

OPINION

THE BIG QUESTION

Laboratory quality management systems and patient benefit: *p.14*

ONE-TO-ONE

ANDREW McINTOSH

Pioneering research that asks if depression is genetic: *p.16*

THE BIG STORY

WAR ON CANCER

A look at the history of chemotherapy until 1950: *p.30*

THE

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MARCH 2019

THE FUTURE IS GENOMIC



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EDITORIAL

- 5 Addressing responses to a recent Institute survey

NEWS

- 7 News in numbers
8 Research, funding, developments and clinical updates
13 Product advances and launches

OPINION

- 14 **The big question:** How does a laboratory quality management system benefit patients?
16 **One-to-one:** Andrew McIntosh discusses an international research study and asks if depression is genetic

SCIENCE

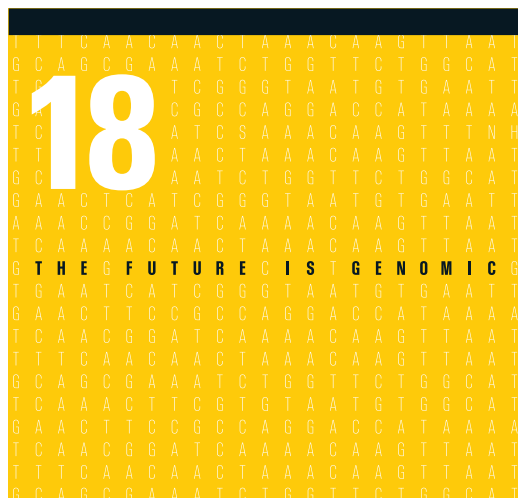
- 18 **The future is genomic:**
What does the future hold for genomics and how can it be integrated into the NHS?
24 **Apprenticeships:** The degree apprenticeship agenda and experiences of working with work-based learners
26 **The sun does not set:** A CPD trip to the Arctic Circle
30 **The big story:** War on cancer pt.1 – a look at the history of the development of chemotherapy until 1950

COVER
FEATURE

CONTENTS

IBMS.ORG

MARCH 2019



- 34 **Lecture to lab:** Covering the application of academic learning in professional practice

ADVICE

- 36 **Diagnostic lab accreditation:**
Reflections of a Quality Manager
38 **How to...** create pathways through partnership

MY IBMS

- 41 **Institute news:** The latest from the IBMS
42 **CPD update:** Training courses, events and activities
45 **Journal-based learning:**
CPD exercises based on journal articles
46 **Here to help:** Expectations of biomedical science graduates

MY LAB

- 50 **Siobhan Taylor** gives a guided tour of the lab at Gloucestershire Hospitals NHS Foundation Trust

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I am trying to decide whether we have gone wrong somewhere along the way, or if we're simply seeing the consequences of over-stretched people without the time to read and inwardly digest information.

We are currently analysing the responses to the recent Institute membership survey and I'm looking at the "free text" comments that are additional to the more structured answers. I have to confess, I am more than a trifle worried at the apparent misunderstanding and resentment from some about Institute qualifications and their purpose.

In response to comments about the Higher Specialist Diploma (HSD), it was not introduced to discourage people from progressing as older members retire; far from it. The HSD was designed to equip the current and future generations to fill the knowledge gaps that arise as senior people, many of whom hold the old Fellowship examination, leave. Band 7 roles require a masters level (or equivalent) qualification and we all know that the time and money to enrol on such a course is out of reach for most, which is why the HSD is the obvious and affordable alternative choice. It is not designed to punish or impede, but to provide a route to promotion that might otherwise be closed.

"The Institute has helped to dumb down the profession". How exactly? We offer the widest range of professional qualifications of all the non-medical

ROUTES TO PROGRESS



Sarah May, IBMS Deputy Chief Executive, addresses some of the responses to a recent Institute survey.

healthcare professions? We have had people undertaking reporting roles in cytology since 2002 and now we have individuals dissecting and reporting histopathology. Does this comment refer to the increase in the number of non-registered support staff? I suspect it does, but to try and prevent the change that is happening in the pathology workforce would be akin to King Canute trying to command the waves to retreat – and about as successful. Our position has not been to stop the unstoppable but to offer routes to progress in the changing and very challenging climate.

I am putting away my soapbox now, but am smarting from the stinging statement that "the IBMS has made it harder for the

young people coming into the profession by adding levels of needless bureaucracy in achieving higher grades". I'm really not too sure where to go with that one; the only mandatory qualification for biomedical scientists is HCPC registration, thereafter it is up to each individual to choose their route and how best to get there. Institute qualifications are there to help, not hinder and I am truly sorry if that is not how they are viewed.

Sarah May
Deputy Chief Executive



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

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SCIENCE NEWS IN NUMBERS

EIGHT WEEKS of cancellations

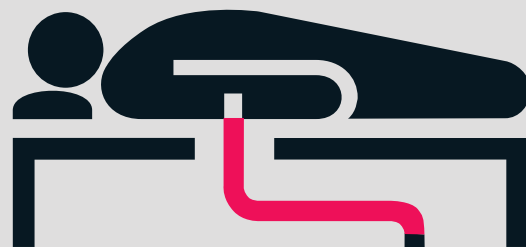
Blood donation sessions in two coastal towns have been cancelled around the 29 March Brexit deadline.

The sessions in Dover and Folkestone have been pulled for **two weeks before and a six week after the date** due to fears of Brexit-related traffic jams.



A California doctor is fighting for his licence after prescribing cannabis cookies to a four-year-old boy.

Dr William Eidelman said **small doses of marijuana would help control the child's temper tantrums.** Medicinal cannabis usage has been legal in California since 1996.



A controversial US start-up charges \$8,000 to fill your veins with "young blood" (from people 16 to 25 years old).

Ambrosia offers: **1 litre of young blood for \$8,000, or 2 litres for \$12,000.** There's no evidence to suggest that the treatments is beneficial. Ambrosia has carried out a clinical trial, but the results have not been made public.



00008\$

45%
New NHS data has revealed **nearly half of people in England with a learning disability did not receive an annual health check last year.**

Although this has increased from **43% in 2013-14**, it is still far short of the new health check uptake target of

75%
of people aged 14 and over with a learning disability getting the annual health check.



8% higher chance of death

Researchers followed over 100,000 post-menopausal women for up to 24 years.

Those who ate any fried food at least once per week had an **8% higher chance of death** than those who did not. People who regularly ate fried chicken saw a **12% increase in the probability of death.**





SCIENCE NEWS

GENOMICS

NHS to launch paid-for genomics tests

Healthy people in England will be able to pay the NHS to sequence their genes, on condition they share their data.

Health Secretary Matt Hancock claimed it will help develop treatments “that will benefit everyone in the future”.

He said: “While healthy people should not have this service free on the NHS, there are huge benefits to sequencing as many genomes as we can. Every genome sequenced moves us a step closer to unlocking life-saving treatments.”

However, there are concerns. Dr Anneke Lucassen, Chair of the British Society for Genetic

Medicine, said: “The NHS has always been free at the point of delivery. It has the potential to create a two-tier system.”

She added: “You can use genetic code to confirm a clinical picture, but you can’t use it to predict what will happen in the future very accurately.”

The project will be led by Genomics England, but no further details, dates or costings have been announced.

The news follows Genomics England’s successful completion of its bid to sequence 100,000 genomes in December 2018.



DNA DAMAGE

BIOMARKER FOR GENOME INSTABILITY

Elevated levels of a protein called ubiquilin-4 can be a biomarker for genome instability, a Tel Aviv University study shows.

The researchers found that ubiquilin-4 takes part in defending the genome from DNA damage, but too much of the protein is harmful.

When the amount of ubiquilin-4 in tumour cells rises, the cells become more prone to genome instability, accelerating the tumour’s progression and making it resistant to commonly used cancer treatments.

Professor Yossi Shiloh, who led the study, said: “This novel biomarker provides new, critical information about the tumour stage and grade, as well as the patient’s chances of responding to treatment.

“Tumours with high levels of ubiquilin-4 may be more resistant to radiation and some chemotherapies than those with normal levels of this protein.

“But the good news is that they may also respond better to other types of cancer therapy.”

→ bit.ly/BS_NewsMar01

DIAGNOSTIC TESTS

SEPARATING BLOOD PLASMA WITH A TOY

Researchers have found a novel use for “fidget spinner” toys – separating blood plasma for diagnostic tests.

Centrifuges are expensive and require electricity that might not be available in resource-limited regions.

The new approach could be useful for medical applications in regions of the world that lack electricity and other resources.

Chien-Fu Chen, Chien-Cheng Chang and colleagues wondered if a commercially available fidget-spinner could

generate enough force to separate blood plasma with the flick of a finger.

They placed human blood samples in tiny tubes, sealed the ends and taped a tube to each of the three prongs of a fidget-spinner.

They found that by flicking the spinner with a finger three to five times, they could separate about 30% of the plasma with 99% purity in only four to seven minutes.

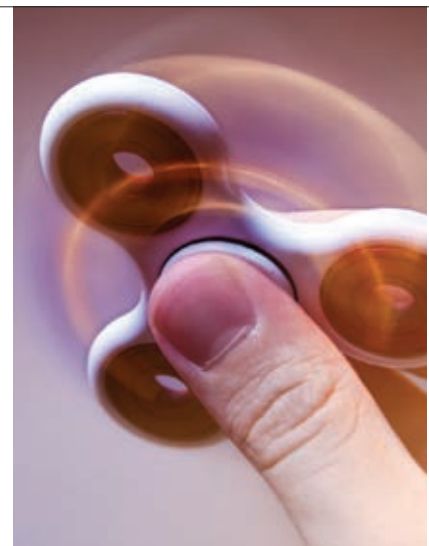
To verify that the plasma was suitable for diagnostic

tests, the researchers spiked blood with a human immunodeficiency virus-1 (HIV-1) protein, separated the plasma with the spinner and performed a paper-based detection test.

The inexpensive, simple method detected clinically relevant concentrations of the viral protein in only a drop of blood.

A video of a fidget spinner being used as a centrifuge can be viewed online.

→ bit.ly/BS_NewsMar06



PROTEINS

HENS THAT LAY HUMAN PROTEINS IN EGGS OFFER FUTURE THERAPY HOPE

Chickens that are genetically modified to produce human proteins in their eggs can offer a cost-effective method of producing certain types of drugs, research suggests.

The study found the drugs work at least as well as the same proteins produced using existing methods.

High quantities of the proteins can be recovered from each egg using a simple purification system and there are no adverse effects on the chickens themselves, which lay eggs as normal.

Researchers say the findings provide sound evidence for using chickens as a cheap method of producing high quality drugs for use in research studies and, potentially one day, in patients.

Eggs are already used for growing viruses that are used as vaccines. This new approach is different because the therapeutic proteins are encoded in the chicken's DNA and produced as part of the egg white.

The team has focused on the human protein IFN α 2a, which has powerful antiviral and anti-cancer effects, and the human and pig versions of macrophage-CSF, which is being developed to stimulate damaged tissues to repair themselves.

→ bit.ly/BS_NewsMar02

NHS ENGLAND

SOCIAL PRESCRIBING DUE TO INCREASE

The prescribing of social activities, such as exercise and art classes, rather than medications, is set to rise under NHS England plans.

The aim is for "link workers" to support GPs and reduce their workload by helping patients find suitable community activities to improve their health and wellbeing.

The NHS plans to recruit more than 1,000 link workers by 2020-21 and aims, in the long term, for them to handle around 900,000 patient appointments a year.

James Sanderson, NHS England's Director of Personalised Care, said: "Social prescribing is an important component of the NHS comprehensive model of personalised care and there is emerging evidence that it can lead to a range of positive health and wellbeing outcomes for people, such as improved quality of life and emotional wellbeing. "The aim is [...] a substantial reduction in the use of NHS services, including GP attendances."

→ bit.ly/BS_NewsMar03

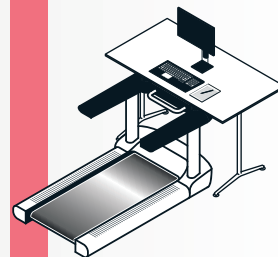
WHAT'S HOT AND WHAT'S NOT



HOT

SLEEPING

A study has found the neural glitches in the sleep-deprived brain that intensify and prolong the agony of sickness and injury.



HOT

TREADMILL WORKSTATIONS

Treadmill workstations appear to be associated with greater positive physiological changes in the body than standing workstations, finds a systematic review.



HOT

THE TONGUE

The tongue microbiome could help identify patients with early-stage pancreatic cancer, according to a new study published in the *Journal of Oral Microbiology*.



NOT

ALCOHOL

Binge and heavy drinking may trigger a long-lasting genetic change, resulting in an even greater craving for alcohol, according to a new study.



NOT

BREXIT

Brexit could contribute to thousands more deaths from heart attacks and strokes by 2030, new research from Imperial College London and the University of Liverpool has found.

NOT

HAND WASHING

Paramedics' compliance with hand hygiene standards seems to be "remarkably low", states an observational study of ambulance staff.





Permits may soon be needed to transport certain items to and from the EU

From iguanas to ivory, rosewood to reptiles, there are over 30,000 endangered species and their products that will need permits and must travel through designated ports in the event of a no deal EU exit.

To find out more, search **CITES** at **gov.uk**



PROSTATE CANCER

Modified flu virus that targets and kills cancer cells

Scientists from Queen Mary University of London have received a grant from Prostate Cancer UK, as London continues to lead the way in advanced prostate cancer research.

Six separate grants worth over £2.5m have been awarded in London as part of the charity's Research Innovation Awards scheme which funds forward thinking, ambitious research proposals from across the UK which challenge the status quo.

Dr Gunnel Hallden is leading one of the studies at Queen Mary. It builds on previous work funded by Prostate Cancer UK, which saw Dr Hallden develop a modified type of flu virus that specifically infects and kills cancer cells, leaving non-cancer cells unharmed.

Dr Hallden from Queen Mary University of London, said: "Our first study proved very successful when the virus was injected directly into cancer

cells in mice and used alongside standard chemotherapy drugs. However, we wanted to find a way of delivering it via the blood, so it can reach all tumours in the body at once, instead of being injected into just one.

"This has proven difficult in the past, but by 'packaging' the virus with special proteins to help protect it as it travels through the blood, we hope the virus can survive long enough to reach the tumours. We'll also modify the virus to give it the ability to alert the patient's immune system to prostate cancer so the patient's own body will continue to fight the disease.

"Thanks to Prostate Cancer UK's grants, we hope we can soon have a new treatment for men with incurable prostate cancer which will improve both the length and quality of their life."

→ bit.ly/BS_NewsMar04

BIOMEDICAL IMAGING

COMBINING OPTICAL, ULTRASOUND TECHNOLOGY

Researchers are developing a novel biomedical imaging system that combines optical and ultrasound technology to improve diagnosis of life-threatening diseases.

Photoacoustic tomography is a noninvasive technique that works by converting absorbed optical energy into acoustic signal.

Pulsed light is sent into body tissue, creating a small increase in temperature that causes the tissue to expand and create an acoustic response that can be detected by an ultrasound transducer.

The ultrasound data is used to visualise the tissue.

The system provides real-time compositional information of body tissue without the need for contrast agents and with better depth penetration compared with conventional optical techniques.

Photoacoustic tomography can be used to detect or monitor a range of diseases, including cardiovascular disease, diabetes, and cancer.

Among other potential uses for photoacoustic tomography is the mapping of lipid deposition within an arterial wall that can cause other health problems, measuring cardiac tissue damage and tumour biopsies.

→ bit.ly/BS_NewsMar05

UNDER THE MICROSCOPE

This month: Kongsfjorden

What is Kongsfjorden?

It's not so much what it is, as where it is – an inlet on the west coast of Spitsbergen, an island which is part of the Svalbard archipelago in the Arctic Ocean.

That sounds very remote. What has been happening there?

Soil samples taken in the region have now confirmed the spread of *blaNDM-1* into the High Arctic – an antibiotic-resistant gene (ARG) originally discovered in surface waters of urban India. It conditionally provides multidrug resistance (MDR) in microorganisms.



What does that mean?

In a nutshell – an ARG first detected in urban India has been found 8,000 miles away in one of the last "pristine" places on earth.

That doesn't sound good.

Nope, it isn't.

The spread of MDG genes is of particular concern because they often target "last resort" classes of antibiotics, including Carbapenems.

How did *blaNDM-1* travel to the Arctic?

Professor David Graham, who led the team that made the discovery, believes it is likely that the ARG was

spread in the faecal matter of birds, other wildlife and human visitors to the area.



What happens now?

This finding has huge implications for the global spread of antibiotic resistance, warned Professor Graham, who said: "A clinically important ARG originating from South Asia is clearly not 'local' to the Arctic. The only way we are going to win this fight is to understand all pathways that lead to antibiotic resistance."

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TECH NEWS

SITRYX

BIOPHARMA

Sitryx, a biopharmaceutical company developing disease-modifying therapeutics, has launched with £23m funding.

It specialises in immunology and immuno-oncology.

Paul-Peter Tak, one of the co-founders, is one of the world's leading biotech experts.

He is a visiting professor at institutions and universities across the world and is known for his pioneering research into the impact bioelectronics can have on rheumatoid arthritis and other chronic diseases.

→ sitryx.com

PROMEGA

GENE EDITING

Promega has signed a non-exclusive license agreement with the Broad Institute of Massachusetts Institute of Technology and Harvard to sell tools and reagents for CRISPR-Cas9 gene editing, providing scientists new tools for interrogating endogenous biology.

Under the agreement, Promega will combine CRISPR-Cas9 technology with its products that knock-in Promega genetic reporters to the genomes of any cell or cell line.

→ promega.co.uk



EKF DIAGNOSTICS

WORLD'S FASTEST HAEMOGLOBIN ANALYSER

The Global *in vitro* diagnostics company EKF Diagnostics has signed a private label distribution agreement with McKesson Medical-Surgical.

This is for the Company's handheld reagent-free haemoglobin analyser, the DiaSpect Tm.

McKesson is the oldest and largest healthcare company in

the US, serving more than 50% of US hospitals and 20% of physicians.

The DiaSpect Tm is the world's fastest haemoglobin analyser and will be sold in the US from February 2019 by McKesson under its own branded line, as the McKesson Consult Hb analyzer.

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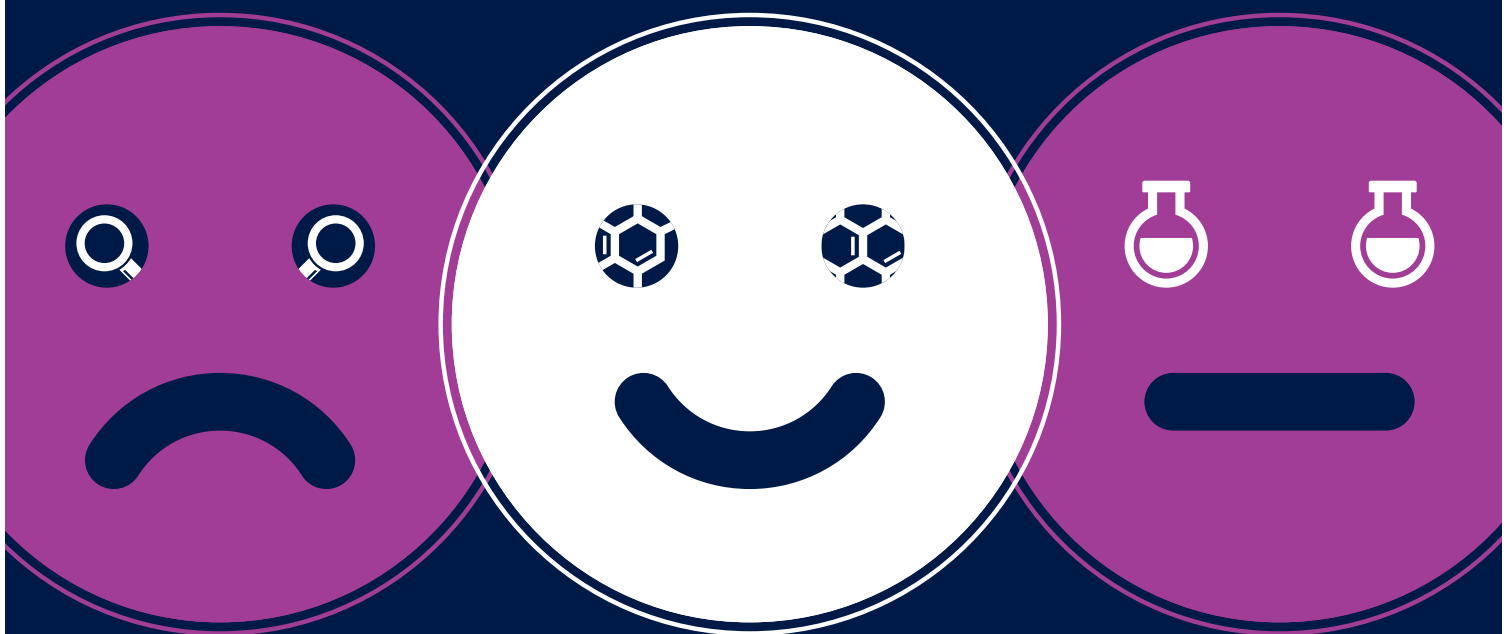
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THE BIG QUESTION



THIS MONTH WE ASK

“How does a laboratory
quality management
system benefit patients?”



Shauna McAuley

**Governance and Quality Manager
Belfast Trust Laboratories**

The essence of a laboratory Quality Management System (QMS) is providing the best service to our patients and service users. Every element is about assuring our patients, our employers and ourselves that we are providing a quality service – and we can prove it.

Each element drives towards ensuring that the results and products we release are as accurate and timely as we can make them. Quality management has been born out of a requirement to ensure products and services are safe for users, despite an increasing demand and limited resources. It allows us to provide a controlled, evidence-based method of assessing our performance and identifying any areas that would benefit from improvement.

The audit and incident management process helps us to identify any potential, or minor, issues in our processes promptly, allowing us to address their cause(s) and ultimately reduce the possibility of patient impacting events happening. This ensures we are continually improving the service for our service users, ensuring patient safety.

Good document control ensures that an updated, accurate, approved procedure is available at the point of use.

Our laboratory quality management system ensures we have the right staff, doing the right thing at the right time producing the right results, for the right patient at the right time. Right?



Janet Wells

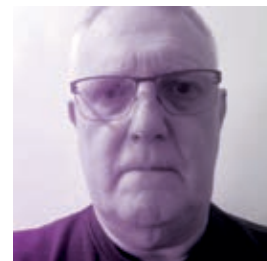
**Head of Department – Stem Cell
Transplant Laboratory
The Royal Marsden NHS Foundation Trust**

The stem cell lab at the Royal Marsden Hospital provides testing, processing, storage and release of stem cells that must be capable of repopulating the patient's bone marrow following high dose chemotherapy or radiotherapy treatments for malignancy.

Our patients must be able to trust that the laboratory staff will follow approved processes and procedures and that the cells they receive will provide them with the best chance of recovery. Our laboratory QMS not only helps us to meet the strict regulatory requirements that govern this area of medicine, but importantly, also provides reassurance to patients and their families as they go through their treatment.

For lab staff, the processing of irreplaceable cells can be quite stressful. The laboratory QMS assists in reducing the risk of errors and increases consistency, which in turn, ensures that all patients receive products of consistent quality. Cells may travel to us from around the world from volunteer donors or from other transplant centres whose quality management systems we, and the patients, rely on to provide us with suitable products.

Our QMS allows us to constantly improve our practice by making evidence-based changes through continual audit, which involves every member of the lab staff. This encourages staff to constantly question and challenge existing procedures and puts quality at the heart of our practice.



Neil Bilbe

**Operations Manager and Support Scientist
UK NEQAS for Immunocytochemistry and
In-Situ Hybridisation**

A QMS comprises a series of interwoven processes, all with a common aim: meeting customer requirements and satisfaction. In the laboratory, customer translates as the patient.

Documentation ensures processes are performed to agreed protocols, standards, and approved reference ranges; that are reproducible and followed unerringly.

The handling of a sample should follow a documented pathway; ensuring that the result/diagnosis is correct, accurate and there is an accessible audit trail.

Monitoring and maintenance of essential equipment, training of all staff and membership of quality assessment schemes – all contribute.

The laboratory's infrastructure, hardware, IT, personnel, and quality are subjected to regular and rigorous checks and scrutiny, to ensure precision and patient safety.

All processes are regularly audited, adverse findings or errors are fully investigated and steps are put in place to prevent repeat incidences. This minimises risk, eliminates bad practice, and provides a vehicle for quality improvement.

People, processes, protocols, performance, precision, patients.

This benefits the patient by providing timely, true, verified and finalised results – correct result to the correct patient

A QMS doesn't benefit anyone, least of all patients, unless properly implemented, overseen and maintained and adverse outcomes are acted upon within a culture of continual improvement.

IS DEPRESSION GENETIC?

Andrew McIntosh discusses an international research study, which analysed genetic data from more than two million people.

According to the 2013 Global Burden of Disease study, the most widespread mental health problem around the world is depression. In the UK, the 2014 Adult Psychiatric Morbidity Survey found that one in six adults has a common mental health problem, such as depression or anxiety, and the same year an ONS study reported that almost 20% of people aged 16 and over in the UK had symptoms of depression or anxiety, with a gender split of 22.5% for women and 16.8% for men.

Mental health conditions such as depression may be as big a problem as any physical disease, and yet the mechanisms that underlie them remain imperfectly understood. They are deeply complex issues, originating as they do in that most intricate of human organs, the brain. These conditions are known to result from altered chemistry in the brain, but what triggers those changes and upsets the balance is at the heart of the mystery.

A link between mental health issues and genetic makeup has long been proposed, and that potential relationship was placed on a firm footing earlier this year with the

publication in *Nature Neuroscience* of “Genome-wide meta-analysis of depression identifies 102 independent variants and highlights the importance of prefrontal brain regions.”

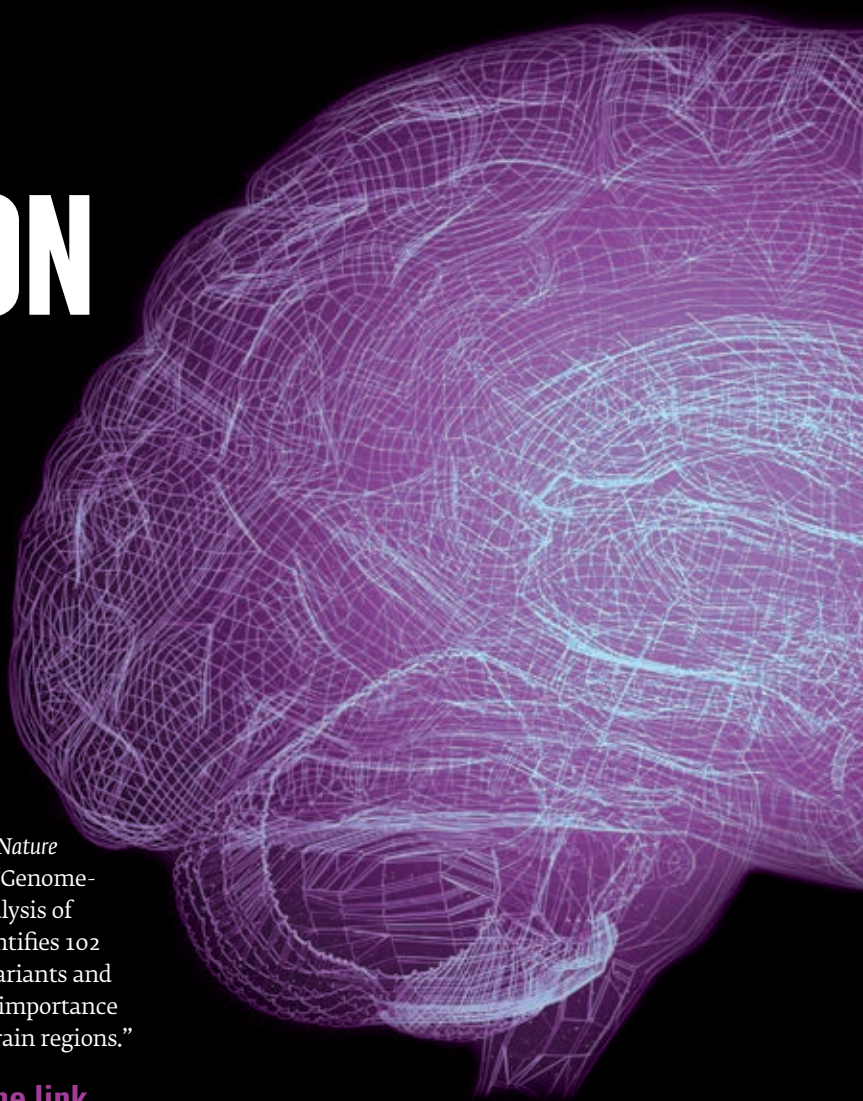
Establish the link

As the title suggests, this international study, which analysed genetic data from more than two million people, has linked 102 genetic variants and 269 genes with depression, and found connections between the condition and a range of other issues. The findings could now throw the way open to new therapies for treating the disease.

While the idea that depression is related to a person's genes has been around for many years, it has taken some time for research to establish this link with conviction. The man who led the research, Andrew McIntosh, Professor of Biological Psychiatry and a senior clinical research fellow at the University of Edinburgh Centre for Clinical Brain Sciences, says it has been a matter of scale: “Genetic research

in depression was initially limited to twin and family studies, which were able to show that there were genetic factors influencing risk, but without showing what the changes actually were. More recently, it has been possible to look at the molecular changes in individuals at greater scales using very reliable methods of genotyping and increasingly consistent and well-established methods of analysis. This has led incrementally to the identification of specific changes in the genomes of people with depression that influence risk.”

The key was having genetic data from more than two million people – though that in itself presents big organisational and technical challenges for research. “The sheer size of genetic data can





“There are almost certainly many thousands of genetic changes in depression”

be very challenging, even before any analysis has been undertaken,” says McIntosh. “But storage costs have reduced gradually over the years and computing speed has increased. In Edinburgh, like other universities, we have a parallel computing facility that can divide large, complex and slow processing tasks into thousands of smaller tasks. Individually, these smaller tasks take a few minutes to process and yield their findings, and because they can all take place together, and their results merged at the end, analyses can take place very quickly.”

Tip of the iceberg

While the results of this analysis may sound weighty – the 102 variants and 269 genes – the likelihood is that there are far more variants and genes waiting to be

ANDREW MCINTOSH

- ✓ Trained in medicine at the University of Aberdeen
- ✓ Post-graduate training in Edinburgh in psychiatry and applied statistics
- ✓ Leads the Generation Scotland Expert Working Group for Psychiatric Disorders
- ✓ Co-chairs the Major Depressive Disorder Working Group of the Psychiatric Genomics Consortium
- ✓ Fellow of the Royal College of Psychiatrists.



discovered. Indeed, McIntosh believes they have only isolated just the tip of the iceberg. “There are almost certainly many thousands of genetic changes involved in depression and, unlike many disorders, none seem to have large effect sizes,” he says. “While individually the effects are small, when taken together genetic risk scores that estimate vulnerability from the genome are likely to become ever more accurate and informative for risk-stratification with potential wider application to personalised treatment.”

These first gene variations detected by the research are clustered in the prefrontal regions of the brain, where the higher functions related to personality and complex thinking reside. The variations are thought to disturb the connections between the brain cells there, throwing some light on the mechanism that triggers depression. “The junctions between brain cells, the synapse, are understood to be very closely related to a number of behaviours and thinking skills, and studies of complex thinking skills and depression-prone dimensions of personality have repeatedly implicated the prefrontal cortex,” says McIntosh.

“This knowledge has been gained through animal research, studies of human post-mortem tissue and neuropsychological investigations. Demonstrating similar findings using a genetic approach demonstrates the ability of genetics to provide insights into the underlying biology of depressive illness. As sample sizes and our knowledge of human genome grow, I expect it will be possible to shed even greater light on how the brain confers the symptoms of low mood.”

Exploring all options

The research also established links between depression and other behaviour and disease traits, such as smoking. “The genetic correlations we found show that the changes associated with depression are associated with many other conditions and traits that are co-morbid with low mood,” explains McIntosh. “This may simply tell us that the same genes have two or more effects, a process known as pleiotropy. It could also mean that the correlated traits are somehow causally associated with each other, something we explored in the paper using Mendelian randomisation. A third possibility, rarely explored in genetic studies to date, is that there are subgroups of depression with different aetiologies – one of which is strongly related to the trait with which depression is strongly correlated. We are exploring all of these options.”

What’s next for McIntosh and his colleagues? Their findings have raised the possibility of new research avenues, which could involve identifying targets for new drugs or even “obtaining cells from people at high and low risk of depression and then modelling depression in a dish”.

Before that, the team is collaborating on a project called Genetic Links to Anxiety and Depression – or GLAD. It’s looking for 40,000 UK volunteers to donate their saliva: to unlock further genetic secrets of depression. See gladstudy.org.uk for more. 

Now the **100,000 Genomes Project** has hit its target, what comes next? We look at whether we are on the cusp of a **genomic revolution**.

Predicting the future is notoriously hard. Even the brightest minds fall foul – in 1932 Albert Einstein said there is “not the slightest indication that nuclear energy will ever be obtainable”. While 16 years ago Bill Gates proclaimed: “These Google guys, they want to be billionaires and rock stars and go to conferences and all that. Let us see if they still want to run the business in two to three years.”

This is perhaps why Professor Mark Caulfield, the Chief Scientist at Genomics England, does not want to be pinned down when it comes to the future of the rapidly evolving branch of molecular biology – genomics.

“The longer that you are involved in life sciences, the more that you know you can never know enough,” he says. “Sometimes you may be on rocky road, but you will always be learning. I don’t see this as

something where we can answer all the questions – when you answer a question, that opens doors to other questions that you’ve then got to try and answer.”

Transformation

Genomics is a relatively new discipline. It was only in 2003 – the same year Bill Gates made the above statement – that the human genome was first fully sequenced. Now, just over a decade on, it is the cutting-edge field that many are investing in, from big pharma (AstraZeneca plans to sequence two million genomes over the next 10 years) to governments (the new target for England is to sequence half a million genomes from the NHS in the next five years).

“We will sequence these genomes across 22 categories of rare diseases and, at present, four cancers,” says Mark. “We want to make sure that in 50 years people will look back and see genomics as an everyday routine thing... it’s got a big role to play. I hope

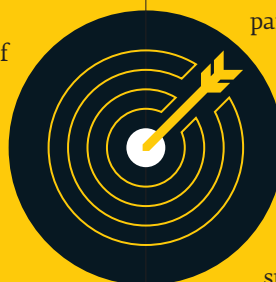
people will look back and see that we’ve done a transformative thing.”

Uncertainty

But because the field is so new, it is not yet known exactly what kind of a transformative effect it will have (See box, overleaf, for an alternative vision, from Gerry Thomas, Professor of Molecular Pathology at Imperial College London). In the future, will everyone have their genomes sequenced as standard? Will it be so integrated and intrinsic to the NHS that when a baby is born, it will have its genome sequenced? It’s something Mark has clearly considered.

“We would need to do significant research into whether society and parents would want that. It

would have to be based on parental choice, but there would be a case for considering that in the future,” he says. “We would need to have evidence and careful planning to make sure that our programme was



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designed with the highest quality outcomes and that it would be of utility and would not lead to anxiety."

Geneticist David Goldstein is heading up AstraZeneca's genomics initiative and is very open about the fact that he sees an uncertain future, too. "Everyone now recognises that genomics really is moving. It's not all hype anymore," he says. "A lot of the problem has been in acting like we can predict when genomic efforts will win clinically relevant insights. It's just not very predictable. He adds that much of the work will "not win insights that are commercially valuable to AstraZeneca" and that they are "not banking on a single project delivering".

While future outcomes may be uncertain, integration into the NHS is well underway. A total of 103,311 genomes have been sequenced from over 85,000 participants and 1,500 NHS staff have been involved in the work, along with 3,000 researchers and trainees worldwide. The National Genomic Medicine Service went live for certain tests in October and Mark expects it will go live for full genomes in July.

He says: "I think that what people will begin to notice is the increase in the range of testing and uniform national coverage, so there will be no risk of a postcode lottery. The founding principle of the NHS being free at the point-of-care will be enshrined."

Volunteering

That said, could the new "genomic volunteering" scheme announced by Matthew Hancock at the end of January undercut this? The Health Secretary said: "Seriously ill children and adults with

genetic conditions, including cancer, will be offered DNA analysis as part of their routine care."

He continued: "And, while healthy people should not have this service free on the NHS, there are huge benefits to sequencing as many genomes as we can – every genome sequenced moves us a step closer to unlocking life-saving treatments."

The scheme (costs and details of which have not yet been revealed) involves healthy people paying to have their genomes sequenced on the condition that they allow their data to be used by Genomic England.

Mark says: "The intention would be that we would recover the cost of the sequencing. There's an opportunity for people to understand more about their genomes, as long as they cover their costs. We are also looking at how we could use that money to pay for people who can't afford to have their genome sequenced. We think that the natural altruism of the British people means they will be happy to do that."

Mainstreaming

The project has already created 21 petabytes of data (50 petabytes would be

enough to store the entire written works of mankind from the beginning of history, in all languages). This is being interrogated by researchers all over the world, who are provided with access to the data on the condition that they share their findings.

But, while many researchers may have an advanced understanding of what all this data means, what about those on the frontline of the NHS? What about the biomedical scientists, doctors and nurses, all of whom will be increasingly involved as genomics becomes more widely used?

It was a subject that was under the microscope at the Festival of Genomics conference, which took place in London at the end of January. Among the dozens of sessions was a panel debate entitled "Mainstreaming Genomics and the Education of Interpretation".

Catherine Houghton, Lead Consultant Genetic Counsellor at Association of Genetic Nurses and Counsellors, said: "The pace of change is making it extremely difficult for us to have time on top of our clinical roles, in terms of the mainstreaming agenda." She added: "You can't expect someone in the mainstream to suddenly become an expert in genomics, it's about gradually increasing

"YOU CAN'T EXPECT SOMEONE IN THE MAINSTREAM TO SUDDENLY BECOME AN EXPERT IN GENOMICS, IT'S ABOUT GRADUALLY INCREASING KNOWLEDGE"

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knowledge and taking it step by step.”

Jonathan Roberts, a Genetic Counsellor from the Wellcome Genome Campus, added: “Uncertainty is a big challenge. There is a lot of uncertainty in terms of the results and the predictive value of what those results can be. I think uncertainty is something that we are all trying to get to grips with at the moment.”

Education

It is hoped that the Genomics Education Programme will resolve this uncertainty. The £20m three-year programme is supported by Health Education England as part of its responsibility to ensure the NHS has the staff it needs to deliver care now and in the future. Its role involves directly supporting those professionals involved in the 100,000 Genomes Project and microbial genomes work; supporting the wider transformation of services to integrate genomic technologies into healthcare; and upskilling existing staff so they can make the most of genomic technologies in their work.

This is being done through a range of means, including online resources and self-directed education, formal academic-based training programmes, workforce planning for the specialist staff, NHS-funded places for staff on training programmes and multi-professional clinical research fellowships and doctoral posts in genomics and bioinformatics.

But it is not just the workforce that needs to be taken into consideration. For the public, the nature of the tests is fundamentally different from the conventional tests they are used to.

Marks says: “One individual test for a single patient can have ramifications

LOST IN TRANSLATION?

Gerry Thomas, Professor of Molecular Pathology at Imperial College London:

“Introducing change into any healthcare system is not easy. Bringing in a whole new way to diagnose patients using DNA sequence rather than the tried and tested methods of biochemistry, morphology and localisation of proteins will be challenging for the NHS.

“Change is facilitated when those who are being asked to change can see the benefit of that change. The ability to be able to give a patient with a rare disease a name for their disease provides psychological benefit to the patient and has the (much) longer term potential to provide better treatments. However, the benefit to cancer patients is less clear, particularly when their care involves a complex multidisciplinary team. To make a difference clinically means turning round a test in a clinically relevant timescale and providing the information back to the doctor and the patient in a way that permits an informed choice to be made on treatment. The biggest challenge of all is the way in which genomics is rolled out in a manner that preserves the principles of ethics. Genomic medicine must be applicable to all relevant patients with the disease, and be proven to be beneficial both clinically and economically.

“It will not be the only way that diagnoses are reached and treatments are given – we are so much more than just our DNA. And only time will tell whether, as with so many other scientific ‘breakthroughs’, this project was the harbinger of a genomics revolution for the NHS or if it simply gets lost in translation.”



family-wide – it may not just tell them something about themselves, but their whole family.”

It’s an issue that Catherine Houghton addressed at the Genomics Festival. “It is important that the education of the patient happens before the tests are carried out, so that the patient knows the implication for themselves and their family. Genetic test results don’t necessarily give you a definitive answer and that needs to be put across to the clinicians and the public.”

Healthier for longer

This complex new world does not come cheap. Hundreds of millions have been spent and many hundreds more will be spent. “It is obviously costing a considerable sum of money,” says Mark. “But you can see where the economics of this can release cash. I’m not saying we

can save [the NHS] money, but we can release cash in some areas.

We’ve got to put money in the front end to get something out of the back end.”

He added: “Genomics could be the gift that keeps on giving by helping people avoid harm – we need to examine how we keep people healthy for much longer. More work is of course required, but we need to deliver a 22nd Century health service.”

We don’t yet know what this future will look like, and we don’t know what role genomics will come to play, or the impact that it may have on managing our health. Predictions about the future are notoriously tricky, but while there are too many variables and unknown factors for any certainty, it is looking increasingly likely that the future is genomic. 

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Our vision: Best care for everyone

Our mission: Improving health by putting patients at the centre of excellent specialist health care – Gloucestershire Hospitals NHS Foundation Trust.

Gloucestershire Hospitals NHS Foundation Trust provides acute hospital services to a population of around 612,000 people in Gloucestershire and the surrounding areas.

The Trust provides a wide range of specialist acute services, including a regional cancer centre, from its two large general hospitals — Gloucestershire Royal and Cheltenham General Hospital — with further services being offered at Stroud Maternity Hospital. These three hospitals provide approximately 1,100 beds to the population it serves. Six additional locations in the region serve as outpatient clinics.

As a major pathology supplier, Beckman Coulter are working with the Gloucestershire Hospitals NHS Foundation Trust to help deliver on their vision, mission and strategic objectives. One priority is to implement a model for urgent care that ensures people are treated with the very best expertise to maximise their chances of survival and recovery. As the Trust's partner, Beckman Coulter offered to replace some aging full blood count analysers with the new DxH 900-based solution, which offers one of the most compact and productive haematology systems available in the UK. The DxH 900 also satisfies the Trust's goal to use technology to improve service.

The DxH 900 platform boasts a 93% first pass rate, which means repeat/reflex analysis and follow-up actions are kept to a minimum. This ensures the best turnaround times can be achieved, including those for some of the most

acute patients arriving through A&E.

This high first pass rate is achieved with the innovative yet robust analytical technology incorporated into the DxH900 platform. The technology features minimal reagent requirements when compared to the rest of the market, releasing staff from laborious tasks related to changing reagents and the subsequent verification activities which are becoming more commonplace. This is a great example of just one of the many interventions which has been reduced or eliminated as one of the key design goals of this new platform. In the event that staff intervention is required or will be in the near future, this is clearly indicated with a

prominently positioned coloured light bar and ceiling projection system. This ensures that even if a workcell cannot be seen, current or pending needs will signal clearly to prevent interruption to workflow, which is key to all NHS laboratories (especially during morning and afternoon peak demand).

With a focus toward patients in A&E with the greatest need, the Pathology team will soon begin investigating a clinical offering unique amongst haematology analysers. The Early Sepsis Indicator application from Beckman Coulter, bearing the CE marking, is a tool to help in the early identification of sepsis in adult patients arriving in the A&E department. With this tool, there are no additional tests for A&E clinicians to order, nor is extra work necessary in the Pathology department in order to benefit from this new capability. And to comply with accreditation requirements, Early Sepsis Indicator measurement is backed with daily quality control which includes an FBC component.

Together Beckman Coulter and Gloucestershire Hospitals NHS Foundation Trust are moving healthcare forward.





APPRENTICESHIPS OPENING DOORS

The blending of vocational learning and academic education is commonplace within biomedical scientist education, and so the recent emergence of the degree apprenticeship agenda offers exciting opportunities, write **Ian Davies** and **Katie Berger**.

Initially launched by the government in 2015, degree apprenticeships are underpinned by a fixed “apprenticeship standard” – a set of knowledge, skills and behaviours written by a trailblazer group of employer representatives.

For practitioners across the healthcare science professions, the level 6

Healthcare Science Practitioner Standard provides the broad, high-level expectations on values and behaviours that employers and the public would expect from anyone working within a clinical diagnostic environment, from cardiac physiologists to biomedical scientists. Importantly though, whilst integrating the apprenticeship standards allows access to Government

levy funding, the standards alone do not confer eligibility to apply for HCPC registration, and so for biomedical scientists, programmes must also provide accessibility to this route through IBMS accreditation and/or HCPC approval.

Integration

At Staffordshire University, the advantages of integrating the apprenticeship standards within our part-time degree structure were an obvious response to an employer need for vocationally-focussed opportunities for staff development. Although part-time study has always been a possibility, finance and delivery patterns often presented hurdles to keen and able staff working within pathology support roles. By developing a blended learning approach, utilising online learning platforms, study days and – as the students develop – incorporating more and more work-based learning, we have been able to develop a programme that is sustainable financially and operationally, to support staff progression.

An important aspect of degree apprenticeships is their role in widening



participation in higher education. They can open up career progression to new or current employees who may be reliant upon earning an income whilst they study. As Professor Ieuan Ellis, Pro Vice Chancellor at Staffordshire University, comments: “The ability to earn while you learn opens up degree education to those who otherwise may face financial barriers, for example those with carer responsibilities or returning to education. The value of this in raising aspiration and providing opportunities to develop social mobility is transformational – from an employer perspective, this can contribute greatly to local staff recruitment and retention.”

Balance

Although apprenticeships offer a great opportunity, they are not an easy option. Students need to work through the academic content of their degree while maintaining performance within their job roles, balancing the expectations to achieve both academically and vocationally. For employers too, there are factors to consider, including an Education and Skills Funding Agency

requirement for 20% of apprentices’ working hours dedicated to “off the job” training. The payback, however, is great, developing a talent pipeline of resilient and vocationally focussed biomedical scientists. Dr Chris Chase, Training Manager at Hull and East Yorkshire Hospitals NHS Trust, strongly supports the development of apprenticeship opportunities. He says: “Apprenticeships are now an integral part of our workforce development, providing a means of developing a skilled, motivated and qualified workforce. At Hull we have apprentices across all areas, biomedical science, IT, and administration and clerical all contributing to the continuity of our vital service.” Karen Kendal, Deputy Cytology Manager at The Royal Wolverhampton Hospitals NHS Trust, who is currently supporting three staff through the degree apprenticeships, adds: “The apprenticeship levy has allowed growth within pathology, giving support staff the opportunity to develop skills and qualifications which current training budgets could not support. Staff have fed back that they feel valued and are motivated to pursue a career in pathology. We are now in a position to ‘grow our own’ staff at a time when recruitment to posts is increasingly difficult.”

Potential

The ability to develop potential is key for students as well. Ian Blanshard, a Medical Laboratory Assistant in the Microbiology Department of Mid Cheshire Hospitals NHS Foundation Trust, was one of the first apprenticeship intake at Staffordshire University. Now in the second year of his degree, Ian reflects on the opportunity to further his education and advance his career whilst not being in a position to leave work and enter into education full time. “It allows me to learn in an environment with knowledgeable staff, and gain the experience I require from within a working laboratory, providing me with the necessary skills to gain a degree level education as well as

KEY FACTS

- ✓ Since 2017, employers with a payroll over £3m must pay 0.5% of their pay budget to Government as their apprenticeship levy.
- ✓ Funding for apprenticeships at all levels can be drawn from the levy paid by your trust.
- ✓ Employees receive 20% of their time “off the bench” to undertake learning and education.

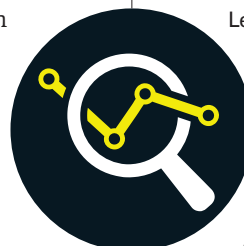
completing my IBMS portfolio”. Similarly, Donna Simms, an Associate Practitioner in the Cellular Pathology Department at University Hospitals of North Midlands NHS Trust, says having worked within the laboratory for 10 years in the same role, the scheme has proved invaluable for her future progression “enabling staff who have the appropriate professional characteristics and technical skills but lack the correct qualifications, to progress”.

As with any learning and teaching, one size does not fit all, and learners on different educational pathways all bring different skills and experiences to their employment. The apprenticeship programme recognises this, and provides an additional pathway towards biomedical scientist education and registration. Employers recognise the need for a mixed economy of pathways and graduates, from full-time applied biomedical science degrees, to degrees with approved supplementary education and degrees achieved through apprenticeships routes. This blend of pathways and experiences will all contribute to an agile and skilful future biomedical science workforce. 

Ian Davies is Healthcare Science Course Leader at Staffordshire University.

Katie Berger is Quality and Training Manager at University Hospitals of North Midlands NHS Trust.

Katie and Ian won the IBMS “Inspiring the Future Biomedical Workforce” award at the 2018 Advancing Healthcare Awards.



Some of you may recall an article that I wrote in *The Biomedical Scientist* on a trip to Antarctica and the opportunities for CPD and risk management on the cruise. It seemed like a good idea to follow that trip up with a visit to the Arctic.

I booked to travel to Svalbard and to spend a short time there before embarking on a cruise round the coast to visit historical sites, do some hiking and look for wildlife.

Svalbard is a Norwegian territory with research stations and the most northerly inhabited settlement in the world, Ny-Ålesund, 790 N, which is basically a town dedicated to research activities. To give context, Svalbard is as far north as the top of Greenland.

Opportunity to learn

The trip to the Arctic was another opportunity for learning about the biology

of plants, birds and animals in a polar environment, with lots of health and safety and risk management information. We had to attend a compulsory briefing on safety e.g. getting in and out of zodiacs from the ship and the shore, have the emergency procedures explained and practiced and, most specifically, have a safety briefing with regard to polar bears.

Other than the centre of Longyearbyen, the main town on Svalbard, you cannot walk around without an armed escort or your own rifle.

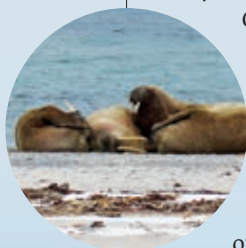
On all the excursions the expedition crew posted look outs and carried rifles which were checked in and out of the ship store. We also had a Russian polar bear expert in the team. The other big risk assessment you could do was assessing whether you would like to do a “polar plunge”, jumping off the ship into the sea. I reckoned this presented an unacceptable risk of a possible heart attack, so declined. As a safety precaution a rope was attached

to all those who did take the plunge and no one fell prey to any wild life.

Another risk assessment that had to be considered was ensuring the zodiacs did not go too close to the faces of glaciers in case of getting swamped following a calving from the front of the glacier. We had an unexpected issue one day when the inlet we were in was quickly filled with floating ice and it took a very long, cold time to negotiate our way back to the ship.

Presentations

As is common place on any cruise ship, there were stations around the ship with antimicrobial hand gel to avoid the spread of infections, notably norovirus. We were advised on a daily basis about the amount of clothing to wear: the weather was truly Arctic and several times the expedition leader advised us to put on everything we had. We came closer to the pole than we did in Antarctica and were the first cruise ship of the season this far north, so it did get rather chilly. At this time of year the sun does not set and remains high in the



THE SUN DOES NOT SET

After last year's article on a CPD trip to Antarctica, Pathology Services Manager **Sue Alexander** sets sail again, this time for the Arctic.



*“It was a chance
to note how
parallel evolution
takes place”*

Pictures. All photographs
taken by Sue Alexander

sky. This is quite disorientating, as you cannot judge the time of day or directions.

On sunny days the landscapes are wonderful: on cold, snowy days it is bleak yet there is still a beauty, even at sites of industrial archaeology.

Each day there was a lecture presentation about something related to the trip: from the complexities of the local dwarf reindeer's circulatory adaptations to the cold, to birdlife via the historical places visited. The first recorded visit to Svalbard was by Willem Barentsz in 1596 who named the island, Spitsbergen, as he landed at an area with pointed mountains. The first ever whaling station set up by the Dutch was the pragmatically named Smeerenburg, or Blubber Town, established in 1619. We also visited two

sites where early historic attempts to reach the North Pole started out, neither successful. The expeditions took little or no regard of the local information provided by experts such as Nansen, nor of weather conditions and did not carry adequate supplies of food. So, useful learning to apply to project planning: be properly prepared and take expert advice.

Seeing wildlife

It was very nice to be able to get close to the reindeer, Arctic foxes hunting and dozing walruses on land, while we saw a number of types of seal at sea and on ice floes. I discovered that polar bears are prey to a parasite, which also affects other wild life, *Trichinella* species, and which can be contracted by man, so hunters are

advised by the CDC website about proper handling and cooking of meat.

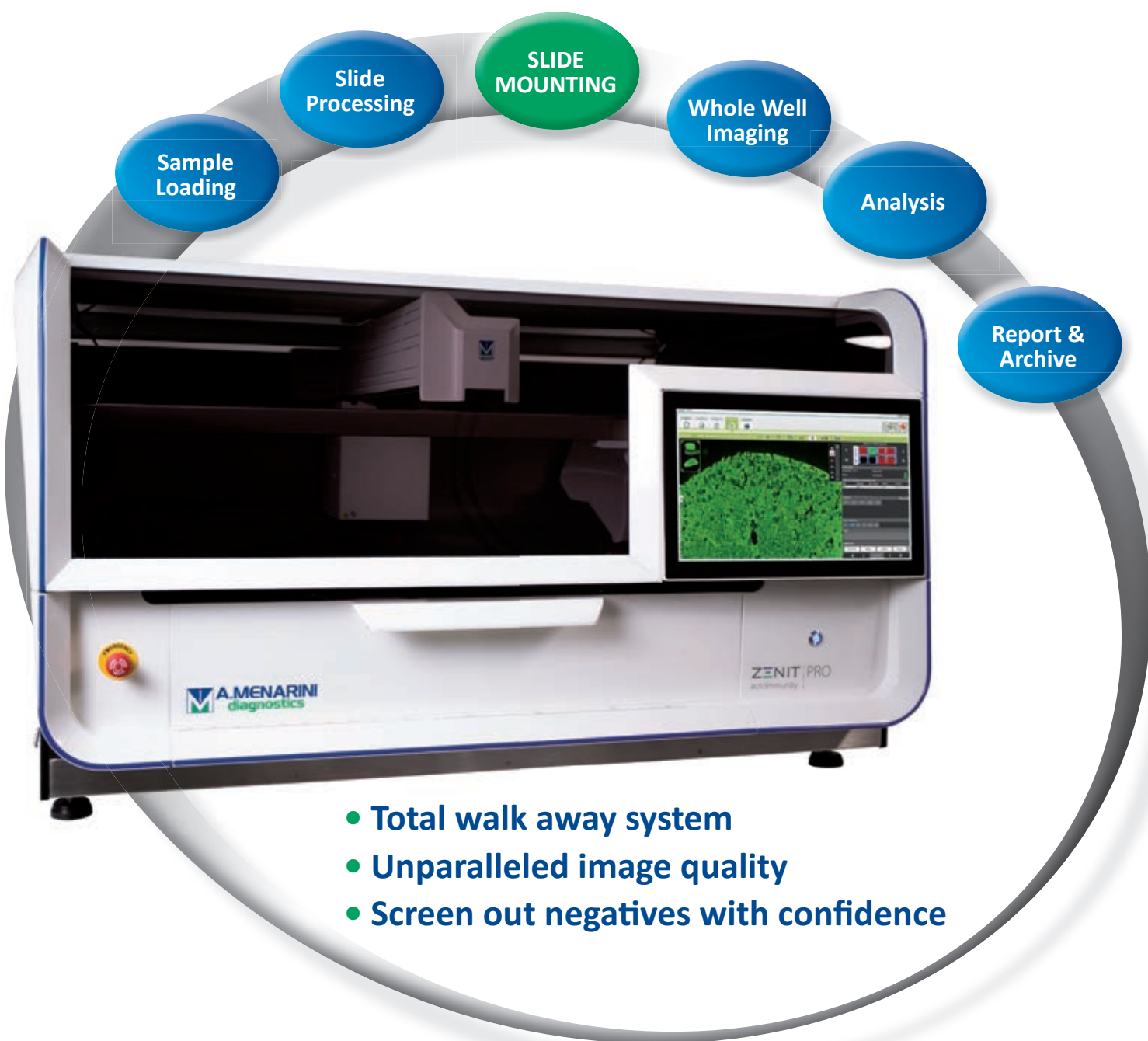
The birdlife is highly diverse: there was a chance to see ptarmigan on a lek and the sadly endangered puffin. Guillemots, resemble penguins, and flock on huge cliff faces and the fulmar is similar to the albatross. It was a chance to carry out comparative biology and to note how parallel evolution takes place.

So, this was another trip with a real difference, lots of biological and historical CPD, quite a lot of risks to consider, plenty of health and safety and food for thought about project planning. If you fancy a diversion into research and don't mind a long, dark winter, Svalbard is the place for you to apply.

And to answer the big question: yes, we did see two polar bears, which was absolutely amazing. Such powerful and beautiful creatures. 

Sue Alexander is the Principal Biomedical Scientist and Pathology Services Manager at The Royal Marsden NHS Foundation Trust.





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Autoimmunity symposium

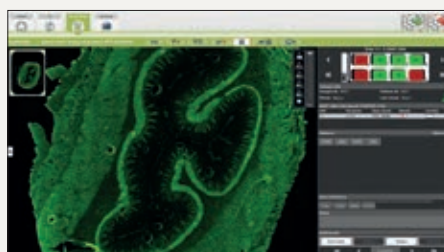
To celebrate the launch of the Zenit PRO, Menarini Diagnostics hosted an Autoimmunity symposium. This was attended by scientific staff from across the country despite very challenging weather conditions. The following is an account by Ms Amani Elhouderi of Imperial College Healthcare NHS Trust; reflecting on the day's events.

I had the pleasure of attending an event on next generation immunofluorescence assay (IFA) testing hosted by Menarini Diagnostics on 1st February 2019. The event took place at the company's UK headquarters in Wokingham.

An expert in the field of 'leaning' NHS pathology services, Mr Terry Coaker, led the first presentation. He shared his knowledge and experience on lean practice. It was insightful to learn about real life examples of laboratories that have managed to improve efficiency and simplify workflow. Mr Coaker, reduced turnaround time for his department from seven days to less than five days despite an ever increasing workload. One of the main components of this success was to divide the team into small groups and to follow a vertical instead of horizontal workflow.

The main focus of the day was Zenit PRO - a new totally automated instrument used for IFA analysis, which streamlines the complete IFA protocol, including slide processing, reading and interpreting results. The audience, who were a mix of experts in IFA testing, had the opportunity to learn more about the analyser through a well constructed presentation and a live demonstration by Mr Jake Morrow (Autoimmune Business Specialist – Menarini Diagnostics).

The main features and benefits of the Zenit PRO were highlighted; eliminating errors due to manual preparation and reader subjectivity, reducing intra & inter



Digital image produced by the Zenit PRO on Endomysial substrate.

laboratory variability and the ability to manage high workload with reduced turnaround times. Glass cover slipping is automated giving true walk away time. Moreover, the Zenit PRO system is uniquely CE marked for result interpretation; this includes HEP2, anti-neutrophil cytoplasmic antibody (ANCA) and Crithidia substrate.

A presentation by Ms Trudy Walker from Hull University Teaching Hospitals NHS Trust followed. The Trust is the first in the UK to start evaluating and using the all in-one, fully automated platform. The team from Hull University presented valuable validation data collated on several autoimmune assays. These included autoantibodies relating to liver disease, LKS (Liver, kidney and stomach), ANA (antinuclear antibodies) and ANCA that were all tested on the Zenit PRO. The analyser's performance characteristics and precision were compared against conventional IFA

methods used. This month Hull University will be the first in Europe to go live using the Zenit PRO.

Ms Filipa Cardoso, a rheumatologist from Lupus UK, presented the final session on a study looking at "the incidence and prevalence of systemic lupus erythematosus (SLE) in the UK, 1999–2012" which pointed to the decline of SLE incidence and the increasing prevalence and risk factors that might contribute to this trend. Ms Cardoso, who is heavily involved in research regarding lupus sub types, ended the presentation by reminding the audience the importance of ANA detection using HEP2 substrate.

Reflecting on my experience, I had the opportunity to learn about the Zenit PRO; state of the art technology, and to network with leading experts in the field of Immunology. I would like to thank and congratulate Menarini Diagnostics on putting together an insightful symposium and I look forward to their future events.'

The Zenit PRO represents the ideal solution for autoantibody testing with gold standard methodology and processing. The combined slide processor and digital microscope produces unrivalled image quality with total automation; including glass coverslip mounting. The Zenit PRO brings IFA in line with the demands of the modern laboratory with the backing of international standardisation through exclusive ICAP reporting.

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WAR ON CANCER PT. I

THE DEVELOPMENT OF CHEMOTHERAPY TO 1950

A review of the early historical development and use of chemotherapy to treat different cancers. The phrase “war on cancer” refers to the recognition of cancer as a major cause of death and the need to act, resulting in increased funding, clinical trials and the development of more effective treatments.

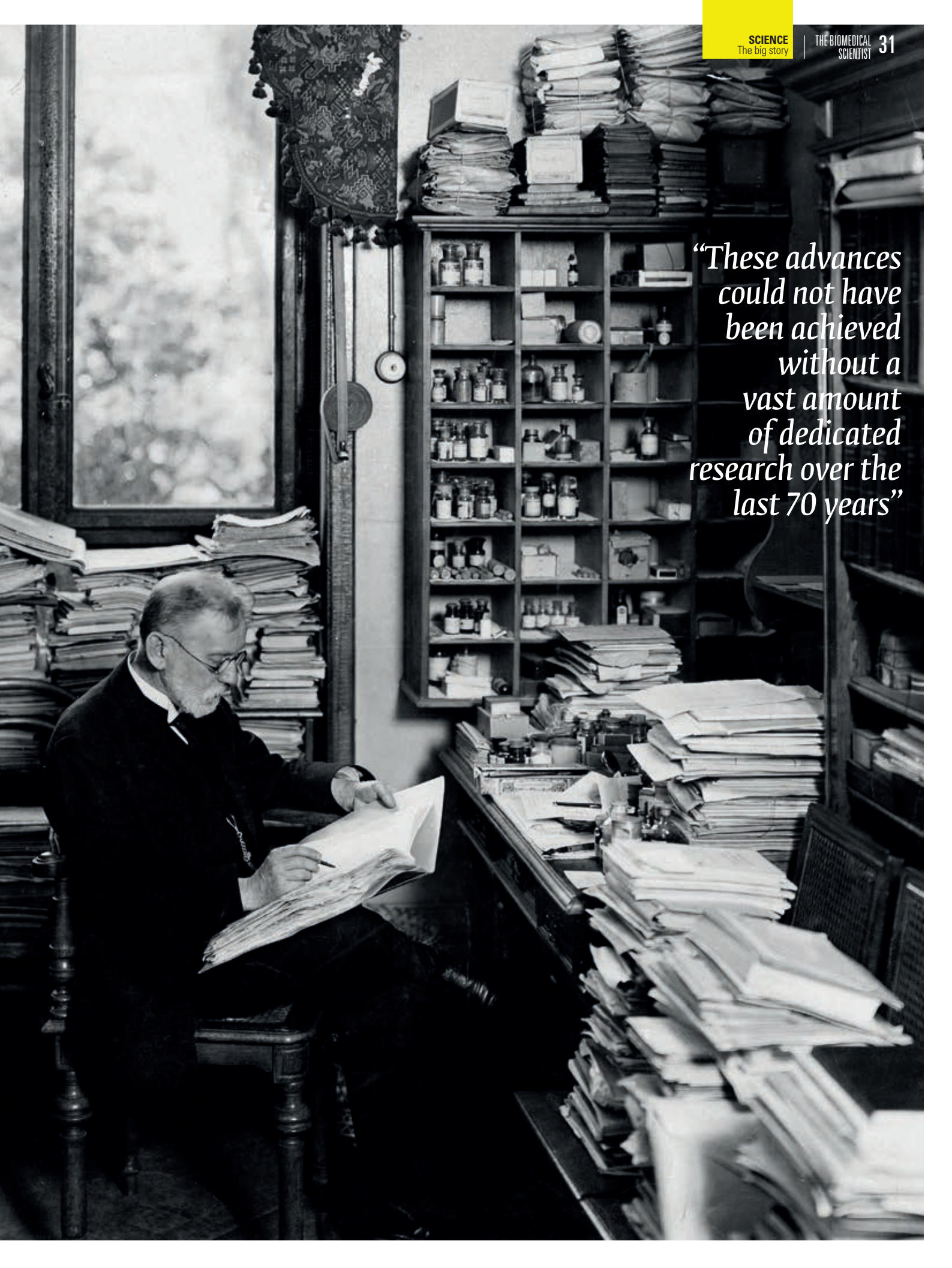
The Nobel laureate, German scientist Paul Ehrlich (1854-1915) pioneered chemotherapy during the early 20th Century. He coined the term “chemotherapy” and researched a large number of chemicals to screen their effectiveness in the treatment of infectious diseases, those succeeding he described as “magic bullets”.

He was also one of the first to use animal models for chemical research, which would much later be used to screen chemicals using transplantable tumours in a range of

animals. In addition, he also experimented with aniline dyes and simple alkylating agents in cancer treatment.

Cancer chemotherapy may be broadly defined as often a cyclical process to deliver a chemical agent (CA) or cocktail of chemical agents to selectively target and destroy cancer cells. At this time a vast range of CA have been developed to optimise this process in different modes, such as adjuvant chemotherapy, based on the type and stage of cancer, response rate, individual patient status and tolerance and with a view to minimise toxic side effects. Standard protocols have





*"These advances
could not have
been achieved
without a
vast amount
of dedicated
research over the
last 70 years"*

now been developed for most types of cancer managed by a consultant oncologist. These advances could not have been achieved without a vast amount of dedicated research over the last 70 years.

Ancient medicine

There is some evidence from Egyptian papyri that suggests herbal preparations were used topically in malignant diseases. The Greek physician and pharmacologist, Dioscorides produced *De Materia Medica* around 70 AD – a five-volume compendium of the medicinal properties of plants and minerals, including some which were used for the topical treatment of cancer.

Around the same period, traditional Chinese medical procedures were using herbal remedies for cancer treatment. Surveys show a long history of herbal preparations, which continues today in cancer patients as alternative or complementary treatment. It should be noted that some studies have demonstrated positive responses in prostate, lung cancer and non Hodgkin's lymphoma.

Arsenic salts

In view of their toxic nature it is perhaps surprising that arsenic salts have been used therapeutically for over 2,000 years. Most literature sources record its first use as 1865 by Lissauer, using Thomas Fowler's solution of arsenic trioxide in sodium bicarbonate (1% w/v), to clinically improve a patient with chronic myelogenous leukaemia (CML). A report from Boston City hospital in 1878 of an arsenic trioxide treated patient with CML includes some haematology results showing a reduced white cell count with this regime. During the next decade arsenical pastes were used for cancers of skin and breast. The introduction of radiotherapy in the early 20th Century reduced the use of arsenic salts.

However, great interest has been generated by reports from Chinese studies in 1996, which show successful clinical and haematological results in acute

promyelogenous leukaemia (APL) with low dose arsenic trioxide, without bone marrow suppression and few side effects. These findings were confirmed by US randomised clinical studies and the commercial form, Trisenox, was approved for use by Federal Drug Agency in 2000 for refractory or relapsed APL.

A number of theories have been proposed for the mechanism of action of arsenic trioxide in cancer. These include induction of apoptosis, antiproliferation and inhibition of angiogenesis using a specific cell line (NB4) derived from the bone marrow of a patient with APL. Waxman and Anderson from the US in their 2001 review of arsenic derivatives in cancer, provide more details on these complex mechanisms. More recent studies in 2015 propose that arsenic trioxide inhibits an enzyme (PIN1) – a key regulator in oncogenic signalling pathways and used with retinoic acid, may be of clinical value in triple negative breast cancer.

Mustard gas

Mustard gas (MG) is the collective name for a group of toxic chlorinated hydrocarbons with a sulphur or

nitrogen atom, thus nitrogen mustard is (methyl bis) (beta chlorethyl) (amine hydrochloride) or more simply mechlorethamine. It was first synthesised in 1860, and the sulphur form was used as a dispersed mist during World War 1 to attack occupied trenches. It is extremely irritant to mucous membranes, may form painful skin blisters and severe respiratory tract damage which may lead to potentially fatal bronchopneumonia.

Imperial War Museum records estimate there were 6,000 war fatalities and 185,000 injuries due to mustard gas and an inestimable numbers of soldiers suffered long-term mental health issues. MG causes suppression of haemopoiesis and was more fully examined in 1919 by US Pathologist Edward Bell Krumbhaar, leading a research team at the University of Pennsylvania who reported low white counts and that autopsy revealed lymphoid atrophy and bone marrow hypoplasia.

Thus its potential was recognised for cancers affecting lymphoid and myeloid proliferation, further studies were made by James Ewing, and also Frank Adair and Halsey Bagg in 1931 to test its





Page 30. Dioscorides studying a mandrake root for *De Materia Medica*

Page 31. Paul Ehrlich in his workroom (1910)

Left. World War I Gas attack, circa 1916

“Records estimate there were 6,000 fatalities and 185,000 injuries due to mustard gas”

Hodgkin's lymphoma. MG is an alkylating agent and is an effective CTA by forming covalent bonds with nucleic acids or key proteins forming crosslinks and interferes with enzymes involved in DNA replication.

Folic acid antagonists

In landmark studies reported in 1931, English haematologist Lucy Wills assessed the effect of diet changes on albino rats with induced macrocytic anaemia and found it was prevented by adding yeast extracts to a diet otherwise lacking B vitamins. In subsequent studies it was shown that a factor in yeast extract (“Marmite”) added to the diet was also found to correct macrocytic anaemia in human pregnancy. Thus an association between a dietary new factor and bone marrow function and erythropoiesis was established. This was also shown to be present in animal liver and green leafy vegetables and identified as folic acid by isolation from spinach leaves in 1941 and its structure determined in 1945. The availability of folic acid provided an opportunity for further research into its physiological role and metabolism.

Sidney Farber, a leading pioneer US paediatric pathologist at Harvard Medical School and Boston Children's Hospital, had many clinical interests, notably acute lymphoblastic leukaemia (ALL) in childhood, to improve the very poor prognosis. Previous studies had shown the clinical value of folic acid in anaemia with some similar haematological features to ALL, however, folic acid treatment failed and results even suggested that folic acid allowed further proliferation of cancer cells in leukaemia.

In 1947 Farber conducted a clinical

trial with the folate antagonist aminopterin in an attempt to block the action of folic acid and 10 of 16 children showed a temporary remission. Farber collaborated with Harriet Kille of Lederle Laboratories to produce other folate antagonists, notably methotrexate, and demonstrated that antifolates could suppress the proliferation of malignant cells and re-establish normal bone marrow function.

Concluding comments

The principle of using such toxic substances as arsenic salts and nitrogen mustards in cancer treatment now seems extreme. The latter was a belated follow-up of autopsy evidence from World War I soldiers exposed to mustard gas. The discovery of the link between folic acid and bone marrow function and erythropoiesis provided the inspiration to use folate antagonists to treat children with ALL. It is also worthy to note that only temporary remissions were achieved with these early agents.

Nevertheless, Paul Ehrlich, Edward Krumbhaar, Alfred Gilman and Louis Goodman with their Yale colleagues and Lederle Laboratory collaborators, and Sidney Farber laid the foundations for chemotherapy in the first half of the 20th Century and there was cautious optimism for the future of chemotherapy. 

Stephen Clarke is a retired IBMS Fellow.

To see the references, view the article online at thebiomedicalscientist.net

suitability for other cancers. With the advent of World War 2 more research was undertaken, most notably by young US pharmacologists Alfred Gilman, Louis Goodman and their co-workers Frederick Phillips and Roberta Allen. Due to wartime security the reports of their work were not published until 1946. Gilman and Phillips reviewed the chemical, pharmacological, toxicological characteristics and animal experimentation results with mustard gas.

The first clinical application took place in 1942 at Yale on a radiation-resistant patient with lymphosarcoma given 0.1mg/Kg i.v. daily, who showed a dramatic improvement with easing of obstructive symptoms due to tumour masses. However, it proved to be a temporary remission and tumours returned.

Further clinical trials were conducted at several centres in the US on a range of patients with different cancers-mainly Hodgkin's disease, lymphosarcoma and various types of leukaemia. The authors reported cautious optimism for these conditions but it was found there were serious limitations for other cancers.

The nitrogen mustard, mustargen was approved by the FDA in 1949 for a defined range of cancers and may be used today in combination chemotherapy for notably



Biomedical science graduates enter a rapidly changing employment environment and have to be able to “hit the ground running”; this often means newly-qualified biomedical scientists are covering shifts much earlier than their predecessors may have done.

The research

A research project was undertaken to ascertain if the current degree course structure and content are aligned with the educational and developmental needs of future biomedical scientists and the requirements of NHS services. A qualitative questionnaire was constructed to evaluate the undergraduate degree process, with questions relating to the institution of study, duration and structure of the course, and whether it consisted of discipline-specific practicals linked to specific lecture topics. These were distributed to 50 Band 5 biomedical scientists in histology, microbiology, clinical chemistry and haematology across seven UK hospitals who had graduated from 16 UK universities.

The Quality Assurance Agency (QAA) for Higher Education released new standards in 2015, which have made some adjustments to the degree course, primarily to reflect the integration of molecular pathology and genomics into mainstream pathology. However, the individuals in the survey would have graduated from courses based on the 2007 QAA benchmark statement contents and it would not be possible to see if the newer standards had made any significant difference to course outcomes.

Practical experience

The survey responses demonstrated there is a difference in the approach to course structure. This would likely be a reflection of differences in lecture staff, research interests, the governance structure of the establishment and whether the course

had a practical placement. Students who had undertaken a laboratory placement felt that the practical experience gained had been highly valuable, irrespective of whether the placement had been for 12 weeks or a full one-year sandwich course. These responses contrasted strongly with those from a non-integrated course, which showed that less than 30% offered practicals that were specifically designed to reflect routine pathology laboratory practice and those whose courses did felt

that they did not replicate the working environment in a meaningful manner. This showed the value of integrated degrees with a laboratory placement as part of the accredited course, enabling a “real” laboratory experience. In this respect, it is not strictly fair to compare the outcome of an integrated biomedical science degree with that of a course without a placement. The students do not have the same level of practical understanding or experience of the

FROM LECTURE TO LAB

Transfusion Practitioner **Lisa McKain** and Haematology Operations Manager **Lorna Philpotts** look at the application of academic learning in professional practice.

employment environment, but should have the same theoretical knowledge.

The use of experienced biomedical scientists as sessional lecturers to deliver discipline-specific material greatly benefited the students by enabling them to learn the most current and relevant clinical information or processes. This experience can be strengthened if students are able to undertake laboratory practicals that mirror the tests that they would encounter in a laboratory. It is well



documented that practical exercises, if used correctly, are a strong teaching tool that aids the student learning experience and onward developmental practice.



Partnerships

This study showed the importance of the university-employer liaison groups that are a key requirement of Institute-accredited courses. The purpose of these groups is to enable designated individuals, who may also be responsible for laboratory training, to have input into the development of course content. This link aids awareness by the university of what is expected in a laboratory, whether hospital or research facility, and is of benefit to all students, not just those with a placement. In courses that do not have a placement, the universities should still work in partnership with employers with the option to organise laboratory tours and maybe during the visit include some minor lab work. This would give students an opportunity, albeit a brief one, to experience a “real” laboratory and possibly gauge if this is the career they wish to pursue.

Critical thinking

Motivation and challenge of the student requires a balance of teaching and learning techniques. Critical thinking is one of the most important skills for biomedical scientists and its development is helped by problem-based learning to prepare them for the professional environment. Although this is the benchmark requirement of post-graduate learning, it is a skill that has its foundations at the undergraduate level and, from the research responses, was felt

to be lacking. Incorporation of critical thinking into teaching practice allows the concept of active experimentation and concrete experience to be harmonised. This fulfils not

just the learning experience, but arms students with a major fundamental employment skill, which will be an asset in any graduate career.

In addition, case study-based learning is an excellent means of preparing for the role of a registered band 5 biomedical scientist. The introduction of practicals that involve reviewing theoretical patient cases with sets of pathology results is an effective means of demonstrating the significance of pathology in a patient care pathway.

In conclusion, we believe an active partnership between employers and HEIs is key to delivering a strong undergraduate course, with graduates ready and prepared for employment in a clinical laboratory. Those graduates best equipped for employment in a clinical laboratory are those that have graduated from an Institute-accredited integrated degree course and this should be a key selection criterion for interviews.

The best outcomes are associated with courses where there is strong engagement between employers and universities to enable regular course reviews for each pathology discipline and exposure to technological advances and new equipment. Such changes will have a major impact on the employability of biomedical science graduates needed within the current climate. 

Lisa McKain is a Transfusion Practitioner at University Hospital, Birmingham and **Lorna Philpotts** is Haematology Operations Manager at Heartlands Hospital, Birmingham. Both are sessional lecturers on MSc Biomedical Sciences at Coventry University.



REFLECTIONS OF A QUALITY MANAGER PT.1

Mairiead MacLennan looks back over the changes in diagnostic laboratory accreditation that have come into force over recent years.

Information on quality management and accreditation is available from a variety of sources. However, there are still misunderstandings and gaps in knowledge when it comes to setting up, maintaining and continually improving systems in our diagnostic laboratories. UKAS is also continually improving its processes for accrediting laboratories, so it's little wonder it can feel like the goal posts are always moving.

The transition project from CPA standards to ISO 15189 was a mammoth undertaking by UKAS, with ongoing recruitment and training of Assessment Managers as the project grew. UKAS also trained self-employed Technical Assessors and "volunteer" Technical Assessors, released on paid absence by their NHS employers, to perform assessments. They are paid their travel and subsistence, but no fees. In return the rate paid by NHS customers is reduced and many laboratories appear to be unaware of this.

Experiencing difficulties

For many, the step up to ISO 15189 has been a much larger undertaking than anticipated, complicated by structural and political developments in the delivery of health care services. Rising costs and new diagnostic developments, coupled with patient awareness and expectation have contributed to difficulties experienced by laboratories in meeting

accreditation requirements. Even after the UKAS road shows, some laboratory staff felt like "rabbits in headlights" during and after initial assessments. There were stories of 'over a hundred findings' at initial assessments. Some staff with 40 years experience called it a day, a little sooner than they might have. A number of experienced staff who had adjusted to the introduction of computers onto the work bench, were lost due to perceptions about the requirements – for example, calibration of measuring devices for simple laboratory tasks. Of course some of the stories were exaggerated and the others were pure myth, but much sound, useful information was shared in laboratory networks. Now, with many laboratories through to their fourth assessments and a few preparing for their second major assessment, where are we? How much have we learned, what has been gained and where do gaps in knowledge and understanding remain?

Evolution

Scotland is extremely lucky in having the IBMS-affiliated Scottish Quality Management Discussion Group (SQMDG), formed by biomedical scientists in 2005 for those working or interested in laboratory quality management.

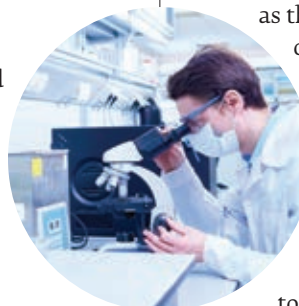


The SQMDG established a model offering biannual meetings and these have been a fertile learning ground. The opportunity to network and discuss our challenges has proved to be a significant support to us all. Most notably, this has supported a consistent approach within Scotland.

Regarding my own development in quality management, with experience of ISO 17025 and 15189, from discussions with colleagues, questions asked at SQMDG meetings as well as from performing Technical Assessments for UKAS, our ability to understand the concepts, the implications and the impact of the requirements is still evolving. I believe that is something to celebrate as this is the whole point of accreditation.

Reinvent the wheel?

It can be stressful and frustrating to face four days of assessment by a team of assessors. It can be just as scary for assessors, who want to be encouraging, put staff at





“There have been significant improvements in laboratory services delivery across the UK”

ease, do the best job they can and not cause too much of a disruption. No one wants to feel they aren't getting it right. We are proud, conscientious professionals trained to work to HCPC standards of proficiency. We all believe we are doing the very best we can with the resources available, so it can be shocking, to have an improvement action report with many findings. However it is worth remembering, we are all in it together, and can help each other – just ask. I'm a firm believer in not reinventing the wheel. Technical assessors performing work for UKAS must not, however, cross the line into providing consultancy. Independence and objectivity is essential and nigh on impossible when reviewing your own work, ideas or thought processes. So it can appear unhelpful when assessors are vague or wary of answering queries put to them.

Inconsistent

Another criticism that some have is that assessors are inconsistent. Of course it happens, and is to some extent unavoidable. Some inconsistencies arise because assessors come from different backgrounds, have different key skills, experience and knowledge. They have different personalities and values, some are more pragmatic than others, some emphatic about detail, some precise and process driven others with a broader helicopter view.

There can be communication failings between assessor and staff being observed. Findings raised in one laboratory may not be in another when circumstances appear similar, however one had been able to justify their approach whereas the other could not. If you believe a finding is not justified or appropriate, calmly explain why. It is the

responsibility of the assessor to demonstrate clearly to the laboratory where the nonconformity with the ISO 15189 clause and/or Technical Policy Statements (TPSs), or other associated document, arises. Many laboratories are unaware of the full extent of TPSs and that these must followed. It is the laboratory's responsibility to describe actions to close any non conformity.

Significant improvement

UK laboratories are through the major part of this massive undertaking, which is no mean feat. UKAS has done a good job in this achievement. The laboratories have performed exceptionally well, from what I hear on the networks with which I'm involved.

Whatever we all think as individuals, I have no doubt that there have been significant improvements in laboratory services delivery across the UK. Evidence of training and competence is more robust. Even if the only difference for some is that their documentation is immediately to hand if HCPC makes a request for CPD audit.

A major concern for all is, at what cost, to date and in the future? There is a balance of compliance, level of detail and pragmatism. UKAS must address the matter of consistency and be transparent in the process. Compliance does not come cheap. If, however, the benefits are measurable, in demonstrating improved quality and performance and service to the patient, then we will ensure we meet requirements. If “box ticking” creeps in and we do anything simply to keep UKAS “happy” then there is no added value and only resource wastage. That must always be our benchmark. 

Mairiead MacLennan is Professional Manager (Quality and Training) at the Department of Medical Microbiology and Infection Control, Victoria Hospital in Kirkcaldy. She is also a technical Assessor for UKAS.

Neville McClenaghan outlines how Ulster University, in partnership with the Institute of Technology Sligo, has established a new suite of innovative online undergraduate programmes.

In a rapidly-changing world, it is imperative we seek to utilise the latest thinking, research, and technologies to support our work-based learning, CPD, and progressive evolution of our profession. This has been a strong ethos of biomedical sciences at Ulster University over many years – we were one of the first to offer an IBMS-accredited/approved co-terminus undergraduate degree programme, an online/blended-learning Graduate Certificate in Biomedical Science, and our popular distance-learning PgD/MSc Biomedical Science programme. Each has served an important role in supporting biomedical scientists, and has helped to play our part in ensuring the visibility and prestige of UK biomedical science nationally and globally.

Partnership

We are delighted to have been invited to share some thoughts and experiences with regards to our latest programme developments, which we believe help us improve our reach and impact through innovative online undergraduate programmes supporting career progression in the healthcare, pharmaceutical and bioscience industries. Since the late 1990s, Ulster's School of Biomedical Sciences has been pioneering distance- and blended-learning

approaches, tools, and technologies to help support educational and career development of biomedical scientists in the UK, Ireland, and beyond.

The author of *Little Women*, Louisa May Alcott, famously said that “it takes two flints to make a fire”, and this cross-border partnership between the School of Biomedical Sciences at Ulster University and the Faculty of Science at Institute of Technology (IT) Sligo – the largest provider of online higher education programmes in Ireland – draws on core strengths from both institutions, paving the way for the first online IBMS-accredited full undergraduate degree in biomedical science.

Mutual benefit

It has also been said that “fortune favours the brave, but chance favours the smart”,

HOW TO... CREATE PATHWAYS THROUGH PARTNERSHIP

and the concept of embarking on a bold cross-jurisdictional enterprise, inherently based on smart collaborative working, with a passion to innovate, really captures the origins and ethos of the Ulster-IT Sligo collaboration. The genesis of this collaboration began through Professor Jacqueline McCormack (then Associate Head of School of Biomedical Sciences at Ulster) being invited by Dr Jeremy Bird (Head of Faculty of Science at IT Sligo) to serve on the Panel of an IT Sligo Programmatic Review. Through this academic engagement and follow-up discussions, it became evident that the quite separate evolution of expertise in online learning at both Ulster and IT Sligo could converge with a fusion between the clinical and industrial skillsets of two independent staff teams.

From the outset, the success of any

such venture lies in the establishment of mutual benefit and respect between teams, most of which is, of course, inherently dependent on the people involved. With that in mind, we had the good fortune to have both academic synergy and a very natural forging of excellent interpersonal relationships between Ulster and IT Sligo teams.

The value of a shared vision and mission and necessary camaraderie between our teams cannot be understated, proving critical to overcome bureaucratic and other inherent hurdles needing to be properly understood and addressed. As with any partnership, a key consideration is whether the will of the two teams is matched and complemented by that of the two providers. For example, overcoming the complexities of marrying up UK Credit Accumulation and Transfer Scheme (CATS) with the Irish/EU European Credit Transfer System (ECTS) for modules offered by Ulster and IT Sligo, respectively in a manner to satisfy both institutions was a considerable achievement. This has allowed the development of awards from both educational systems facilitating exits through different levels of attainment.

Responding to need

Successful establishment of any academic programme relies on sensitivity and responsiveness to the needs of students, professions, and employers. Given that our suite of novel online undergraduate programmes was targeted solely at those in employment, the expectations of students undertaking part-time study, and their motivation/drive would, from the outset, be understandably different than entrants from school to full-time undergraduate programmes. Also, given the differences in mode of delivery, whilst learning outcomes, quality, and standards must be equivalent,

“The value of a shared vision and mission and necessary camaraderie between our teams cannot be understated”

there were naturally going to be different expectations with regards to how students engage with learning through a Virtual Learning Environment (VLE).

The learning models include a mix of live (synchronous) online evening lectures, non-live (asynchronous) online lectures, discussion boards, and other online learning tools and material, together with practical work undertaken remotely coupled with periodic intensive on-campus practical workshops.

Keeping momentum

The merits of online learning are well described – including accessibility, helping address socioeconomic disadvantage, plus overcoming geographical and other barriers. However, offering this type of flexible learning and ease of access for students requires particular resources, skills, attitudes, and approaches from staff designing and delivering such programmes of study.

Supporting online learners requires a different infrastructure and outlook to that needed for traditional on-campus programme delivery, and the dedicated team of staff comprising Ulster University eLearning Support Unit (eLSU) plays a pivotal role in fielding and managing a spectrum of

student enquiries. Our eLSU is vital to support academics, eTutors, and others contributing to teaching and learning delivery and assessment, and so it was imperative appropriate resourcing was in place from the outset.

In this joint degree provision, it was critical to establish up-front agreement on programme design and structure, the academic syllabus, modular content, and overall/devolved responsibilities of Ulster and IT Sligo Teams. In all this, it was important to keep momentum, maintaining robust communication channels, with regular meetings of staff, whilst ensuring benchmarking against professional standards, and a strong focus on student, institutional, professional body, and employer needs. With the course documents in place, and post-programme validation (including endorsement by professional bodies), the next consideration was marketing, importantly providing clarity to prospective students on entry requirements and expectations.

Delivery

While successful online programme delivery has been underpinned by committed teams at Ulster and IT Sligo, it would be remiss not to particularly acknowledge the efforts of the two Course Directors, namely Peter Mitchell (Ulster) and Dr Stephen Daly (IT Sligo), engaging in a wide range of core activities from recruitment through to graduation – their dedication and day-to-day leadership and management is admirable and essential to the success of our exciting joint venture. 

Neville McClenaghan is a Professor and Fellow of the IBMS



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MY IBMS

NEWS

BIOMEDICAL SCIENCE DAY

CHAMPION OF BIOMEDICAL SCIENCE



The IBMS has announced that for Biomedical Science Day, which is held on 20 June, each region will crown a Champion of Biomedical Science.

The champions will be IBMS members who in the past year have shown dedication to the promotion, development and delivery of excellence in biomedical science.

Examples of expected nominations include members who are verifiers or examiners, training officers or lab managers, and those involved in public engagement activities or

making any other kind of contribution to the profession.

Nominations can be made via the online application as a written statement and must include how the nominee has championed dedication to the promotion, development and delivery of excellence in biomedical science.

All nominations must be submitted by 13 May 2019.

→ For more information, visit the IBMS website.

HIGHER SPECIALIST DIPLOMA

HSD preparation day

The IBMS is due to run a Higher Specialist Diploma (HSD) candidate preparation day on Wednesday 13 March.

All candidates seeking more information on undertaking the HSD are strongly encouraged to attend.

The day will start at 10.30 am and will finish no later than 3.30pm.

The day includes:

- A chance to network with others on the HSD
- Presentations on what makes a good HSD portfolio, the examination structure and a successful candidate's explanation of why they did the HSD and how they passed the qualification
- Workshops on the generic and discipline-specific examination papers with IBMS examiners, which will give delegates an opportunity to understand the level of detail required in the HSD exam.

Places are limited at this free event. To reserve a place, please email examinations@ibms.org including details of your IBMS membership number and the HSD discipline in which you are interested.



BIRMINGHAM BRANCH

HAEMATOLOGY CPD PRESENTATION

A CPD presentation with a multi-disciplinary slant has been organised by the Birmingham branch of the IBMS.

Colin Mudd from Nottingham University Hospital will deliver the session, which will be based around haematology.

It will take place on Thursday 11 April. A buffet will be served from 5.30pm and the presentation will start at 6.30pm.

It will be in the Seminar Room of the Education Resource Centre at Birmingham Women's Hospital.

→ All are welcome. For further details, contact Nigel Coles at nigel.coles@nhs.net or on 0121 335 8034.

IBMS NOTICE

ANNUAL GENERAL MEETING

The seventy-seventh Annual General Meeting of the Institute of Biomedical Science will be held at the Institute of Biomedical Science, 12 Coldbath Square, London, EC1R 5HL, on 8th June 2019 at 11.30am.

Official notification of the meeting will be published in the April issue of *The Biomedical Scientist* and online.

ALL MEMBERS ARE INVITED TO ATTEND





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.

EVENTS AND TRAINING COURSES

DATE	TITLE	VENUE CONTACT
March		
4 Mar	BDIAP Molecular Pathology study day	London lisa.browning@ouh.nhs.uk
5 Mar	12th BDIAP Seminar for Trainees in Histopathology	London lisa.browning@ouh.nhs.uk
5 Mar	POCT governance and quality event	Reading info@thornhillhealthcareevents.co.uk
6 Mar	One-day update in Cervical Cytology Metaplasia/Cancer audit day	Bristol SWRCTC@nbt.nhs.uk
6-7 Mar	Beginners immunohistochemistry course	Sheffield l.baxter@sheffield.ac.uk
12 Mar	UK NEQAS Cellular Pathology Technique Mohs workshop	Gateshead chantell.hodgson@nhs.net
13 Mar	UK NEQAS Cellular Pathology Technique BMT workshop	Gateshead chantell.hodgson@nhs.net
14 Mar	UK NEQAS Cellular Pathology Technique renal workshop	Gateshead chantell.hodgson@nhs.net
15 Mar	UK NEQAS for CPT Neuropathology and Muscle Histochemistry Schemes Annual Participants' Meeting	Manchester richard.mathias@srft.nhs.uk
19 Mar	Serious Fluid	Bristol SWRCTC@nbt.nhs.uk
19-21 Mar	BMS/cytoscreener update course in gynaecological cytology	Harrow LNWH-tr.Irctcbooking@nhs.net
21-22 Mar	2019 Spring Conference: Global views, local problems: Innovative solutions to AMR and infection challenges	Birmingham ecarruthers@bsac.org.uk
28 Mar	UK Newborn Screening Laboratory Network Annual Scientific Meeting	Manchester beverly.hird@mft.nhs.uk
29 Mar	British Association for Cytopathology spring tutorial	London christianburt@ibms.org
29 Mar	Blood Sciences short course	London c.ferrier@westminster.ac.uk
April		
2-3 Apr	European Histopathology Forum	Leamington Spa michael.2.fulleylove@gsk.com
3 Apr	Intermediate Immunohistochemistry	Sheffield l.baxter@sheffield.ac.uk
3 Apr	Urinary Tract Cytology for Technical Staff	Bristol SWRCTC@nbt.nhs.uk
5 Apr	Blood Sciences short course	London c.ferrier@westminster.ac.uk
7-11 Apr	Microbiology Society Annual Conference 2019	Belfast conferences@microbiologysociety.org
8-12 Apr	Pre-exam course in gynaecological cytology	Harrow LNWH-tr.Irctcbooking@nhs.net
8-12 Apr	BMS/cytoscreener update course in gynaecological cytology	Harrow LNWH-tr.Irctcbooking@nhs.net
10 Apr	UK NEQAS Cellular Pathology Technique immunocytochemistry staining beginners workshop	Newcastle-upon-Tyne chantell.hodgson@nhs.net
11 Apr	UK NEQAS Cellular Pathology Technique immunocytochemistry intermediate/trouble shooting workshop	Newcastle-upon-Tyne chantell.hodgson@nhs.net
12 Apr	Blood sciences short course	London c.ferrier@westminster.ac.uk
13 Apr	Biomed online learning courses	Online c.e.ronan@gre.ac.uk
17 Apr	Medical laboratory assistant - introductory course	Harrow LNWH-tr.Irctcbooking@nhs.net
25 Apr	Microbial genomics workshop	London v.b.patel@westminster.ac.uk
May		
2 May	One-day update in Cervical Cytology	Bristol SWRCTC@nbt.nhs.uk
2-3 May	Focus 2019	Glasgow focus2019@acb.org.uk

DATE	TITLE	VENUE CONTACT
4 May	BDIAP Molecular Pathology Study Day	London lisa.browning@ouh.nhs.uk
8 May	UK NEQAS Cellular Pathology Technique non-gynae cytology beginners/refreshers workshop	Gateshead chantell.hodgson@nhs.net
9 May	UK NEQAS Cellular Pathology Technique non-gynae cytology intermediate workshop	Gateshead chantell.hodgson@nhs.net
10 May	Blood Sciences short course	London c.ferrier@westminster.ac.uk
14 May	CM-PATH Biobanking Workshop – "Do we really need another Biobank?"	London helen.pitman@ncri.org.uk
16 May	Respiratory Microbiology – a day of inspiration!	London swallis@mastgrp.com
17 May	Blood Sciences short course	London c.ferrier@westminster.ac.uk
24 May	Haematinics and white blood cell disorders	London c.ferrier@westminster.ac.uk
June		
6 Jun	IBMS Registration Portfolio Workshop	London c.ferrier@westminster.ac.uk
6 Jun	Update in Cervical Cytology for pathologists, consultant BMS and holders of the Advanced Specialist Diploma in Cytology	Bristol SWRCTC@nbt.nhs.uk
10 Jun-21 Jul	Introductory Course in Cervical Cytology	Bristol SWRCTC@nbt.nhs.uk
19 Jun	UK NEQAS Cellular Pathology Technique special staining beginners/refreshers workshop	Newcastle upon Tyne chantell.hodgson@nhs.net
20 Jun-20 Jul	UK NEQAS Cellular Pathology Technique specialist workshop A	Newcastle upon Tyne chantell.hodgson@nhs.net
25 Jun	One-day update in Cervical Cytology – metaplasia/cancer audit day	Bristol SWRCTC@nbt.nhs.uk
July		
8-12 Jul	Electron Microscopy Summer School	Leeds katejermy@rms.org.uk

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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 5 JUNE 2019

Diagnostic accuracy, risk assessment, and cost-effectiveness of component-resolved diagnostics for food allergy: A systematic review. Flores Kim J, McCleary N, Nwaru BI, Stoddart A, Sheikh A. <i>Allergy</i> 2018; 73 (8): 1609–21 (https://onlinelibrary.wiley.com/doi/epdf/10.1111/all.13399). Assessment No 030519		Association of <i>Helicobacter pylori</i> and protozoal parasites in patients with chronic diarrhoea. Yakoob J, Abbas Z, Moore J et al. <i>Br J Biomed Sci</i> 2018; 75 (3): 105–9. Assessment No 030119	
01	Prevalence of food allergy has been estimated to be between 3% and 6% for children and between 4% and 7% for adults in economically developed countries.	01	<i>E. moshkovskii</i> and <i>E. histolytica</i> are distinguishable microscopically.
02	Gal d1 had higher sensitivity and lower specificity than SPT and sIgE.	02	Results showed that patients were more likely to be infected with <i>Blastocystis</i> sp. and <i>E. dispar</i> than controls.
03	Twelve other studies were found to have an unclear ROB, mainly because they did not explicitly indicate their sampling methodology and/or did not avoid inappropriate exclusions.	03	Dietary non-starch polysaccharides appear to be important factors in controlling prevalence of <i>H. pylori</i> and parasitic infection.
04	The studies included in our review that analysed peanut components also found that sIgE levels to the components Ara h1, 3, 8, and 9 showed varying results, most with underperforming diagnostic values.	04	Of the patients with known symptoms of diarrhoea, 37 were found to have <i>E. dispar</i> .
05	Two studies reported data on CRD for shrimp allergy. One study tested the component Pen a1, and the other study investigated the components Lit v1 and Lit v4.	05	<i>E. histolytica</i> and <i>E. dispar</i> require PCR using specific primers for differentiation.
06	Two studies evaluated the diagnostic accuracy of CRD for hazelnut allergy and the following components were assessed: Cor a1, Cor a8, Cor a9 and Cor a14.	06	Abdominal discomfort is not associated with <i>Entamoeba histolytica</i> infection.
07	Diagnosis of food allergy is dependent on a thorough clinical history as well as an objective marker of allergic sensitisation and, in some cases, oral food challenge tests.	07	Results showed the prevalence of <i>E. histolytica</i> exceeded that of <i>E. dispar</i> .
08	The reported sensitivity-specificity for Cor a1 was 7.7% and 79.3% (at >0.35 kUa/L).	08	The study revealed that patients were more likely to be co-infected with <i>Blastocystis</i> sp. and <i>E. histolytica</i> .
09	For peanut allergy, Ara h6 showed higher DTA measures than SPT and sIgE.	09	Amoebiasis is a faecal-oral route transmitted infection with the amoebas of the <i>Entamoeba</i> group.
10	None of the studies meeting our inclusion criteria evaluated the cost-effectiveness of CRD or made mention of any economic considerations.	10	Over 15% of giardiasis cases may be asymptomatic.
11	Three studies evaluated CRD for hens' egg allergy and the following components were assessed: Gal d1, Gal d2, Gal d5, and Gal d7.	11	Of the 33 patients infected with <i>H. pylori</i> , 27 were found to have at least one parasite.
12	For heated egg allergy, the reported sensitivity-specificity for these components were as follows: for Gal d1, 84.2% and 89.8% (at >4.4 kUa/L).	12	The authors hypothesise that <i>H. pylori</i> may influence the virulence of parasitic protozoan infections.
13	Selected CRD components have the potential to diagnose food allergies with a higher specificity and sensitivity than current first line tests.	13	Mucosal dendritic cells are not involved in creating an overall tolerant state towards intestinal antigens.
14	A quantitative synthesis of CRD diagnostic accuracy data is not possible because of the paucity of studies for each of the components that have been studied.	14	The results obtained led to the hypothesis that there may be a mechanical link to the co-infection seen.
15	Two studies assessing CRD for hens' egg allergy found that sIgE levels for all components tested were higher in patients with more severe allergies.	15	Nineteen <i>Blastocystis</i> subtypes have been identified using small subunit ribosomal RNA differences.
16	The component with the highest diagnostic accuracy, along with the sensitivity-specificity pairs, was Cor a14 for hazelnut allergy (100% and 93.8%).	16	Results showed an association with <i>H. pylori</i> and <i>E. dispar</i> .
17	There is a need to standardise all CRD assays to ensure that results are comparable between different tests.	17	In the study, the exclusion criteria for participants included those aged >60 years.
18	The component with the highest diagnostic accuracy for cows' milk allergy, along with the sensitivity-specificity pairs, was Bos d4 (82.0% and 67.5%).	18	<i>Blastocystis</i> sp. transmission occurs through water but not faecal-oral contamination.
19	It is likely that the prevalence of allergies in the study populations is considerably higher than in more population-based settings, rendering the tests' PPVs higher and NPVs lower than they would be in populations with lower allergy prevalence.	19	Patients and controls were not age matched in the study.
20	This study found that all severe allergic patients were sensitised to Ara h2 or Ara h6, and none of them were sensitised to Ara h1, 3, or 9 without Ara h2.	20	<i>Helicobacter pylori</i> infection is associated with lymphoma.

REFLECTIVE LEARNING

01	Critically appraise the cost-effectiveness of using CRD testing in your laboratory.	The study was carried out in Pakistan reflecting the infections found in developing countries. How could your laboratory improve detection and identification of parasitic infections given the low numbers seen in the UK?
02	Discuss the relative sensitivity and specificity of peanut allergy testing using SPT, mixes, individual allergens and CRD.	

HERE TO HELP

REALISTIC EXPECTATIONS

Alan Wainwright, IBMS Executive Head of Education, asks the question: “What are the realistic expectations of a new biomedical science graduate?”

In the UK there are 54 universities offering IBMS-accredited degrees with different modes of delivery (full-time, with and without placements or part-time) and structures (full-time academic programme, academic programme with integrated IBMS registration training portfolio, apprenticeship degree (work-based with “day-release”), placements in industry, placements in clinical laboratories).

Without doubt, IBMS accreditation is respected by universities and recognised by students as adding value to their degree. It does not automatically follow that students fully appreciate what an accredited degree offers, or for that matter that they have chosen the degree specifically for a career as a registered biomedical scientist. Many do, but many more may seek a career in research or industry. Such is the popularity of these degrees and the choices students have.

Flexible and adaptable

The choices have developed from traditional routes required to deliver an educated and trained workforce for clinical pathology services, but also in response to

professional standards of practice, regulatory requirements and the wider application of biomedical science in industry. They are informed by the needs of employers who desire the ability to employ students of their choice, including those from non-accredited degrees, and the resources they have to contribute to academic teaching or to offer placement opportunities to students. It requires a flexible and adaptable approach to the application of IBMS accreditation standards, without losing sight of the underpinning need to ensure graduates are fit for purpose.

Whilst it is arguably a good thing to have choices, the downside is that it can lead to misunderstanding or misrepresentation of what IBMS accreditation achieves, which can be further complicated by whether the graduate has spent time in a clinical laboratory in their degree, whether they have graduated eligible to apply for HCPC registration (having met requirements for a minimal standard for safe, effective practice), and expectations of hard-pressed employers who want students to “hit the ground running”.

What to expect?

All IBMS-accredited degree programmes must deliver academic teaching in subject specific knowledge defined by section 6 of the Quality Assurance Agency benchmark statement for Biomedical Sciences (2015) that relates to the main pathology disciplines, including clinical genetics. This includes the theory and practice of laboratory investigations and understanding of scientific principles for quality assurance and basic laboratory techniques. Unless completing a placement in a clinical laboratory, graduates will not be familiar with how to operate large automated analysers, although they will have been taught some of the theory underpinning them. Graduates can be expected to have an understanding of the biology of disease and the effective diagnosis and treatment of patients, know how to formulate and test a hypothesis, use data for critical analysis and present their results. They should have acquired other skills, such as team working, independent learning, and reflective practice.

Student views

Meeting students is an integral part of the IBMS accreditation process. Their views are sought with regard to the assessment, support they receive from academic staff and the research opportunities they have. But also, because students need to have the information to make informed choices, the accreditation panel check to confirm that students have

information on professional and regulatory bodies, know about IBMS student membership, understand the procedures for accessing placements and the importance of the IBMS registration training portfolio.

Some students are more knowledgeable than others, and human nature being what it is, students can be selective in what they pay attention to. This does not mean they haven't been told!





Employers

Employer engagement is another crucial aspect of delivering an IBMS-accredited degree. Links between the university and local laboratories are essential for creating opportunities for students to engage with employers who contribute to academic teaching or offer placement opportunities. Furthermore, there is a requirement for universities to actively engage with employers to input to the development of the programme.

This is the employers' opportunity to guide the university in producing graduates they want to employ by ensuring the curriculum is appropriate to service requirements. No employer or student from an accredited biomedical science degree should be able to claim they don't know the basics of each laboratory discipline. They may have forgotten, but they have been taught it.

Training portfolio

One of the biggest changes that occurred with biomedical science degrees was the introduction of the IBMS registration training portfolio and the opportunity to complete it as part of a degree so that students could graduate with their degree and a certificate of competence (hence coining of the term "coterminous degree") which rendered graduates eligible to apply for HCPC registration as a biomedical scientist. The requirement for registration is to meet a threshold level of competence, something that continues to split opinions in terms of meeting a level of standards that apply to all regulated professions and employers seeing a newly registered biomedical scientist as someone fully conversant with all aspects of their discipline.

Perhaps it is time for a reality check. Newly registered biomedical scientists

work as part of the team, they learn quickly and they have the background on which to gain more in depth experience and build specialist knowledge. They know the limit of their capabilities and are safe to practice. In this respect, they are no different from anyone else that starts work for the first time, whether their first job or in a new environment.

Reflecting requirements

All this and more is brought together for a degree award that reflects the requirement for the student to achieve an acceptable performance in respect of all the major course components, but with particular regard to biomedical science and laboratory investigations.

A university degree, with or without a placement, can only at best offer a limited experience, and experienced practitioners should not be used to judge the competence of graduates, but rather to set a benchmark to which graduates can reasonably be expected to aspire in a relative short timeframe. Placements vary in length, resources, the ability and commitment of trainers/students, but they provide a wonderful opportunity for students to achieve a common standard through the registration portfolio and HCPC standards of proficiency.

Graduates may not be the finished article, they are after all at the start of their career, but the thorough grounding in biomedical science theory and practice that they receive equips them for safeguarding flexibility and adaptability of roles, which are an integral part of multi-professional team working and the delivery of patient-centred services.

Accredited biomedical science degrees may have their critics but they continue to grow in popularity and reputation in the UK and in many countries abroad further enhancing the reputation of the IBMS as a standard-setting organisation. This does not mean we rest on our laurels. We look to improve even more, but we also look for realistic expectations. 

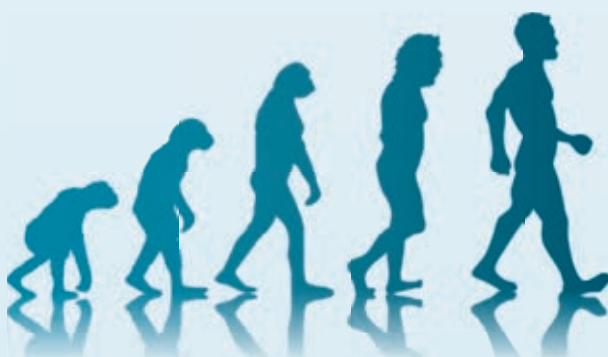
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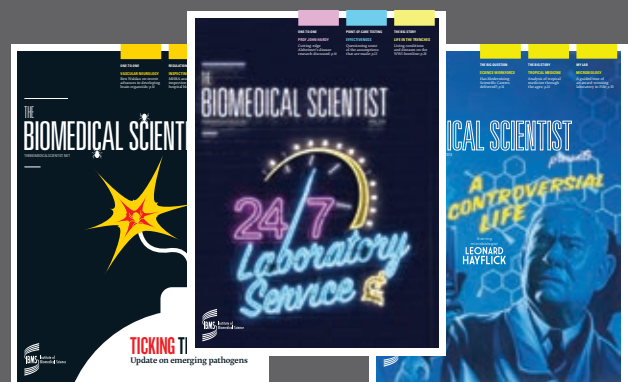
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MY LAB

MOLECULAR PATHOLOGY SERVICES

Clinical Scientist and Molecular Pathology Lead
Siobhan Taylor gives a guided tour of the laboratory
at Gloucestershire Hospitals NHS Foundation Trust.

My laboratory, a fully ISO-accredited laboratory, is located at the top of the South West in the regency spa town of Cheltenham. Together the two large general hospitals of Cheltenham General Hospital and Gloucester Royal Hospital, make up Gloucestershire Hospitals NHS Foundation Trust, serving the ~900,000 inhabitants of Gloucestershire. The pathology services run from both sites; the histopathology department is mainly based at Cheltenham, with a smaller hot lab at Gloucester for frozen and renal biopsies.

Receiving over 40,000 specimens per year from 82 GP surgeries across the region, in-patient and out-patient clinics and theatres from both general and outlier hospitals within the area, the department is one of the largest in the South West region. To ensure timely arrival of specimens, the pathology department has a fleet of vans transporting samples the eight miles between the two sites and visiting GP surgeries and outlier hospitals daily. A shuttle bus transports passengers and staff between the two hospital sites.

We have a large multi-professional team of 68 staff, consisting of 24 biomedical and clinical (healthcare) scientists, 15 consultant pathologists,



14 medical laboratory assistants and 15 administration and clerical staff. Our laboratory performs standard dissection, microtomy and special stains and is complemented by a comprehensive immunohistochemistry (IHC) repertoire. Scientist staff are trained and work flexibly across all areas of the laboratory, rotating on a two-week basis. We also perform frozen sections and immunofluorescence and offer a renal biopsy attendance service.

In addition to managing the HER2 service, my role is to develop, organise and manage the provision of modern molecular pathology services. The special techniques section houses four BenchMark ULTRA platforms (Roche/Ventana), which perform IHC, chromogenic/silver *in-situ* hybridisation and dual colour dual probe *in-situ* hybridisation techniques, providing in-house services for diagnosis, monitoring and predictive profiling. Most recently, rapid testing for the presence of mutations to guide therapy decisions

in melanoma and colorectal cancer using the Idylla™ platform (Biocartis) is in the process of being implemented. These tests will further strengthen the delivery of personalised medicine in a timely and effective manner to the patients in our region.

As an IBMS-accredited training laboratory, we are committed to training at all

levels, with trainees completing a variety of training portfolios, including apprenticeship, biomedical scientist registration, Specialist Portfolio, Diplomas of Expert Practice and Biomedical Scientist Reporting. We collaborate with the University of the West of England and Griffith University Gold Coast in Australia, giving students the invaluable opportunity to train and gain experience within the laboratory as part of their undergraduate degrees.

In addition to myself, there are now a further two HCPC-registered clinical scientists within the department, each of us having taken very different journeys to registration; one of our scientists has recently completed the Scientist Training Programme in Cellular Sciences, whilst another has successfully undergone equivalence with the Academy for Healthcare Science. 

Siobhan is the current recipient of the Chief Scientific Officer Women in Science and Engineering Fellowship.



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