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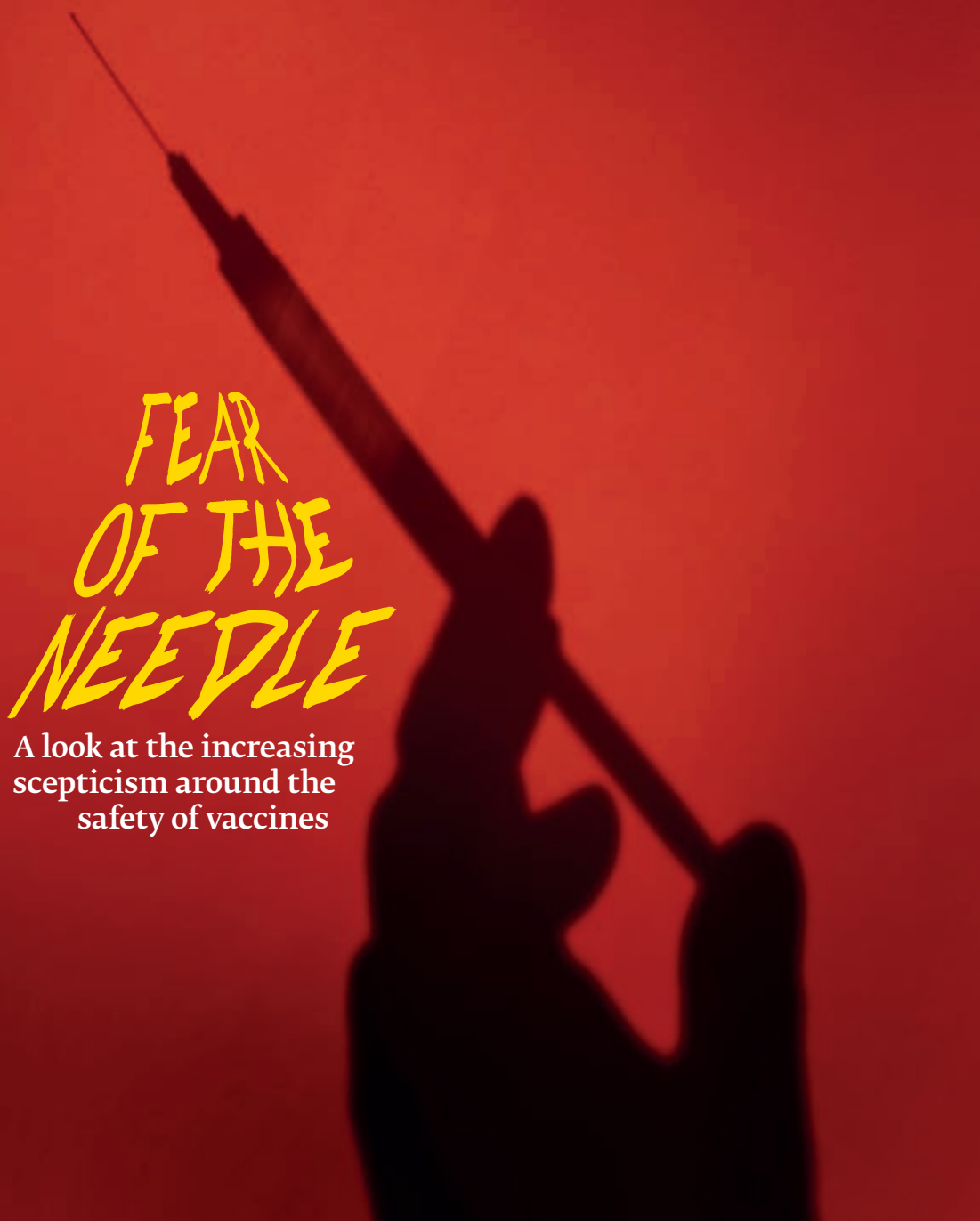
THE BIOMEDICAL SCIENTIST

THEBIOMEDICALSCIENTIST.NET

AUGUST 2019



FEAR OF THE NEEDLE

A look at the increasing scepticism around the safety of vaccines

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A.MENARINI diagnostics

EFFICIENT REGULATION

A more consistent and transparent regulatory system can only be for the good, writes Sarah May.

The Department of Health and Social Care has just published its response to its consultation "Promoting professionalism, reforming regulation". This has been a slow-burn project, one that was first floated three years ago but which is becoming increasingly necessary if regulation of healthcare professionals and the regulators themselves are to remain fit for purpose.

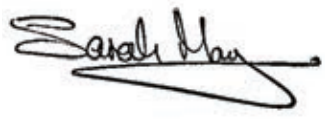
One of the primary issues with our current regulatory arrangements is the bureaucratic and inflexible legislation that governs the UK regulatory bodies, which has led to complex and inefficient systems that now sit at odds with the need for an increasingly flexible workforce. Anyone who receives the monthly alerts lists from the Health and Care Professions Council cannot help but be struck by the relentless number of fitness to practise hearings that take place. These in themselves constitute a mini industry and go a considerable way to demonstrating why the cost of maintaining one's registration continues to rise and why a different approach to fitness to practise powers is needed.

A key element of the original consultation was the question of who should be regulated by statute in the future and whether the currently regulated professions should all remain as such. I hope I am not being naïvely optimistic but I would not expect this to present a threat to our profession. The opportunities for biomedical scientists to take on increasingly complex roles continues to increase; the involvement of biomedical scientists in histopathology reporting is gathering traction and a steering group is soon to be convened to explore a more restricted reporting role with a shorter training period that would be attractive to, and attainable by, a significantly greater number of individuals. Scientists undertaking histological dissection is now commonplace and the opportunity to develop a consultant level role for biomedical scientists in microbiology is now being explored.

Like all things that involve changes to legislation, this will be a slow process that will require further consultation on the specifics of the proposals now that the principles, and support thereof, has been established. Meanwhile, the new advanced biomedical scientist roles are establishing and growing in number.

Looking beyond our own profession, a more accountable, transparent, consistent and efficient regulatory system can only be for the good. There is broad support to see the current nine regulators reduced to a smaller number and for there to be greater consistency between how the different regulators work. A shared online register of all regulated healthcare professional is proposed and a single set of generic standards for all healthcare professionals

It is essential that our profession is informed of potential changes to regulation and understands any implications thereof. I will write more fully on the Government's response to the consultation in the next edition of *The Biomedical Scientist* to ensure our profession is fully aware of the future direction regulation could take.



Sarah May
Deputy Chief Executive

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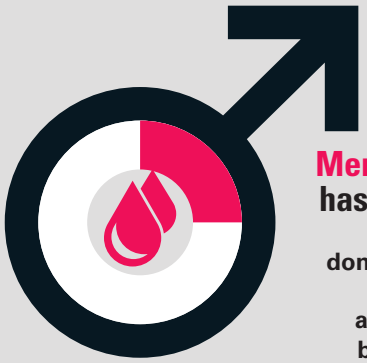
SCIENCE NEWS IN NUMBERS



25%

Men and blood: The number of men giving blood has fallen by almost 25% in the last five years.

This is a problem because **men are allowed to donate more frequently** than women, as they typically have higher iron stores. **Men** now make up just **a third of all new sign-ups**, and are **outnumbered by women** on the register by **more than 100,000**.

800 LIVES

a year could be saved by closing local stroke wards.

A model was trialled in London and Manchester that now saves around 170 lives a year.

Local stroke wards were closed and ambulances **took victims to larger centres** with access to **brain scans and specialist drugs and procedures**. The NHS National Medical Director wants to introduce the model in **English towns and cities**, aiming to **save more than 800 lives a year**.

Food allergies: an issue that is on the increase

4,500

hospital admissions a year are due to food allergies.

10

food allergy deaths per year.

8%

of **children** are affected by **food allergies or intolerances.**

1 in 4

children are affected by **food allergies or intolerances.**

170%

Referrals through the NHS Urgent Medicines Supply Advanced Service increased by 170% from 2018 to 2019, leading to a **sharp increase in requests for antibiotics**. **Emergency antibiotics** supplied to patients by community pharmacies without a prescription **almost doubled, from 957 to 1,797**.

12 DEATHS

Twelve people died during an outbreak of a rare contagious bacterial strain, it has been revealed.

A total of **32 people** across Essex **were infected** with the invasive **Group A streptococcal** infection. The outbreak began in **Braintree** and cases have been found around **Chelmsford** and **Maldon**.

PERSONALISED MEDICINE

High hopes for pioneering CAR-T

NHS patients with lymphoma have been given a pioneering treatment that genetically reprogrammes their immune system to fight cancer.

CAR-T, is a personalised medicine, created using a patient's own cells.

It featured in the October 2018 issue of *The Biomedical Scientist*, when it was labelled the "most exciting treatment advance for decades".

Now, doctors at King's College Hospital, London, have said some patients are being completely cured in a way that had "never been seen before".

It works by removing T-cells from the patient's blood, freezing them in liquid nitrogen and sending them to laboratories in the US.

These cells, which will later be injected back into the patient, are genetically reprogrammed so that rather than killing bacteria and viruses, they will seek out and destroy cancer.

Clinical trials have shown that 40% of patients had all signs of their otherwise untreatable, terminal lymphoma eliminated from their body 15 months after treatment.

CAR-T is a new therapy and long-term data is still lacking, but it is thought that up to 200 NHS patients a year could benefit.

→ **bit.ly/BS_NewsAug01**

SCIENCE NEWS

GENOMICS

MITOCHONDRIA DNA DISCOVERY

Mitochondria, the "batteries" that produce our energy, interact with the cell's nucleus in subtle ways previously unseen in humans, according to new research.

The study describes the architecture of the mitochondrial genome, which shows variation between these cellular batteries, even within the same cell.

The paper demonstrates connections between nuclear DNA and mitochondrial DNA to nuclear DNA, which may need further investigation in potential donors for the recently-approved mitochondrial donation treatment.

The research is the first major population study to arise from data collected as part of the 100,000 Genomes Project, which collects genetic data from patients through the NHS with the aim of transforming the way people are cared for and providing a major new resource for medical research.

Professor Mark Caulfield, Chief Executive of Genomics England, said: "The involvement of the 100,000 Genomes Project in major discoveries like this demonstrates the importance of large-scale, carefully collected datasets with whole genome sequencing that enable new biological insights which then pave the way for major healthcare transformation."

→ **bit.ly/BS_NewsAug02**

VAPING

US CITY BANS E-CIGARETTE SALES

San Francisco has become the first US city to ban sales of e-cigarettes until their health effects are clearer.

Officials voted to ban stores selling the vaporisers and made it illegal for online retailers to deliver to addresses in the city.

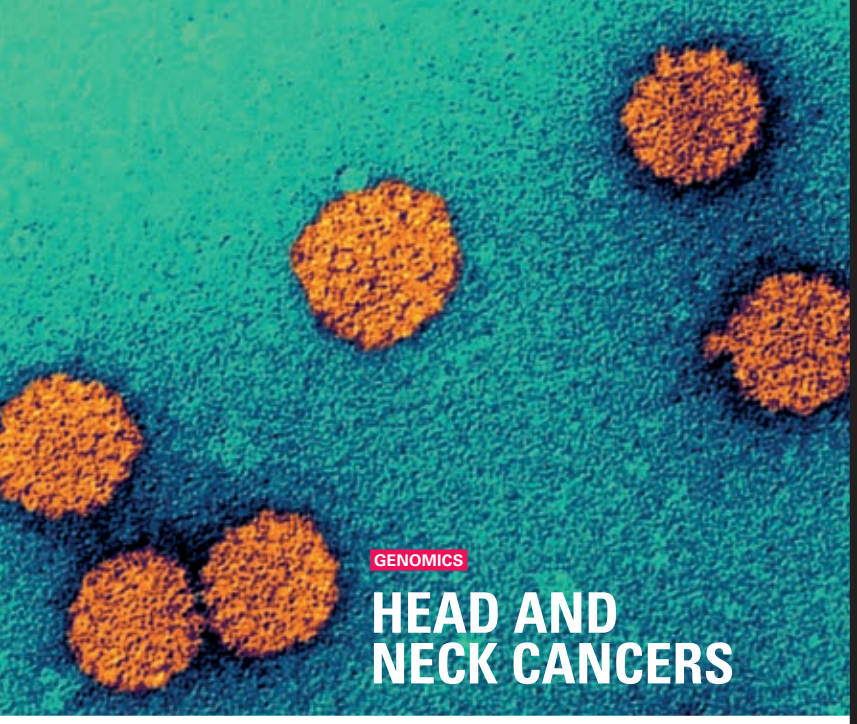
The law is set to come into force in February next year, but there have been reports that firms could mount a legal challenge.

Anti-vaping activists say young people are being deliberately targeted, by offering flavoured products.

While critics of e-cigarettes say more evidence is needed on the impact and claim that vaping can encourage young people to switch to cigarettes.

Juul Labs, the most popular e-cigarette producer in the US, said the move would drive smokers back to cigarettes and "create a thriving black market".

Earlier this year, the US Food and Drug Administration issued proposed guidelines giving companies until 2021 to apply to have their e-cigarette products evaluated.



GENOMICS

HEAD AND NECK CANCERS

Vaccinating schoolboys against the potentially deadly human papillomavirus (HPV) could dramatically reduce head and neck cancers in men, it is claimed.

A two-year project studied 235 patients in Scotland with head and neck cancer and found that 78% of people with head and neck cancers were men, while HPV was present in 60% of the cancers.

This means the vaccine may reduce some of these cancers in the long term in Scotland, say scientists.

The study also went on to report that head and neck cancers are disproportionately experienced by people from deprived backgrounds.

A previous report, published in April, said a vaccine for girls had nearly wiped out cases of cervical pre-cancer since an immunisation programme was introduced 10 years ago.

Over the last decade, schoolgirls across the UK have routinely received the HPV vaccine when they are 12 or 13.

→ **bit.ly/BS_NewsAug03**

NHS POLICY

"SCRAP UPFRONT MIGRANT CHARGES"

Doctors have voted overwhelmingly to stop charging foreign patients for NHS care, claiming that doing so is "fundamentally racist".

Up to 500 delegates at the British Medical Association (BMA) annual conference in Belfast backed a motion that said asking overseas visitors to pay made medical staff "complicit" in racism.

The BMA will begin lobbying the Department of Health to overhaul the rules.

In a pilot in London to check people's eligibility for healthcare, only one of the 180 people whose cases were looked at was found to not qualify.

Health charities and groups working with migrants welcomed the BMA's decision.

The Department of Health and Social Care said: "British taxpayers support the NHS and it is only right that overseas visitors also make a contribution to our health service so everyone can receive urgent care when they need it.

"We have exemptions in place to protect public health and the most vulnerable patients. Urgent treatment must never be withheld."

IMAGES: ISTOCK/SHUTTERSTOCK/SCIENCE PHOTO LIBRARY/GETTY

WHAT'S HOT AND WHAT'S NOT

HOT

MICE

Scientists have succeeded in using mice with transplanted human immune systems to look at functions in the immune system, which are otherwise difficult to study.

HOT

TAXES

A research paper analysing settings where a 10% tax on sugary drinks has been imposed, reveals a 10% reduction in consumption.

HOT

OCTOPUSES

New research supports previous findings that octopus arms can process sensory and motor information and take action without waiting for commands from the brain.

NOT

BREXIT

The drive to tackle child obesity has stalled, with a raft of measures stuck in a Brexit backlog, it has been claimed.

NOT

PETS

A Royal Society for Public Health report lists pets as one of the "hygiene hot spots" that people should be careful around to avoid harmful microbes.

NOT

PLAYGROUNDS

Dozens of states in the US have banned the crumb rubber that often covers playground floors, afters concerns about possible health effects on children.

IMMUNOLOGY

HELPFUL AND HARMFUL GUT IMMUNE CELLS

A type of immune cell that contributes to inflammatory bowel disease exists in two forms – "good" and "bad".

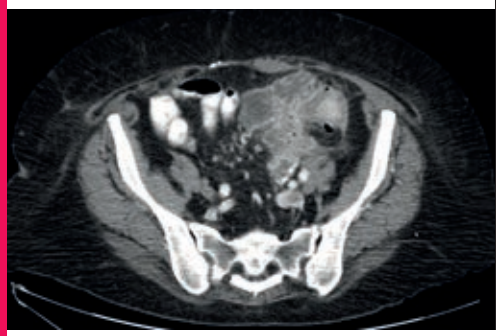
These two populations are akin to worker and soldier ants, playing different roles depending on their context.

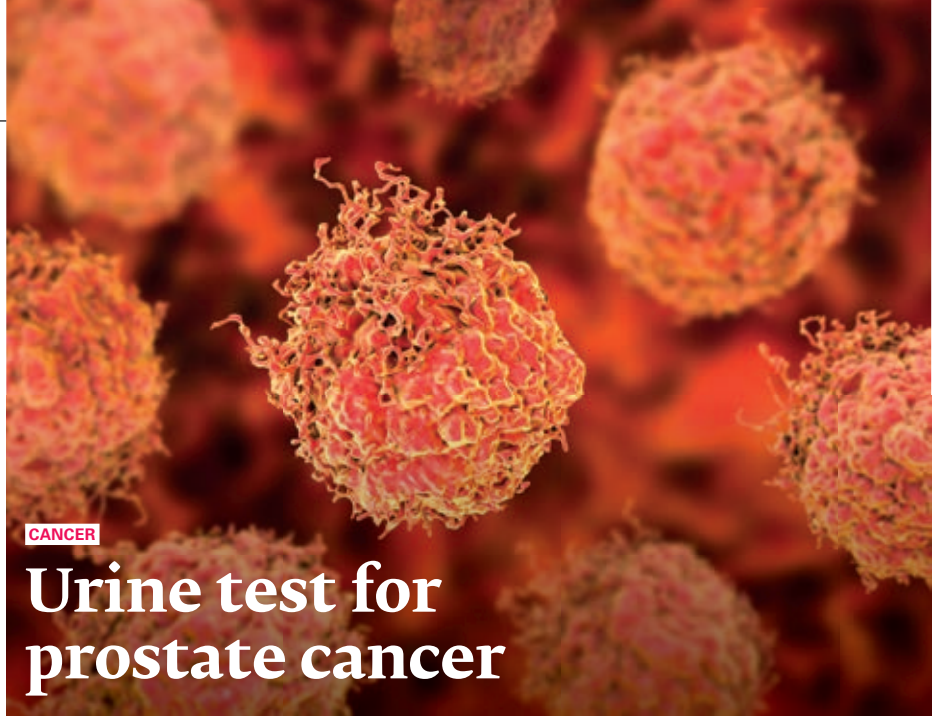
The "worker ant" population of immune cells is found naturally in the gut and helps keep the lining of the intestines healthy. The other population is triggered in response to infection by a pathogen.

Similar to soldier ants, these immune cells are called in to help fight infection, travelling from lymph nodes to the gut and other parts of the body to attack the invading pathogens. Although they are necessary to fight infection, these cells can cause excessive inflammation.

Studying the differences between these two cell populations in mice, a multidisciplinary research team has revealed potential ways to target the cells associated with immune-inflammatory diseases, while sparing the ones that help keep the gut healthy.

→ **bit.ly/BS_NewsAug04**





CANCER

Urine test for prostate cancer

Scientists have developed a urine test to diagnose aggressive prostate cancer and predict whether patients will require treatment up to five years earlier than standard clinical methods.

The experimental new test called "PUR" (Prostate Urine Risk) also identifies men who are up to eight times less likely to need treatment within five years of diagnosis.

It is hoped that the breakthrough could help large numbers of men avoid an unnecessary initial biopsy, and repeated invasive follow-ups for "low-risk" patients on active surveillance.

Prostate cancer is the most common cancer in men in the UK. It usually develops slowly and the majority of cancers will not require treatment in a man's lifetime. However, doctors struggle to predict which tumours will become aggressive, making it hard to decide on treatment for many men.

The most commonly used tests for prostate cancer include blood tests, a digital rectal examination (DRE), an MRI scan or a biopsy.

Lead author Shea Connell, from University of East Anglia's Norwich Medical School, said: "Prostate cancer is more commonly a disease men die with rather than from. Unfortunately, we currently lack the ability to tell which men diagnosed with prostate cancer will need radical treatment and which men will not."

The scientists developed the PUR test using machine learning to look at gene expression in urine from samples collected from 537 men.

By examining the cell-free expression of 167 genes in urine samples, the team found a mathematical combination of 35 different genes that could be used to produce the PUR risk signatures.

→ **bit.ly/BS_NewsAug05**

UNDER THE MICROSCOPE

This month: Sulfur mustard

What is sulfur mustard?
A type of chemical warfare agent, more commonly known as mustard gas, that causes severe, delayed burns to the eyes, skin, and respiratory tract.

Has this been in the news?
Yes, a qualitative study has been published, which is based on in-depth interviews with 16 patients from Halabja in Iraq who were diagnosed with chronic pulmonary complications.

Presumably sulfur mustard was used in Halabja?
Yes, in the 1980s, it was used on a large scale in Iraq, with the most notorious and severe gas attacks against the city of Halabja, where some 5,000 people died and tens of thousands were injured.

What has this new study found?
The victims suffer from severely impaired health, both physical and mental. As well as respiratory problems, insomnia, fatigue and eye problems, they also have depressive symptoms, anxiety, suicidal thoughts and post-traumatic stress disorder.

What impact does that have on their social and work life?
The scientists refer to "chemical contamination anxiety" – a powerful reaction to exposure that has limited victims' family lives, social relations and work capacity. Unemployment and loss of social capital have, in turn, led to social isolation.

What needs to be done now?
Holistic care of the victims and detection of their somatic and mental ill-health are vital. Also, hundreds of gassing victims migrated to Sweden, and may need care and monitoring.

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TECH NEWS

FLUIDIC ANALYTICS

DIFFUSIONAL SIZING

Fluidic Analytics' diffusional sizing technology has been influential in a recent study that investigates protein binding and self-assembly in Alzheimer's disease. The work was presented during the Women in Science Award plenary lecture in Krakow, Poland last month.

The work on the mechanism of amyloid β aggregation and the role of inhibitors demonstrates the unique ability of diffusional sizing to assess protein binding in-solution and for difficult-to-study systems.

→ **fluidic.com**

PROMEGA

SUSTAINABILITY

Promega UK, the life sciences company, has announced the winners of this year's Helix Sustainability Awards.

The awards recognise UK organisations who gained the most environmental benefit from using the Helix On-Site Stocking System. The three winners are: the University of Manchester, the University of Edinburgh and Newcastle University.

By using Helix, the top five organisations saved over 1000 deliveries combined.

→ **promega.co.uk**

NATIONAL HORIZONS CENTRE

LAUNCH OF CPD COURSES

The new £22.3m National Horizons Centre in Darlington hosted a three-day workshop on practical proteomics as its first continuing professional development course.

The course was led by Professor James Scrivens, a leading expert in the field of mass spectrometry, who has published more than 100 peer-reviewed papers, as well as numerous book chapters and industrial reports.

The centre is a state-of-the-art bioscience education, training, research and innovation facility, specialising in providing the full range of skills for the biosciences sector, and in applying digital technologies to improve performance and productivity.

→ **tees.ac.uk/nhc**

Trace elements

NHS
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Cobalt blood	£15	2-5 days
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Lead	£18	2-3 days
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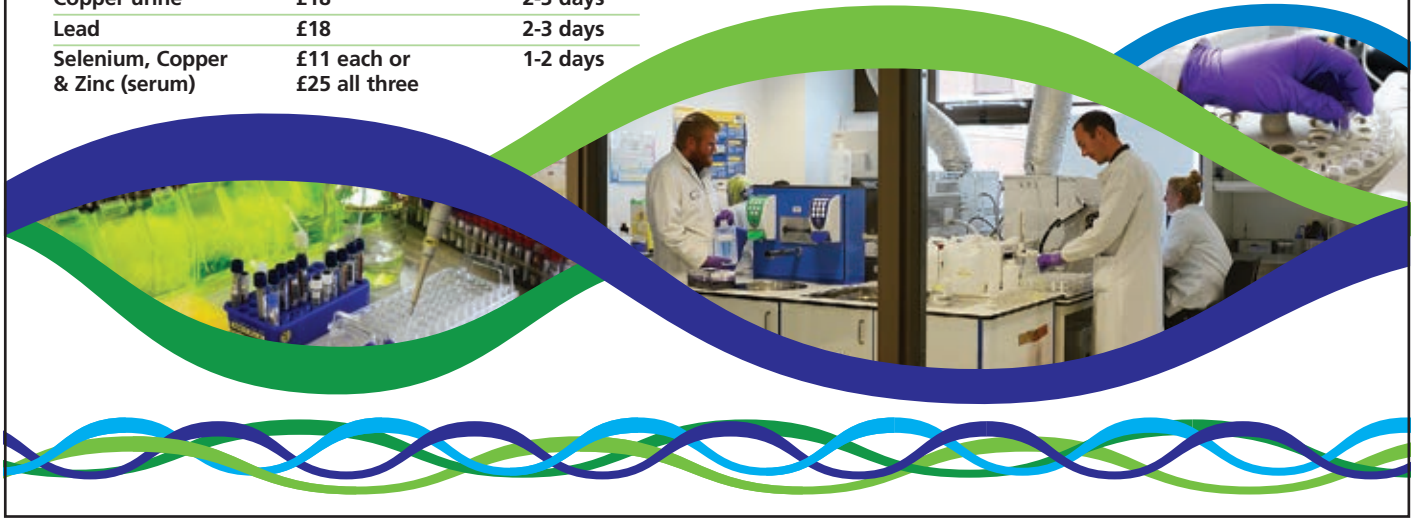


THE BIG QUESTION

THIS MONTH WE ASK

Why do people believe fake science?

David Ricketts

Head of Laboratory Process Improvement
Health Services Laboratories

The internet, social media and 24-7 television has never made instant communication more accessible. With this accessibility there has been an increase in fake science and news. Science traditionally relies on peer review and examination of evidence before publication, to ensure rigour. Science stories can now appear instantly, without checks and balances to prevent bad, or fake, science hitting the headlines.

Often fake science relies on just enough plausibility to gain traction to be accepted as real. The more effective ones look to harness mistrust, conspiracies and tap into preconceived prejudice. The increase in flat earth proponents, anti-vaccine champions and global warming deniers are the most obvious examples that fly in the face of established scientific evidence. A celebrity endorsement counts for more than most scientific papers.

Science needs to challenge fake science with fact, but in a way that non-scientists can understand. Simply challenging the premise using data and evidence can just fuel the fire of the target audience. Often evidence is anecdotal and can be easily challenged, although people can profess to emotive personalised stories to make any argument seem inhumane.

While fake science can seem amusing, the threat to public health of the anti-vaccine lobby is real and diseases are reappearing that should be eradicated by now.

Biomedical scientists are uniquely placed here; to support vaccine uptake and refute the insidious fake news stories on the subject.

IMAGE: GETTY

Catherine Otto

Director
International Federation of Biomedical Laboratory Science

For some individuals, it may be because they believe science is "difficult"; that only smart people understand it. Then, when fake science is published and labelled as science, it appears valid because of the preconceived notion that one is not expected to understand it. This premise is supported when reports of fake science use complicated, multi-syllabic words requiring a dictionary to decipher the meaning or statements such as "evaluated in clinical trials", without evidence described in the report.

For others, believing fake science may be linked to how individuals adopted skills from science courses in their education. Were individuals taught and, more importantly, do they remember the scientific method and how to critically evaluate publications? Critical analysis and questioning are valuable skills that can be applied to more situations than just evaluating whether science is fake or real.

Lastly, it may be wishful thinking or fear of change that leads some to believe fake science. Reading and believing a report that supports what one already believes is a human trait, we want validation for what we already believe. It is easy to understand why individuals who are looking for treatment for cancer or an incurable disease would believe fake science; they are looking for hope, a solution to their problem. Finally, most people do not like change. If fake science supports their views, then their beliefs are not wrong and they don't have to change.

Stephen Mortlock

Pathology Manager
Nuffield Health, Guildford Hospital

From the Piltdown man to the flat Earth theories, there have always been people willing to accept what they read or hear. Is it simply that some people are unable to distinguish between fake and real science or is the reason far more disturbing?

Misinformation arises from traditional media and social networks and we are bombarded daily with stories, some more preposterous than others. But the more we read and accept the impossible, the more likely we are to believe it.

In 1998, a study by Andrew Wakefield published in the *BMJ* linked vaccination to autism, causing vaccinations to decline and measles cases to increase. When a retraction was published in 2004, this was, for many people, the proof that the original work was correct and vaccinations did indeed cause autism.

Studies have shown that although some retractions follow from scientific misconduct or possible plagiarism, in the minds of some of the general public, the reason for the retraction was far more sinister. In this instance, the obvious answer was that the pharmaceutical companies and big business were conspiring together to increase the sales of their products. People rely on a biased set of cognitive processes to arrive at a given conclusion or belief. They will often twist the facts to fit their existing beliefs, which can tip the scales to make them more likely to accept something as true if it supports what they want to believe.

SELF-DESTRUCTING CANCER CELLS

Constantinos Koumenis says his new target for cancer may be an important step in progress, but stresses that there is no magic bullet to stop the disease.

In the ongoing fight against cancer, biochemical scientists have made solid progress over the past 20 years. They have isolated many of the mechanisms of the disease, developed new screening techniques and devised more effective treatments, all with the result that survival rates for many types of cancer are now much improved. But rather than making the giant leaps beloved by newspaper headlines, most of these advances have come one small step at a time – and another of those small steps has been taken with the publication in *Nature Cell Biology* of new research that may have found a way to make certain cancers self-destruct.

The study has emerged from the Perelman School of Medicine of the University of Pennsylvania, where a research team headed by Constantinos Koumenis, professor and research director of radiation oncology, has been working to unlock the secrets of MYC, a gene that has long been associated with tumour growth in a range of cancers.

Prime target

"Like most of the genes that promote cancer, MYC has a regular function in the cell," says Koumenis. "When it is on it promotes cell growth, and helps cells to divide and proliferate. For example, it has an important role in the developing embryo and in tissue regeneration. However, in cancer it can become over-active by gene amplification, making many copies of itself, and then it stimulates uncontrolled proliferation. But it is not enough to have copies of MYC turning on, as our cells have safeguards to prevent uncontrolled growth when they sense that. So when MYC is on, you also need a second or third factor, and that is sometimes enough to turn a cell into a tumour. We have also known for some years that many cancers have a high copies or higher activity of MYC."

Naturally, this has made MYC a prime target for research, which has looked to isolate the exact properties of the gene that cause it to malfunction and promote the growth of tumours. But it has so far proved to be a tough nut to crack.

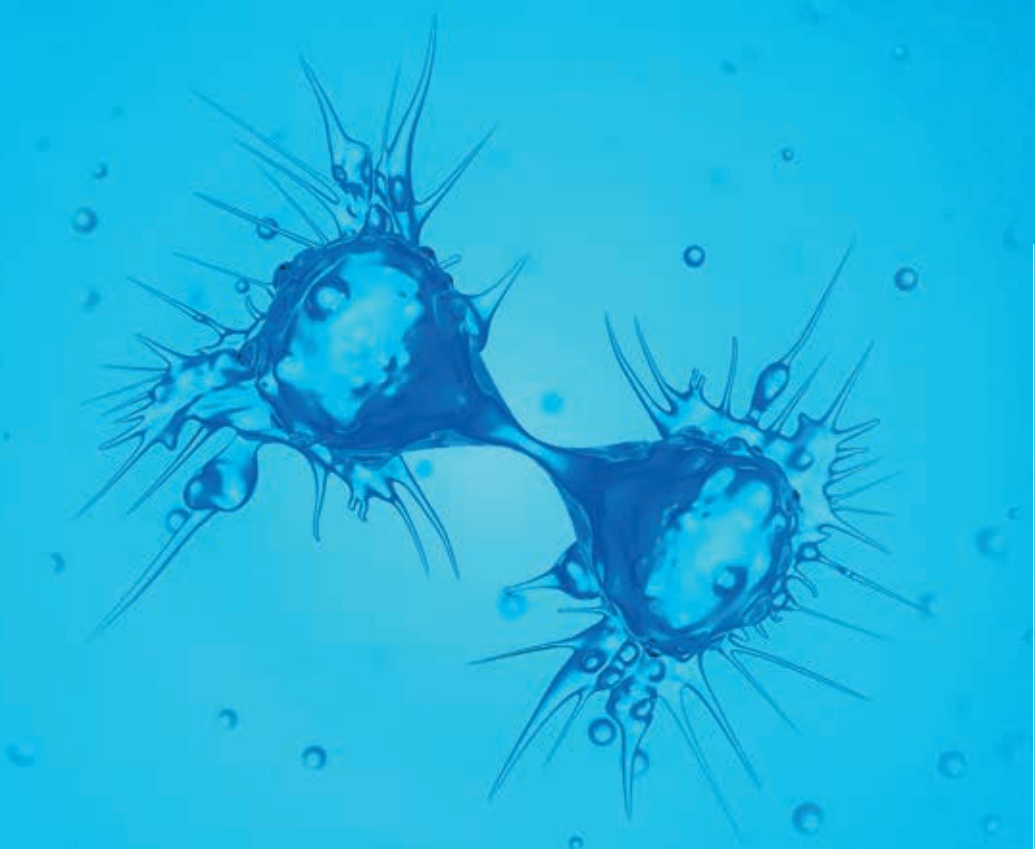
"There is a big problem," says Koumenis. "For a lot of other targets we have good drugs that target specific proteins. But MYC is different, in that it's a transcription factor, which binds to the DNA and tells the cell what proteins to make. In that sense it is notoriously difficult to manage. Several scientists and companies have started to develop specific drugs that target MYC by trying to block the interaction of this transcription factor with other factors. Chemically it is a much tougher proposition to inhibit this, so we had to think whether we could disrupt this interaction via other factors."

Gas pedal and brake

So the hunt was on to find other parts of the mechanism surrounding MYC that

CONSTANTINOS KOUMENIS

- ✔ **1989:** BS (Pharmacy With Honors) Aristotle University, Thessaloniki, Greece
- ✔ **1994:** PhD (Biochemistry) University Of Houston, Houston, US
- ✔ **2006:** Professor of Research Oncology, University of Pennsylvania, US.



might respond more readily to existing drug therapies. Koumenis and his team soon began to observe some interesting effects with another transcription factor, called ATF4. "We found a connection between MYC and this protein. It turns out that this protein acts as a partner to MYC in the cell when MYC is on, and tells the cells to grow, they need fuel, they need amino acids, lipids, nucleotides. Together, MYC and ATF4 turn on a group of about 30 genes that bring that fuel into the cell."

Even more interestingly, they found that ATF4 also controls another factor, known as 4E-BP, which acts as a brake on cell growth by telling the cell to make less protein. "If MYC is the gas pedal for tumour growth, you need a brake," says Koumenis, "because with uncontrolled growth, if you can't get enough fuel, the cells will die. As a consequence, if you have MYC on without ATF4 and 4E-BP, without this brake to moderate the proliferation of tumour cells, the cells cannot actually respond." In effect, they self-destruct.

Looking at MYC-related mouse tumours, the team saw that when MYC is high, ATF4 and 4E-BP is also high. Working on the assumption that this correlation was causation, they turned on MYC and found that mice with cancer survived much longer with ATF4 turned off compared to those where it was left on.

Inhibit action

A review of human tumour databases revealed the same correlation between MYC, ATF4 and 4E-BP. Human trials to test the concept are the next logical step, but while finding a drug to block MYC directly remains a work in progress, ATF4 is a different matter. One promising drug is being developed by another group, though it is still at the preclinical phase. In the meantime Koumenis and his team are searching various drug libraries for any existing, approved medications that might also inhibit the action of ATF4. "All this is with the grain of salt that we don't have a suitable drug for humans yet, but the context of our work remains that while we cannot target MYC directly, inhibiting ATF4 may be able to block some of the critical aspects of the MYC biology and so prolong the survival of people with MYC-related cancers."

The work of Koumenis and his team has been trumpeted in some quarters as a potential major breakthrough in cancer research, even a significant advance towards a "cure". Is that the way he sees it? "In terms of what we know about the biology of cancer, we are making progress every day," he says. "But it is important to emphasise that cancer is not a single disease with just one key secret to be cracked. Scientists have made remarkable progress in some types of cancer but barely a dent in others. You can't generalise. Our work is primarily on the fundamental biology of cancer and, though a small step, we feel that we have identified a promising new target. We think ATF4 is important and in mice we have shown that by blocking its activity in tumours we can prolong life. As for the idea of a cure, we will still be dealing with cancer for years to come. Malignancy is a problem of human biology, of ageing and accumulating mutations. But if we can prolong life or ease suffering for some types of cancer, that is a task worth pursuing." BMS

With uncontrolled growth, if you can't get enough fuel, the cells will die. In effect, they self-destruct.

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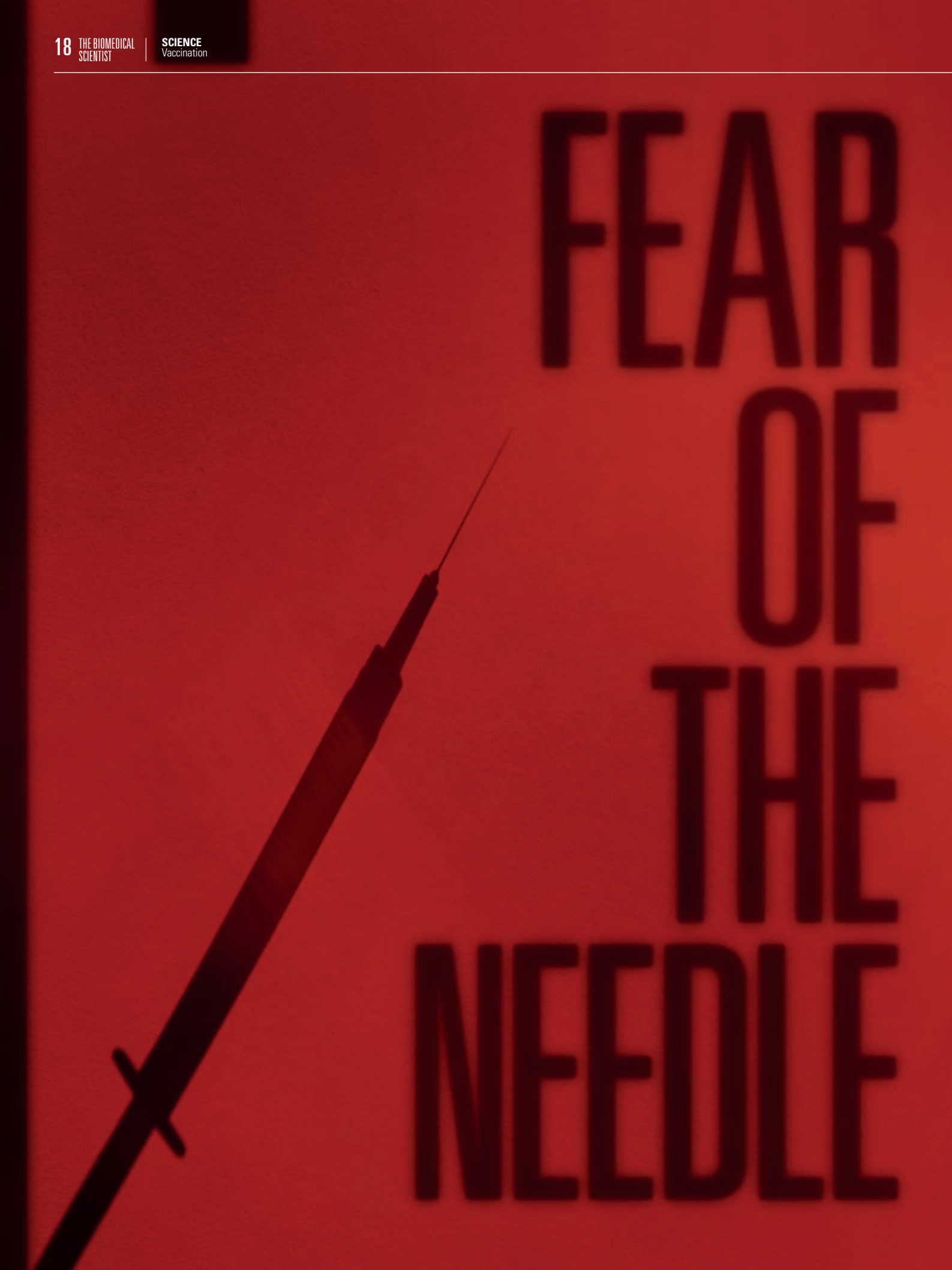
FEAR OF THE NEEDLE



With a new report showing **increasing scepticism** around the **safety and effectiveness of vaccines**, we look at the social drivers behind this shift and ask what can be done to **increase uptake**.

Mistrust in vaccination is growing, both in high-income and low-income countries. A new survey published by the Wellcome Trust shows that, across the globe, only 79% of people believe that vaccines are safe – a figure that drops to 59% in Western Europe. The *Wellcome Global Monitor 2018* surveyed over 140,000 people from more than 140 countries to find out more about their perceptions of science and of global health challenges. Part of the study focused on vaccination and how people think about it. "What we find is a complex picture and we are talking of correlation rather than causation, but the trend we see is that the more wealthy a country is, the more distrust in vaccines there is. And the more people trust science, the more likely they are to trust vaccines," Imran Khan, Head of Public Engagement at the Wellcome Trust, points out.

This loss of faith in the safety and efficacy of vaccination is not a new subject. This year, it has even prompted the World Health Organization (WHO) to call vaccine hesitancy one of the top 10 biggest global health threats. In many countries, a growing number of parents express their concerns over the idea of vaccinating their children. One of the most recent examples is Scotland, where the number of children receiving the MMR vaccine by five years of age was reported to have fallen from 97% to 96.6% in the last year.

The reasons why people refuse vaccination are multiple, and complex. They often vary with the local context, the scares of the day and the personal history of the individuals involved. Getting a more coherent picture of these evolutions is crucial to better address this major global health problem, whose consequences are already starting to be seen on health systems.

Back from the pages of history

While vaccination protects individuals from infectious diseases, it also stops the spread of those illnesses to the larger population. This means that even people who cannot get vaccinated for medical

> *The trend we see is that the more wealthy a country is, the more distrust in vaccines there is*

PHOTOGRAPHY: RICHARD GLEED

reasons can be protected. This is the concept of "herd immunity", but it only works if enough of the population, usually between 85 and 95%, gets the vaccine. For the most contagious diseases, like measles, a drop of the vaccination coverage below 90 or 95% of the population is problematic, but this is less the case for less contagious diseases, such as polio.

Yet, as mistrust increases and vaccination coverage drops, epidemiologists are seeing the return of many diseases in geographical areas where they had previously disappeared.

In the first four months of 2019, for instance, more than 6200 cases of measles were reported in Europe, especially in France, Italy, Bulgaria and Poland.

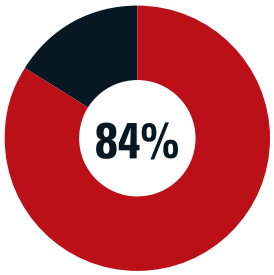
That it is those countries that are struggling with those epidemics is significant when you look at the Global Monitor Survey : France, in fact, had the highest percentage of citizens who disagreed that vaccines were safe. Mistrust in vaccines thus seems to correlate with epidemics making their comeback. All these countries had a vaccination coverage rate of below 95%. "Diseases that should be in the pages of history, we are now seeing in our communities. Cases of measles notably, because it's a disease that is more visible and very infectious, but other preventable diseases, like diphtheria, are also coming back. It's hugely important for all of us to understand the fact that whenever a disease exists in any part of our world, we are all at risk, as viruses don't respect borders", says Dr Siddhartha Datta, Manager of the Vaccine-Preventable Diseases and Immunization Programme at the WHO Regional Office for Europe.

VACCINES IN NUMBERS

72%
of people globally trust scientists

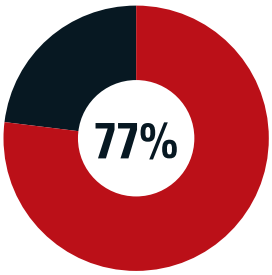
79%
of people worldwide agree that vaccines are safe

57%
of the world's population don't think they know much – if anything – about science



of people worldwide agree that vaccines are effective

59%
of people in Western Europe agree that vaccines are safe



of people in Western Europe agree that vaccines are effective

While the health consequences are often the most visible, a drop in vaccination coverage also comes at an important economic cost. As more and more people get sick from diseases that could have been prevented, the burden on doctors and hospitals becomes heavier. This situation may ultimately lead to an increase in expenditure for the health system as a whole, as more children are hospitalised with vaccine-preventable diseases and more time and resources are dedicated to treating them. "Out of all the public health interventions, vaccination is one of the most cost-effective, with a high return on investment. There are direct health benefits, children suffer less, less investment is needed in curative services. But vaccinated children also grow up better, they are less often absent from school for being ill, their parents might lose less time at work and thereby

6200

IN THE **FIRST FOUR MONTHS OF 2019, MORE THAN 6200 CASES OF MEASLES** WERE REPORTED IN **EUROPE**, ESPECIALLY IN FRANCE, ITALY, BULGARIA AND POLAND.

contribute more to the economy. Immunisation has a huge public value that goes beyond preventing the suffering of children", Dr Siddhartha Datta explains.

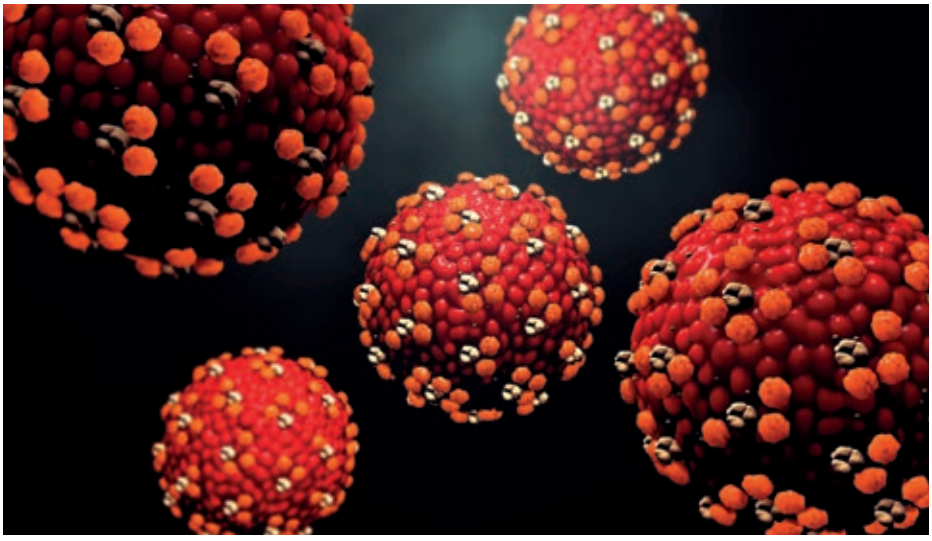
Studies have proven this time and time again. In 2016, a study by researchers from Johns Hopkins Bloomberg School of Public Health showed that for every dollar invested in vaccines between 2010 and 2020, there would be a return on investment of 16 times the costs, taking into account treatment costs and productivity losses.

Untangling the causes of vaccine hesitancy

People are driven away from vaccination by multiple factors that are more often than not time- and context-specific. Although there are some commonalities, the determinants of vaccination vary in nature and importance, depending upon the vaccine and the country of interest, and experts often point out that socio-psychological factors are more relevant to understand vaccine hesitancy in high-income countries, because there are fewer access barriers to vaccination.

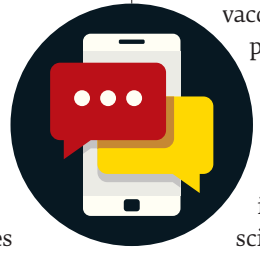
What is certain is that, all over the world, parents take the decision to vaccinate their children based on their risk perception of the vaccine. "Risk perception and vaccine confidence influence vaccination decisions. If people feel they or their children are likely to get a disease that is quite serious, and they believe vaccines are safe and effective, most will get vaccinated," says Dr Ana Wheelock Zalaquett, a Behavioural scientist at Imperial College London.

In the past decades, specific media moments have contributed to decreased



confidence in vaccines, and it has led parents to perceive some vaccines as dangerous. This was for instance the case at the time of 1998 MMR scandal, when a paper published that year claimed that the MMR vaccine was linked to autism spectrum disorder – a statement which was widely reported in the press at the time. While both the findings of this work and the lead researchers were then discredited, it is clear that this made many parents worry over whether or not to get their children vaccinated.

These claims of a link between the vaccine and autism have since then often resurfaced online, and they are shared extensively on social media. In this respect, social networks are a force to take into account when tackling vaccine hesitancy today, as these platforms enable misinformation around vaccines to travel fast, and to reach a much greater audience than ever before. "We tend to give greater weight to negative information. This is known as negativity bias. So, negative stories about vaccines are likely to stick, particularly if people are already concerned about side-effects," Dr Ana Wheelock Zalaquett adds.



The Wellcome survey also highlighted a gap between higher and lower income countries, suggesting that mistrust in vaccines was greater Europe and in the US. Countries like Bangladesh and Rwanda on the other hand scored higher when it came to expressing their confidence in vaccines. A very large majority of people in both countries agreed that vaccines are safe, effective and that it is important for children to be vaccinated.

This discrepancy is also interesting to behavioural scientists and may be explained

A **NEW SURVEY** PUBLISHED BY THE **WELLCOME TRUST** HAS NOW SHOWN THAT, ACROSS THE GLOBE, ONLY **79% OF PEOPLE BELIEVE THAT VACCINES ARE SAFE**.

by the fact that in many higher income countries, infectious diseases like measles had virtually disappeared from communities for generations, potentially luring people into a false sense of security and leading them to see less of a need in vaccination. "An interesting idea is that of the 'complacency effect'. If you live in those high-income countries, several generations may have passed since measles or other infectious diseases were endemic, and so you have forgotten how bad they are, and how important vaccines are. Because the daily reality in some lower-income countries may be much more coloured by infectious diseases, people may be more aware of the need for vaccines," explains Imran Khan.

Learning about these different factors and all the nuances that explain why people don't want to vaccinate requires frequent, robust studies at country-level to understand what can be done and how vaccination uptake strategies should change overtime. "Vaccination uptake is also linked to other factors such as weather patterns – particularly in the case of influenza – trust in government, science and vaccine manufacturers, and of course, vaccination scares. To address emerging issues opportunely, we need to measure vaccination sentiment routinely using validated instruments, ideally as part of national immunisation surveys," Dr Ana Wheelock Zalaquett says.

Increasing vaccination uptake

As the causes of vaccination hesitancy become untangled, researchers, public health institutions and policy makers are trying to harness this knowledge to come up with new strategies to change people's minds about vaccines. What they all agree on is that a one-size-fits-all approach will not work, especially considering the variety of possible reasons that people put forward to reject vaccination.

A recent study led by Noel Brewer, a Professor of Health Behaviour at the University of North Carolina, has explored the success of different interventions to increase vaccination uptake. It found in particular that vaccination can be facilitated directly by leveraging, but not by trying to change what people think and feel. In that context, focusing on people who are hesitant to vaccinate, but not entirely against it, can be an interesting approach. "Strategies to increase vaccination coverage should take into account people's stance toward vaccination. We know that those who are completely against vaccination are a small minority. We also know that changing entrenched beliefs is difficult. So, as Brewer and colleagues suggest, focusing our efforts on harnessing the favourable beliefs of people who are in two minds about vaccines could yield more impactful results," Dr Ana Wheelock Zalaquett says.

Working with local health professionals is also crucial to understand what is happening in specific communities and to tweak the vaccination uptake strategy accordingly. This is something that the WHO is trying to develop more in the European region. "Health professionals and experts in the clinic might know best why parents in an area are not coming to have their children vaccinated. We have to start zooming in to see what the problems are in local communities" Dr Siddhartha Datta says.

And relying on health professionals may be helpful not only because it can tell us more about what's going on at various localities, but also because their recommendations of vaccination may be the key to unlocking people's resistance. As the Wellcome survey suggests, there is still a high level of trust in medical staff around the world. In total, 73% of people who took part in the study said they would trust a doctor or nurse more than any other source of health advice, including family, friends, religious leaders or famous people. What remains to be done is find out exactly how these doctors and nurses should speak to the people they see in the clinic, and how they should tailor their message to different types of patients to convince them of the need to get a vaccine. "A key factor linked to vaccination is a provider's recommendation, but we are less clear about which aspects of a recommendation lead to vaccination uptake and for whom," Dr Ana Wheelock Zalaquett says.

Vaccine hesitancy will continue to be a major global health threat unless governments invest time and resources in tackling this problem. Working hand in hand with NGOs, international institutions and scientists, they need to prioritise research that allows them to catch a glimpse of people's reasons to doubt vaccination, and to repeat this research overtime, to understand how perceptions evolve and how they can be addressed with well-designed, relevant strategies that rebuild people's trust in science and in vaccines. BMS

TOP FIVE... CONGRESS TIPS

Next month sees the return of the much anticipated **IBMS Congress**. With just weeks to go until the International Convention Centre in Birmingham opens its doors, here are five top tips to make the most of the four days.

01 Visit the exhibition

The exhibition at the IBMS Congress is the UK's largest free-to-attend biomedical showcase, featuring many of the leading companies and organisations displaying and demonstrating instrumentation, equipment and professional services. It also offers a learning experience, enabling delegates to extend their awareness of new and emerging techniques and technologies, while networking with colleagues and exhibitors.

02 Take part in a microscopy workshop

The IBMS is running a series of microscopy workshops, in partnership with Olympus and with thanks to Leeds Teaching Hospital and the University of Leeds. On Sunday (1pm-5pm) is the cytopathology session: an intensive microscopy workshop of 40 pre-marked cases of respiratory, urinary tract and effusion preparations followed by a guided case-by-case discussion. On Monday (2pm-3.30pm) there is a cellular pathology session.

03 Attend the Sunday programme

In order to make congress as accessible to all members as possible, the IBMS is again running a Sunday lecture programme, including the Quality Management, Education and Training and Molecular Pathology streams. The programme features topics that have universal appeal and concludes with the Congress Welcome Evening.

04 Watch a plenary lecture

This year's plenary sessions offer a wide range of topics, from looking to the future of the profession, with the integration of genomic medicine and digital pathology, to more offbeat topics, such as the science of laughter and "The Importance of Forensic Pathology to Health, Justice and Fictional Crime Writing".

05 Engage with the IBMS

Congress offers the ideal opportunity to engage with the Institute. When you have some spare time between sessions, visit the IBMS stand to talk to staff members about the services that are on offer and the on-going work of the IBMS to represent and further the interests of biomedical scientists.

For more information on the IBMS Congress 2019, visit congress.ibms.org


"It could be argued that the introduction of any new test should give as much weight to how the result will be handled as to the test itself"

Microbiologist **Mark Wilks** looks at some of the themes of the recent conference of the British Society for Microbial Technology.

TESTING TIMES FOR MICROBIAL TECHNOLOGY

A striking feature of this year's British Society for Microbial Technology (BSMT) conference was the increasing disconnect between traditional culture-based methods, which are still the mainstay of nearly all diagnostic microbiology labs for diagnosing infection, and the number of commercial molecular tests available.

There is now a huge range of what can almost be called "traditional" multiplex PCR tests, available in a bewildering number of combinations and run on a number of different platforms. For example, should you wish to introduce a commercial CE marked test for respiratory viruses into your laboratory, there are at least 20 available tests in various combinations of viruses and they only have Flu A and Flu B in common.

Having decided the particular combination of targets that suits your purpose (or budget), which one should you choose? In practice, it's impossible to do a trial of more than two or three for reasons of cost and time, so in practice the decision to introduce one test or another may be quite arbitrary and dependent upon the willingness of a particular diagnostic company to offer kits for evaluation at a reduced price.

Although rarely stated, with unusual pathogens it is virtually impossible to validate the claimed performance of a test. Raiding the back of your -80 freezer for elusive aliquots of a specimen which may have been frozen and thawed repeatedly is not ideal but is quite common.

Testing times

It would make more sense if there was some kind of coordination of testing perhaps, by a consortium of companies and laboratories which would make testing more rational and meaningful by specifying and supporting validation studies more precisely although, admittedly, the chances of this being done are very low. Ironically, the HPA evaluation service, which operated in this area, was disbanded 10 years ago, just as the rush of molecular tests was starting. In the absence of such a body, the onus is on manufacturers and distributors to support more ambitious clinical evaluation studies.

At the same time that more syndromic and multiplex PCR tests are being introduced, there is also a trend for much simpler tests designed for point-of-care testing (POCT) or near-patient testing (NPT). These are generally for single targets – for example, in the form of LFDs – and are being introduced at a relatively low cost. In fact, to call them simple is a bit of a misnomer, as to get a test to the level where it appears to be so simple to perform represents a huge technical feat, much more so than the conventional PCR test. Validation of these is generally simpler, as they have fewer targets but they bring their own problems of quality control when used outside the laboratory by staff who are not trained in testing.

IMAGES: GETTY

Next-generation sequencing

Another category, which is likely to be increasingly popular and on which increasing attention will be focused, is next-generation sequencing. Although still prohibitively expensive costs are decreasing – albeit not as rapidly as its proponents claim. To be affordable, in many cases, it is essential to batch specimens and to run them on the sequencer when a sufficient number of specimens has been accumulated to fill the capacity. This can often negate one of the claims of molecular methods over culture – that of speed.

In a few cases, most noticeably sequencing of *Mycobacteria tuberculosis* as described at the BSMT meeting has been astonishingly successful both for the identification of mycobacteria, studying its epidemiology and predicting its susceptibility to different antibiotics. It's worth bearing in mind that the success has been achieved by investing enormous amounts of effort and money in an area where the number of isolates is relatively low, traditional methods, although reliable, have been often very slow, and the need for accurate ID and sensitivity is paramount. Having said that, the basis of some of the costs showing that molecular methods are cheaper than conventional methods seem quite dubious to me.

When it comes to applying next-generation sequencing directly to clinical specimens, as opposed to pure cultures, the problems of interpreting results increase massively. It seems unlikely that it will be possible to overcome these within the next three to five years sufficiently for the methods to be applied in routine diagnostic laboratories. Most reagents are contaminated with low levels of bacterial DNA and these are often detected when sequencing sites of low microbial load. There is very little data on reproducibility of the results, for example how reproducible are successive runs from the same clinical specimen.

This kind of experiment, although simple in principle, is quite expensive to perform and is rarely done, but information on reproducibility is essential if the technology is to be introduced into the clinical laboratory. A recent QC exercise in human genetics, where the technology is much more developed, showed that four laboratories using different platforms detected less than 80% of the gene targets in all the cases. As well as detecting a target, the problem of quantitation has to be resolved. What is the significance of a particular number of reads of a bacteria in a respiratory site where you might expect colonisation anyway? Answering that kind of question will take a considerable amount of time.

Host response

A relatively new area of interest is to look at the host response and use this in combination with a microbiology result to decide if treatment is warranted. The "traditional" markers of host response, such as C-reactive protein (CRP) and procalcitonin (PCT), have been in existence for a many years, but the significance (for example, of a positive CRP result to guide therapy) is still debated.

The belief in these tests seems, in some cases, to follow national preferences, which is never the sign of a good test!

The PCT test, which is more recent, appears more promising, especially when used quantitatively and serially to look for falls in levels over successive days as a guide to treatment. The fact that these tests been around for such a long time without having established themselves unequivocally suggests they probably never will, although there are large-scale trials in progress. Dr Kate Templeton, in her talk at the BSMT conference, looked at some of the more common current approaches, which is to look at multiple host response factors, rather than look at single markers, such as CRP or PCT.

A recent study showed that patients infected with influenza A showed marked differences if they were symptomatic or asymptomatic in their immunological response. Another study looked at host gene transcription or profiles, which appear to differentiate viral from bacterial pneumonia.

Patient management

Lastly, it should be noted that in many cases much attention is focused on the actual performance of the test and less regard is given to its clinical relevance. With the introduction of any test, however technically ingenious, sensitive and whether the result comes from a tiny LFD and or is the product of large and expensive molecular analyser, the question "will it make a difference to patient management" is too often ignored. It could be argued that as much attention should be paid to reporting results in such a way as to draw the attention of the relevant clinician and force them to act by stopping or starting antibiotics, isolation or whatever is necessary.

Nearly half a century ago a famous American microbiologist, John Bartlett, made the point that a result that was not conveyed to the ward by 11am when the physician made his or her rounds would make no difference to the management of the patient that day. This is something that has arguably become even worse, with the majority of lab results passively relayed electronically and whilst nominally available to all 24hours per day, in practice are often ignored. It could be argued that the introduction of any new test should give as much weight to how the result will be handled as to the test itself. BMS

Mark Wilks is a Clinical Scientist at Barts Health NHS Trust and Honorary Senior Lecturer at Barts and the London School of Medicine and Dentistry. The Annual Scientific Conference of the British Society for Microbial Technology was held in May at the RAF Museum in Hendon.

UKAS PROCESSES AND MAINTAINING ACCREDITATION

Senior Assessment Managers **John Ringrow** and **Al Bryant** give an update with the latest from UKAS.

It has been some time now since the completion of the project to transition medical laboratories from CPA accreditation to ISO/IEC 15189:2012. Those laboratories that had initial assessments at the beginning of the transition are now preparing for (or have had) their reassessments to renew the accreditation for another four years. Other laboratories are in the first cycle of surveillance visits.

Alongside this, there are many changes and external pressures upon laboratories to maintain a service throughout immense change within the NHS, with new networks being formed, re-organisation and rationalisation of health boards in Scotland, modernising health and social care projects in Northern Ireland, centralisation of microbiology services across Wales and consolidation of key parts of pathology services, for example cervical cytology and human papillomavirus primary screening.

Such influences require mechanisms for maintaining accreditation and processes to accurately reflect a laboratory's schedule of tests.

As UKAS is appointed as the national accreditation body by Accreditation

IMAGES: ALAMY

Regulations 2009 and EU Regulation 765/2008, it operates through a memorandum of understanding with the Government, through the Secretary of State for Department for Business, Energy and Industrial Strategy (BEIS). UKAS must assess to international standards and must also comply with ISO/IEC 17011:2017 – Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies.

It may be of interest then to briefly take a look at ISO/IEC 17011:2017, to understand why we at UKAS have to do what we do and why we follow certain processes.

ISO/IEC 17011:2017 specifies requirements for any accreditation body engaged in accrediting conformity assessment bodies (in this instance, medical laboratories) and as customers of UKAS, this gives confidence that the accreditation body is competent to perform such tasks. UKAS is peer-evaluated by other accreditation bodies within the European co-operation for accreditation (EA), not just to establish competence to assess to ISO15189:2012, but to all other ISO standards that UKAS assesses. This peer evaluation takes place every four years and the next time evaluation of UKAS' compliance with the requirements of ISO/IEC 17011:2017 will be in late 2020.

EA peer assessors attend on-site assessments and review UKAS documents and records. Findings may be raised, and UKAS is required to provide evidence to clear these, exactly as laboratories are required to after assessments.

Key areas of ISO/IEC 17011:2017 include the organisation and management of assessments and set out general requirements for accreditation agreements, use of accreditation symbols and claims of accreditation, impartiality, financing and liability, establishment of accreditation schemes and structural requirements for the accreditation body. These parts of the ISO/IEC 17011:2017 set out how UKAS function as an organisation. There are also requirements on how an accreditation body manages personnel and management processes to ensure that the right teams at the right time is able to competently assess a laboratory's scope.

ISO/IEC 17011:2017 also sets out requirements for an accreditation body to demonstrate that processes are in place for the administration of the assessment processes. That includes contract review (the process whereby UKAS plans which technical assessors will participate in each assessment, what they will assess, and which aspects of the quality management system will be assessed and for how long), preparation for assessment (visit plans – which will define exactly what is to be assessed and how), the assessment itself and how it is conducted, and then the post-assessment processes, which include reporting (the content of the assessment report and IAR) and mechanisms for clearing mandatory findings.

ISO/IEC 17011:2017 also defines how an assessment body manages the accreditation cycle, how accreditation is extended and limited (through suspensions and withdrawals). UKAS, as an assessment body, must also demonstrate that the information management processes and systems are in place.

Similarly, as there are management requirements for ISO15189:2012, UKAS has to demonstrate that it has a management system that includes document and record control, a process and procedures for nonconformities and corrective actions, improvement processes and

Working with your assessment manager will ensure smooth changes

internal audits and that we undertake management reviews.

The documentation in place and the processes that UKAS uses prior to, during and post-assessment are all peer reviewed and have been shown to demonstrate conformance with ISO/IEC 17011:2017 and are a requirement of remaining as a signatory to the EA.

Maintaining accreditation

There are many changes, with drivers for this coming from either internal trust and health boards, or external to medical laboratories. The latter would include formation of networks in the light of on-going changes proposed within the NHS across England, Northern Ireland, Scotland and Wales, consolidations and rationalisation across trusts and health boards and work on-going with specific service areas, as mentioned previously.

It is important through any changes that there is an overall awareness and consideration of the risk to the service and also the risk and impact upon the laboratory's accreditation. Therefore, very early involvement with your assessment manager is vital, so that UKAS can work with you through the change. Sometimes formation of networks will involve mergers of pathology services across trusts or health boards, and that may involve changes of legal entity. Appropriate documentation to demonstrate that a legal entity to whom accreditation is transferred is prepared to accept all contractual, legal, financial and other obligation, which relate to both the current and historic accredited activities, will be required. Working with your assessment manager well before any changes will ensure smooth transitions and minimise risk of any loss of accreditation.

During periods of change, regular review of a laboratory's current schedule of accreditation (which is visible in the public domain on the UKAS website) is important. Tests may need to be removed from scope from time to time, and that is all part of a laboratory's journey. For instance, tests may no longer be required by a user, new methods supersede previous assays, or tests may need to be removed from scope as a result of sanctions. The key message is to inform your assessment manager at the earliest opportunity of any change, however small that may seem, so that we can work with you and that there are no surprises when the team arrive on site for an assessment.

There are many external pressures upon labs to maintain a service throughout immense change

Extensions to scope have been reviewed in earlier articles. However, it is always worth a reminder that all the information that a laboratory needs to apply for an extension is available on the UKAS website.

With reference to sanctions, it is important that laboratories understand what these are and why they are there. Sanctions can be imposed by UKAS and, as discussed earlier, ISO/IEC 17011:2017 states that accreditation bodies are required to have procedures for suspension, withdrawal or reduction of the accreditation scope – collectively what are known as "sanctions".

A sanction can be full, and that covers the entire scope of accredited activities, or partial, which may cover a specific location or technical discipline (or individual tests/groups of tests).

Imposed suspensions are applied when UKAS has identified that the laboratory is unable to continue to meet the requirements of the standard for which they hold accreditation. As a consequence, there is a significant probability of invalid work being performed.

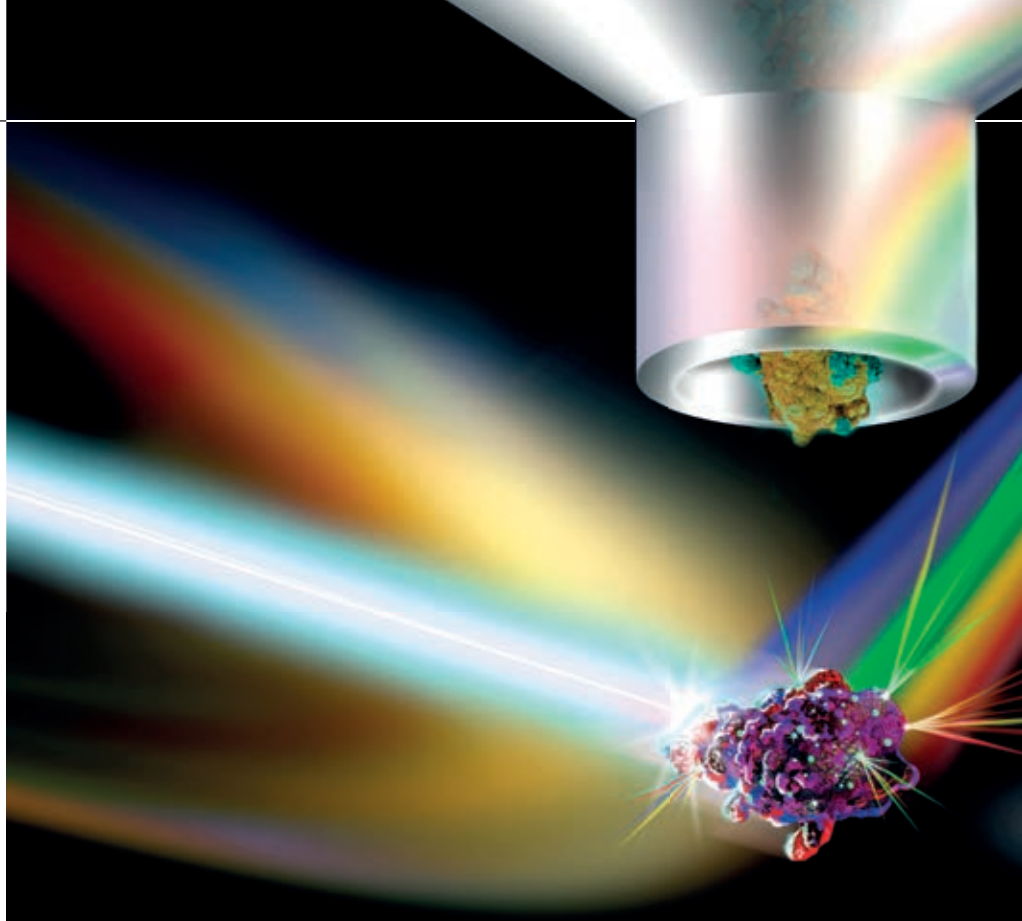
Voluntary suspensions are applied if the laboratory has identified a temporary inability to meet the requirements of the standard, or if they lack the necessary competence for their activities. This might include the departure of key technical staff or a move of facilities.

Withdrawal of accreditation is generally applied when a suspended laboratory has failed to address the issues that resulted in suspension adequately or in a timely manner (e.g. failure to satisfactorily close out findings raised). It will also apply if there are failings in the integrity of the laboratory's senior management.

It is important for a laboratory that wishes to regain accreditation for part or all of the service where a sanction is applied, is aware that it is in their hands as to how long it might take to address any issues.

Again, information on sanctions is available on the UKAS website. BMS

UKAS will be at the IBMS Congress in September, where it is presenting at various sessions and also be delivering a specific laboratory accreditation programme on Monday 23 September. It also has a stand where staff from the UKAS office and assessment managers will be available to answer any questions.



FLOW CYTOMETRY CHALLENGES

Clinical Scientist **Helen Watson** explains the challenges faced working in a leading haematopoietic stem cell transplantation centre.

Flow cytometry has come a long way – from the innovation of the coulter principle in the 1950s, to the wide variety of cell categorising and sorting uses we see today. The technology and automation of fluorescence-activated cell sorting (FACS) was driven forward when CD4 counts were needed for HIV patient diagnosis and monitoring, but the knowledge gained allowed for much broader application and the process is routinely used in the clinical setting for diagnosis of haematological malignancies, immunodeficiency and to measure impact of treatment.

Working in Newcastle upon Tyne Hospitals NHS Foundation Trust, our flow cytometry service is a combined haematology and immunology laboratory, housing the region's specialist integrated haematological malignancy diagnostic service (SIHMDS), adult and paediatric immunology and bone marrow transplant support.

Innovative technology

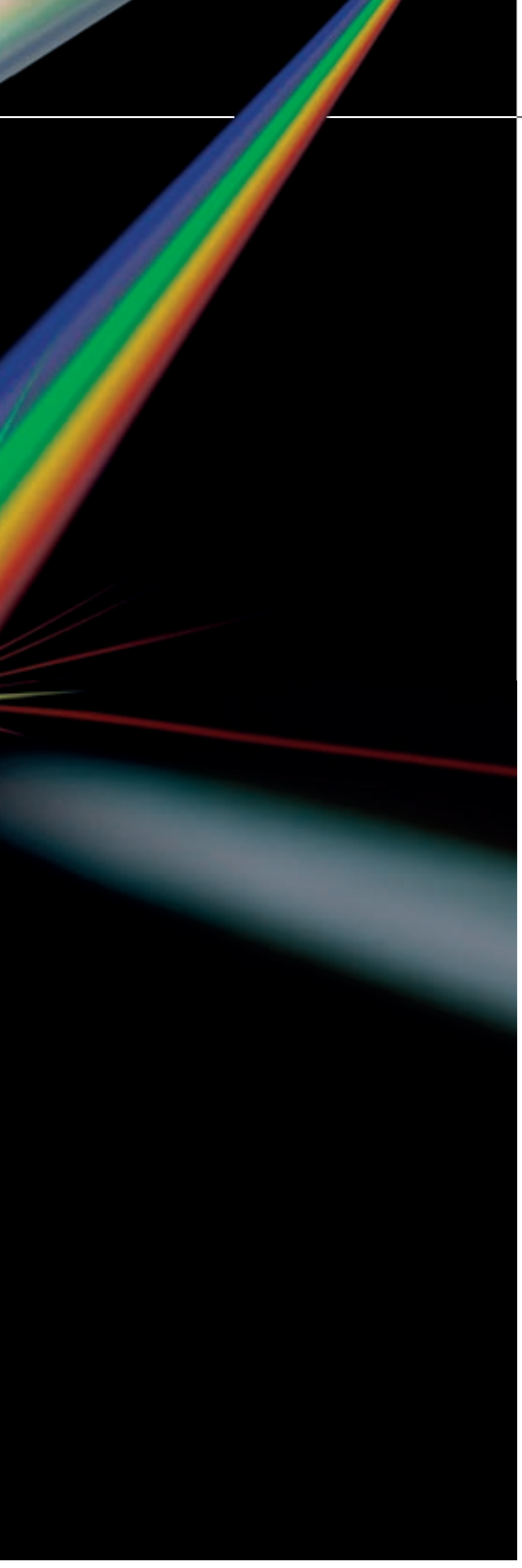
The ever-developing world of primary immunodeficiency (PID) is fascinating, with over 300 disorders now defined by the 2017 International Union of Immunological Societies (IUIS). It includes severe combined immunodeficiency (SCID), which involves genetic defects associated with lymphocyte development and function.

PID is possibly one of the best examples of where innovative technology and management strategies are being used to treat and cure inborn errors of immunology through gene therapy and, more commonly, haematopoietic stem cell transplant (HSCT).

Many patients have a good chance of finding a matched donor through a sibling or a donor registry, but approximately 25% need alternative sources. Haploidentical (HLA-partially matched) donors are then used. A haploidentical donor can be in the form of an unrelated donor or, possibly better still, a parent; the advantages being they are local and invested. However, patients are at higher risk of graft versus host disease (GvHD), so increased manipulation of the donation is required. Conversely the transplant must not be compromised so much so that the donation becomes unsuccessful. The aim is prevention of GvHD and helping the patient become immunocompetent and healthy once again.

International trial

As part of an international trial by Bellicum Pharmaceuticals, patients were treated with an innovative form of HSCT. Haploidentical donations are routinely depleted of B cells and T cells to prevent graft verse host disease. For this trial, the donations were depleted of B cells and specifically TCRαβ T cells, leaving stem cells, NK cells and TCR. In addition, some



IMAGES: SCIENCE PHOTO LIBRARY

"The ever-developing world of primary immunodeficiency is fascinating, with over 300 disorders now defined"

T cells were genetically modified (Rivo-cel) and "given back" post-transplant to help boost the immune reconstitution and prevent infection. The genetic modification meant that should these T cells cause trouble a drug (Rimiducid) could be given that induces apoptosis in these cells, and therefore allow recovery from GvHD.

One of the cases seen in Newcastle presented a particular challenge, where routine analysis of the lymphocyte subsets proved inadequate.

After an uncomplicated pregnancy the patient presented with severe atypical dermatitis. Over the next few months there were recurrent respiratory infections, eczema and a variety of food allergies developed. This prompted further investigations that showed CD4 lymphopenia, absent class switch memory B cells, raised eosinophil and markedly raised IgE.

The patient was transferred to the care of immunology and a diagnosis of DOCK8 (a protein required to regulate cytoskeletal organisation of immune cells) deficiency was confirmed through genetic analysis (homozygous deletion of exons 3 to 7 in the *DOCK8* gene). In 2017, the patient underwent HSCT as part of the Bellicum trial where the donor was the patient's mother.

As per protocol, patients are routinely monitored post-HSCT for signs of immune reconstitution with early signs of T cell counts normalising, the presence of naïve T cellls and eventually class switch memory B cell all immunological markers of a functioning immune system.

The patient was discharged and seen regularly in a outpatient clinic setting. On one occasion, approximately 9 months after HSCT, we noticed a significant rise in class switch memory (CSM) B cell ($CD19^+$ $CD27^+$ IgD negative).

Erroneous result

Although unusual, there was no initial cause for concern, other results were in keeping and quality controls processes all passed. However, on the same day another patient also showed a similar rise in CSM B cells. This was unusual; both tests were repeated, new reagents used, all the usual checks performed.

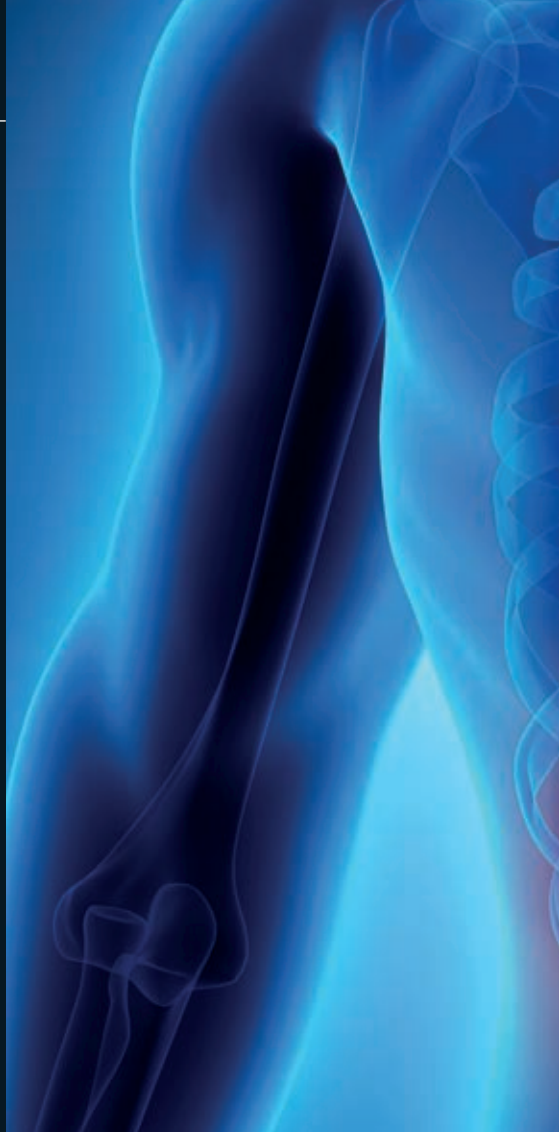
However, when reviewing both patients' records, we quickly noticed they were both post-HSCT and part of the Bellicum trial. After some consultation with their respective clinicians we uncovered the cause of the erroneous result was in fact the add-back T cells – Rivo-Cel.

Several months had passed since the last patient was recruited in Newcastle, but the patients were still on the trial. The add-back cells are there to improve their immune reconstitution, but after re-reading the protocol we learnt these T cells were also labelled with CD19, for the purpose of identifying and monitoring them.

Adding CD3 to our B cell phenotyping showed these cells to be $CD3^+$ and $CD19^+$, unlike any other naturally occurring cell. So their slightly adapted phenotype of $CD3^+$, $CD27^+$ IgD neg and $CD19^+$ all meant they snuck into the CSM B cell population. Adding anti-CD3 and drawing these cells out of the genuine B cell population meant we could easily separate the cells and provide accurate counts.

What was clear is that with such pioneering processes it is really important for biomedical scientists to keep up to date – communication between clinicians and laboratory staff and indeed between centres is vital. An awareness of what is happening to the patients we look after is key and we need to be ready to adapt our processes to ensure that we are providing results that are accurate and of real value. BMS

Helen Watson is a Clinical Scientist in the flow cytometry laboratory, in the blood sciences section at Newcastle upon Tyne Hospitals NHS Foundation Trust



British Journal of Biomedical Science, Issue 3 2019 – a synopsis

Editor **Andrew Blann** outlines the content of the summer issue of the journal.

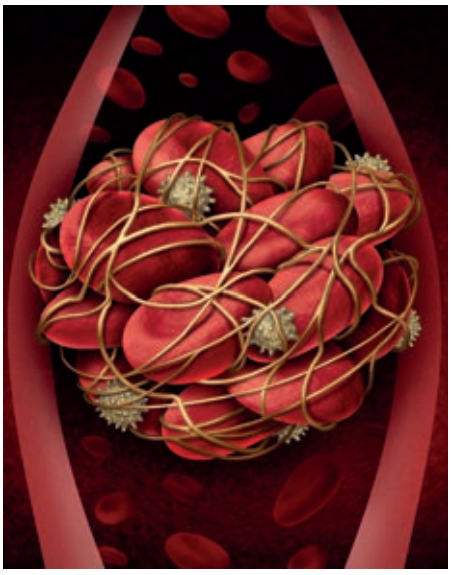
One of the problems with traditional blood science is the tendency to view any one particular result in isolation. Two papers demonstrate the value of combining markers for the assessment of liver fibrosis. Attallah *et al* (pages 105-110) looked at a combination of PDGF, albumin and age, finding it to be superior to a combination of AST and the platelet count. Similarly, Lu *et al* (137-142) reported the Gamma GT to platelet ratio to be valuable, surpassing the predictive value of the AST to platelet ratio, and also FIB-4, a score derived from age, AST, platelets and ALT. There is ample scope for scores of this nature in both diagnosis and management.

ONCOLOGY

Three papers reported advances in oncology. Li *et al* (111-116) found that levels of serum miR-25 had a receiver operator characteristic area under the curve of 0.62 (95% CI 0.53-0.69, p<0.001) in diagnosing non-small cell lung cancer, and that low levels were linked to overall and relapse-free survival. Abbas and colleagues (117-121) showed that certain SNPs in genes for DNA repair genes are linked to cervical cancer, whilst Li *et al* (147-149) reported that tissue levels of long non-coding RNA of XIST (a product of *XIST* [X-inactive specific transcript] that regulates X chromosome inactivation) were higher in those with advanced disease and with lymph node metastases. Perhaps one day all these markers will enter routine clinical practice.

HAEMATOLOGY

Haematologists (or, some specifically, clotologists) are accommodated by the work of Kin *et al* (122-128), who provide evidence of the value of a rivaroxaban-specific normalised ratio, which effectively minimises inter-thromboplastin variability in assessing the anticoagulant effect of that drug. Despite the advantages of these new oral anticoagulants, warfarin is still in common use, with a wide range of doses from 0.5mg/day to 20mg/day. Gopisankar



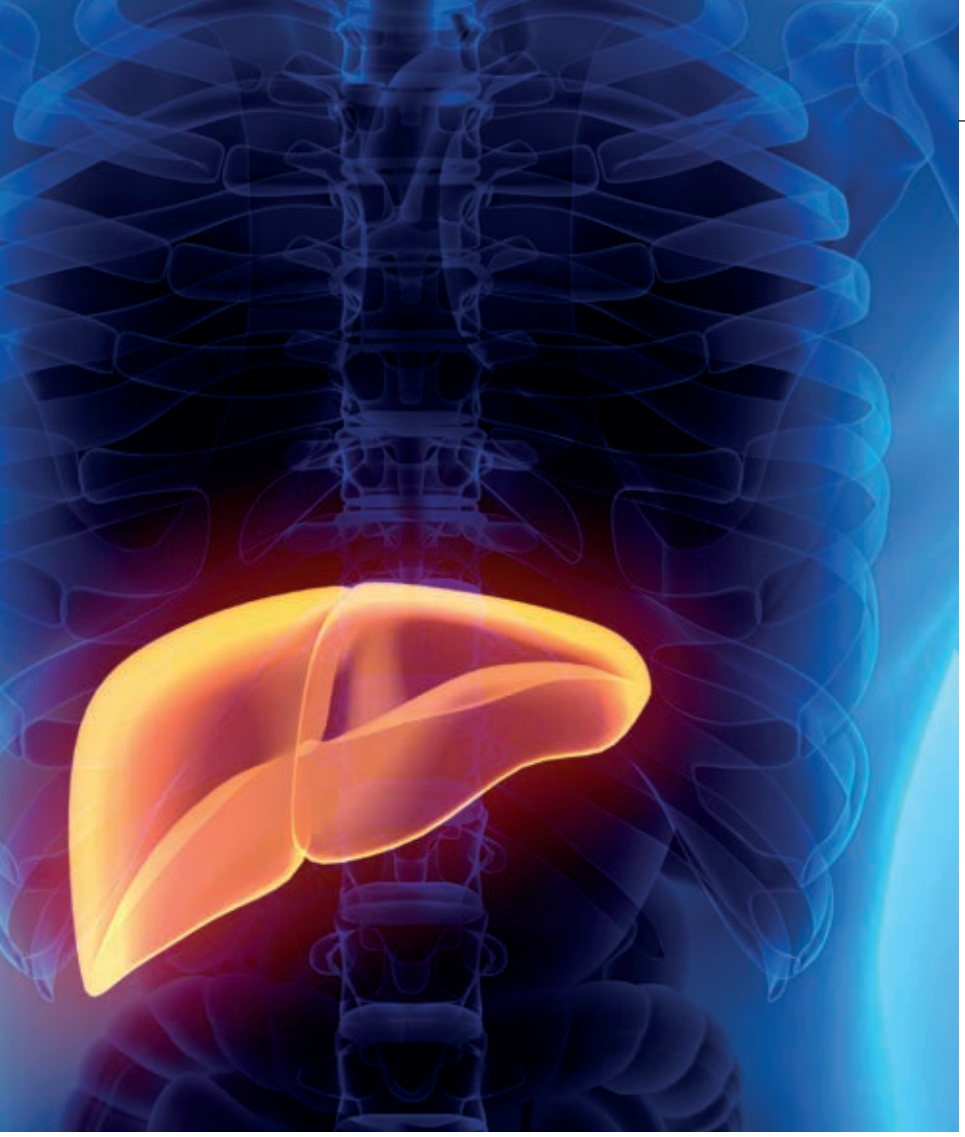


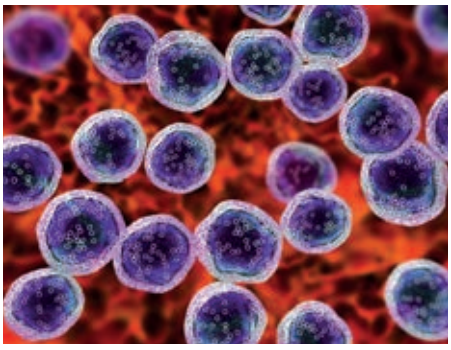
IMAGE: ISTOCK/SHUTTERSTOCK/SCIENCE PHOTO LIBRARY

and colleagues (150-152) show that a SNP in *ABCB1* (which codes for P-glycoprotein, extensively distributed and expressed by intestinal epithelium where it exports xenobiotics back into the lumen) is a determinant in the daily dose of warfarin, which varies by 20%, depending on genotype.

ANTIBIOTICS

The search for new antibiotics is important. Pitt and colleagues extend their earlier work in the journal (Pitt *et al*, 2015:73;49-50) with further characterisation of an antibiotic they have isolated from mucus of the brown garden snail (*Cornu aspersum*), harvested from the fields and gardens of leafy Sussex (pages 129-136). Certain proteins are effective in agarose plate growths of *Pseudomonas aeruginosa*. It remain to be seen whether these molecules are effective *in vivo*, but now we know more about their molecular profile.

An antibiotic was isolated from the mucus of the brown garden snail, harvested from Sussex



LYMPHOMAS AND DIABETES

The demonstration of specific nucleic acids in fixed tissues is demanding. Warford and colleagues (143-146) show that low copy mRNA can be demonstrated in formalin-fixed paraffin-embeded samples using the branched DNA *in-situ* hybridisation method, and has the potential to be used alongside immunocytochemistry for the demonstration of light chain restriction in follicular lymphomas. The issue concludes with a study by Abbass *et al* (153-155), who looked at three complication of diabetes – nephropathy, hypertension and dyslipidaemia. They hypothesised that SNPs in *GSTP1*, coding for glutathione transferase, an enzyme linked to anti-oxidation, would be linked to these conditions. However, the results of their well-powered study of 370 diabetics failed to confirm their hypothesis, so they concluded that *GSTP1* genotype is unrelated to three of the major complications of this important disease.

CPD

In common with previous articles, any of the above may be the subject of Journal-based learning. BMS

Andrew Blann is the Editor of the *British Journal of Biomedical Science*.

COST-EFFECTIVE PRACTICES IN GHANA

Associate Practitioner in blood science **Christina Silby** discusses the lessons learned from a recent trip volunteering in a Ghanaian laboratory.

One day I thought to myself, I need to experience what it means to work in a clinical laboratory that has fewer resources and to discover exactly how they can sustain the running of the lab.

I acted on that impulse and six months later I was among the hustle and bustle of Accra, capital of Ghana. I decided to embark upon a two-week volunteering project through Kaya Volunteer, in partnership with VPWA (Volunteer Partnerships for West Africa). The laboratory to which I was assigned, Anezka Medical Laboratory Services, was a community-based, small- to medium-sized operating laboratory. The staff are dedicated to meet the needs of the clinicians and patients coming from the nearby hospitals to provide diagnosis and aid their treatment.

During my time in this laboratory, my tasks included drawing blood from patients, using the laboratory equipment to diagnose, learning new manual

"My tasks included drawing blood from patients, using equipment to diagnose, learning manual diagnostic techniques and data handling"

GHANA
A LOOK AT HEALTH IN THE COUNTRY

Medical illnesses in Ghana overlap with those in developed countries, but infection, trauma, and women's health problems are much more prominent.

Limited resources

Medical practice in rural Africa faces extremely limited resources, a multiplicity of languages (hundreds in Ghana), and presentation of severe illnesses at later stages than seen elsewhere. Despite these limitations, Ghana has established a relatively successful national medical insurance system.

Common diseases

According to the World Health Organization (WHO), the most common diseases in Ghana include those endemic to sub-Saharan African countries, particularly: cholera, typhoid, pulmonary tuberculosis, anthrax, pertussis, tetanus, chicken pox, yellow fever, measles, infectious hepatitis, trachoma, malaria, HIV and schistosomiasis.

Common causes of death

The most recent report from the WHO identifies the top causes of death in Ghana as lower respiratory infections (11%), stroke (9%), malaria (8%), ischemic heart disease (6%), HIV/AIDS (5%), preterm birth complications (4%), birth asphyxia and birth trauma (4%), meningitis (3%), and protein-energy malnutrition (3%).

diagnostic techniques and data handling. The two main analysers the laboratory possessed are commonly used in a small laboratory setting. The semi-automated analyser, Mindray BA-88A, is used to run up to 200 biochemistry tests, while the fully-automated analyser, Mindray BC-2800, can be used for all parameters and three-part differentiation of white blood cells.

My challenges

I knew straight away that the most challenging experience was going to be drawing blood from the patients. In Ghana, all biomedical scientists are capable of drawing blood. As this was my first time, I had to learn the syringe method patiently and understand the techniques. It was very important to follow the health and safety regulations, such as wearing gloves, disinfecting the skin, finding the appropriate vein for draw and the technique of emptying the blood to the right tube. By practising, I became more confident. When it came to children, I watched the staff drawing blood since I wasn't confident with them – I found the process more complicated with children, especially as they can find the process upsetting and their behaviour can be unpredictable.

Another challenge I faced was the daily commute to and from the laboratory. The public transport, called "tro tro", can be very confusing for a foreigner. As they don't have a fixed stop, they can collect and drop anywhere on the route. I had to wait in the middle of a road construction site every day, while trying to listen for the conductor shouting the name of the destination in a language that was completely new. It was initially difficult, but with more exposure to this routine, I became more confident.

Government vs private

One of the common perceptions of the Ghanaian people was that work based in private labs is more efficient than that of government labs. To understand the reasoning behind this, after a few days working in the Anezka Lab, I visited the nearby government-based lab of GA West Municipal hospital. I saw straightaway that there were more staff for different sections and everyone was extremely busy, as patients were coming in and out continually. I also noticed that there were trainees as well. I understood that the immense load of the work coming in probably produces poor efficiency. However, the stream of patients coming to the Anezka lab was quite steady, so the reporting of results was done in an organised manner. I also noted that the patient will pay much less per test in a government lab in comparison to the private. If the majority of people can only afford the government charges, it makes sense that there is such an imbalance between the work of these two sectors.

I had to learn the syringe method and understand the techniques

Rapid dipstick tests

Most virology and pregnancy tests were performed by the rapid dipstick kit (see table 1), which was new to me, as I am more used to seeing these tests done on analysers. I noticed that this was not only used in Anezka lab, but also in the government hospital labs. The main reasons for this are that they are quick and cost-efficient, compared to analyser tests. The specificity and sensitivity

Test	Rapid strip test		
	Specificity (%)	Sensitivity (%)	Confidence interval(%)
hCG	100	100	95
HIV	100	100	95
SYPHILIS	>99.9	99.7	95
HCV	100	97.5	95
HBSAG	>99.9	99.9	95

Table 1: Differences in specificity, sensitivity, accuracy and confidence interval against other commercially available tests.

values suggest they are reliable and only when they are positive, do the doctors ask the patients to go to bigger labs, such as MDS Lancet, which has the analysers to provide more accurate results. The price of one dipstick can be around 10 Ghanaian cedi, while analyser tests could cost to about five to six times more. So it is understandable that rapid dipstick kits are used for initial screening, to save costs for both the lab and the patient.

Strategies to be cost effective

My current role as an Associate Practitioner means that I do not have any responsibility in managing the budget for the running of a lab. But when you are working in a small laboratory, such as Anezka, all the staff take responsibility.

This was seen with staff working together to clean, bleach and sterilise the EP tube V bottom vials, slides, urine containers and pipettes every day.

During my time in the lab, I saw that doctors more often requested HB (haemoglobin) only, rather than FBC (full blood count). This was perfect for the analyser Mindray BC-2800, because you can change the mode and enable it to perform only one test, which in return saves the use of other reagents or even consumables. Also, depending on the proximity, a hospital or clinic can give an indication of the tests or even analysers that the laboratory would need, avoiding the stocking of unnecessary supplies.

Additionally, as mentioned in the previous section, use of rapid dipstick kits is cost-effective, quicker and produces accurate screening method. As most tests in labs only require EDTA plasma, using EDTA tubes would be cheaper than SST tubes and would also help maintain costs within the lab.

Final thoughts

One of my biggest expectations before I started this two-week project was to see and study more examples of positive malaria or parasites. But this wasn't the case. Instead, I learnt the importance of the presence of a small laboratory in a developing community along with a government lab. This gives people the option to choose, depending on the urgency of the results and the cost of a test. All staff take equal responsibility for the maintenance and running of the lab, showing that dedication and team work is necessary for success in this environment. This consequently is connected to the cost-effective practices within the management of a small laboratory.

Ultimately, no matter how big or small the lab, it's about everyone working together to provide the most accurate diagnosis for the people in the community. My dream is to help build clinical labs in developing communities, so next year I plan to do another project where I want to be located in a more rural part of the world. BMS

Christina Silby is an Associate Practitioner in the automated blood sciences department of Health Services Laboratories, central London.
To see the references for Table 1, view the article online at **thebiomedicalscientist.net**

ADVANCED HEALTHCARE SCIENCE CAREERS WITHIN MICROBIOLOGY

Deputy Laboratory Manager **Francis Yongblah** looks at future opportunities from the perspective of a senior biomedical scientist working to advance their role.

The healthcare science (HCS) workforce plays a central role in safe and effective patient care across all pathways, from conception to end of life. There are about 50,000 employees in the HCS workforce in the NHS in the UK, and they are involved in approximately 80% of all clinical diagnoses.

Most microbiology laboratories across the country are heavily medically-led by medical consultant microbiologists. Over the last few years there has been a steady decline in the number of students applying to medicine. This has been exacerbated by "negative publicity" in 2015 in addition to cost. In 2016, it was the first time that places in medicine were offered through clearing.

There are a large number of consultant microbiology posts that it is a struggle to fill, with fewer applicants and more vacancies appearing. For this reason, NHS Improvement and Health Education England are working hard on the long term plan for workforce, which is looking at developing a Healthcare Science Workforce Programme to support implementation of the NHS Long Term Plan and expand the frontiers of medical science and innovation, introducing new treatment possibilities for 21st century care, such as whole genome sequencing.

The programme will bring together partners to model and plan the workforce, introducing flexible entry routes, better careers, new roles and ways of working, and competency-based development frameworks. These will underpin flexible and responsive systems of education, training and leadership and build on good practice in the system. Workforce planning for the future is crucial to ensure that the NHS remains sustainable and that it can still provide a crucial service to patient.

It can be observed from this evidence that there are some future risks to the NHS. So in order to ensure sustainability and prepare succession planning, advanced healthcare scientist roles will be a future requirement to ensure that microbiology departments are able to provide a vital service, and that scientific staff within microbiology have an opportunity to develop further. Currently, the only route within microbiology to develop is through the management route, however, this is not for everyone.

Within healthcare, advanced roles have become a crucial part of planning, to ensure that services are still able to run and provide a service. This is seen within wards where there are now consultant nurses and consultant midwives who are trained to a higher level, that are highly qualified to give advice and that are competent to carry out a higher and more responsible role.

Opportunities to develop

The Higher Specialist Scientist Training (HSST) is a five-year programme available to registered and experienced clinical scientists who may want to become a consultant clinical scientist. The work-based training programme is equivalent to the standards of training undertaken by medical postgraduate trainees and gives trainees the possibility of gaining Medical Royal College qualifications. For many biomedical scientists the only option to develop further is through the management route. However, many would prefer to be connected to the science and the diagnostics.

HSST in microbiology enables further development within a distinct diagnostic area of healthcare science, with the addition of innovation and research, leadership and management.

Succession planning for the future

Laboratory managers and service managers responsible for microbiology should seriously consider looking at the options for taking on in-service and direct-entry

IMAGES: ALAMY

HSST training posts and integrating advanced healthcare roles within Microbiology departments. This is a key opportunity to develop staff within their departments that are academically focused and highly skilled already

Is an advanced healthcare scientist career the right option for you?

Before considering going into an advanced healthcare scientist training programme, such as HSST to become a consultant healthcare scientist, you must ask yourself some serious questions and be completely honest with yourself. The HSST programme is a very hard programme that will require applicants to be hardworking, dedicated and focused. Completing the professional doctorate, Fellowship of the Royal College of Pathology (FRCPath) exams and clinical training is not easy and requires applicants to reflect on themselves and their current situation to determine whether they will be able to dedicate the extra time that is required to reach a consultant level. This will mean doing extra work and studying on the weekends and after work so that the individual can keep up with the requirement. It's also important to remember that an advanced healthcare scientist career will require you to be an "all rounder" and be able to balance being a microbiologist with also being a leader and manager, innovator and researcher, as well as a consultant. Work is currently being undertaken by workforce planning to see whether there is a place within microbiology for a role of a consultant biomedical scientists in the same way there is in histopathology. The role of a consultant healthcare scientist will require an individual to work hard to shape the future of the NHS.

What do I hope to achieve at the end of HSST?

At the end of HSST I hope to have a professional Doctorate, completed the FRCPath by examination, completed the Postgraduate diploma in Leadership and Management in Healthcare and finally be registered as a consultant healthcare scientist. I hope that I will be in a position to shape the future of diagnostic microbiology and to bring around a change to the culture and structure within my microbiology department as well as being an example for other departments across the UK. BMS

Francis Yongblah is Deputy Laboratory Manager at Great Ormond Street Hospital

MY IBMS NEWS

TRUST AWARDS

"CHERIE IS AN AMAZING INDIVIDUAL"

IBMS Licentiate Cherie Beckett has received the Amazing Individual Award from the Princess Alexandra Hospital NHS Trust, Harlow.

The trust's Amazing People Awards are for staff members who deserve recognition for the amazing work they do.

Cherie was nominated for her work to raise the profile of biomedical scientists by working with the IBMS to create #IBMSChat on social media, and her work with the children's charity Harvey's Gang.

She said: "I started at the very bottom, with no degree and no experience, but through sheer determination and motivation, and a huge amount of support from Princess Alexandra, I have been able to progress and hope to continue to do so.

"I am still processing the fact that someone noticed me and was kind enough to put my name forward, but also that the judging committee felt me worthy of this achievement. It has truly humbled me."

PROFESSIONAL PROMOTION

Lab in the park in Jersey

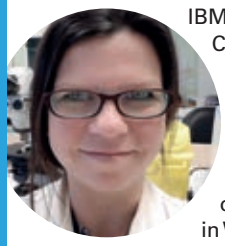
The "Cepheid Xperience" has been in Jersey showcasing the life-saving work done in hospital laboratories.

A mobile virtual laboratory visited Jersey to show islanders the work that is undertaken by biomedical science staff at Jersey General Hospital. This follows on from the work the laboratory did for Biomedical Science Day, when they organised guided tours of pathology for healthcare workers.

Islanders were able to board the Cepheid Xperience on 2 July and learn about the technology that helps pathology staff identify, research, monitor and treat disease. The truck was parked in Parade Gardens, opposite the hospital and the public were invited to drop-in for free, throughout the day, to see the equipment firsthand and to speak to staff about their work.

CPD REVIEW

Hayley wins CPD award



IBMS Associate Hayley Pincott has received the Cyril Sanders Memorial Award for her exemplary CPD.

This award is granted for the best CPD review return by an IBMS member at Registered Science Technician level, and will be presented to Hayley at IBMS Congress in September.

Hayley works as a Medical Laboratory Assistant in the oral pathology department at University Dental Hospital in Wales.

She said: "To be honest I wasn't very confident about my CPD and always questioned whether the content was enough, but after my CPD review I had some amazing feedback and I was told that I would be put forward for the Cyril Sanders Memorial Award.

"I was absolutely shocked to hear that I had won the award. Slightly overwhelmed as well – it's quite humbling to be recognised for something, especially as I wasn't expecting it."

Christian Burt, Professional Services Manager at the IBMS, said that Hayley's submission included "excellent examples of public engagement" and "demonstrated an ability to reflect upon the CPD undertaken".

OBITUARY

JIM CHAPMAN

It is with deep regret that we inform IBMS members of the death of Mr Jim Chapman on 15 February 2019.

Until his retirement, Jim was Senior Chief Biomedical Scientist in histopathology at Bradford Royal Infirmary.

Towards the end of his career, he was instrumental in seeing through the merger of his department with Leeds General Infirmary.

Jim had a distinguished academic career, teaching cellular pathology at both final and special levels at what was then the Leeds Polytechnic College.

He was also an examiner for our professional body and was well known nationally.

Jim was a staunch supporter of the IBMS and an active branch member. On his retirement, Jim was awarded honorary membership of the IBMS.

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JOURNAL-BASED LEARNING EXERCISES

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

DEADLINE WEDNESDAY 6 NOVEMBER 2019

Prevention of hemolytic transfusion reactions with intravenous immunoglobulin prophylaxis in U- patients with anti-U.
Win N, Almusawy M, Fitzgerald L, Hannah G, Bullock T.
Transfusion 2019; **59** (6): 1916–20. doi: 10.1111/trf.15230.
Assessment No: 080219

01	The U– phenotype is found predominantly in black African populations at a frequency of between 0.5% and 2.7%.
02	The MNS locus is found on chromosome 4.
03	With this and other related papers it is no longer considered necessary to make the effort to provide U– units to patients with anti-U.
04	The acronym IVIG stands for intravenous immunoglobulin.
05	For Patient 1, NHSBT provided 37 units of U– blood from the National Frozen Blood Bank (NFBB) over a period of 20 months.
06	For Patient 2, a combination of IV iron infusion and oral ferrous sulfate supplementation resolved her iron deficiency anaemia.
07	The NFBB is located at NHSBT-Filton Centre.
08	The post-thaw shelf life of most reconstituted cryopreserved red cell units is 72 hours.
09	Tranexamic acid is prescribed to prevent pain.
10	For Patient 2, a total dose of 2 g/kg/day was given over three days.
11	A hospital multidisciplinary team consists, where such teams are available, of a haematologist, an anaesthetist, a representative from the cell salvage team, an obstetrician (depending upon the patient case), a transfusion practitioner and a senior member of the hospital transfusion laboratory.
12	In the case of Patient 2, 800 mL of autologous red blood cells were returned to the patient via intraoperative cell salvage.
13	In the case of using reconstituted cryopreserved red cells, they will always be available within four to six hours.
14	The only symptoms of a delayed haemolytic transfusion reaction are lethargy, yellow colouring of the whites of the eyes (the sclera) and the passing of dark urine.
15	In the case of Patient 3, she suffered a large postpartum haemorrhage of approximately 3 L, due to uterine atony.
16	In the case of Patient 3, placental swabs grew *Streptococcus aureus*.
17	Case reports of anti-U in the literature include descriptions of one case of a fatal acute haemolytic transfusion reaction and at least one case of stillbirth due to anti-U.
18	The 2015 SHOT report describes one case of mortality due to severe delayed HTR and four additional reports of major morbidity, all attributed to Kidd blood group antibodies.
19	Use of the monocyte monolayer assay (MMA) to predict clinical severity of an antibody is used widely in the UK blood service as an accurate prediction of the severity of antibody reactions *in vivo*.
20	Therapeutic plasma exchange (TPE) can be used for the removal and neutralisation of free Hb caused by a delayed HTR, allowing for the restoration of tissue perfusion and to limit renal toxicity.

Breast cancer biomarkers in clinical testing: analysis of a UK national external quality assessment scheme for immunocytochemistry and *in situ* hybridisation database containing results from 199 300 patients.
Dodson A, Parry S, Ibrahim M *et al. J Pathol Clin Res* 2018; **4** (4): 262–73 (https://www.ncbi.nlm.nih.gov/pubmed/30066480) **Assessment No: 080719**

01	More than 299,000 patient biomarker data sets were collected in the study.
02	Menopause status was not captured, patient age at test ≥56 years was defined as post-menopausal.
03	Cut-points for defining oestrogen receptor-positive disease were Allred >3.
04	Two cut-points were used to define progesterone receptor status of Allred ≥3 and Allred ≥4.
05	The results collected by NEQAS suggest that practice for assessing progesterone receptor positivity were not standardised.
06	After exclusions, 182,413 (97.4%) were collected between 2011 and 2015.
07	The median age of patient ER/PR status assessment was 51 years.
08	The inter-quartile range of patient testing was 51–71 years.
09	HER2 status in UK patients showed an overall positivity rate of 13.2% in the collected sample data.
10	Out of the cohort of breast cancer patients examined, 61.8% were symptomatic.
11	No difference in the frequency of HER2-positive cases was observed in ER-positive versus ER-negative breast cancers with respect to nodal status (whether Nx, N0, N1 or N2) and grade.
12	ER-negative breast tumours were much more likely to be HER2 3+ than ER-positive tumours.
13	Intraductal carcinoma accounts for 80.1% of the entire examined cohort.
14	The majority of breast tumours in the report were less than 20 mm in diameter.
15	The number of ER-negative / PR-positive cases was large (69.3%).
16	In ER-positive / PR-positive tumours, the HER2 positivity rate increased rapidly with increasing patient age, up to age 60 years, after which it plateaued at approximately 6.5%.
17	Table 2 describes the majority of HER2-positive patients to be most likely to have an N3 node status.
18	There is a change in ER positivity status related to age. The collected data show younger patients <35 years had a 66.6% positivity to 86.9% in ≥90-year-old patients.
19	Across the whole cohort group, the progesterone positivity rate was 74.9%.
20	Increasing HER positivity rates were strongly associated with symptomatic versus screen-detected tumours.

REFLECTIVE LEARNING

01	How does this paper reflect the findings of the few other studies cited by the authors? Discuss this in detail.
02	In what other circumstances, including antibody specificities and ethnicities, would it be wise to have the same discussions with a multidisciplinary team, even if, after the discussion, the decision is not to go ahead with 'least-incompatible' units?

01	Review the mechanisms used in your laboratory to assure accuracy of test sensitivity to record breast HER2, ER and PR.
02	Review the local failsafe mechanisms for attending to assay drift for ER, PR or HER2 rates.

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EVENTS AND TRAINING COURSES

A wide range of training courses, CPD and local events and activities is listed below. Members are advised to contact organisers for further information. A full list is available on the IBMS website.

DATE	TITLE	VENUE CONTACT
August		
7 Aug	**UK NEQAS Cellular Pathology Technique tissue preparation techniques workshop**	Gateshead I chantell.hodgson@nhs.net
8 Aug	**UK NEQAS Cellular Pathology Technique tissue morphology and recognition workshop**	Gateshead I chantell.hodgson@nhs.net
8 Aug	**UK NEQAS Cellular Pathology Technique non-gynae cytology beginners/refresher workshop**	Gateshead I chantell.hodgson@nhs.net
9 Aug	**UK NEQAS Cellular Pathology Technique non-gynae cytology intermediate workshop**	Gateshead I chantell.hodgson@nhs.net
14 Aug	**UK NEQAS Cellular Pathology Technique special staining beginners/refresher workshop**	Newcastle upon Tyne I chantell.hodgson@nhs.net
15 Aug	**UK NEQAS Cellular Pathology Technique specialist workshop B**	Newcastle upon Tyne I chantell.hodgson@nhs.net
20-22 Aug	**BSAC Residential Workshops for EUCAST Susceptibility Testing**	Cardiff I ecarruthers@bsac.org.uk
21 Aug	**UK NEQAS Cellular Pathology Technique Non Gynae Cytology Intermediate workshop**	Dublin I chantell.hodgson@nhs.net
22 Aug	**UK NEQAS Cellular Pathology Technique Tissue Morphology and Recognition Workshop**	Dublin I chantell.hodgson@nhs.net
September		
4 Sep	**One-Day Update in Cervical Cytology**	Bristol I SWRCTC@nbt.nhs.uk
4 Sep	**UK NEQAS Cellular Pathology Technique immunocytochemistry staining beginners workshop**	Newcastle upon Tyne I chantell.hodgson@nhs.net
5 Sep	**UK NEQAS Cellular Pathology Technique immunocytochemistry intermediate/trouble shooting workshop**	Newcastle upon Tyne I chantell.hodgson@nhs.net
9-13 Sep	**Flow Cytometry course**	York I katejermey@rms.org.uk
10 Sep	**POCT "The Power to Disrupt"**	York I info@thornhillhealthcareevents.co.uk
11-12 Sep	**Beginners Immunohistochemistry**	Sheffield I l.baxter@sheffield.ac.uk
16-17 Sep	**Introduction to NGS: DNA**	Cambridge I SREGO1@ILLUMINA.COM
17-19 Sep	**BMS/Cytoscreener Update Course in Gynaecological Cytology**	Harrow I LNWH-tr.lrctcbooking@nhs.net
22-25 Sep	**IBMS Congress**	Birmingham I congress.ibms.org
30 Sep-25 Oct	**Introductory Course in Gynaecological Cytology**	Harrow I LNWH-tr.lrctcbooking@nhs.net
October		
7-8 Oct	**Introduction to Practical HPLC Course**	Rochester I stuart@laserchrom.com
8 Oct	**UK NEQAS Clinical Chemistry Roadshow Manchester**	Manchester I birminghamquality@uhb.nhs.uk
9 Oct	**Intermediate Immunohistochemistry**	Sheffield I l.baxter@sheffield.ac.uk
9-10 Oct	**Intermediate Practical HPLC Course**	Rochester I stuart@laserchrom.com
11 Oct-10 Dec	**Regional Educational Workshops 2019: The partnership of AMS & IPC "Stewarding new antimicrobials & IPC practices"**	Various (UK) I ecarruthers@bsac.org.uk
14-16 Oct	**Practical HPLC Method Development Course**	Rochester I stuart@laserchrom.com
14-15 Oct	**Introduction to NGS: DNA**	Cambridge I SREGO1@ILLUMINA.COM

DATE	TITLE	VENUE CONTACT
15 Oct	**UK NEQAS Cellular Pathology Technique Mohs workshop**	Gateshead I chantell.hodgson@nhs.net
16 Oct	**UK NEQAS Cellular Pathology Technique BMT workshop**	Gateshead I chantell.hodgson@nhs.net
17 Oct	**UK NEQAS Cellular Pathology Technique renal workshop**	Gateshead I chantell.hodgson@nhs.net
17-18 Oct	**Practical HPLC Troubleshooting Course**	Rochester I stuart@laserchrom.com
November		
4-8 Nov	**Advanced Practical HPLC Course**	Rochester I stuart@laserchrom.com
6 Nov	**UK NEQAS Clinical Chemistry Roadshow Belfast 2019**	Belfast I birminghamquality@uhb.nhs.uk
11-12 Nov	**UK NEQAS CPT Annual Participants Meeting**	Dublin I chantell.hodgson@nhs.net
11-14 Nov	**FIS 2019: Federation of Infection Societies Conference**	Edinburgh I k.mistry@microbiologysociety.com
12 Nov	**Fine Needle Aspiration Cytology for Technical Staff**	Bristol I SWRCTC@nbt.nhs.uk
13 Nov	**UK NEQAS Cellular Pathology Technique non-gynae cytology beginners/refresher workshop**	Gateshead I chantell.hodgson@nhs.net
13-14 Nov	**Advanced Immunohistochemistry**	Sheffield I l.baxter@sheffield.ac.uk
14 Nov	**UK NEQAS Cellular Pathology Technique non-gynae cytology intermediate workshop**	Gateshead I chantell.hodgson@nhs.net
26-28 Nov	**BMS/Cytoscreener Update Course in Gynaecological Cytology**	Harrow I LNWH-tr.lrctcbooking@nhs.net
27 Nov	**UK NEQAS Cellular Pathology Technique TEM workshop two**	Leicester I chantell.hodgson@nhs.net
27 Nov	**Update in Cervical Cytology for pathologists, consultant BMS and holders of the Advanced Specialist Diploma in Cytology**	Bristol I SWRCTC@nbt.nhs.uk
28-29 Nov	**Antibiotic Resistance and Mechanisms Workshop for Researchers**	Birmingham I ecarruthers@bsac.org.uk

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HERE TO HELP

FREE IBMS CONGRESS TALKS PT.2

Jocelyn Pryce, IBMS Deputy Head of Education, highlights complimentary talks and workshops in Hall 4 over the four days of Congress 2019.

On Tuesday 24 September, the IBMS Head of Examinations, Chris Ward, will be unveiling the outcomes of the work of the Higher Specialist Diploma (HSD) review group.

Representatives from each of the IBMS advisory panels formed the group and it has been led by the Deputy Chief Executive, Sarah May. The group has been working to ensure that this, one of the IBMS' most important qualifications, continues to help prepare candidates for senior roles within their organisation. This session will outline the changes to both the portfolio requirements and examination for this qualification.

Later in the morning, Examiners from the IBMS/RCPath Conjoint Boards will be providing tips and advice on best practice, strategies for planning time and boosting confidence, as well as highlighting challenges candidates might face and potential solutions when pursuing our Histological Dissection and Histopathology Reporting qualifications.

This will be valuable not only to those undertaking, or thinking of undertaking, these popular qualifications, but also those who are supporting their colleagues through that process.

On Wednesday 25 September, the IBMS Executive Head of Education, Alan Wainwright, will be giving a Specialist Portfolio update that will be aimed at both candidates and training officers. This talk will draw together the expectations of those undertaking this qualification and offer suggestions on how to manage these in the context of the ever-changing profile of laboratories. Additionally, it will consider how this qualification might be revised and restructured going forward to better reflect the needs of the workforce in a modernised pathology structure.

On Wednesday afternoon we will be putting science and research under the microscope, and looking at ways of communicating scientific advances. Clinical biomedical science and biomedical science in research should be closely aligned, but in the past this alignment may not have been overt. Contemporary practitioners of biomedical science are expected to be omni-competent and our talks will explore ways to gain confidence in research communication. They will include skills required to write a successful scientific paper, review scientific literature and how to present a scientific subject to an audience. Guidance will be given on how to approach research with a critical eye, recognising strong, high-quality research and how it might impact on your own development. Communication of a scientific subject can require a complex set of skills and our talks will cover areas such as adapting your approach to meet the needs of your target audience and ensuring clarity in the message you want to convey.

We hope that these articles have whetted your appetite and encouraged you to consider attending one or more of these sessions. There will be a great deal to see and do at Congress, even if you can only join us for a single day. Please remember that everything in Hall 4 is free to attend so why not create CPD opportunities for yourself by joining us? We look forward to seeing you there! The latest information can be found on the IBMS Congress website – congress.ibms.org

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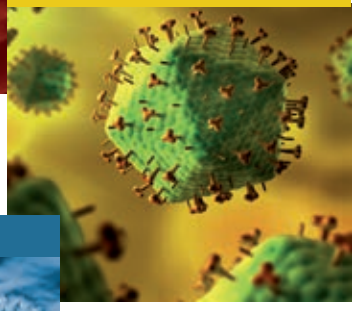
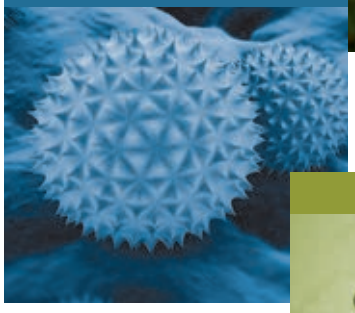
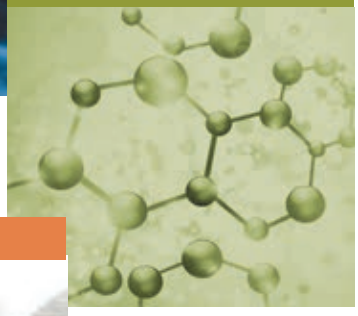


Allergology



Antigen Detection



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HSL is searching for a full time Manager to run our Rapid Response Laboratory (RRL) at Barnet & Chase Farm Hospitals.

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The departments are currently undergoing complete refurbishment as part of the transition of pathology services into HSL, and this is due to complete in September 2019. New equipment is being installed throughout and improved staff facilities are also part of the project.

The role includes supervision of all activities within the RRL and ensuring all documented procedures are implemented and maintained. Other duties will include the responsibility for the organisation and performance of clinical laboratory tests within target deadlines, to ensure appropriate training and supervision of Laboratory Managers, Biomedical Scientist and MLA staff, and to regularly review workflow operations, ensuring agreed standards for quality and turnaround times are met.

For further information about this position or if you wish to visit the laboratory, contact **Ann Hannah**: **ann.hannah@hslpatholgy.com**

Closing Date: **11th August 2019**

The closing date may be earlier where there is high interest.

HSL is a committed equal opportunities employer and does not unlawfully discriminate on the basis of any status or condition protected by applicable UK employment law.

MY LAB

RED CELL IMMUNOHAEMATOLOGY

Specialist Biomedical Scientist **Helen Owens** gives a guided tour of her reference laboratory at NHS Blood and Transplant, Newcastle.

Just a stone's throw from St James' park, lies the red cell immunohaematology (RCI) laboratory at NHS Blood and Transplant (NHSBT), Newcastle, providing a comprehensive reference service for the investigation of blood grouping and red cell antibody problems.

With a small team of 11, consisting of the Head of Laboratory, Laboratory Manager, two support staff, and seven biomedical scientist staff (six of whom participate in the out-of-hours on-call rota) we provide a 365-day, 24/7 service for 15 hospital transfusion laboratories across the North of England.

Accredited to ISO 15189 by the United Kingdom Accreditation Service (UKAS) and licensed by the Medicines and Healthcare Products Regulatory Agency (MHRA), the Newcastle laboratory is split into three sections: sample reception, manual serology and antibody quantification, with biomedical science staff rotating between sections.

Samples are booked in throughout the day and the workload prioritised to meet urgent requests. The majority of requests are processed manually, due to the complex nature of our work. Reference services include serological investigations and crossmatching for atypical red cell antibodies, red cell phenotyping and genotyping, haemolytic transfusion reaction investigations, routine and anomalous ABO and RhD typing, titration of anti-A and anti-B for ABO incompatible renal transplants and autoimmune haemolytic anaemia (AIHA) investigations.

We have multiple tools at our disposal, including access to numerous reagent panels, including a rare cell panel, alloadsorption cells and a wide range of anti-sera. Antenatal services include investigations for the prevention of haemolytic disease of the fetus and newborn (HDFN), antibody quantification for alloanti-D and alloanti-c, antibody titration and paternal phenotyping.

As a laboratory that prides itself on training, we support a wide array of trainees, from placement students to trainee specialist registrars. Four of our current staff, including myself, were placement students in RCI who completed their HCPC registration portfolios during their clinical placement year while at university. We accommodate students undertaking the NHS Practitioner and Scientist Training Programmes. All staff enjoy sharing their knowledge and experiences with others, participating in training and are also actively involved in supporting courses run by NHSBT for hospital transfusion staff and work closely with local universities, with staff running practical sessions and delivering lectures for transfusion science modules.

We also provide laboratory tours for schools, blood donors, hospital staff and non-scientific NHSBT staff. We recently had our first Harvey's Gang event, which was a huge success, and are looking forward to more of these in the future.

As well as offering training for external staff and students, NHSBT is committed to training and developing its own staff. At RCI Newcastle, our current placement student has just completed her registration portfolio, two staff have recently started their specialist qualifications, one is undertaking an MSc, and another is due to start in September.

Myself and one of the Advanced Specialists, have successfully completed the IBMS Higher Specialist Diploma in Transfusion science in 2018 and 2017, respectively, and the Reference Section Head is following the NHS Higher Specialist Scientist Training pathway. The staff are passionate about training and development, and it is this passion and drive which ultimately provides the best care for our patients.

Helen was awarded the **The R J Lavington Prize**, as the IBMS member who achieved the highest mark across all disciplines in the IBMS Higher Specialist Diploma exams.

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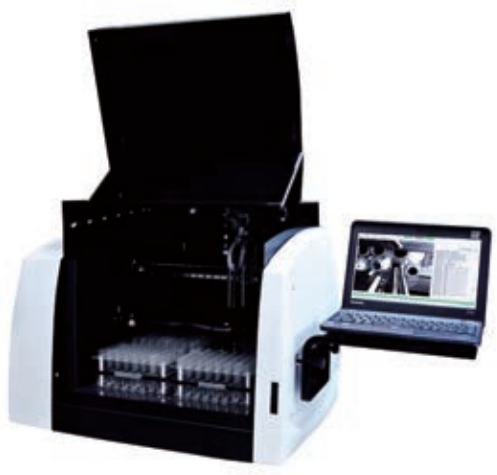

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