the patients. Moreover, the antibiotic drugs kill too many good bacteria and the infection can return within a few days or weeks after finishing the antibiotic course. A report published in 2013 in *The New England Journal of Medicine* showed that faecal transplantation is more effective than oral administration of antibiotic drugs in preventing further recurrences in individuals who have already had recurrent *C. difficile* colitis.

Johns Hopkins School of Medicine in the US developed faecal transplantation therapy and now it is being used routinely for the patients suffering from pathogenic bacterial infections. Faecal transplantation is usually performed by colonoscopy and during the therapy the colonoscope is advanced through the entire colon. As the colonoscope is withdrawn, the donor stool is delivered through the colonoscope into the colon. However, the following precautions are taken by the doctors prior to faecal transplantation:



"All over the world, biomedical research is being carried out on the human microbiome and this field is progressing rapidly"

- Patients need to stop any antibiotic therapy two days before the operation
- It is advised to follow a liquid diet followed by an enema or laxative preparation the night before the scheduled procedure
- Inform the doctors if the patients have any allergies
- Patient medication history is essential.

Generally, the donor of the faecal microbiome transplantation has to take some precautions. Only healthy people who have no history of bowel problems and have regular bowel movements are permitted to go through the extensive screening process. It is compulsory that the donor should not have illness or health disorders in their body. Such persons are generally identified as potential candidates and then they must complete a series of blood and stool tests for all known and detectable pathogens and diseases. Only after this three-stage process has been completed and the candidate has passed all steps, will they be approved as a donor, but screening continues on a regular basis while they are participating on the faecal microbial transplantation programme.

Human Microbiome Project

The microbiome is very important, not only for the human beings, but it also plays a pivotal role for animal and plant life, as their presence in the surroundings is essential for the survival and sustenance of entire biological forms of life. The microbiome community associated with the human body during birth and until death is involved in carrying out various physiological functions, though a few microbes that are pathogenic may be harmful to the body.

Microbes are found in many parts of the body, including skin, gastrointestinal tract, mouth, respiratory tract, urinary tract, and vagina. The human respiratory tract, mainly the nose, is colonised by *Staphylococcus aureus*, which is the main cause of surgical wound infection. The mouth contains biofilms of *Streptococcus mutans*, which are present as plaque on teeth. Similar to the skin, and unlike the small intestine, not many microbes live in the stomach, because of the gastric acid, *Helicobacter pylori* is an example of stomach bacteria. Considering the significant role played by the microbiome community associated with different body parts, the National Institutes of Health in the US initiated the Human Microbiome Project (HMP) in 2007. The focus of the project was to study the microbes which are living in and on the human body and develop a catalogue of the genetic identity of the microbiome species and characterise them. The project received $153m from the Common Fund of National Institutes of Health and $20m of additional support. This project was planned with different goals to achieve, including investigation of the microbiome community in different groups of people and on the different sites of the human body and their correlation with different health conditions. It was also hoped to explain relationships between changes in microbiome and disease. The project has contributed to developing new fields in technological advancement and bioinformatics tools.

Conclusion

Though research on the microbiome is considered an emerging science, there are many areas where scientists have paid a lot of attention and advances are being made. All over the world, biomedical research is being carried out on the human microbiome and this field is progressing rapidly. Researchers are making significant headway not only understanding what the microbiome does, but how it influences human health and disease, especially through its interaction with diet. Several protocols are being developed to build a healthy microbiome community in the body system to create a healthy environment. Evidence suggests that gut microbes and their human host share much of the same metabolic machinery. It has been also established that the diet always influences the microbiome composition, with significant implications for disease risk.

This growing understanding of the role of diet in microbiome-human interactions is creating much interest and investment in developing probiotic and prebiotic food products to help to build and maintain health. BMS

Dr D Diwan is Emeritus Professor in the Mahatma Gandhi Mission's Institute of Biosciences and Technology in Maharashtra, India. **Dr SN Harke** is the Director of the Mahatma Gandhi Mission's Institute of Biosciences and Technology.

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BLOOD ON BOARD

Blood Bank and Stem Cell Bank Discipline Manager **Beverly Craig** outlines an innovative project with the emergency services.

The Northern Ireland Helicopter Emergency Medical Service (HEMS) was launched in July 2017. It operates between the hours of 7am and 7pm. It provides pre-hospital care to patients who have sustained serious trauma. A significant number of these patients have life-threatening haemorrhages, which must be rapidly controlled. The HEMS team has the ability to administer pre-hospital tranexamic acid, together with the application of haemorrhage control interventions. Statistics have shown early administration of red blood cells (RBCs) may confer a survival benefit. Indications for pre-hospital transfusion include:

- Systolic BP <90mmHg with suspected active haemorrhage.
- Traumatic cardiac arrest where hypovolaemia is considered a contributory factor and the patient may be salvageable.

Over the course of a year, key stakeholders met with the objective of establishing a HEMS pre-hospital blood transfusion service for Northern Ireland, including Northern Ireland Blood Transfusion Service (NIBTS), Belfast Health and Social Care Trust (BHSCT) Blood Bank and Haemovigilance Team, Northern Ireland Transfusion Committee and the Henry Surtees Foundation. The project successfully went live in December 2019.

Substantial costs were involved and a successful application was submitted for funding from the Henry Surtees Foundation – a charitable organisation founded by motor sport legend, John Surtees CBE, following the tragic death of his son,who was killed aged 18, while competing in a Formula 2 race in 2009. This funding enabled the purchase of a number of items, including a blood bank freezer, temperature-monitoring equipment, six HEMS transport boxes and blood warming units. The funding also covered costs associated with blood bank staff and the projected overall costs for the first five years. Temperature data loggers were donated.

Training and Competency

Prior to go-live, a robust framework and governance structure conforming to Medicines and Healthcare products Regulatory Agency (MHRA) requirements was essential. A collaborative training day was held with the HEMS doctors and paramedics, good manufacturing practice (GMP) training and training on the importance of pre-transfusion sampling was provided by the blood bank. Haemovigilance delivered a dedicated session called "safe transfusion practice", applicable to the pre-hospital setting.

E-learning was also completed in line with Better Blood Transfusion 3 NI requirements for Right Patient Right Blood (RPRB). Selected HEMS staff were trained as RPRB assessors, who then carried out one-to-one staff simulated competency assessments.

NIBTS presented information on the limited number of blood donors and emphasised the fact emergency O RhD-negative units are a valuable resource.

IMAGES: AIR AMBULANCE NORTHERN IRELAND/ISTOCK

A database has been devised to keep up-to-date training records. A collaborative HEMS Standard Operating Procedure, "Prehospital Transfusion of Red Blood Cells (RBCs)", was compiled to clearly define the process for all stakeholders.

Strict guidelines are followed when considering use of the red cells provided:

- RBCs should be taken on all primary missions
- Emergency RBCs are a precious resource and should only be transfused when clinically indicated
- Only one patient should receive RBC transfusion on any given HEMS mission
- RBC transfusion is not a replacement for haemorrhage control measures
- The judicious use of intravenous fluids is also essential to avoid dilutional coagulopathy
- The seal on the blood transport boxes should not be broken unless RBC transfusion is required.

Pre-hospital blood transfusion

If a decision is made to transfuse RBCs, every effort is made to obtain a pre-transfusion sample. A sample tube and NI transfusion request form accompany each HEMS transport box. An orange label is applied to indicate that this sample has been taken by the HEMS team.

"It provides pre-hospital care to patients who have sustained serious trauma"

This pre-transfusion sample avoids possible delays later in patient care. Some issues encountered if this sample is not obtained include: discrepancies in blood group resulting in the continuation of O RhD-negative use until resolved. This depletes O RhD-negative supplies. In addition, dilution effect after multiple transfusions means antibodies may not be detected.

The blood sample is kept in a safe place until arrival at the receiving hospital, then the remaining patient details are written on the sample tube and the request form by the sample taker.

These are taken from the patient identity band that will be applied in the destination hospital and checked verbally, if the patient is capable of giving an appropriate response.

The HEMS team explicitly states in handover that the patient has been transfused RBCs prior to hospital admission. The completed sample tube and form is handed to the Trauma Team Scribe. It is then their responsibility to send this blood sample to the local hospital blood bank.

A transfusion record and traceability form (TR&T) is supplied with the first unit

"Blood on board has been administered four times in two months"

of blood. A peel-off sticker with the unique donation number from the RBC unit is placed on the TR&T form. Patient identification details should be completed as fully as possible. The hardcopy is returned to RVH blood bank and one copy of this TR&T form is kept with the patient in the destination hospital and a second copy held at the HEMS base.

Logistics of the blood movement

Red cell units are packed into the HEMS transport box by BHSCT blood bank laboratory staff and sealed before delivery to the HEMS base. The box contains two units of O RhD-negative RBCs, accompanying traceability documentation, pre-transfusion sample tube and request form plus the data logger.

Handled appropriately, a sealed and unopened box will maintain the necessary temperature (2-6ºC) for up to 36 hours. This allows the RBCs to be available for HEMS use on any mission during this period or for re-allocation on return to the BHSCT Blood Bank. The box will stay on base for 24 hours.

An authorised courier makes a daily delivery and collection at the HEMS base at approximately 7am. Motorbikes are used where possible to deliver the HEMS transport box, due to time factors and traffic congestion.

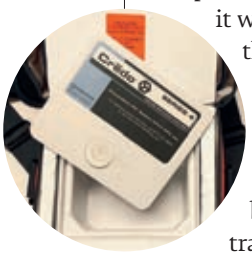
The box is placed on a "blood-in" shelf area and a "sign-in" sheet completed on delivery by the courier.

Collection of the box by the courier is from the "blood-out" area and a "sign-out" sheet completed.

All movements of the box during a shift are documented on the blood box movement log.

Transport box

The validation of the transport box was carried out in strict compliance with the principles of GMP and MHRA regulations. The guidelines for the storage and supply of RBCs state:



"The cold chain for the hospital transfusion laboratory starts from the receipt of blood from the blood centre to the time the unit is transfused or otherwise disposed of." Good Distribution Practice requires us to "ensure that the storage conditions are observed at all times, including transportation".

During the testing phase, ambient temperatures of -12 ºC to +26 ºC were tested as the most extreme environmental conditions. A flight test was carried out by the team – they flew the transport box for the longest possible flight time, taking into account air pressure changes. Results from these tests concluded that the transport box needed preconditioning in the blood bank freezer for at least 24 hours before use. Once packed the boxes are stored in the cold room.

A data logger is used to monitor the air temperature of 2-6ºC in the transport box, when packed with a maximum of two units. An air temperature of 2-6ºC was selected as it was not possible to monitor the core temperature of RBCs. It was felt this was the most accurate way to ensure the temperature of product.

At any one time, the blood bank has two HEMS blood transport boxes ready to go. This minimises any delay in replenishing the supply for HEMS.

The outer covers of the transport boxes have been replaced by a bespoke solution. These outer covers/bags are padded and insulated in micragard, a material which is fuel and water resistant. The covers are highly visible (fluorescent orange) and may be wiped clean.

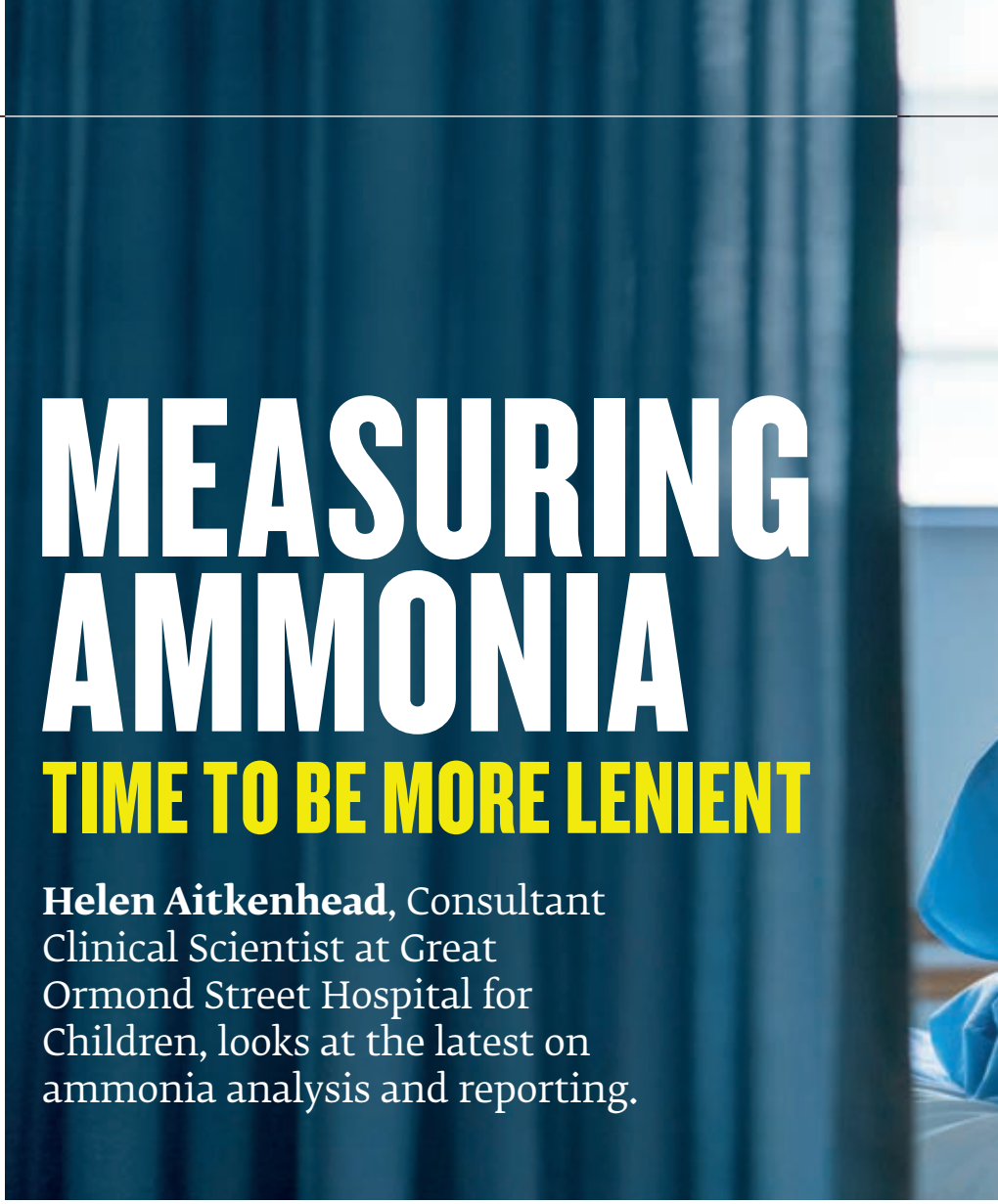
Looking to the future

Blood on board has been administered four times over the period of two months. As part of the validation and service improvement, the process will be reviewed initially after six months and then one year. Each case is audited on an individual basis.

Plans for the future include working with the BHSCT blood bank and emergency department to potentially provide prothrombin complex concentrate and fibrinogen concentrate on board.

The HEMS team intend to host a blood donation day to encourage the team to donate and raise the public awareness of the importance of blood donation.

Beverly Craig is the Blood Bank and Stem Cell Bank Discipline Manager at Royal Victoria Hospital in Belfast. To read the acknowledgements, view the article at **thebiomedicalscientist.net**



MEASURING AMMONIA

TIME TO BE MORE LENIENT

Helen Aitkenhead, Consultant Clinical Scientist at Great Ormond Street Hospital for Children, looks at the latest on ammonia analysis and reporting.

Recognition and treatment of hyperammonaemia, especially in the neonatal period, is a clinical emergency. If patients are left untreated, morbidity and mortality are high. Hyperammonaemia can be difficult to identify and clinicians are reliant on laboratories for the diagnosis. Sadly, the literature is littered with case reports of both children and adults who die as a consequence of hyperammonaemia. The rejection of samples for ammonia analysis by laboratories may be contributing to the problem.

Ammonia toxicity

Ammonia is produced from the deamination of amino acids in the liver, muscle and kidney, and by the action of gut bacteria. In the liver, ammonia is converted to urea, via the urea cycle, for excretion by the kidneys. In both children and adults, plasma ammonia levels are typically less than 40 µmol/L. In neonates, levels tend to be somewhat higher, but typically less than 100 µmol/L.

Mildly raised levels up to 80 µmol/L are seen quite commonly in children and adults, and in neonates any illness may result in levels around 150 µmol/L. Any ammonia >150 µmol/L in children, or >200 µmol/L in neonates and >100 µmol/L in adults requires immediate attention. Ammonia is neurotoxic, so symptoms are essentially neurological. However, there is a wide clinical spectrum with varying severity and age of onset. Neonates, with inherited metabolic disorders resulting in hyperammonaemia, may have overwhelming illness (often mistaken for sepsis) with rapid deterioration from poor feeding and vomiting to tachypnoea, convulsions and coma. Respiratory alkalosis may be an early sign.

There should be a low threshold for suspicion of hyperammonaemia in any neonate with neurological deterioration for no apparent cause. Patients may die during an acute episode, due to cerebral oedema. Those who survive the crisis often have a remaining handicap or neurological deficit. Milder defects may result in chronic hyperammonaemia and may not present until later in life.

Symptoms may be episodic and non-specific, such as vomiting, faddy eating, behavioural changes, slow developmental progress and neurological deficits, meaning hyperammonaemia may be difficult to recognise. Untreated hyperammonaemia can cause irreversible brain damage and death at any age.

Pre-analytical issues

Rapid measurement of plasma/blood ammonia is vital in any sick patient in whom a metabolic disease may be present. The quicker hyperammonaemia is recognised, the earlier the treatment and the better the outcome. Plasma/blood ammonia analysis is challenging because of the various pre-analytical factors that can lead to artificially high results. Once a blood sample has been collected, the ammonia levels start to rise. Red blood cells release ammonia into the sample and ammonia continues to be produced by the deamination of amino acids by plasma enzymes.

Good sampling technique is required to avoid artefactual increases in ammonia and haemolysis. Speedy delivery of the sample to the laboratory and rapid analysis is required to minimise such increases. Chilling blood samples by putting them on ice reduces enzyme activity and sample deterioration.

Although a poor quality sample may result in an overestimate of the plasma ammonia, reporting a high result with an appropriate comment and making a request for an urgent repeat is not likely to do any harm. The clinicians do not need an accurate result in the first

IMAGES: ISTOCK

instance - they just need to know whether the ammonia is normal/slightly raised or is very high so the patient can be managed and investigations initiated.

New guidelines

In December 2018, metbio.net updated their guidelines on the investigation of hyperammonaemia and measurement of plasma ammonia. An important new recommendation is that laboratories should accept all blood samples for ammonia analysis, even if the quality is less than ideal. It is also recommended that laboratories should append appropriate comments to all ammonia results where samples have been delayed, haemolysed or compromised. Laboratories should request a repeat sample for confirmation of hyperammonaemia when the ammonia result is elevated for the first time. Samples for ammonia analysis should not be rejected.

Audit of practice

Last year, after the new guidelines were published, there was a national ammonia audit of UK clinical biochemistry laboratories. Laboratories were asked about the pre-analytical requirements of ammonia samples, such as whether samples must be received within a specific time interval, whether samples must be sent on ice and whether samples must be unhaemolysed. In total, 76 laboratories replied.

Most recommend that samples are sent rapidly to the laboratory. However, 64% of laboratories said they reject samples that they consider too old for analysis.

Seventy-eight percent of laboratories recommend that samples are sent on ice. However, 24% of laboratories reject samples that are not received on ice.

All but two laboratories assess the haemolysis status of samples sent for ammonia analysis. Unfortunately, the majority are rejecting samples that are haemolysed (see chart). In total, 72% reject haemolysed samples and 80% reject grossly haemolysed samples. Only 66% of those who reject samples request repeats.

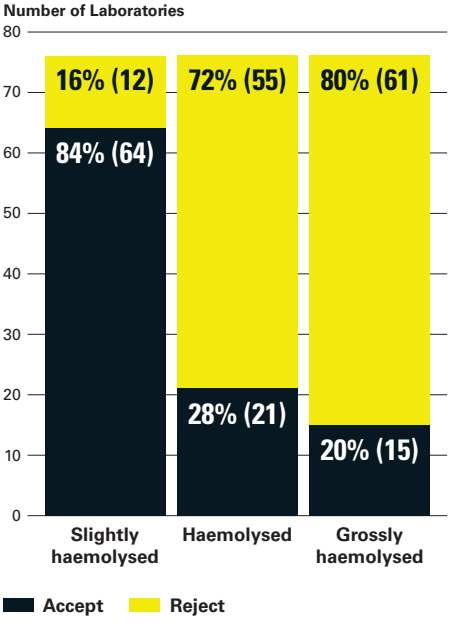
Audit summary

The audit clearly shows that laboratories are continuing to reject samples for ammonia analysis despite the release of updated guidelines. The audit found that 83% of laboratories were aware of the new metbio.net guidelines.

This may be because laboratories have yet to update their SOPs and implement these new guidelines. With the ISO 15189:2012 for medical laboratories, it is possible that some laboratories have become averse to deviating from the manufacturers' instructions, and some state "do not analyse haemolysed samples". However, central to the standard are two clauses – "Needs of users" (4.1.2.2) and "Risk Management" (clause 4.14.6).

Clause 4.1.2.2 states: "Laboratory management shall ensure that laboratory

NUMBER OF LABORATORIES ACCEPTING/REJECTING HAEMOLYSED SAMPLES



services... meet the needs of patients." Clause 4.14.6 states: "The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate identified risks."

Conclusion

Laboratories should analyse all samples received for ammonia analysis, even if the quality of the sample is less than ideal. If the ammonia is high, an urgent repeat should be requested before treatment is initiated. This will reduce the chance of diagnosis of hyperammonaemia being missed or delayed and may save lives. BMS

Helen Aitkenhead is a Consultant Clinical Scientist and Director of Newborn Screening Chemical Pathology at Great Ormond Street Hospital for Children NHS Foundation Trust.

CERVICAL SCREENING IN MOLDOVA

Lead Biomedical Scientist **Hedley Glencross** introduces a project to improve the outdated cervical screening programme in the Republic of Moldova.

For nearly three years I have been involved with a small project team concerned with introducing an organised cervical screening programme to the Republic of Moldova (RM). This has been an interesting project, not only coming at a time when UK cervical screening programmes are stopping cytology-based screening in the midst of a move to primary HPV testing, but also encountering the obvious cultural differences between the UK and RM.

I have visited RM three times, conducting laboratory assessments and participating in a wider cervical cytology education and training programme, delivering lectures and workshops.

Common cause of death

RM is a landlocked eastern European country that is surrounded by Ukraine and Romania. It is a poor country – one of the poorest in Europe – and has a mostly rural-based economy. The most recent figures show RM had a population estimated at just under three million in 2016. Out of the main urban areas, water tends to be drawn from wells and there is little or no electricity or mains sanitation.

Cervical cancer is a large burden in the country, with approximately three women, mostly younger women, a week dying from cervical cancer. Although cervical cytology does exist in RM, and it has been claimed that in 2015, 250,000 smears were "screened", enough to result in a 70% coverage rate of the population, based on a three-yearly screening programme, the incidence of and mortality rates from cervical cancer remain stubbornly high.

This disparity may be explained by a number of factors, not least the distinct lack of training in the screening and interpretation of cervical smears, but also the way in which smears are taken and stained. Almost contemporaneously with Papanicolaou, a Romanian pathologist, Aurel Babes published a paper on the diagnosis of cervical cancer using air-dried smears and Romanowsky/Giemsa (R/G) staining. Unfortunately, Babes published this paper in a French language journal and did no further work on this matter, so went largely unnoticed in English-speaking and wider European countries. His work though persisted in eastern Europe, especially during the cold war when much of eastern Europe was in effect closed to outside influences.

While R/G staining has a valuable place in diagnostic cytology, the often subtle chromatin disturbances, cellular variation and active keratinisation seen in dyskaryosis are largely "invisible", making accurate identification of CIN 3 very difficult. Left untreated CIN 3 will progress to cervical cancer in approximately a third of women after 10 years. I did see Papanicolaou-stained smears as well, but their quality left a lot to be desired.

Screening programme

The laboratory facilities were rudimentary at best and although there was some (very) modern equipment seen, it was either underused or not used at all. Coupled

with this observation was also the lack of quality measures we take for granted at both the smear-taking and the screening and reporting stages. Fortunately, the project group was able to call on the expertise of UK-based cytopathologists and histopathologists, as well as myself and a number of committed and enthusiastic Moldovan-based gynaecologists and pathologists, all led and driven by the International Cervical Cancer Prevention Association (ICCPA).

As RM is a resource-limited country, a decision was made to base, at least initially, this screening programme on conventional cytology smears taken using a Cervex-Brush and reported using modified Bethesda terminology. Although this may seem an odd decision, given international moves to primary HPV testing and vaccination, historical data from the UK and other countries have shown the large positive impact on cervical cancer incidence and mortality rates following the introduction of such screening programmes. What the project team has been able to achieve includes:

- Training and converting primary health clinics to accurately take and fix cervical smears, ensuring each woman is uniquely identified and smears are properly labelled
- Giving screening laboratories a working Papanicolaou staining method that allows proper visualisation of smears
- Delivering a number of training courses and workshops in cytology screening and reporting
- Delivering a number of courses and workshops in histopathology reporting.

Future plans

While there is much work to do regarding computerisation, call/recall, fail-safe, quality assurance and many other aspects of the programme, the work done so far is a sound base upon which to build.

One of the next planned phases for the laboratory part of the project, alongside further cytology training, will be to address histological laboratory matters, including fixation, block selection, tissue processing, embedding, cutting and staining procedures. Work on setting up this part of the project is on-going, which will likely involve reciprocal visits between UK and RM to train one of their staff, who will then cascade this to other laboratories in RM.

This has been and continues to be an interesting experience for me, not only working outside the UK, but also my first encounter with simultaneous translation of lectures. I have met and worked with a brilliant group of people. Special thanks must go to Dr Philip Davies (ICCPA), Drs Mary Brett and Mike Coutts (UK), Drs Eugen Melnic, Ruslan Pretula and Ecaterina Foca (RM), plus all of the medical and laboratory staff from RM, who are too many to name individually, but who have been a wonderful group of students. Personally, I hope to continue with this project and help see it through to a successful outcome. BMS

Hedley Glencross is Lead Biomedical Scientist in Diagnostic Cytology and Andrology at Queen Alexandra Hospital, Portsmouth. He is an Executive Committee member of the British Association for Cytopathology.

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CliniSys
Diagnostics Intelligence

One Dorset Pathology adopts a single LIMS from CliniSys

WinPath Enterprise will replace ageing IT at three trusts and support the development of a pathology hub-and-spoke service.

Pathology services across one of England's most advanced health economies are to use a single laboratory information system (LIMS) from CliniSys.

One Dorset Pathology, which covers the three acute trusts within the Dorset Integrated Care System (ICS), which serves a population of around 800,000 people, will deploy WinPath Enterprise – a next-generation LIMS designed to meet the specific needs of pathology networks.

The new LIMS will replace the 20-year-old pathology systems that are currently in use at the trusts and support the creation of a state-of-the-art pathology hub.

The LIMS will be fully integrated with CliniSys' order communications solution, ICE, to create an end-to-end workflow for ordering and conducting tests, while the creation of a single lab system will make it easier for clinicians to access the results from any hospital or GP practice.

The contract has also been structured so that it lays the foundations for a group of hospital trusts in Hampshire and Wiltshire, known as Southern Counties Pathology, to use the same integrated pathology IT service in the future.

Stephen Harding, Head of Service at One Dorset Pathology, said: "The new CliniSys LIMS is a significant enabler of the transformations we are looking to achieve.

"It would be difficult to run a consolidated testing service without a single LIMS, because our hub and spokes need to use the same processes and communicate effectively with each other.

We will also be able to open-up results across the network

"By having a single system, we will also be able to open-up results across the network, so that patients who have tests in one hospital will have the results available if they go to another hospital. That will be a significant benefit and will significantly improve patient care and safety across the county."

Dorset has three acute foundation trusts: The Royal Bournemouth and Christchurch Hospitals, Dorset County Hospital, and Poole Hospital. They have been working on a One NHS in Dorset vision for some years – initially as an acute care collaboration vanguard and more recently as an integrated care system.

As part of their work, and following Lord Carter of Coles' report recommending the move to hub and spoke processing models, the three trusts agreed to set up One Dorset Pathology in 2016.

Following the proposal to form 29 pathology networks in England from NHS Improvement, One Dorset Pathology was credited with being the first new pathology network to launch a procurement for a common LIMS when it went out to tender the following year. The procurement concluded last summer, with the network deciding to take WinPath Enterprise as a hosted solution.

One Dorset Pathology is now working with CliniSys to develop a roll-out plan for the system, based on the company's extensive experience in delivering technology for pathology networks.

The LIMS is likely to be deployed as a single activation rather than a site by site go-live over the next 18 months.

Please visit clinisysgroup.com and clinisys.co.uk for more information.

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SCIENCE COUNCIL CPD REVIEW

Christian Burt, Professional Support Services Manager at the IBMS, looks at an opportunity for members to demonstrate their excellence.

"You have been selected for the annual Chartered Scientist CPD review." Does this sentence instil a sense of the foreboding? Or can it provide the platform to demonstrate the outstanding service provided by biomedical scientists?

I strongly believe the latter, with registrants who are chartered with the IBMS consistently commended for their CPD submissions at the Science Council annual CPD Awards.

Here to support you

It is my responsibility to ensure the IBMS continues to meet its licence requirements with the Science Council. As such, the IBMS randomly selects 2.5% of its Chartered Scientists for a review of their CPD activities. The initial paragraph of my email to selected registrants clearly states there is no need to panic and that the IBMS will help you as much as possible to be successful in your CPD review.

We grant a three-month period for a CPD review return and attach detailed guidelines for what is expected together with the review form.

A fully redacted model example is also sent to offer guidance in terms of layout and concision. Recent articles and documents relating to reflection are also provided. The IBMS office is committed to the provision of first-class support for members and I am always happy to offer guidance and advice.

The review form to be returned contains six sections:

- Current professional profile
- CPD that is relevant to current and future practice
- Contribution to the quality of your professional practice and service delivery
- How your CPD has benefited the users
- Future planning
- Summary of CPD activity.

Do registrants initially struggle with any of the sections?

In my experience, it is: "Contribution to the quality of your professional practice and service delivery" and "How your CPD has benefited the users of your work". These sections are often where I will request a registrant expand on their initial submission.

I am always thankful that registrants act upon advice to improve a submission and, in the vast majority of cases, feel supported throughout the process.

A key message for these sections is to not just state what you have done; you must describe how the activity has improved yourself, users and the service.

In other words, it is vital to not only detail the activity undertaken, but also to reflect and detail the practical outcomes.

Section 2 has five sub-sections:

- Work-based learning
- Professional activity
- Formal/educational
- Self-directed learning
- Other (i.e. voluntary work).

A registrant at Chartered Scientist award level will be expected to undertake activities across at least three (exceptionally two) of these sub-sections.

For IBMS registrants, this aligns with the IBMS CPD online scheme portfolio and underlines the importance of regular recording of activities undertaken.

Plan for the future

Clearly defined future planning of CPD activity is essential. During the year, you

should be identifying (therefore, recording) positive and negative learning points. Use these to coordinate the next 12 months (and beyond) and any specific examples of activities to be undertaken would be well received.

The IBMS learns from you

Our team of trained assessors not only assess that the CPD standards are met, they can also identify examples of self and service improvements, best practice and CPD activities that would benefit dissemination to the wider biomedical science community.

Post-CPD review, registrants are often asked to consider the submission of an article for *the Biomedical Scientist*, give further details on a course that may benefit others, or expand on research and innovation to present at a local or national level.

Those submitting particularly high-level submissions are often asked to consider joining the team of CPD review assessors; an ideal way to recruit volunteers is from those who have already gone through the process.

Chartered Scientist award

If you have yet to make an application at Chartered award level, I'll be more than happy to open up an email conversation. If you can briefly describe your current role and qualifications, that would be really helpful for me to signpost to the appropriate Science Council registration award. As a general rule of thumb, a biomedical scientist will be working at Band 7 level (or equivalent in a non-NHS environment) in order to successfully demonstrate the Chartered competences. IBMS

"You must describe how the activity has improved yourself, users and the service"

Christian Burt is Professional Support Services Manager at the IBMS and a member of the Science Council CPD Learning Group. **christianburt@ibms.org**

FEEDBACK FROM REGISTRANTS

How did you feel when called for CPD review?
"Slightly surprised, it was unexpected. I can't say I was recording my CPD as rigorously as I would have liked to have been! However, we have had UKAS accreditation for our POCT department for a number of years now and this has forced me down the route of being more mindful about how I choose to spend my time and at least keeping some records. As a result, I can usually put something together in a more presentable form if needed." **Nicky Hollowood CSci FIBMS, POCT Manager**

Were you already recording CPD and confident in completing?
"I really appreciated the support, as I felt I had someone to ask for advice in case I encountered any problems. It was also reassuring to know that Christian would check my first submission on a pre-assessment basis, if needed. I appreciated the outcome report, as I received feedback on my CPD review rather than just notification of acceptance." **Vesna Broom BSc MSc CSci FIBMS, Advanced Specialist Biomedical Scientist**

"I don't really consider the activities that I submitted as CPD – they are just part of my role as a POCT manager. These are things I would be doing and attending whether CPD was a requirement in my profession or not. I think POCT is such a rapidly growing and evolving discipline that there is always something new to learn and more personal growth to be achieved. I am the sort of person who is keen to know more about new ways of working so I naturally gravitate towards these opportunities to learn and develop when they arise." **Nicky Hollowood CSci FIBMS, POCT Manager**

How did you feel about the support during the process and the outcome report?
"The support I received was great. I wasn't sure how much detail was required and the initial feedback by the IBMS was very quick and extremely helpful. Completing the forms was not difficult, the IBMS is always very approachable and helpful." **Angela Richard-Londt MSc, CSci, MIBMS, Head Biomedical Scientist, Neuropathology**

Would you encourage others to make a CSci application?
"I think the CSci award brings credibility to any role in science. Any award or qualification that backs up experience and knowledge will add credibility to our profession and as the term chartered is universally accepted and used in other professional areas (including surveyance, accountancy, engineering) it is more meaningful outside the science profession." **Nicky Hollowood CSci FIBMS, POCT Manager**

"Yes, definitely. The process can initially feel a bit daunting, but there is a lot of guidance and help available and it is definitely worth doing." **Angela Richard-Londt MSc, CSci, MIBMS Head Biomedical Scientist, Neuropathology**

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MY IBMS NEWS

INAUGURATION

IBMS PRESIDENT INAUGURATED

Allan Wilson has been inaugurated as the new President of the IBMS.

He will serve until 2022 and will be the 34th IBMS President since the founding of the Institute in 1912.

IBMS Past President Allison Geddis was on hand to present Allan with the presidential chains.

Also in attendance were IBMS Council members and executives, along with distinguished guests from the healthcare profession, including Jo Martin from the Royal College of Pathologists and Karen Stewart, Health Science Officer for the Scottish Government.

Allan said: "As IBMS President, I will use my connections with fellow organisations and professional bodies to build more partnerships to create opportunities for biomedical scientists to improve patient care. During this politicised climate, I want to ensure that we are involved as an organisation when decisions are being made that will impact our members and the laboratory service."

Allan started as a trainee in 1976 and spent more than 40 years working in laboratories across the globe. He trained in Glasgow and is an expert in cytology. Today, Allan works as Lead Biomedical Scientist in Cellular Pathology and Advanced Practitioner in Cervical Cytology at Monklands Hospital, where he has been based since 1988.

Allan has also worked in senior level management for 25 years and is a cellular pathology network manager and cervical cytology consortium manager for Scotland. He has lectured across Europe, in addition to New Zealand and Africa, which gives him a unique perspective on international laboratory practices.

ANNUAL GENERAL MEETING

The seventy-eighth Annual General Meeting of the Institute of Biomedical Science will be held at the Grand Central Hotel, 99 Gordon Street, Glasgow, G1 3SF on 6th June 2020 at 10.30 am. Official notification of the meeting will be published in the April issue of *The Biomedical Scientist* and online.

→To register to attend, please email mail@ibms.org

ALL MEMBERS ARE INVITED TO ATTEND

AWARDS UPDATE

BIOMEDICAL SCIENTIST OF THE YEAR SHORTLIST

The Advancing Healthcare Awards (AHAwards) shortlist for Biomedical Scientist of the Year includes three IBMS Fellows: Dr Guy Orchard, Dr Alison Watt and Dr Sarah Pitt.

The IBMS is proud to sponsor the Biomedical Scientist of the Year award, which celebrates an exceptional biomedical scientist who has used his or her skills and expertise to advance practice in an innovative and impactful way, making a real difference to patients' lives and inspiring those around them.

The AHAwards recognise and promote the achievements of healthcare professionals and organisations across the UK.

The nominees met with a judging panel in February, and are due to attending the AHAwards ceremony on 20 March where the winner will be announced at the annual healthcare award ceremony in London.

→ **ahpandhsawards.co.uk**

JOURNAL-BASED LEARNING EXERCISES

Institute of Biomedical Science Continuing Professional Development

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

DEADLINE WEDNESDAY 3 JUNE 2020

Covert pathogenesis: transient exposures to microbes as triggers of disease.
Gilbert NM, Lewis AL. *PLoS Pathog* 2019 Mar 28; **15** (3): e1007586. doi: 10.1371/journal.ppat.1007586. eCollection 2019 Mar (https://doi.org/10.1371/journal.ppat.1007586). Assessment No: 030120

01	Covert pathogenesis is another term for polymicrobial infection.	**11**	The authors suggest that *G. vaginalis* is able to act as a covert pathogen to promote recurrent incidences of UTIs.
02	The authors suggest that in some cases transient microbial exposures may result in host responses resulting in disease after a microbe has been cleared.	**12**	Studies to date support the existence of a urinary microbiome.
03	A covert pathogen may reside in another bodily reservoir, which may allow for diagnostic opportunities.	**13**	Human recurrent UTI episodes are often caused by the same strain of *E. coli*.
04	A leading risk factor for UTIs is sexual activity but this is not thought to aid in the transfer of organisms to the urinary tract.	**14**	*G. vaginalis* is an infrequent member of the vaginal microbiome.
05	The covert pathogenesis model discussed in the paper could also be involved in reactivation of latent infections.	**15**	The authors' model of bladder exposure in mice to *G. vaginalis* resulted in exfoliation but did not result in neutrophils being detected in urine.
06	Covert pathogenesis as described in the paper does not refer to a situation whereby an organism can contribute to the severity of disease.	**16**	Women with bacterial vaginosis have lower rates of UTI than those with a lactobacilli-dominated vaginal microbiota.
07	The authors suggest that covert pathogenesis could be involved in some situations where standard culture techniques cannot locate high levels of a single organism.	**17**	It is believed that *E. coli* gains access to the urinary tract from nearby microbial niches.
08	The authors conclude that soluble toxins would not fall into the paradigm.	**18**	Bladder exposure to lactobacilli caused recurrent UTI and exfoliation in mouse models.
09	*Gardnerella vaginalis* has not been linked to symptomatic UTI.	**19**	Identification of covert pathogens in human disease is challenging due to the organisms not being present at the time of disease presentation.
10	Studies to date have not shown *Escherichia coli* capable of establishing latent infection in intracellular tissue reservoirs in the bladder.	**20**	An estimated 2% of women suffer more than six recurrent UTIs each year, equating to 70 million worldwide.

REFLECTIVE LEARNING

01	Given the thoughts detailed in the paper, reflect on whether there is a need to review those cases where standard culture techniques fail to find high levels of a single organism in cases presenting with clear urinary symptoms.

DEADLINE WEDNESDAY 3 JUNE 2020

Tissue staining for THSD7A in glomeruli correlates with serum antibodies in primary membranous nephropathy: a clinicopathological study. Sharma SG, Larsen CP. *Mod Pathol* 2018; **31** (4): 616–22 (www.ncbi.nlm.nih.gov/pmc/articles/PMC5908687/pdf/modpathol2017163a.pdf). Assessment No: 030520

01	THSD7A was detected in paraffin wax-embedded sections by immunoperoxidase staining using anti-THSD7A antibodies at a dilution of 1:80.	**11**	Membranous nephropathy is a pattern of glomerular immune complex disease with a variety of aetiologies.
02	Complete remission was defined as urinary protein excretion less than 0.3 g/d (uPCR <300 mg/g or 30 mg/mmol), confirmed by two values at least one week apart, accompanied by normal serum albumin and normal serum creatinine.	**12**	The identification of PLA2R as the antigenic target in most cases of primary membranous nephropathy has led to rapid changes in the area of treatment and diagnosis of the disease.
03	Membranous nephropathy is characterised by the renal biopsy finding of subepithelial immune-type deposits and the clinical presentation of nephrotic syndrome.	**13**	Cytoplasmic fluorescence of the transfected cells only at 1:10 dilution was considered to be positive.
04	THSD7A stain was interpreted as positive or negative. The stain was called positive if the staining was present in the granular pattern within the subepithelial side of the glomerular basement membranes.	**14**	Circulating autoantibodies to PLA2R and THSD7A were detected using indirect immunofluorescence assays. Each of the slides contained two different biochips in one incubation field. One biochip was coated with human embryonic kidney (HEK)293 cells that express the PLA2R or THSD7A protein, whereas the second biochip, which serves as a negative control, contained non-transfected HEK293 cells.
05	Low-titre THSD7A antibodies (1:10) at the time of diagnosis did not correlate with the level of proteinuria.	**15**	Among these 31 THSD7A-positive patients there were 12 males and 19 females. The mean age was 62 years (range 17–91 years).
06	Tissue staining for THSD7A is highly sensitive and specific for the detection of THSD7A-associated membranous nephropathy and it correlates strongly with serum positivity.	**16**	THSD7A-positive membranous nephropathy from December 2016 to June 2018 accessioned in our laboratory were selected for the study.
07	More data are needed to determine the clinical utility of similar testing for serum THSD7A antibody testing.	**17**	A total of 31 of the 131 membranous nephropathy cases diagnosed in the laboratory during the study period were positive for THSD7A.
08	The THSD7A antibody titre correlated with the level of proteinuria and was predictable of disease remission or response.	**18**	This male gender predominance seen in our cohort is different to that which is described in case series detailing PLA2R-associated membranous nephropathy.
09	Among the patients with known ethnicity (n=25) the disease was more common in Indians.	**19**	The PLA2R immunofluorescence staining procedure was performed as previously described on formalin-fixed, paraffin wax-embedded tissue.
10	The case series suggests that malignancy might be as common as previously reported in patients with THSD7A-associated membranous nephropathy.	**20**	The role of serum testing for anti-PLA2R antibody levels has become important in treating and monitoring the therapy of patients with PLA2R-associated membranous nephropathy.

REFLECTIVE LEARNING

01	Critically appraise the histological direct biopsy versus the indirect serological detection of THSD7A antibodies.	**02**	Discuss the relative frequency of PLA2R and THSD7A antibodies in idiopathic membranous nephropathy.

EVENTS AND TRAINING COURSES

IBMS Institute of Biomedical Science Continuing Professional Development

More training courses, CPD and local events and activities are available on the IBMS website.

DATE	TITLE	VENUE CONTACT
March		
2-3 Mar	**Introduction to Practical HPLC Course**	Rochester I stuart@laserchrom.com
4-5 Mar	**Intermediate Practical HPLC Course**	Rochester I stuart@laserchrom.com
5-6 Mar	**Liver Biopsy in the Assessment of Medical Liver Disease and Liver Pathology Workshop**	London I kristen.pontello@rcpath.org
6-7 Mar	**Introduction to NGS: DNA**	Cambridge I ecanepa@illumina.com
9-11 Mar	**Practical HPLC Method Development Course**	Rochester I stuart@laserchrom.com
12-13 Mar	**Practical HPLC Troubleshooting Course**	Rochester I stuart@laserchrom.com
15-16 Mar	**Practical HPLC Troubleshooting Course**	Rochester I stuart@laserchrom.com
20 Mar	**Clinical Biochemistry Short Course 1**	London I c.ferrier@westminster.ac.uk
27 Mar	**Clinical Biochemistry Short Course 2**	London I c.ferrier@westminster.ac.uk
30 Mar	**British Association for Cytopathology Spring Tutorial**	London I christianburt@ibms.org
30 Mar-3 Apr	**Microbiology Society Annual Conference**	Edinburgh I conferences@microbiologysociety.org
April		
3 Apr	**Clinical Biochemistry Short Course 3**	London I c.ferrier@westminster.ac.uk
7-9 Apr	**BSAC Residential Workshops for EUCAST Susceptibility Testing**	Cardiff I ecarruthers@bsac.org.uk
15 Apr	**UK NEQAS Cellular Pathology Technique Introduction to Immunocytochemistry Workshop**	Northumbria I cpt@ukneqas.org.uk
16 Apr	**UK NEQAS Cellular Pathology Technique Advanced ICC Applications in Laboratory Practice A Workshop**	Northumbria I cpt@ukneqas.org.uk
18 Apr	**Biomed Online Learning courses**	Online I c.e.ronan@gre.ac.uk
24 Apr	**Association of Anatomical Pathology Technologists and Human Tissue Authority Consent Training Day**	London I christianburt@ibms.org
25-27 Apr	**BSAC Residential Workshops for EUCAST Susceptibility Testing**	Cardiff I ecarruthers@bsac.org.uk
27-29 Apr	**British Society for Haematology 60th Annual Scientific Meeting**	Petersfield I BSH2020@mci-group.com
May		
6 May	**UK NEQAS Cellular Pathology Technique Non Gyn Cytology Beginners/Refresher Workshop**	Gateshead I cpt@ukneqas.org.uk
7 May	**UK NEQAS Cellular Pathology Technique Non Gyn Cytology Intermediate Workshop**	Gateshead I cpt@ukneqas.org.uk
14 May	**The Genomic & Microbiology Revolution: in Technology we Trust (or do we?)**	Hendon I swallis@mastgrp.com
20 May	**UK NEQAS Cellular Pathology Technique TEM workshop**	Leicester I cpt@ukneqas.org.uk
June		
3 Jun	**IBMS Registration Portfolio Workshop**	London I c.ferrier@westminster.ac.uk
10-12 Jun	**The Laboratory Diagnosis of Malaria**	London I claire.rogers@lshtm.ac.uk
15-19 Jun	**The Laboratory Diagnosis of Parasites**	London I claire.rogers@lshtm.ac.uk
17 Jun	**UK NEQAS Cellular Pathology Technique Introduction to Specialist Demonstration Techniques**	Northumbria I cpt@ukneqas.org.uk

HERE TO HELP

TRAINING PROGRAMME SPREADSHEET

Deputy Head of Education at the IBMS, **Jocelyn Pryce**, advises on the completion of the revised training laboratory re-approval process.

Many of you will have been through the revised training laboratory re-approval process since its adoption around 18 months ago. The feedback has been excellent, with trainers reporting that it is much easier than preparing the large volumes of documentation, as was the case previously.

The rationale behind our training programme spreadsheet is that we can now quickly see how a training team anticipates the standards will be covered and, in cases where the information is complete, it has allowed us to reduce our turnaround time.

It is our aim to hold comprehensive training programmes for every training route undertaken in all of our approved laboratories. Although we have been successful in capturing a large majority of them, we are still finding that some laboratories provide training programmes within their laboratory that have not been captured within their spreadsheet. Ideally, there should be a separate sheet provided by the laboratory for each programme.

One area that laboratories often forget about is the training programmes that they provide for university placement students. If they follow the same programme as your in-house trainees, there is no reason to supply further information. If they follow a different path, for example a shorter exposure period to a test or bench, then we would expect to see a spreadsheet reflecting this.

Many of our placement students undertake parts of the portfolio in university and some with the placement host laboratory. It should be clear on the spreadsheet where each part is expected to be covered. The training programme outlined in the spreadsheet is purely indicative, but serves to demonstrate how a trainee might move around a laboratory collecting evidence. Aside from being a valuable tool in allowing us to meet the HCPC standards of education and training, it can also be given to the trainee at the point of induction, so they know what to expect of their time in the laboratory and can be a point of reference if they are not proceeding with the portfolio as fast as a trainer might expect.

One of the issues that delays assessment of training approval is the use of generic terms in the "laboratory section" column. We often see "all laboratory areas" or "all sections"; essentially, what this translates to is "somewhere, at some point over the training period our trainee will do this". This is not detailed enough. We need reassurance that the candidate is in safe hands and they are being guided throughout their training programme.

We recognised, during the development of this process, that one size does not fit all and since inception I have been working closely with laboratories that have difficulties in defining the "laboratory section" information. Often it requires them, instead of considering actual laboratory sections, to think in terms of benches or tasks. Most trainees undertake some form of rotation around a laboratory and rarely do the same task for the duration of their training period. The key to success when filling this out is to break down the tasks and reflect that rotation in the spreadsheet.

We will now be reviewing the guidance we provide and creating an exemplar spreadsheet with prompts for how you might approach the completion.

IMAGES: SHUTTERSTOCK

MY LAB

FORENSIC DRUGS DEPARTMENT

Forensic Scientist **David W Jones** gives a guided tour of Eurofins Forensic Services.

The Eurofins Forensic Services drugs department is one of the largest forensic science departments in the country. The drugs department is based over three sites – Tamworth, Wakefield and Teddington. It also has one satellite lab, based in central London.

We have circa 50 staff, consisting of technicians, administrators, purity analysts, management and forensic scientists.

All of our drug laboratories are compliant with, and accredited to, the ISO 17025 quality standard, administered by the United Kingdom Accreditation Service, and also with the Forensic Science Regulator Codes of Practice and Conduct.

We provide chemical analysis using presumptive testing, Fourier Transform infrared spectroscopy, gas chromatography mass spectrometry, thin-layer chromatography and high-performance liquid chromatography in order to determine the identification and purity of substances that are controlled under the Misuse of Drugs Act 1971, Misuse of Drugs Regulations 2001 and the Psychoactive Substances Act 2016.

These types of analyses help support simple possession cases, test purchase operations and searches to reveal drugs concealed in everyday items. We serve the majority of police forces within England and Wales, government agencies and the Crown Prosecution Service. We also offer our services to criminal defence lawyers. We receive hundreds of items of evidence every month from our customers, ranging from drug paraphernalia, such as digital scales and medicinal syringes, to deal-size and bulk drugs, such as cocaine, diamorphine (heroin), herbal cannabis, cannabis resin, cannabis plants, amphetamines and pharmaceutical drugs.

All of our staff are trained to exceptionally high competency levels and are subject to regular performance reviews and provided with further training, if required.

We offer more complex services and opinion-based reports, such as connections between drug seizures, advice on potential origin of supply, identification of new types of drugs, cannabis grow rooms and suspected illicit laboratories.

We also offer training courses in evidential drug identification testing to enable police officers to carry out screening tests for commonly encountered drugs, to recognise different types of drugs and take the best samples for analysis.

In addition to this range of services, we also offer expert witness training to prepare upcoming forensic scientists for when they have to give evidence in a court of law.

We have an excellent record of passing proficiency trials, which ensures that staff are competent and kept up to date with our procedures.

The staff who work at Teddington, where I am based, are very dedicated, friendly and approachable. We are an excellent team and pride ourselves in the work and service we provide to our customers in order to help with their investigations. We are extremely proud to support the UK criminal justice system with the work that we undertake to help tackle the problem of drug misuse in today's society. BMS

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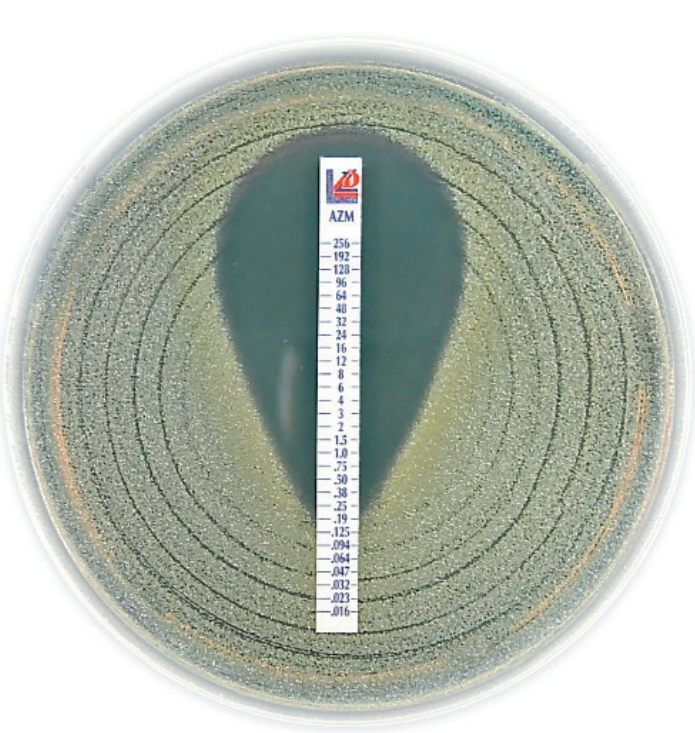

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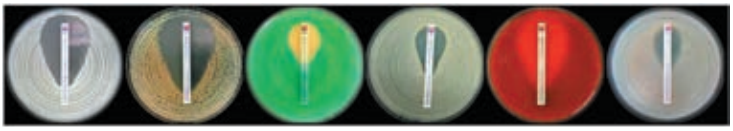

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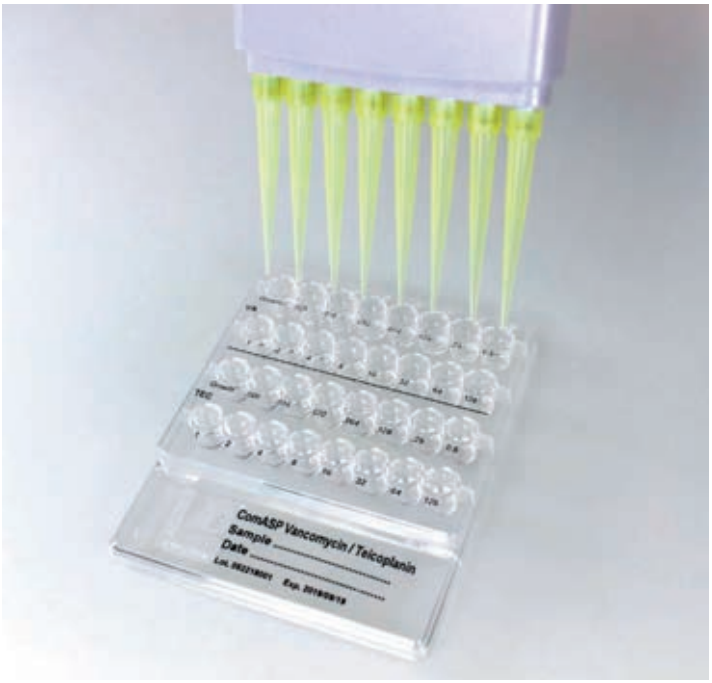

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