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NOVEMBER 2019

THE RISE OF POCT

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EDITOR
Rob Dabrowski

SENIOR DESIGNERS
Gary Hill, Sarah Auld

PICTURE EDITOR
Akin Falope

PUBLISHING DIRECTOR
Aaron Nicholls

PRODUCTION
Rachel Young

DISPLAY ADVERTISING
+44 (0)20 7880 7556
biomedical@redactive.co.uk

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INNOVATIONS IN CELLULAR PATHOLOGY

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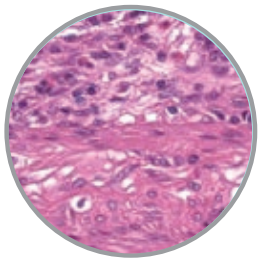

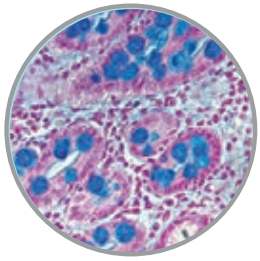

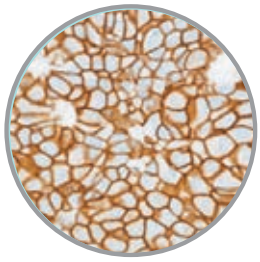

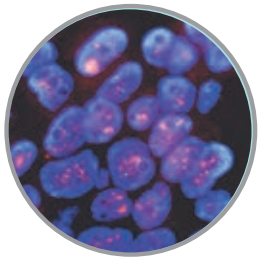

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GENETIC TESTING

With the commercialisation of genetic testing now with us, **Sarah May** looks at the potential and the ethics.

Across the centuries, societies and individuals have had very particular views about the human body. From the ancient Egyptians, who preserved the body (of those with wealth and means) in preparation for its journey into the afterlife, to the infamous English 16th century punishment, which persisted until well in to the 18th century, of post-execution dissection. The punishment of "desecration" of the body after death was feared more than death itself, hence the reason why the early anatomists were viewed with a mixture of both fascination and revulsion.

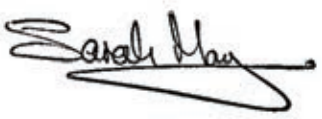
Our relationship with the body has changed significantly over the centuries but there remains very differing views, both personal and religious, on its use and treatment both pre- and post-death.

A gift of life that is usually dependent upon a death. Many people would be willing to receive a donated organ if it held the potential to save their life, but a smaller number would be willing to offer their own or, more particularly, those of a loved one, regarding the removal of organs as a form of "desecration" of the body, or simply an abhorrence.

The 21st century is seeing the expansion of understanding of how our bodies work, which pales the early anatomical discoveries almost in to insignificance in terms of scale and impact. We are moving from the discovery of why death has occurred to the discovery of how death might occur; yes, I'm talking about genetic testing.

Barely a day goes by without news of another medical breakthrough or discovery made possible by our burgeoning knowledge of the human genome. Rather than bath salts or books, gene testing kits are now being advertised as the desirable novel gift for the curious; discover your ancestry, or unlock the secrets of your genes. What a potential Pandora's box inside each of us; cancer, dementia, diabetes, baldness or bunions – the list of genetic possibilities with their varying likelihoods is endless, as is the combinations of contributory risks associated with lifestyle and other external factors.

As a scientist, I am struggling to reconcile my interest in, and respect for, scientific facts with a somewhat more visceral and fearful respect for the hidden programming of my genes. I think the benefits to understanding and hence enabling the "reprogramming" of faulty genes is nothing short of amazing. There is now immense hope for people afflicted with devastating genetic conditions, but I think that there are also huge ethical considerations, and not least an element of social responsibility, associated with the freely available online kits and testing services. Maybe I'm a coward, but I for one do not want to know my potential future if it is something I am powerless to stop or change. So, in the meantime, I'll settle for the bath salts.



Sarah May
Deputy Chief Executive

IBMS

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INSTITUTE OF BIOMEDICAL SCIENCE
12 Coldbath Square
London, EC1R 5HL
United Kingdom
+44 (0)20 7713 0214
+44 (0)20 7837 9658
Email: mail@ibms.org
Web: www.ibms.org

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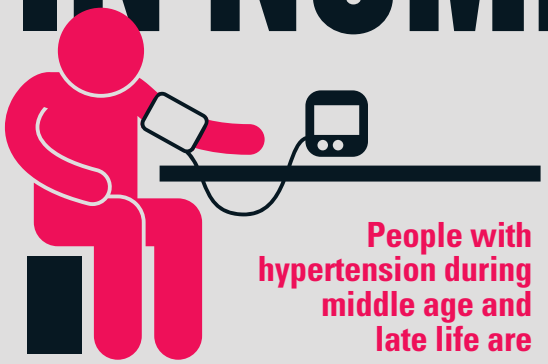
SCIENCE NEWS

IN NUMBERS



DEMENTIA

People with hypertension during middle age and late life are

49%

more likely to develop dementia than those with normal blood pressure, according to new research.

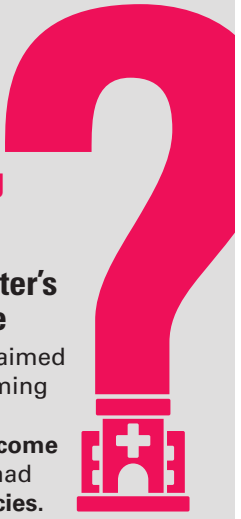
However, having hypertension in middle age and then low blood pressure in late life increases dementia risk by

62%

4.41m

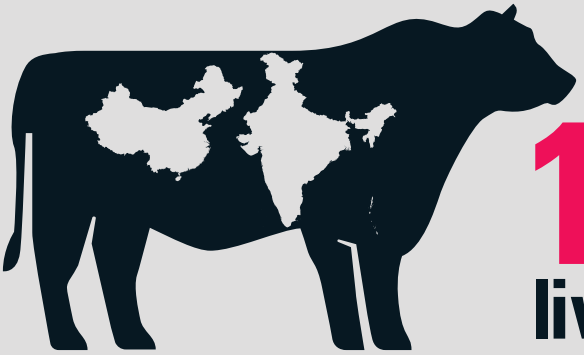
NHS waiting lists are at an all time high with 4.41million people waiting for routine operations, shows a new report. The figure is an increase of 250,000 from last year. It also shows **662,053 people have waited more than 4 months** for routine treatments.

£1.8bn



The UK's statistics watchdog has said the Department of Health and Social Care must explain how the prime minister's £1.8bn spending boost for the NHS is being funded. It was claimed the funding was "new money" coming from the Treasury. But it has now emerged that **around £1bn would come from cash reserves** that hospitals had already earned by **making efficiencies.**

X3



Antibiotic resistance in livestock has nearly tripled since 2000, it has been reported.

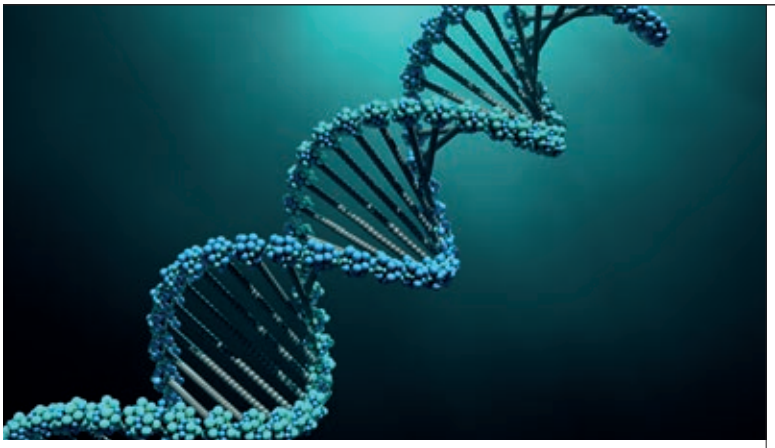
Scientists gathered nearly 1000 publications and unpublished veterinary reports from around the world to create a map of antimicrobial resistance in low-to middle-income countries. **Antibiotic resistance was most widespread in China and India**, with Brazil and Kenya emerging as new hotspots.

130k

lives saved

More than 130,000 UK breast cancer deaths have been avoided in the last 30 years, according to new Cancer Research UK analysis.

Breast cancer deaths in the UK hit a record high in 1989, when around 15,600 women lost their lives to the disease. New tests and better treatments mean the rate has since fallen by 44%.



SCIENCE NEWS

GENOMICS

New cancer-driving mutation

Scientists have discovered a novel cancer-driving mutation in the vast non-coding regions of the human cancer genome, also known as the "dark matter" of human cancer DNA.

The mutation, as described in two related studies, represents a new potential therapeutic target for several types of cancer including brain, liver and blood.

This could be used to develop treatments for patients with these difficult-to-treat diseases.

Lincoln Stein, study co-lead, said: "Non-coding DNA, which makes up 98% of the genome, is notoriously difficult to study and is often overlooked since it does not code for proteins.

"By carefully analysing these regions, we discovered a change in one letter of the DNA code that can drive multiple types of cancer. In turn, we've found a new cancer mechanism that we can target to tackle the disease."

The research group discovered that the mutation, termed "U1-snRNA", could disrupt normal RNA splicing and thereby alter the transcription of cancer-driving genes.

These molecular mechanisms represent new ways to treat cancers carrying the mutation. One of the potential treatment approaches includes repurposing existing drug.

→ **bit.ly/31fDTJq**

ANTIRETROVIRAL THERAPY

HIV "RESERVOIR" FINDING

Antiretroviral therapy (ART) can suppress HIV to the point where the virus is nearly undetectable, and people on medication can live for many years.

But therapy cannot completely eradicate the virus; it persists in reservoirs inside immune cells, a phenomenon called "latency".

This latent reservoir forms even when a person begins therapy very early after infection, but the dynamics of the reservoir's formation have been largely unknown.

Now scientists have discovered evidence that the initial use of ART alters the host environment to allow the formation or stabilisation of most of the long-lived HIV reservoir that is then present for many years.

This research was published in *Science Translational Medicine* and led by scientists at the University of North Carolina School of Medicine, the University of Cape Town, and the CAPRISA research team in South Africa.

Their research shows that the long-lived reservoir of HIV in blood mostly reflects viral strains that were present at the time treatment was initiated, with these latent viruses persisting after years of treatment.

→ **bit.ly/32iYONa**

TB RESEARCH

NEW INSIGHTS INTO TUBERCULOSIS

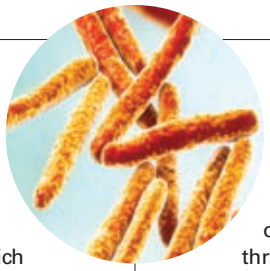
During infection the main causative agent of tuberculosis, *Mycobacterium tuberculosis,* secretes a large number of effector proteins through type VII secretion systems.

These small nanomachines, are composed of proteins that reside in the cell envelope.

The effector proteins are specialised in fighting the immune defence or enabling the uptake of nutrients to ensure the bacterial survival in the host. How these systems work, is poorly understood.

Scientists from the Julius-Maximilians-Universität Würzburg and the Centro Nacional de Investigaciones Oncológicas have now succeeded in deciphering the molecular architecture of these nanomachines.

Over the past five years, the research group has worked intensively on the stable reconstitution of one of these secretion machines and the preparation of the sensitive sample for measurements on the cryo electron microscope.



In collaboration with the research group of Oscar Llorca in Madrid, which computed three-dimensional maps of the protein complex using a sophisticated data processing strategy, the scientists have been able to create a model of its molecular structure.

They were able to identify important elements of the nanomachine that form the transport pore, and elements that convert chemical energy into motion and drive the transport of effector proteins through the pore.

The findings of the researchers lead to a deeper functional understanding of type VII secretion systems. In times of rising resistance of mycobacteria to the antibiotics in use and no effective vaccination against tuberculosis in place, the research provides an important basis for novel antibiotic development.

→ **go.nature.com/2ONrZUC**

IMAGES: ISTOCK/SHUTTERSTOCK

BLOOD TEST

DIAGNOSING BRAIN CANCER

A blood test which could help to accelerate the diagnosis of brain cancer has been developed.

The technology uses infrared light to produce a bio-signature of a blood sample and applies artificial intelligence to check for the signs of cancer.

Matthew J Baker, who led the study, said: "This is the first publication of data from our clinical feasibility study and it is the first demonstration that our blood test works in the clinic.

"Earlier detection of brain tumours in the diagnostic pathway brings the potential to significantly improve patient quality of life and survival, while also providing savings to the health services."

The scientists analysed samples from a prospective cohort of 104 patients, they found that the blood test could distinguish patients with brain cancer from healthy individuals correctly 87% of the time.

The results suggest that the approach may be useful in helping to prioritise patients needing brain scans in order to diagnose tumours.

→ **go.nature.com/319Y3Vb**

NHS SCREENING

GPs GIVING ALCOHOL ADVICE – LINKED TO PAY

In 2008 the Department of Health in England introduced financial incentives to encourage GPs to talk to patients about their drinking. There was a small, gradual increase in screening and the provision of alcohol advice.

However, when the incentives stopped in 2015, rates of screening and advice-giving decreased immediately.

Under the incentive scheme, participating practices were paid £2.38 for each newly registered adult patient they screened for higher-risk drinking. The scheme was withdrawn in April 2015.

A paper analysing the incentive states: "Removing a financial incentive for alcohol prevention in English primary care was associated with an immediate and sustained reduction in the rate of screening for alcohol use and brief advice provision."

→ **bit.ly/2MI9IFs**

WHAT'S HOT AND WHAT'S NOT

HOT

TOMATO PUREE

Healthy men who took the equivalent of two tablespoons of tomato puree a day as a supplement were found to have better quality sperm, claims a study.

HOT

TEXT MESSAGES

A suicide prevention text message service to encourage more men to "open up" was launched by the Kaleidoscope Plus Group on World Mental Health Day.

HOT

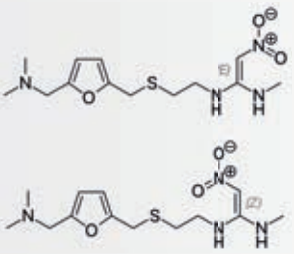
BREAST MILK

New research states that glycerol monolaurate in human breast milk fights infections by harmful bacteria while allowing beneficial bacteria to thrive.

NOT

SNACKS

Snacking should be banned on public transport and extra taxes placed on unhealthy foods to tackle child obesity, said departing Chief Medical Officer Dame Sally Davies.



NOT

ZANTAC

UK doctors are being told to stop prescribing heartburn medications Zantac or ranitidine as a "precautionary measure" after concern that they could be linked to cancer. Currently, there's no evidence of harm.

NOT

VAPING

New research published in the *American Journal of Roentgenology* details patterns of inhalation lung injury associated with vaporisers and e-cigarettes.

MOLECULAR DIAGNOSTICS

New test for chronic hepatitis B

A new laboratory tool may improve the diagnosis and treatment of hepatitis B virus (HBV) infection.

The technique can simultaneously assess several indicators important for optimal patient management, according to a new report in the *Journal of Molecular Diagnostics*.

A team of scientists has developed a highly sensitive coamplification at lower denaturation temperature PCR (COLD-PCR) coupled with probe-based fluorescence melting curve analysis (FMCA) for precision diagnosis of chronic hepatitis B patients.

This novel tool is simple, stable, convenient, practical, inexpensive, and may be used routinely in the average hospital laboratory.

Lead investigator Qishui Ou said: "Guidelines have confirmed that dynamic monitoring of HBV DNA, genotypes, and reverse transcriptase mutant DNA is of great importance to assess infection status, predict disease progression, and judge treatment efficacy in HBV-infected patients.

"We believe COLD-PCR/FMCA provides a powerful laboratory tool for precise diagnosis and treatment of HBV-infected patients."

Although a number of molecular methods have been developed, many are limited by poor sensitivity or inability to detect more than one mutation at a time.

→ **bit.ly/2VGbcUV**

MUSCULOSKELETAL RESEARCH

NERVOUS SYSTEM'S ROLE IN AGE-RELATED WEAKNESS

A study found new evidence to support the belief that the nervous system plays a major role in age-related weakness.

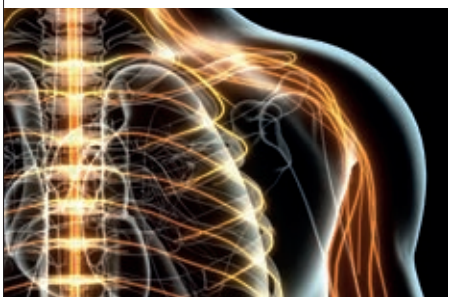
Scientists compared how much muscle strength older people could muster voluntarily, with when their muscles were stimulated electrically.

The results suggest that physical weakness in ageing may be due, at least in part, to impairments in brain and nerve function, rather than changes in the muscles themselves.

One of the authors behind the paper, Brian Clark, said it is "confirmatory evidence that the nervous system is a key culprit in weakness".

Subjects were asked to push against resistance with as much strength as possible. When they reached their self-perceived limit, the muscles were stimulated electrically. If this caused more force, it indicated strength limitation did not come from the muscle itself.

→ **bit.ly/2MIFT7O**



UNDER THE MICROSCOPE

This month: Full-service restaurants.

What's a full-service restaurant?
It's basically any establishment with a relatively broad menu that has table or counter service and waiting staff.

Sounds like the type of thing that food industry magazines should be discussing...
Well, yes, usually. But it's relevant to these pages due to some new research that has been published in *BMJ Open*.

OK, tell me more.
A University of Liverpool study reported that the calorie content of popular starters, sides and desserts served in UK restaurant chains is too high and only a minority meet public health recommendations.

Do they name names?
No, details of the restaurants are not included, but they reveal that they analysed the calories in 1009 dishes, 212 starters, 318 sides and 479 desserts, from 27 large UK restaurant chains (21 full-service, six fast-food).

What did they find?
An average of 488 kcal for starters, 397.5 kcal for sides and 430.6 for desserts. The percentage of dishes exceeding the recommended number of calories in a full meal (600 kcal) was 26.4% for starters, 21.7% for sides and 20.5% for desserts. So, in essence, one in four starters and one in five sides and desserts in UK chain restaurants exceed the recommended energy intake for an entire meal.

Was there much difference between fast-food chains and full-service restaurants?
Compared with fast-food chains, desserts offered at full-service restaurants were on average more calorific and were significantly more likely to exceed 600 kcal.

What is the calorie consumption for a three-course meal in a major UK chain?
The average energy content for a starter, main meal and dessert (without the addition of an extra side or any drinks) would be approximately 1896 kcal – which equates to over three times the recommended energy intake for a main meal, and 95% of the recommended daily consumption of kcals for women, or 76% for men.

IMAGES: ISTOCK/SHUTTERSTOCK

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→ **ohaus.com**

IMAGINAB

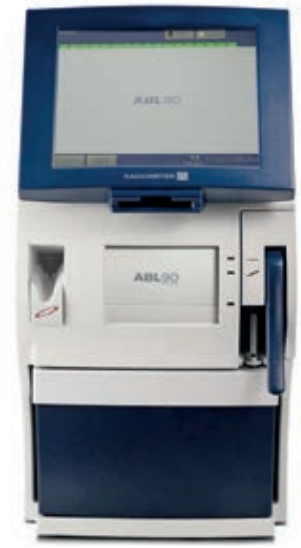
IMAGING

A clinical stage immuno-oncology imaging company has announced the publication of data on first in-human imaging in patients with solid malignancies

The paper reports the results from a first *in vivo* clinical study to assess the safety, tolerability and efficacy of ImaginAb's lead product, CD8 tracer, 89Zr-Df-IAB22M2C, in visualising the immune system.

The study found 89Zr-DfIAB22M2C imaging to be safe and with favourable kinetics.

→ **imaginab.com**



RADIOMETER

POCT SOLUTIONS

Radiometer exhibited its innovative range of point-of-care solutions at this year's IBMS Congress 2019.

It held a breakfast presentation entitled "Point-of-care testing – more than an (arterial) stab in the dark", presented by Katy Heaney, POCT Lead, Consultant Biochemist at Frimley Park Hospital.

She discussed her personal experience of elevating the historical perception of blood gas analysers from unreliable and inaccurate to reliable, multi-test analysers producing high-quality results.

→ **radiometer.co.uk**

THE BIG QUESTION

THIS MONTH WE ASK

"How have the ways we think of competence changed?"

Jacqueline Wales

Head of Laboratories
NHS Golden Jubilee

The Oxford English Dictionary defines competence as "the ability to do something successfully or efficiently". I would have been happy with this, if I hadn't been so heavily involved in the training and education of our future biomedical scientists. I've been Head of Laboratories since 2014, but in 2004 I was appointed Departmental Training Manager, just six months after the introduction of the IBMS Certificate of Competence Portfolio as a route to registration with the Health and Care Professions Council (HCPC).

In my opinion, the advent of these forced us to look at what attributes are demanded from registrants by forcing them to submit evidence that their practice meets a minimum set of standards i.e. Standards of Proficiency.

Owing to the limited number of places in the laboratories, universities have a strict selection process that underpinned and changed my understanding of competence. The layout of all versions of the portfolio requires the student to demonstrate their developing knowledge, skills and understanding; however, the evidence required also demands that students demonstrate their professionalism. High academic marks are not enough; students must demonstrate professionalism i.e. communication skills, ability to work as a team, respecting confidentiality, equality and diversity in the workplace, organisational skills and overall practising to a professional code of conduct.

IMAGE: ISTOCK

Mairead MacLennan

Professional Manager (Quality and Training)
Victoria Hospital, Kirkcaldy

During my time as a biomedical scientist, it has been like night and day. Individuals could be in post for many years, or return to work after a significant absence, without ever having the tasks they performed assessed and recorded. Competence assessment was unheard of.

The evolution to the HCPC with Standards of Proficiency, followed by the introduction of portfolios and mandatory CPD, has brought requirements of registrants into sharp focus. High-impact improvements in skills, knowledge and scientists' work is the outcome. Competence assessment emerged in the late 1990s. However, ISO 15189 accreditation has resulted in the need for structured training programmes to reflect skills and knowledge matrices, involving scheduled and recorded training with competence assessment and reassessment within justifiable, defined time frames. When independently assessed, the competences required for a given role and the overall competence of the individual must be evident.

Never before has the function of training managers and officers been so vital, necessitating that these are performed full time. Multifaceted knowledge, skills and experience combine to demonstrate job role competence. Departments that do not have dedicated training personnel will find it hard to build and maintain a system that supports staff to evidence competence.

Shauna McAuley

Governance and Quality Manager
Belfast Trust Laboratories

In recent years, competence has become more evidence-based, with a clearly defined set of standards to achieve or be demonstrated. It is led by documented evidence and reflective practice and must be available when competence is queried. This can become a "paper exercise" with the ability of the individual to complete paperwork being tested, rather than their ability at the task.

We need evidence that competence exists. That should not be replaced with a bureaucratic process that measures ability to complete paperwork.

In recent years, competence has become more evidence-based, with clearly defined standards

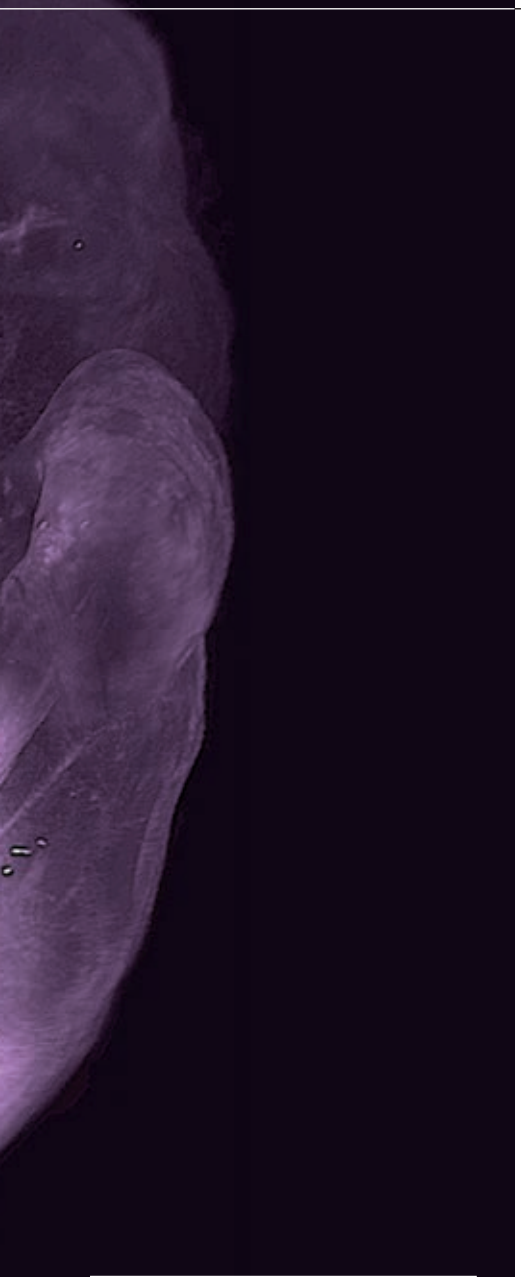
REPTILIAN MUSCLES

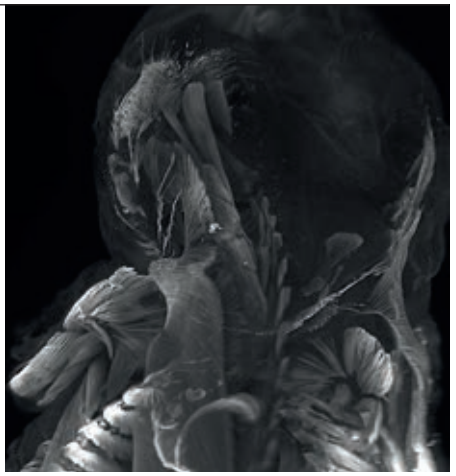
Biologist **Dr Rui Diogo** discusses the discovery of embryonic hand muscles and their evolutionary implications.

When the amphibians first crawled out of the water and ventured onto land over 300 million years ago, they began the evolutionary process that saw them branch off into two distinct classes of animals: the reptiles and the mammals. The first small mammals appeared around 225 million years ago, the first apes around 60 million years ago, the first humans at about six million years ago, and the first members of our species, *Homo sapiens*, about 300,000 years ago. Given all that time, you would be forgiven for thinking that every trace of the amphibian (and the reptilian) might have been expunged from our biology, but a study of human embryos has found that we retain a few unexpected vestiges of that common ancestry.

The research, headed by Dr Rui Diogo at the Howard University in Washington DC, looked at images of the hands of embryos from seven to 10 weeks old and fetuses from 10 to 13 weeks old and discovered what appear to be the traces of muscles. However, these muscles don't hang around for long. They tend to disappear, and most babies are born without them, though they may persist in birth defects and may be the cause of certain deformities.

The images of the 15 embryos were taken by a team of French scientists, using a technique that attaches modified antibodies to body matter, in this case the myosin that forms the muscles. But while the French team were mainly concentrating on producing detailed images, it took the trained eyes of Diogo to





Left. Dorsal view of the left hand of a 10-week-old human embryo.
Right. Dorsal body view of an 8-week-old human embryo.

realise the evolutionary and medical significance. "When I saw their images I began to see strange things," he says. "Things that I know are in non-human adult animals that should not be present in humans. I asked them for the full images and I saw one by one, at seven, eight, nine weeks and so on – clearly there were a lot of these atavistic muscles."

Diogo believes the findings can tell us a lot about evolution and why certain parts of our biology persist even though they serve no practical use. "If everything had a purpose, we would not have the appendix or these muscles. They are not doing any harm and clearly we can survive with them."

At the heart of this, he argues, is whether evolution produces results that are optimal or simply good enough.

"I think it is probably not easy for evolution to just remove stuff. A lot of animals have this repetition of muscles going to each of the five digits, and each muscle will have three or four smaller muscles just to control extension and contraction. What happened in human evolution is that our thumb is very mobile, with a lot of muscles, and those remain. But the other digits lost many of these small muscles and so lost a lot of precise movement. We think that it is probably very difficult for the growing embryo to say we need just one of the five muscles going to each digit, so probably we have to form layers that go to all the digits, then as the layers begin to build up we lose those parts of the layer that go to the digits that we don't need to move in such a precise way. I think this is an example of 'good enough' evolution."

Another issue the muscles pose is the notion of 'progress'. "We can call them vestigial muscles because they are doing nothing in the embryo, they don't have a purpose. But 'atavistic' should be applied because it emphasises that these traits were lost in evolution, whereas vestigial structures like the appendix were never lost in our adult ancestors. Take for instance the tail. We lost it 20 million years ago during the transitions from monkeys to apes, which have no tail. No adult mammal has the muscles we see in the picture, meaning that they were lost more than 250 million years ago. So these muscles are a powerful illustration of atavisms that were lost a long time ago, but remain in prenatal development."

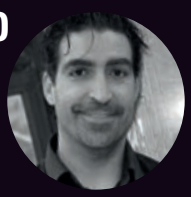
The reason we lose certain traits and features as adults, says Diogo, is because they are not useful. "Each animal will adapt to its local conditions. So when fish go to a cave, the cave is dark and they cannot see anything, they lose the eyes during evolution. During the evolutionary stages to humans, it became less and less useful to use the other four digits so precisely. That is not better or worse, just good enough.

"Most people think that humans are more complex, but what this clearly shows is that even during our normal development we lose structures. A human embryo has more structures than a human adult. We have around 30 muscles in the hands and feet at only seven weeks and around 20 when we are adults. Our evolution is mainly an evolution of simplification. In total, a human adult has fewer muscles and bones than an adult mouse or an adult salamander."

Diogo is now hoping that the French team will produce images of different parts of the embryos. "I would like to look at the head because I know we have some atavistic muscles there as well, based on preliminary observations. One of them is a facial expression muscle, but we have also lost this during evolution and I really want to look at it in detail." BMS

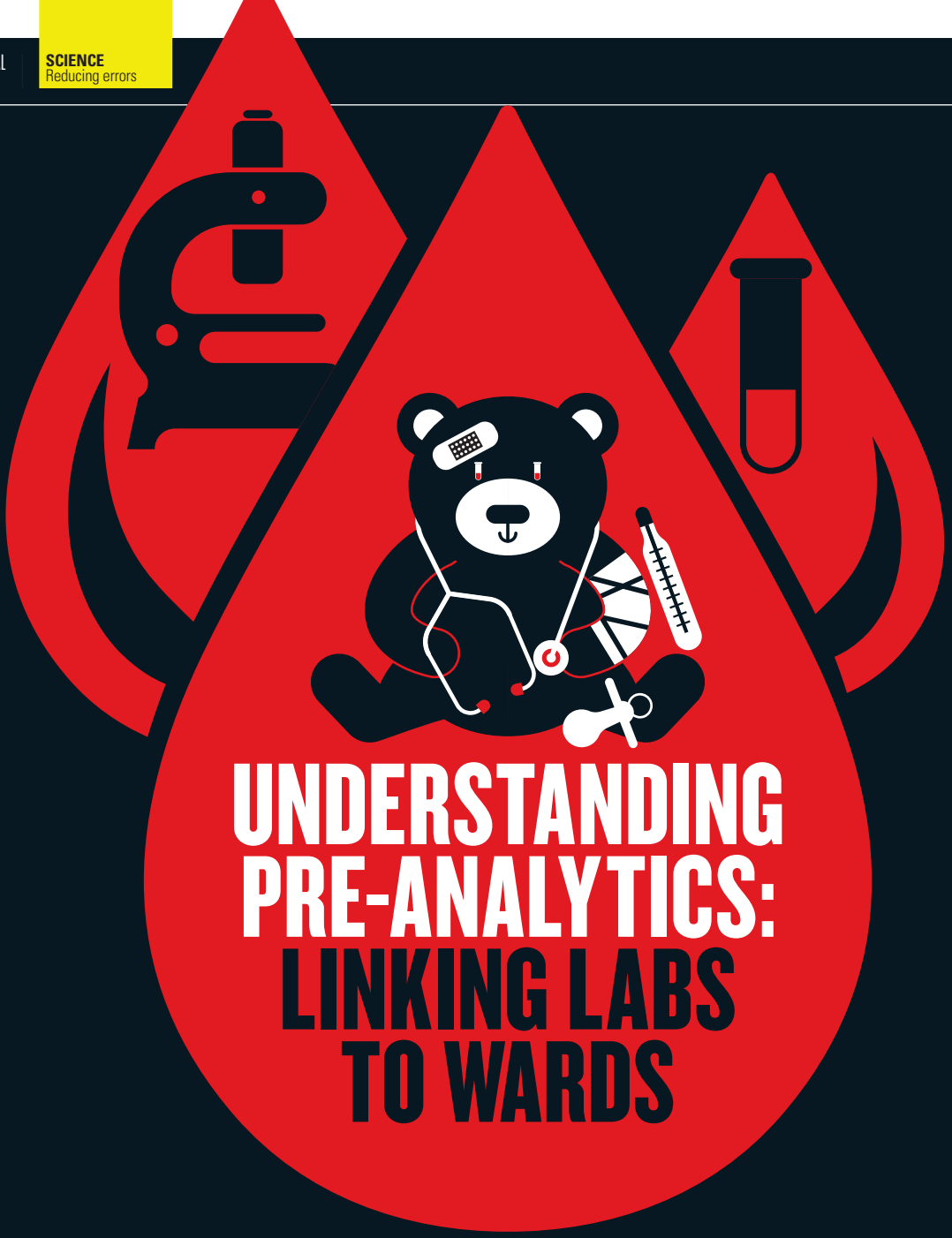
Dr Rui Diogo is Associate Professor at the Howard University College of Medicine

DR RUI DIOGO ASSOCIATE PROFESSOR



- ✔ Has a PhD in Evolutionary Biology and in Hominid Paleobiology
- ✔ Associate Professor at the Howard University College of Medicine in Washington DC.
- ✔ A resource faculty member at the Center for the Advanced Study of Hominid Paleobiology of George Washington University, in Washington DC.

IMAGES: RUI DIOGO, NATALIA SIOMAVA AND YORICK GITTON



UNDERSTANDING PRE-ANALYTICS: LINKING LABS TO WARDS

Wisdom Musabaike and **Malti Nakrani** from Great Ormond Street Hospital for Children outline a project to reduce the number of pre-analytical errors.

At Great Ormond Street Hospital for Children (GOSH) the laboratory receives more than 500,000 samples and performs more than 2.1 million tests a year. An audit in 2017, which was limited to a few departments, revealed that at least 4000 samples were rejected in that year due to pre-analytical errors (PAE) alone.

High rates of rejection lead to a high rate of specimen recollection, mostly blood draws, which in paediatric patients can have significant consequences. It further contributes to delays in results being available, potential delays in diagnosis, treatment and discharge, as well as having a significant impact on patient experience.

Our mission is to always put the child first. For many of the children who come to GOSH, a daunting experience of their stay is when a needle is introduced into a vein. Paediatric blood collection is known to be more challenging because of the patient's smaller body size, low circulating blood volume, and developing physiology. Collection methods routinely used for adult patients, such as venepuncture, are not always an option for children.

Why change was needed

It is estimated that 70-85% of clinical decisions are based upon the information derived from laboratory test results, so ensuring optimal sample quality and timely delivery is crucial to the patient, the clinician and the efficiency of the

hospital. For this reason, the laboratory has a crucial role to play in ensuring that we continue to deliver the exceptional standards of service and patient-centred clinical care.

Evidence suggests that most sample errors occur in the pre-analytical phase. The ISO15189:2012 standard also recognises the importance of the pre-analytical phase by setting out requirements for laboratories under clause 5.4.

PAEs can occur at a number of stages, including test ordering, patient preparation, specimen collection and transportation. Since the activities are not performed in the laboratory, or under the control of laboratory personnel, they are harder for laboratories to monitor and improve upon.

At GOSH, the numbers of samples rejected in the laboratory due to pre-analytical reasons has been recorded for many years. However, the laboratories have had no direct control of the pre-analytical process to effect corrective actions. Data at GOSH showed the main reasons for rejection as: clotted blood, insufficient sample volumes, haemolysed or unlabelled or blood contaminated with EDTA.

In order to address these issues we have initiated the project "Pre-analytical laboratory samples project" in collaboration with the trust's Quality Improvement team, working on QI methodology. The aim is to develop the organisation's pre-analytical capabilities and to reduce the number of pre-analytical errors and improve patient care and operational efficiency. The main focus was to improve communication between the hospital staff in the clinical areas and laboratory staff, to train staff in procedures for ordering, collecting, handling, preparing and transporting biological specimens, all in order to improve the quality of samples and reduce errors in the sample pathway.

We anticipate that the project will help reduce numbers of repeated sample collections, which can be uncomfortable and distressing for patients and families, and help the clinicians involved in sample collection to manage their workload effectively. We foresee fewer delays in medical teams receiving results, enabling fewer delays in diagnosis, treatment and discharge.

Evidence suggests that most errors in the process fall outside the analytical phase

What we did

Early in 2018, we decided to explore other opportunities for improvement in sample collection practice and to implement solutions, with the overall aim of significantly reducing the number of sample rejections. The rejection of nasopharyngeal aspirate (NPA) samples due to container leaks was considered as an area for improvement. Issuing guidelines for staff to send all of these samples through porters rather than via the pneumatic tube system ("chute") reduced the rejection rate.

The weekly percentage of NPA samples rejected due to leakage has reduced from a mean of 1.79% to a mean of 0.3%. This has been sustained since March 2018.

After a "quick win" with the pilot NPA project, a steering team was formed of clinical and non-clinical stakeholders, chaired by the Medical Director and with support of the hospital's executive. Based on the reasons for rejection, four key work streams were set as integral to achieving a quality sample: collection resources; transport; training and education; and policy and guidelines.

To understand the main reasons for rejection and where the greatest areas for improvement were, we developed a real-time report statistical control process (SCP) chart on the intranet issuing data from the laboratory information system. Data can be viewed at trust- and ward-wide level and is accessible by all staff.

From the data we were able to identify that the most common reasons for rejection were: clotted coagulation test samples, insufficient/underfilled samples and labelling errors.

The causes were identified as incorrect technique when taking the sample (such as insufficient mixing or vigorous shaking), issues with the equipment (such as loss of vacuum, expired tubes or incompatible resources), or delay in transporting samples to the laboratory.

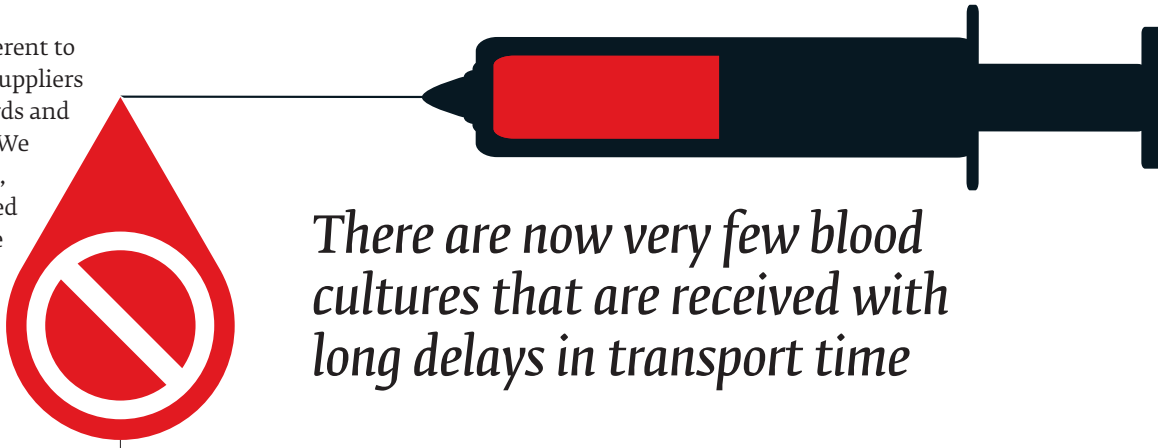
Blood must be drawn in a specific order to avoid cross-contamination between blood tubes. We found the collection

IMAGES: ISTOCK/REX-SHUTTERSTOCK

sequence used at GOSH was different to the order recommended by the suppliers of the bottles, laboratory standards and the World Health Organization. We have now changed our guideline, created new resources, and shared the rationale with staff under the banner "New Year; New Draw". It wasn't until we started looking into collection practices and having conversations outside the laboratory that we became aware of the need to standardise the order of blood draw.

Delayed transport was identified as a frequent issue. It is important that blood cultures are sent to the laboratory as soon as possible, so that any bacteria that might be present in the sample can grow, be detected and be treated.

We developed visual guides to remind staff to send these samples via the pneumatic chute system for speed of delivery. Consequently, the increased use of the pneumatic chute has seen a great improvement in the transportation of blood cultures from the ward to the laboratory. There are now very few blood cultures that are received with long delays in transport time. This means that the blood cultures can be incubated quickly, which will reduce the time to detection of pathogens that cause sepsis and allow for quicker patient treatment and management.



There are now very few blood cultures that are received with long delays in transport time

The weekly average transport time mean has reduced from 239 minutes (June 2017 to October 2018) to 148 minutes (November 2018 to May 2019)

GOSH has had a new electronic patient record (EPR) system, EPIC, since April 2019. When blood tests are requested on EPIC, the ward staff will be prompted to print a patient label for the tube and will also be reminded of the blood collection sequence in which to take their samples. We are still in the transition phase, but we envisage EPIC will have significant benefit to the PAE project.

Small changes, big returns

Our interventions have shown demonstrable quality improvements. As we move forward we will continue to develop and implement changes to reduce sample rejections. We plan to develop a training strategy and practical best practice guide with quick tips for decreasing the likelihood of a sample being rejected, particularly for paediatric patients. We're going to continue to evaluate the blood collection system in order to standardise the product from one brand. Work is in progress for implementing an alternative coagulation tube for neonates with a reduced minimum volume requirement to facilitate reduction in PAEs.

Establishing a pre-analytical project role has been key in driving this quality improvement. Countless ward visits, engaging with stakeholders, going out there and having conversations with nurses, matrons, HCAs, practice educators, all worked to connect with people who often are not aware of "why" we do things the way we do. Delivering training and education, teaching sessions, and cascading key messages have all been embedded in the work that's been done so far. Preparing visual aids, posters, screensavers, and newsletters has been the key in disseminating information. We are putting every effort into building pre-analytical relationships and closing the gaps between the laboratories and direct patient care.

We believe that laboratory scientists can make a big impact on patient pathways, and it is crucial we work with the streams of other professionals across trusts to understand pre-analytics – the "unbreakable quality chain" in linking laboratories to clinical areas. BMS

Wisdom Musabaike is Pathology Lead for Quality and Risk Manager and **Malti Nakrani** is Quality improvement Lead (Pre-analytical), both at GOSH.

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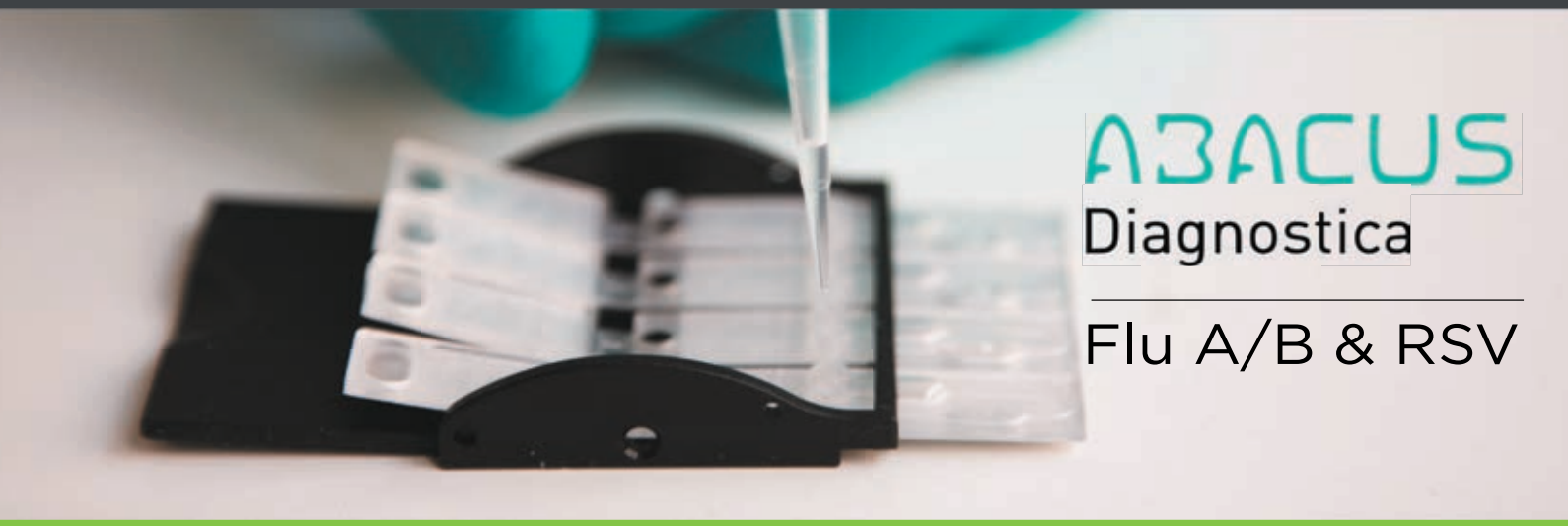
INTRODUCING A NEW RAPID MOLECULAR SAMPLE–TO–ANSWER TEST FOR FLU & RSV



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THE
RISE
OF
POCT.

We look at the **rapid ascent of POCT** – the tests that are **redefining diagnostics** and **breaking down barriers** between laboratories and patients.

This year, for the first time ever at IBMS Congress, there was a whole programme dedicated to point-of-care testing (POCT). There were nine sessions throughout the day, covering a wide variety of aspects of the rapidly emerging discipline.

The sessions were held in a packed hall – with many scientists standing, crowded around the back of the room to hear the speakers' insights.

Dr Sarah Glover, a Consultant Clinical Biochemist, is a clinical lead for POCT and was the chair for the Congress POCT programme.

"I'm really excited that we had a whole day on POCT at this Congress," she says. "It's always difficult to know how many people are going to turn up for a new session, but the room was full most of the morning and it was standing room only for much of the time. It's been really successful and the audience have been really engaged in the topic.

"We decided we needed a dedicated programme because there are so many interesting topics and speakers coming through at the moment," she continues. "Previously, we've had individual session that have been well attended and POCT is a discipline which is growing and growing and that's only going to continue going forwards."

Market trends

A report on the global POCT market, published in October, states that it is now a multi-billion-pound industry "with intense competition and areas of growth".

It says that a major force driving the industry expansion is the effort to provide better patient care through the improved turnaround time that POCT offers.

While other forces include cost containment through less time spent in the accident and emergency and other critical care environments, the ageing population that requires proportionately

POCT is a discipline which is growing and growing and that's only going to continue

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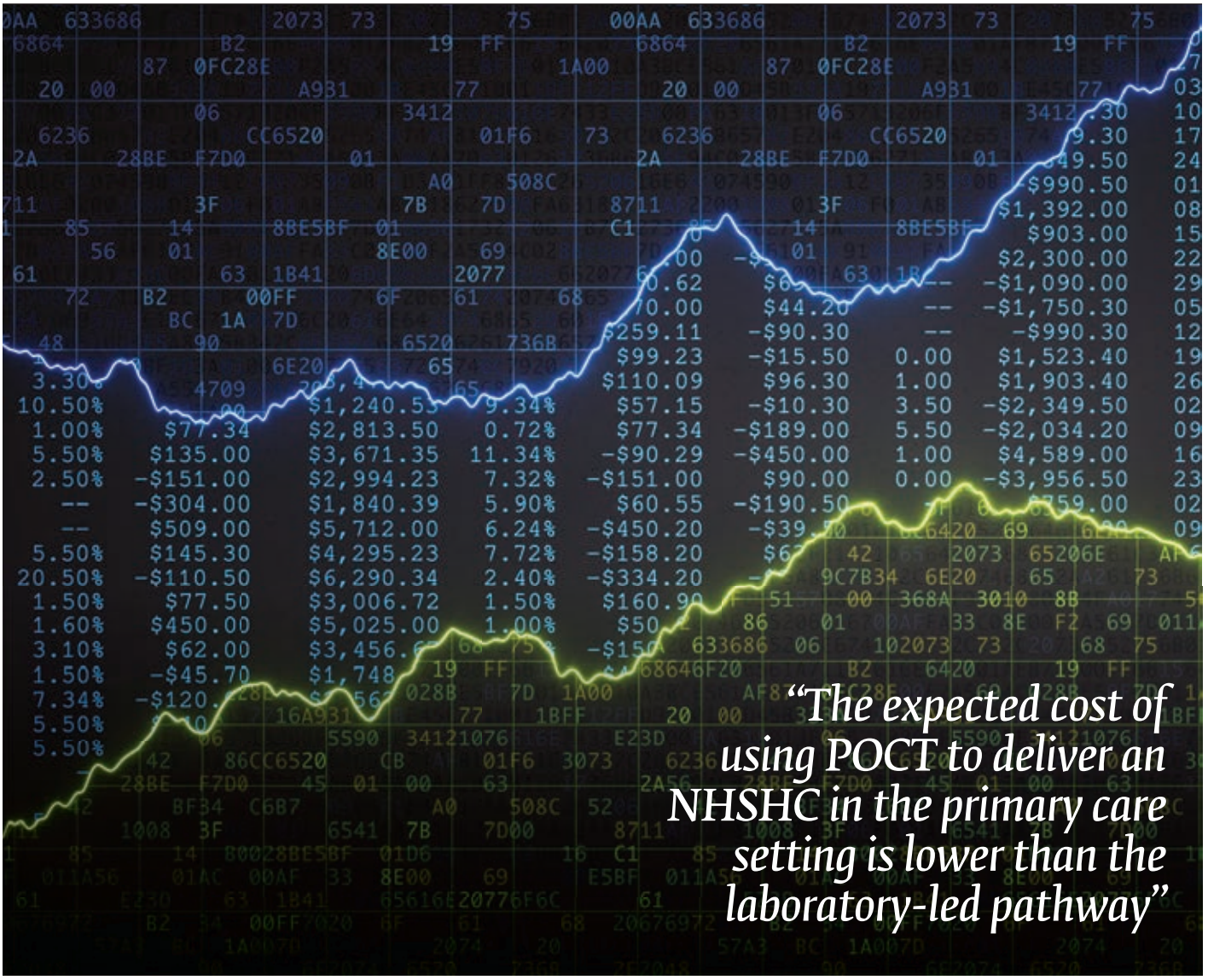


greater healthcare, the increased incidence of certain diseases, health worker shortages, and technological advances allowing for small, portable, easy-to-use POCT devices.

The report predicts that the market will be worth £34bn by 2026 on the back of an expected annual growth rate of 8.4%.

It goes on to list 27 different areas currently within the POCT sector, from the common blood glucose testing kits, to prothrombin time testing kits and activated clotting time testing kits.

Making savings?

There is a seemingly constant stream of new tests and devices being developed and rolled out.

In October, the NHS Health Research Authority announced that it had granted approval to start testing an antibiotic-induced hearing POC test in hospital trials.

It is due to be trialled in 1000 patients from two large UK intensive care units and is scheduled to start in November and run for six months. This represents the world's first ethical approval for a POC genetic test used to influence neonatal management in an acute setting.

POC tests have also been making newspaper headlines, for example *The Independent* ran the story "20 minute flu test could save the NHS up to £24m a year and free up beds, manufacturer says". Public Health England said there are a number of tests coming on to the market, and while some early adopter trusts have found benefits, there is yet to be a national assessment of their cost-effectiveness.

But, while the data may not be available yet, research into the area indicates that cost savings are likely. A recent paper published by the *BMJ* sought to determine if POCT is less costly than laboratory testing in delivering the NHS Health Check (NHSHC) programme in the primary care setting.

Working with nine general practices (seven using POCT; two not using POCT) data were collected on cost, volume and type of pathology services performed.

Their paper concludes "the expected cost of using POCT to deliver an NHSHC in the primary care setting is lower than the laboratory-led pathway. Using POCT minimises did-not-attend rates associated with laboratory testing and enables completion of NHSHC in one sitting."

NICKY HOLLOWOOD ON UKAS POCT ACCREDITATION

Our decision to apply for accreditation was a joint one with UKAS at our pre-inspection meeting as both parties felt it was achievable. Having an ongoing dialogue with UKAS regarding our expectations and what was achievable was central to us securing the accreditation as we were able to address any issues and solutions ahead of the assessment. We were also able to plan accordingly and identify any additional resources that we would need to achieve this.

The biggest challenges for us were mainly during the transition stage; continuing to run a POCT service that was functional for our users while developing and implementing new systems and ways of working. Going forward; now this transition has been completed the assessment visits are far more streamlined and there isn't the same preparation required for the visits as our service is continually changing and evolving.

The absolute starting point is to do a gap analysis; assess where you are and where you want to be and then you can determine how much work is needed and whether you have the resources to achieve this. There are some services that we haven't submitted for UKAS accreditation such as fetal fibronectin (and may never submit) as it would be too challenging to meet UKAS requirements for them. For these services we work towards UKAS requirements and implement the quality standards that we can achieve to ensure we standardise our POCT service as much as possible.

There are some POCT services that don't feel they can achieve this accreditation but may choose to work towards it by incorporating the ISO standards that they feel bring value to their service. Either way, the ISO standards are the main quality benchmark we have available to work towards.

A changing NHS

Nicky Hollowood is POCT Manager working in pathology at Harrogate and District NHS Foundation Trust. She says the scope and range of POCT devices available has "increased enormously", especially over the last decade. She continues: "This has been driven by technology improvements. The commercial scientific industry is able to produce smaller, portable diagnostic platforms with improved data management and operator functionality.

"As well as technology improving, the government's strategic plans for the NHS have increasingly been centred on moving care from the hospital to the community and reducing length of stay in hospital. The main focus being on prevention, early intervention and self-management.

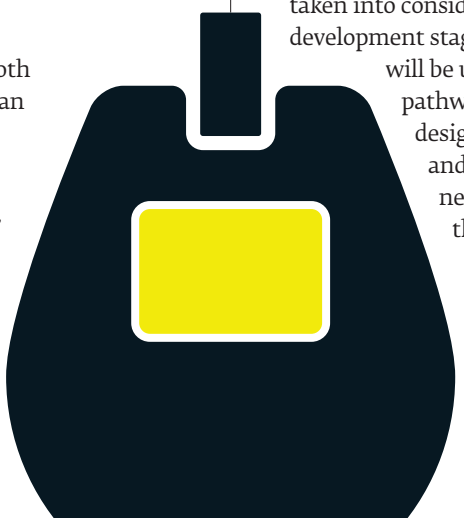
"NHS strategic plans and technology improvements have both jointly contributed to an increase and a more widespread use of POCT devices across healthcare pathways."

"We will enable staff to capture all health and care information digitally at the point of care"

This is a shift in focus that is immediately apparent in the NHS Long Term Plan, which aims to move the NHS forward so that in 10 years' time "we have a service fit for the future". The first section of the plan is titled "We will boost 'out-of-hospital' care, and finally dissolve the historic divide between primary and community health services". It goes on to mention the word "community" 140 times across its 136 pages and states: "We will enable staff to capture all health and care information digitally at the point of care, and optimise clinical processes to reduce administrative burden. We will support the workforce to develop the digital skills they need to make effective use of these tools and mobile access to digital services to allow health and care workers to work more flexibly."

Changing dynamics

In order to allow the capture of data at the point of care, the companies that are developing and manufacturing the kits are changing their focus. Nicky Hollowood says: "Traditionally, POCT devices have been developed for chemistry tests but we are increasingly seeing more haematology and microbiology tests being incorporated onto POCT platforms. The strategy for the development of POCT devices in industry is also shifting. In the early days, the key driving forces for POCT product developments were based around what tests could feasibly be replicated on a smaller platform with sufficient accuracy. Now we are seeing the commercial sector taken into consideration during the development stage; where the device will be used, what care pathways they are being designed to support and what tests are needed to support this clinical service."



She continues: "When the product comes to market, there is a clear marketing strategy

around the intended use of the device and many platforms are now hosting an array of tests covering chemistry, haematology and microbiology specialties. This in itself is changing the dynamics of the POCT service as it is becoming more of a standalone multidiscipline specialty in its own right."

The fast-evolving nature of the sector means that issues such as training and accreditation are still in flux and evolving in tandem with POCT.

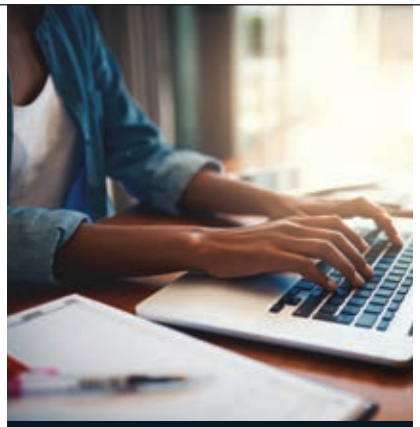
Ben Courtney, Accreditation Manager at UKAS, explains the fluidity of POCT. "The UKAS approach is adaptable and collaborative with POCT," he says.

"We want to understand what the problems are and devise an accreditation programme that suits biomedical scientists' needs. Those thinking about seeking accreditation should conduct a gap assessment and then address those gaps – we want to see that you know what you are talking about. There are so many different ways that POCT can be delivered and will work." He adds that those who seek accreditation who are unsuccessful should not worry about their lab accreditation – "think of it as an extension to scope," he says "it has no impact on the accreditation of your lab". Only a handful of labs have POCT UKAS accreditation at present, including Harrogate – see the box, on the previous page, for advice from Nicky Hollowood on how the trust sought and secured accreditation.

New qualification

It is also early days for POCT training, but it was announced at Congress that a new IBMS POCT qualification is set to launch at the start of next year. Lee Peters, Section Manager in Swansea Bay Health Board, who is currently completing a doctorate in POCT education for laboratory staff, outlines the qualification and explains the reasons behind it.

"There have been calls for a POCT qualification for some time, it's always been bubbling below the surface," he says.



NEW IBMS POCT QUALIFICATION

The new IBMS POCT qualification is a Certificate of Expert Practice

It comprises six modules, each of which runs for two weeks

- There are two reflective pieces of work required during the course and an exam at the end
- The course will cost £675 and is run in conjunction with Ulster University, which will host it online
- The pilot is due to launch in January 2020 and will be limited to 60 places
- The qualification is aimed at new and aspiring POCT staff.

For more information, visit the IBMS website over the coming weeks.

POCT IN NUMBERS

£34bn
The expected POCT market value by 2026

8.4%
The predicted annual growth rate of sector

27
There are 27 different areas within POCT

"But because of the scope and the increase in use and demand we thought that a POCT qualification was required."

In August last year, the IBMS set up a working group which discussed the gaps in knowledge around POCT for biomedical scientists and over the following months the group designed a set of modules that were aimed to fill those gaps.

"Quality runs through these modules and you will be in a group with like-minded individuals and it'll be interesting to see how other people are working with POCT," says Lee Peters, before stressing: "Apart from the reflective pieces and the exams, everything can be done quite flexibly depending on your workload." See box for more information on the qualification.

Breaking barriers

As more POCT tests are launched and more scientists train and become qualified in the discipline, as well as patients getting better, faster care, the nature and perception of laboratories may also start to change. "Traditionally the laboratory has been seen as the ivory tower," says Dr Sarah Glover. "People don't have access to the laboratory and probably don't understand the processes. POCT brings that laboratory testing out to the patient, and the laboratory staff who are running POCT services are very much engaging with users – they are out there providing a face for the laboratory and asking how we can develop services which help patients, improve patient pathways and optimise patient experience. It's becoming much more of a two-way dialogue, rather than the laboratory being seen as something that is behind closed doors." BMS

This month the IBMS launches its new series of monthly podcasts. The first episode features interviews with Dr Sarah Glover and Lee Peters. To listen to the episode, which is an exclusive IBMS members-only benefit, visit the IBMS website.

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PRE-ECLAMPSIA BLOOD TEST

How an integrated team improved the safety of mothers and babies using angiogenic biomarkers for pre-eclampsia.

An Oxford team that developed and introduced a new blood test to rule out pre-eclampsia in pregnant women at Oxford University Hospitals NHS Foundation Trust (OUH) has won a UNIVANTS of Healthcare Excellence Award. The award recognises "teams that collaborate across disciplines, including the core laboratory, to reshape care pathways and ultimately achieve better outcomes for patients, clinicians, payers and entire health systems".

The team, including IBMS Fellow, Tim James, Head Biomedical Scientist in OUH's clinical biochemistry department, trialled the test at the John Radcliffe Hospital's Women's Centre. A key finding is that the test predicts that a pregnant woman will not develop pre-eclampsia

within the next seven days with almost 100% accuracy. It was accepted as routine clinical practice at OUH in 2018 and is now being rolled out across the NHS by the Oxford Academic Health Science Network (AHSN).

Significant strides

The test demonstrates how clinical chemists can make significant strides in improving care. Tim James' role was to support the clinical trial (The INSPIRE study), manage a business case for introduction into routine practice in Oxford, and support the Oxford AHSN in helping other labs set up the test. He says: "One of the important things we have learnt is that the new test helps clinicians make important decisions about patient care at a critical stage of pregnancy and in many cases reduces uncertainty about those decisions. We are, therefore, keen to make sure the test benefit can be delivered across the NHS."

Pre-eclampsia is a serious disease that causes high blood pressure, protein in the urine, and oedema, and can result in liver failure, kidney failure and seizures in the mother. It can also lead to restricted growth in the baby and often premature delivery. However, many pregnant women who show symptoms do not have pre-eclampsia. The disease continues to be a poorly understood complication of pregnancy, affecting 2% to 8% of pregnant women worldwide. Women presenting with suspected pre-eclampsia are often tested for a range of common biochemistry analytes, including creatinine, ALT, uric acid and albumin. None of these tests have good diagnostic accuracy for pre-eclampsia and only change late in the developing pathology. Consequently, there has been a large unmet need for more accurate diagnostic tests of this condition.

Markers

One of the biochemical characteristics associated with pre-eclampsia is an imbalance between angiogenic factors, and these factors give good diagnostic accuracy in the detection of the condition. Two proteins are used: placental growth factor (PlGF), which promotes angiogenesis, and soluble fms-like tyrosine kinase-1 (sFlt-1), which inhibits angiogenesis. The markers may be used in two ways: PlGF can be used as a single test, or both markers may be measured to produce an SfLT:PlGF ratio. In Oxford, the latter approach was adopted following an evaluation of the ratio's value in terms of patient outcomes within a clinical study. The ratio has been running in routine clinical practice for a year and applied in a well-defined patient pathway to categorise patients into low risk (SfLT ratio <38), medium risk (ratio 38-85) or high risk (ratio >85). The markers are easy to run on standard automated instruments with good precision, are highly stable, and compare well across different laboratories in sample exchange programmes.

Before the introduction of the new test, almost 70% of patients admitted did not actually have pre-eclampsia and there was no accurate method to determine who would get the disease. Currently, patients with suspected pre-eclampsia are often admitted to hospital, sometimes for several days, in order to make the diagnosis. It is diagnosed by excluding all the other possible causes of high blood pressure and protein in the urine through a series of tests, which take time and cause anxiety for the mother-to-be and her family.

> *The new test helps clinicians make important decisions at a critical stage of pregnancy*

The results of the INSPIRE study, where the tests were evaluated in a real-world routine setting, were reported in the October edition of the journal *Hypertension*. Key findings were the new test's negative predictive value of 99.3% for the following 7 days - meaning improved confidence in discharging patients without pre-eclampsia and the improved safety of mothers with pre-eclampsia. When the test was used it correctly identified 100% of this group compared to 83% with standard clinical practice alone.

The UNIVANTS award is now open for applicants and based on his experience Tim commented: "With the many pressures we have in the NHS laboratory services it is important to not lose sight of the very important developments we can achieve and I would encourage any laboratory who has worked with clinical colleagues on projects of this kind to consider submitting an application." BMS

THE UNIVANTS OF HEALTHCARE EXCELLENCE AWARD

Annually recognises teams who collaborate across disciplines and transform healthcare delivery and patient lives. Applications are open until February 28. For more information on how to enter, and to read about previous winners, visit **abbo.tt/35JCr5v**

IMAGES: ISTOCK

RARE TESTICULAR TUMOUR

A CASE STUDY

Louise Greenhalgh, a Specialist Biomedical Scientist in Cellular Pathology, presents a case study of a cancer with less than 50 examples reported in the literature.

The Higher Specialist Diploma (HSD) portfolio requires the completion of two case studies. These must follow the patient from presentation to treatment, through the pre-analytical, analytical and post-analytical phases.

When completing a case study, it is important to take a multidisciplinary approach, documenting the considerations of both clinician and pathologist. Differential diagnoses must be discussed; patient history, alongside clinical and pathological findings, must be utilised to reach an accurate final diagnosis.

The following case study was included in my HSD portfolio submission. I successfully gained my HSD in 2018.

Testicular tumours

A 65-year-old male presented with a progressive, painless left testicular swelling. There was no history of trauma and no other genito-urinary symptoms. Upon hospital referral, the patient underwent physical examination, blood tests, ultrasound and computerised tomography (CT) scanning. Palpation revealed a hemi-scrotal swelling, consistent with a tense hydrocele. This is an abnormal collection of fluid between the two mesothelial layers of the tunica vaginalis and can arise from numerous events, including trauma, infection and testicular tumours. Since the patient had reported no trauma to the area and presented with no signs of infection, a testicular tumour was suspected as the most probable cause.

The most commonly encountered testicular tumours are germ cell tumours, which usually result in abnormal serum levels of alpha fetoprotein (AFP) or beta-human chorionic gonadotrophin (βhCG). However, germ cell specific markers for the patient were all within normal ranges. The patient did not fall into the usual age range for the more common germ cell tumours. Average ages for presentation of seminoma, yolk sac tumour, teratoma, embryonal carcinoma and choriocarcinoma are 30-40 years, 1-3 years, 10-30 years, 20-30 years and 10-30 years, respectively.

Ultrasound examination did not indicate a solid mass, as would be expected with most tumour types.

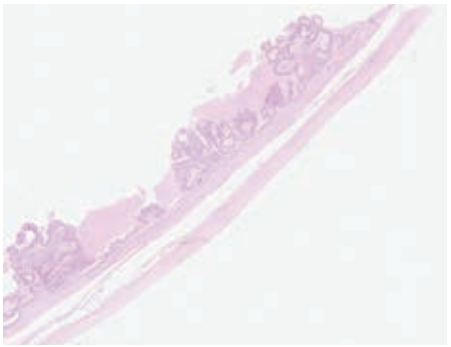
A cystic lesion with features suspicious of lymphoma was observed.

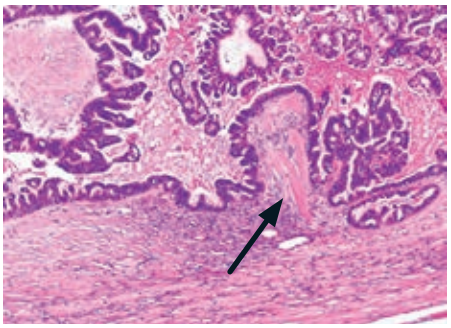
Primary malignant lymphoma of the testis usually occurs in patients over 60 years of age, fitting with the patient profile. Although the patient's serum lactate dehydrogenase (LDH) level was within normal range, not all lymphomas present with elevated LDH levels.

CT scan of the chest, abdomen and pelvis was performed, with no significant intra-abdominal or mediastinal lymphadenopathy observed. No bony lesions were observed and organs, including liver, spleen, kidneys, pancreas and adrenal glands, were unremarkable. Left radical orchidectomy was performed under general anaesthetic and the specimen was sent to histopathology.

Examining the specimen

On gross examination, the specimen was described as an enlarged testis measuring 10x7x6 cm. The external surface and attached spermatic cord





Left. Low power (x10). Serous lining overlying ovarian type stroma.
Below. High power (x40). Papillary tufts with fibrovascular cores and lined by stratified columnar epithelial cells.
Bottom. Immunocytochemical epithelial staining of the papillary tufts.

were unremarkable. Slicing at dissection revealed a thin walled, unilocular cyst, surrounded by a thin fibrous capsule and filled with thick chocolate coloured fluid. Multiple papillary excrescences were observed on the inner surface of the cyst.

At this stage, the pathologist commented that the macroscopic appearance of these papillary lesions resembled a mesothelioma, the most common malignant pretesticular tumour with an "epithelial" growth pattern, which usually occurs within the sixth or seventh decade. However, the papillary morphological features of the specimen unusually showed great similarity to those seen in borderline lesions of the ovary.

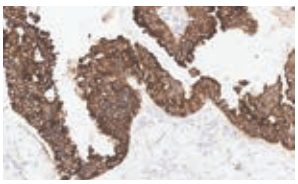
Microscopic examination confirmed the cystic nature of the lesion, with epithelium showing a serous lining, overlying ovarian type fibrous stroma. Multiple papillary tufts with branching architecture were observed. These tufts, lined by stratified columnar epithelium, had hyalinised fibrovascular cores. Mild nuclear atypia was noted, but mitosis and necrosis were absent. The epididymis was unremarkable, as was the spermatic cord. Stromal involvement and lymphovascular invasion were not observed.

The diagnosis

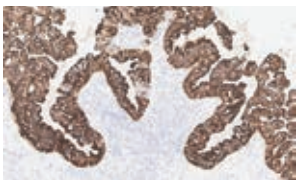
Differential diagnoses for testicular tumours with papillary pattern should include metastatic adenocarcinoma, primary adenocarcinoma of the epididymis or rete testis, Müllerian-type epithelial tumours and mesothelioma. As documented in previous publications, along with morphological appearance, the use of immunocytochemistry is essential for the differential diagnosis of testicular tumours.

The epithelium of papillary tufts expressed cytokeratin AE1/AE3, CK7, CK5/6, WT1, CA125, PAX8, but not CK20, calretinin or carcinoembryonic antigen (CEA). The morphology and immunoprofile for this patient are in keeping with a diagnosis of ovarian type serous borderline tumour (SBT).

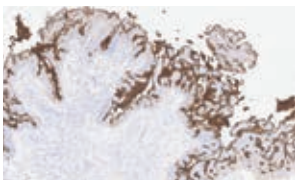
This diagnosis corresponds to similar reported case studies in the literature; all with patients presenting at similar age to this patient, with similar macroscopic and microscopic characteristics and identical immunocytochemical staining patterns. SBT of the testis is a rare tumour, with fewer than 50 cases reported in the literature.



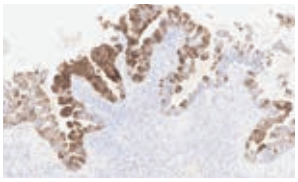
AE1/AE3



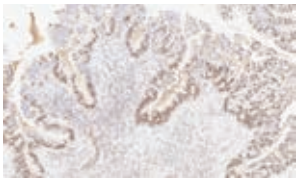
CK7



CA125



CK5/6



WT1

Calretinin

Understanding

Prognosis and long-term implications for patients are not clear. Guidelines from The Royal College of Pathologists state: "Due to the rarity of testicular tumours, there are few randomised, large scale international studies of prognosis and outcome, especially in low-risk tumours."

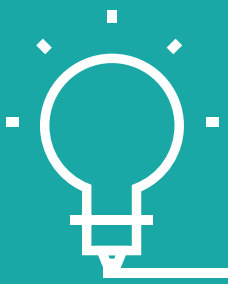
Continual surveillance is, therefore, required for this patient, who continues to have regular blood tests for CA125, βhCG and AFP, along with six-monthly monitoring CT scans. At the time of this case study, the patient remained an outpatient at the medical oncology unit.

The pathogenesis of SBT remains unclear. Several publications have suggested that the tumours develop from remnants of Müllerian ducts within the testis, while others support the theory of Müllerian metaplasia of the mesothelium of the tunica vaginalis testis. Several recent studies have demonstrated the presence of the *BRAF* V600E mutation in SBTs of the testis, that are also seen in similar tumours of the ovary, suggesting similar pathogenesis in both genders and strengthening the argument for Müllerian metaplasia theories. It is evident that further studies aimed at investigating the molecular pathogenesis and possible targeted treatment of these tumours, along with long-term patient follow-up is essential to increase our understanding of this rare tumour type. BMS

Louise Greenhalgh is a Specialist Biomedical Scientist in Cellular Pathology, based at Lincoln County Hospital.

To read the article with references, visit thebiomedicalscientist.net

BIOMEDICAL SCIENTIST SPECIALIST TRAINING



Blood Sciences Manager **Victoria Moyse** looks at how to deliver and recognise specialist training.

The current UK career and development route for a biomedical scientist necessitates registration with the Health and Care Professions Council (HCPC). This requires attainment of an IBMS-accredited degree (or successful completion of a non-accredited degree plus "top-up" modules) and completion of the IBMS Registration Portfolio for the Certificate of Competence. Following registration, biomedical scientists can complete a Specialist Diploma in their chosen discipline, but this is not compulsory.

The previous system for registration required completion of a logbook that encompassed generic, registration-level training and specialist, discipline-specific training together. Trainees had to complete both generic and specialist elements in order to become state registered. The switch to the current system took place for various reasons, but now raises the question: has the change led to fewer biomedical scientists with the same breadth of discipline-specific, specialist knowledge and skills? Has removing elements of specialist knowledge from the requirement for registration had an impact on the workforce?

Standards of Proficiency

In July 2003, the Council for Professions Supplementary to Medicine (CPSM) was replaced by the Health Professions Council (HPC), later to become the Health and Care Professions Council (HCPC). The HPC Standards of Proficiency became a legal requirement for safe and effective practice, which had a significant impact on the way in which laboratory scientists became registered. These standards were generic for all 12 regulated professions – a diverse group of professional roles.

Formerly, the CPSM logbook was a series of subject-related tick boxes, covering generic laboratory topics and skills, as well as discipline-specific knowledge addressed in a set of specialist modules. Not all of these modules had to be covered, but each trainee was required to complete a minimum number to meet the logbook requirements. Once complete, the candidate had to pass a *viva voce* – an oral examination with one internal and one external assessor, a professional peer representative of the CPSM, focusing on specialist-level knowledge.

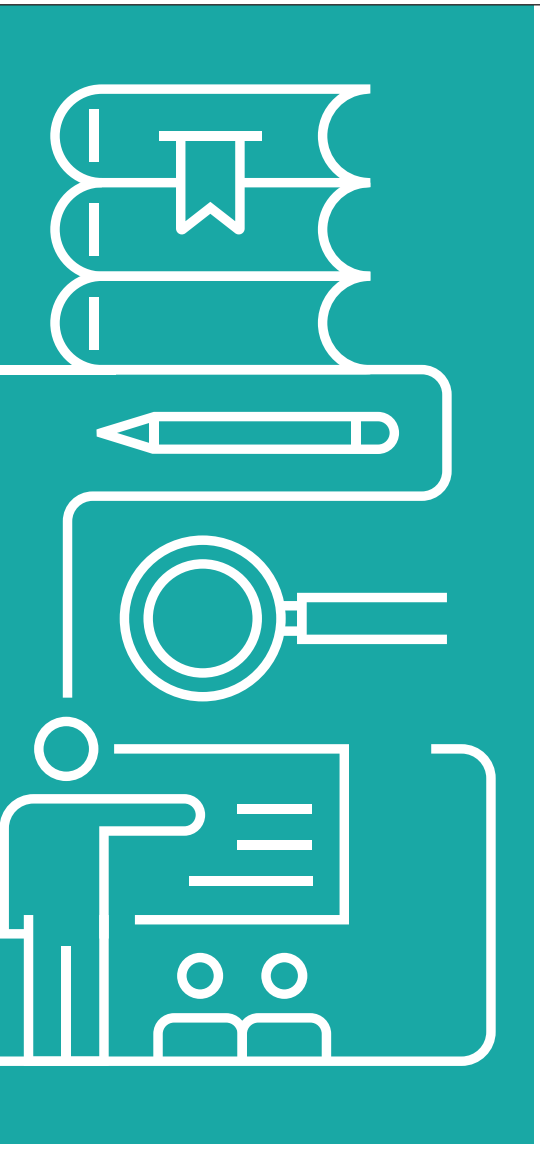
This method of assessment lacked standardisation and consistency, as did the training delivered by labs to complete the logbook. All applicants to the HPC professional register were required to meet the standards of proficiency and have hard evidence to demonstrate they had done so within their laboratory training and practice. As a result, the IBMS introduced evidence-based assessment, in the form of the Registration Portfolio to demonstrate the HCPC requirement to meet the standards of proficiency at a threshold level for safe, effective practice.

However, the Registration Portfolio only covered generic topics and skills applicable to all disciplines. The discipline-specific knowledge and skills would now be covered in post-registration training, via the Specialist Portfolio.

Initial implementation of these portfolios was challenging – it was a big change to the system and laboratories had to adapt their training programmes to accommodate the new requirements. Some found this easier than others; the production of evidence was an especially novel element for some.

Specialist Portfolio

In my personal experience at the time, the Specialist Portfolio was particularly



difficult – training officers weren't sure what was "enough" and no one wanted to risk applying for an assessment only to be told they hadn't hit the mark. Some Specialist Portfolios took years to complete – when I took on my first training officer role I inherited two Specialist Portfolios that were getting on for five years in progress. Things eventually settled down, and as an assessor I've got to see some great examples of Specialist Portfolios, and some fantastic biomedical scientists produced through this training route. However, I am aware that this is not the full picture.

In my professional role, I have often found it difficult to motivate biomedical scientists to undertake and complete the Specialist Diploma. Those who choose not to, may accumulate years of post-registration experience, but the knowledge and skills gained in those years may be lacking compared to the recommended curriculum. But is the recommended curriculum still as relevant to the modern service?

Laboratory experience is invaluable, but it doesn't necessarily add up to a fully developed specialist biomedical scientist. Variation in scope of practice, training and support from the local laboratory means that five years' experience produces a spectrum of knowledge and skills. The aim of the Specialist Portfolio is to help address this. It is supposed to support a biomedical scientist's immediate post-registration training; to get them from a basic, generic level to the level of a fully functioning biomedical scientist within their department. Is this how your laboratory uses it?

All sections of the Specialist Portfolio are mandatory. It aims to ensure candidates are knowledgeable in all key areas of their discipline, even if it doesn't fall within the scope of their current laboratory repertoire, and to encourage some consistency and comparability in what this level can be expected to be.

Training staff

In practice, I've noticed that people often have long gaps between completing the Registration Portfolio and starting the Specialist one. Either they have chosen to do so, or the laboratory encourages it. In effect, however, the training they are receiving at the bench during this time is exactly the training that the Specialist Portfolio is designed to support.

Some labs find it difficult to support Specialist Portfolio training, whether that be in terms of time or expertise, but they must still be training their staff above the generic registration level. I have also experienced laboratories where Specialist Portfolios are applied for and given to candidates, but the laboratory support ends there and candidates are left to get on with it for themselves, which is far from the intended process. To some end, UKAS may have helped us with this – the requirement to provide objective evidence of competence falls in line with the aim of collecting evidence for the portfolio. Well-designed competence assessment exercises can be used to generate some evidence for the portfolio.

Personal observation has shown that recruitment issues can be a factor in motivating and retaining staff long enough to complete the Specialist Portfolio. Biomedical scientists without a Specialist Diploma often advance into roles for which it is a recommended requirement. It may be that some staff can demonstrate relevant knowledge and skills through an alternative route, but this is not always the case.

Different laboratories

This diverse subject is where my current interest lies. As part of an education qualification, I am embarking on a research project and have chosen to look at the area of specialist training in clinical laboratories. I'm interested to see how the existing system is used and regarded in different laboratories. Why do some staff choose to do the Specialist Portfolio and some do not? Why do some laboratories support this qualification and some do not? I would like to investigate how it shapes up to the previous system and whether laboratories use it for career progression, or find it a suitable way of producing staff with the knowledge and skills they need.

Should the Specialist Portfolio be mandatory? Or designed more like a preceptorship used in nursing and other allied health professions? If you would be interested in participating in a survey as part of my research, I would love to hear from you. BMS

Victoria Moyse is Blood Sciences Manager at Northwick Park Hospital. She can be contacted on **Victoria.Moyse@tdlpathology.com**

IMAGES: ISTOCK

HOW TO... MANAGE A MULTI-GENERATIONAL WORKFORCE

At this year's Congress, IBMS Deputy Chief Executive **Sarah May** delivered a session on multi-generational workforces. Here are some of her thoughts on the generations. We also hear from three scientists from different age groups.

...on baby boomers

"They are the original 'it's-all-about-me' generation. They are motivated by (and protective of) career, status and money. They have strong work ethics, which is a hangover from the previous generation, and they like face-to-face meetings and details – they don't like waffle. Don't regard them as blocking the upcoming millennials who are coming through, rather regard them as bringing experience and stability to a workforce that is going through change."

...on generation x

"These are often our managers and senior managers and it is with this generation that we start to see the rise of the dual-income family – they are the original 'latchkey kids'. They are self reliant, which is a product of how they were raised, and they are the first generation of job-jumpers and will go to work wherever is best for them. They are straightforward people who are sceptical and questioning and they don't like being messed around. They can be quite hard managers."

...on millennials

"They are our future. They can achieve anything that they want to and are open and diverse. They are the first Internet generation and are going to come at us with lots of different ideas. They have a completely different way of thinking. They want flexible ways of working and a healthier work-life balance. They like flexible schedules, are socially conscious and are natural collaborators. The NHS has enjoyed a lot for free from previous generations, which it may not get from millennials. But if you figure out what they like and stimulate them, you have a very creative, hard-working group."

...on generation z

"They will be coming in as your trainees – they are very good multi-taskers and are going to be a huge asset. They are constantly communicating and expect instant access to information. They are the products of over-protective generation x parents and you should hold them accountable for their work. Make it clear what you expect for them and the quality of work that is required. Real life and the real world can seem harsh to them. The best way to treat them is to pay them attention, show respect and assume that they want to do a good job." IBMS

MILLENNIAL
MATTHEW BURDETT

What matters most to me about the workplace and workforce is that the workers are able to own up to their mistakes, build upon them and to reflect on them to grow.

GENERATION X
EMMA VICTORY

The most important thing for me is that my work helps others – by teaching students, training scientists, and providing a high-quality diagnostic service.

BABY BOOMER
CHRIS CHASE

What matters to me in my current role as Pathology Education and Training Manager is ensuring that we strive for a sustainable and qualified workforce for the future.

MY IBMS

IBMS CONGRESS 2019

In the final coverage of IBMS Congress 2019, we thank the IBMS Birmingham Branch and congratulate the competition winners and best stands.

IBMS CONGRESS

THANK YOU BIRMINGHAM BRANCH VOLUNTEERS

IBMS Congress was a huge success thanks to the help and support of the Birmingham branch members, whose volunteers proved essential for this year's event.

They helped fill 3000 delegate packs and over 400 student bags. For the four-day conference, Birmingham branch members showed their dedication to the profession and the Institute by devoting their time to ensuring the conference ran smoothly.

They helped to greet, register, prepare and guide over 300 speakers around the convention centre.

Among the first to arrive each day, Birmingham branch members provided assistance for delegates, ensuring they were headed in the right direction for the programme and exhibition. They also helped manage the poster competition.

Without the hard work and dedication of the Birmingham branch volunteers, Congress would not run as efficiently. Their commitment is proof of the fundamental contribution that IBMS branches and regions give to the organisation and the profession.

The IBMS would like to thank the Birmingham branch volunteers for their hard work and dedication.

IBMS CONGRESS

Congress exhibition winners

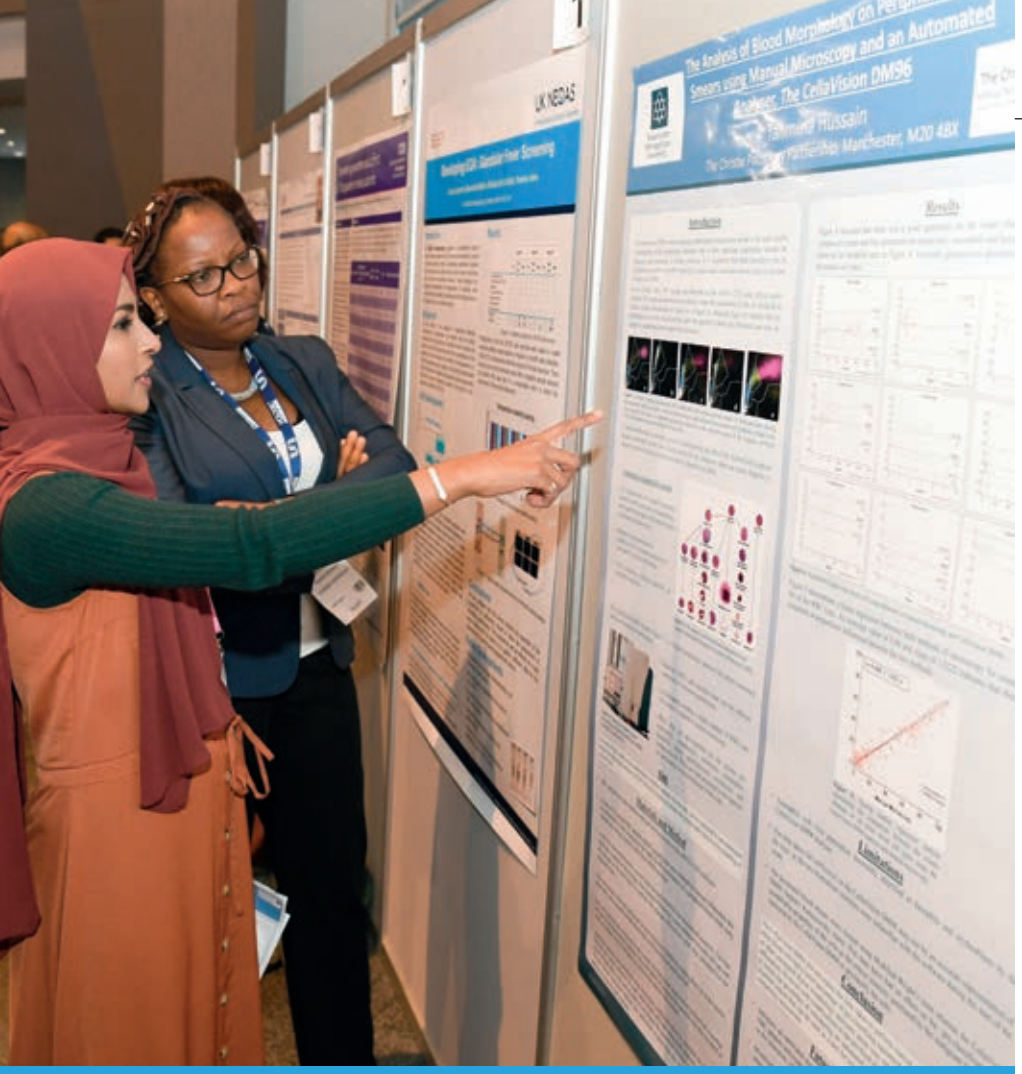
At each Congress a panel of judges, including the IBMS President Alison Geddis, Chief Executive Jill Rodney and Company Members Liaison Group Chairman Mark Reed, attend the exhibition.

Visiting the stands, the judges assess each display on appearance and the welcome visitors receive. This year saw over 140 exhibitors at Congress, who impressed the judges with the interactive and informative displays on show.

This year's winners included Best Stand, which was won by CellPath, and Best Shell Scheme, won by Scientific Laboratory Supplies (SLS).

Tim Davies of CellPath said: "This is the first time we have won the best stand award, and it was great to hear that the decision from the judges was unanimous. The stand design was fantastic, allowing hands-on demonstrations. This, with the enthusiasm and welcoming approach of our employees working on the stand, led to the award being presented to CellPath."

Peter Chapman of SLS said: "The IBMS Congress is an important event for SLS, providing us with an ideal opportunity to meet with so many customers in such a short period of time. We look forward to raising the bar again at the next Congress."



IBMS CONGRESS

Poster competition

As part of the IBMS Congress programme, a poster competition was held to showcase the best new research and ideas in biomedical science disciplines.

The judging process was very difficult due to the exceptionally high standard of posters received. With so many noteworthy entries, the judges wish to thank all the poster presenters for their strong entries.

The winners are:

- **Cellular Pathology, Daniel Simmons**, The first national digital pathology service: the PITHIA trial
- **Clinical Chemistry, Cerin John**, Do overloading sampling devices affect faecal immunochemical test (FIT) haemoglobin concentration?
- **Education and Management, Martin Khechara**, Engaging in SciCom from the students' perspective – more than just engaging the next generation of biomedical scientists?
- **Genomics and Molecular Pathology, Adewale Oke**, Molecular detection of *Mycobacterium ulcerans* strains in South-West, Nigeria
- **Haematology, Tahmina Hussain**, The Analysis of Blood Morphology on Peripheral Blood Smears using Manual Microscopy and an Automated Analyser, The CellaVision DM96
- **Immunology, Faye Sims**, Antibodies in type 1 diabetes pregnancy
- **Medical Microbiology, Jennifer Henderson**, Prevalence of carbapenemase producing organisms in East London
- **Point of Care Testing, Gareth Davies**, Development of an External Quality Assessment Programme for POCT D-dimer
- **Quality Management, Agatha Christie Saez**, Review of EQA specimens containing multiple faecal parasites: a three-year analysis
- **Transfusion Science, Caroline Smith**, Is the Kleihauer test still relevant in the blood transfusion laboratory?
- **Virology, Louise Nugent**, HHV-6 detection in Ireland: significance of age

We wish warm congratulations to all of the poster winners and thank everyone who contributed.

To see tweets from the conference, use the hashtag #IBMScongress2019 on Twitter, or for the highlights, see the IBMS' stories on Instagram.

DIARY DATES

COUNTRY AGMs

Scotland AGM

The IBMS Scotland Annual General Meeting (AGM) and Scientific Meeting will be held on 14 November at 9.30am to 5pm.

It will take place at The Studio, 67 Hope Street, Glasgow.

The AGM is a free event for all IBMS Scotland members to attend.

The Scientific Meeting is a paid-for event for members and non-members and tickets must be purchased online from the website Eventbrite.

Further details can be found on the events section of the IBMS website.

Northern Ireland AGM

The IBMS Northern Ireland Branch Annual General Meeting (AGM) will be held on 14 November at 5.45pm

It will take place at the Raddisson Blu Hotel, The Gasworks, Cromac Place in Belfast.

It will feature an audience with the IBMS President, Alison Geddis, which will be followed by the AGM. A light buffet will be provided.

Registration is essential for catering purposes and any dietary requirements should be stated.

→ Register by Thursday 7 November by emailing NI_IBMS@hotmail.com

IBMS CONGRESS

CONGRESS AWE-INSPIRING FOR MARY MACDONALD AWARD WINNERS

The IBMS Congress 2019 Mary Macdonald Congress Award winners have commented on their experiences at Congress.

The award was created in honour of former IBMS Council Member Mary Macdonald, who wished to encourage and recognise excellence in others working in laboratory support worker roles.

The award sponsors up to 20 free places for non-HCPC registered members to attend the Biomedical Support Staff programme at IBMS Congress.

Sandra Power said: "The talks were very informative, interesting and enjoyable and were relevant to my job as a Medical Laboratory Assistant in microbiology at Macclesfield District General Hospital as I am currently studying General Certificate in Biomedical Science (Distance Learning) at Ulster University to top up my biology degree and hopefully progress."

Vanimira Dzhugdanova said: "I'm grateful to have had this amazing opportunity. I found all the talks so useful and informative, it was fascinating seeing and hearing about new technology and the future of pathology. I would really encourage anyone to attend this event."

Matthew Burdett said: "Being one of the winners of the Mary Macdonald award helped me so much by giving me and the other winners the opportunity to attend Congress and to improve our CPD. The biomedical science support staff session was very informative."

Nikita Delgaty said: "Experience is the best teacher and being given the opportunity to visit Congress has opened up my mind to ideas around other areas of research and the chance to explore new roles in science and healthcare. Thank you for offering me the Mary Macdonald bursary and giving me an insight into the world of biomedical science."

Zoe Andrews said: "It was an awe-inspiring experience and there were so many interesting lectures. The closing plenary was just fantastic and Professor James Grieve summed up my learning in his speech when he said: 'How important entertainment is to education'. IBMS Congress 2019 was definitely entertaining – we were provided with enjoyment in endless amounts."

IBMS CONGRESS

Jen Johnson Bursary winners enjoy Congress 2019

The IBMS Congress 2019 Jen Johnson Bursary winners' have given their feedback on this year's event.

Created in 2017 in honour of Jen Johnson, a former IBMS Council member who was passionate about IBMS Congress, and wished for more people in the profession to have the chance to attend, the bursary supports the applications of 20 IBMS members to attend Congress, providing a grant of up to £1000.

Following Congress 2019, some of the bursary winners report back on their experiences at Congress.

Laura Willis LIBMS said: "Attending Congress was an exciting, positive experience for me. I came away with much more up-to-date knowledge in the field of microbiology and a renewed enthusiasm for biomedical science in general."

Danny Gaskin LIBMS said: "It was both a privilege and an honour to attend my first IBMS Congress, facilitated by the award of the Jen Johnson Bursary. The event was brilliantly organised, and it was fantastic to meet up with many familiar faces from the online biomedical science community and enjoy learning and socialising together."

Nina Harrison LIBMS said: "I thoroughly enjoyed attending IBMS Congress for the first time, receiving the Jen Johnson Bursary provided me with a fantastic opportunity to explore everything Congress had to offer over the three days."

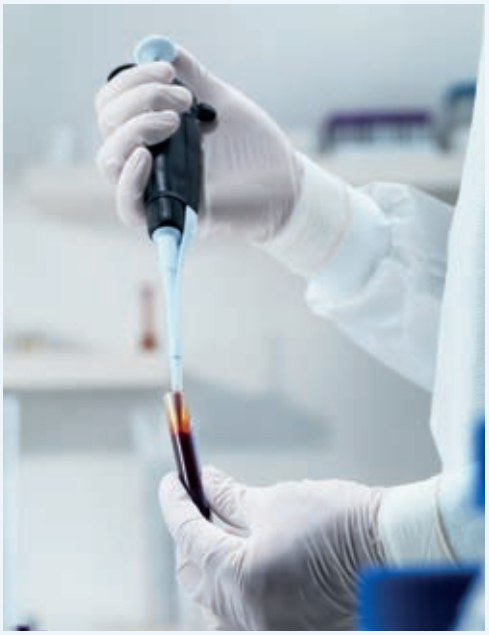
Cherie Beckett LIBMS said: "Winning the Jen Johnson bursary and being able to attend IBMS Congress 2019 in its entirety was an incredible opportunity for me. Not only to learn from experts in their field, but also to network with many of the like-minded individuals who share my passion for biomedical science."

The IBMS is looking forward to supporting more members to attend Congress in the future.

MY IBMS NEWS

PROFESSIONAL PROMOTION

NATIONAL PATHOLOGY WEEK



National Pathology Week takes place on 4-10 November, with the theme "exploring innovations big and small".

The week is supported by the IBMS and run by the Royal College of Pathologists.

It is an annual week-long celebration of activities and events promoting disciplines and professions in pathology.

It provides an excellent opportunity for IBMS members to showcase their roles and specialties in the profession.

A range of resources and advice is available for members on the IBMS website.

→ For more information, visit bit.ly/2lCmStX

IBMS RESOURCES

New activity resources for children

For those who are interested in getting youngsters involved in biomedical science activities, IBMS members have helped to develop some new activity sheets for children.

Each sheet represents a 10-20 minute activity, which introduces and puts into practice an aspect of biomedical science.

They outline the things you will need, what aspects of the science to explain and how to put the experiments in motion.

→ The full page of new activities for children is available to view at ibms.org/activities

AHA AWARDS

Biomedical Scientist of the Year

The Advancing Healthcare Awards (AHA) are a now open for entries.

It is a unique awards programme for healthcare professionals and the IBMS is proud to again sponsor the award for Biomedical Scientist of the Year.

The award celebrates an exceptional biomedical scientist who has used their skills and expertise to advance practice in an innovative and impactful way, making a real difference to patients' lives and inspiring those around them.

To enter, you can nominate yourself or a colleague through the AHA website by 5pm on 8 January 2020

Entrants must show evidence of: measurable achievement, leadership and team working and impact on patient care.

IBMS Fellow Dr Jo Horne won the award in 2019.She said: "Receiving recognition from my peers was incredible enough, but to then go on and win the award was one of the proudest moments of my professional life."

→ For more information, visit ahpandhsawards.co.uk

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BRANCH ACTIVITY

IBMS BIRMINGHAM BRANCH LECTURE

The Birmingham branch evening lecture will be held on 14 November at 6.30pm.

It will taker place at Rooms 3+4 (lower ground floor) of the Education Resource Centre at Birmingham Women's Hospital

There will be a CPD presentation on PITHIA Trial (Pre-Implantation Trial of Histopathology In renal transplant Allografts). This will be followed by the West Midlands IBMS Awards for most improved placement students in BSc Biomedical Science (hons) for local universities. A light supper will be available from 5.30 pm. For details, contact Nigel Coles on **0121 335 8034** or **nigel.coles@nhs.net**

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EVENTS AND TRAINING COURSES

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

DATE	TITLE	VENUE CONTACT
November		
4-8 Nov	**Advanced Practical HPLC Course**	Rochester I stuart@laserchrom.com
6 Nov	**UK NEQAS Clinical Chemistry Roadshow Belfast 2019**	Belfast I birminghamquality@uhb.nhs.uk
11-12 Nov	**UK NEQAS CPT Annual Participants Meeting**	Dublin I chantell.hodgson@nhs.net
11-14 Nov	**FIS 2019: Federation of Infection Societies Conference**	Edinburgh I k.mistry@microbiologysociety.com
12 Nov	**Fine Needle Aspiration Cytology for Technical Staff**	Bristol I SWRCTC@nbt.nhs.uk
13 Nov	**UK NEQAS Cellular Pathology Technique non-gynae cytology beginners/refresher workshop**	Gateshead I chantell.hodgson@nhs.net
13-14 Nov	**Advanced Immunohistochemistry**	Sheffield I l.baxter@sheffield.ac.uk
14 Nov	**IBMS Northern Ireland Branch Annual General Meeting**	Belfast I NI_IBMS@hotmail.com
14 Nov	**IBMS Scotland Branch Annual General Meeting**	Glasgow I scotland@ibms.org
14 Nov	**UK NEQAS Cellular Pathology Technique non-gynae cytology intermediate workshop**	Gateshead I chantell.hodgson@nhs.net
19 Nov	**Into Clinical Practice: Meeting the Challenges of Gram-negative Infection Management**	London I ecarruthers@bsac.org.uk
19 Nov	**Waters UK and Ireland Clinical User Meeting**	London I helen_macdougall@waters.com
26-28 Nov	**BMS/Cytoscreener Update Course in Gynaecological Cytology**	Harrow I LNWH-tr.lrctcbooking@nhs.net
27 Nov	**UK NEQAS Cellular Pathology Technique TEM workshop 2**	Leicester I chantell.hodgson@nhs.net
27 Nov	**Update in Cervical Cytology for pathologists, consultant BMS and holders of the Advanced Specialist Diploma in Cytology**	Bristol I SWRCTC@nbt.nhs.uk
28-29 Nov	**Antibiotic Resistance and Mechanisms Workshop for Researchers**	Birmingham I ecarruthers@bsac.org.uk
December		
2-3 Dec	**Agilent HPLC Equipment Servicing Course**	Rochester I stuart@laserchrom.com
2-5 Dec	**British Society for Immunology Congress**	Liverpool I j.sessenwein@immunology.org
3 Dec	**One-Day Update in Cervical Cytology – HPV cancer audit day**	Bristol I SWRCTC@nbt.nhs.uk
4 Dec	**Medical Laboratory Assistant – Introductory Course**	Harrow I LNWH-tr.lrctcbooking@nhs.net
5 Dec	**POCT: The Power to Disrupt**	London I info@thornhillhealthcareevents.co.uk
11 Dec	**BSAC OPAT Conference 2019 – A Global overview of drug development and effective use through diagnostics, stewardship and shared learning**	London I ecarruthers@bsac.org.uk
16-17 Dec	**Advanced Agilent HPLC Servicing Course**	Rochester I stuart@laserchrom.com
2020		
March		
2-3 Mar	**Introduction to Practical HPLC Course**	Rochester I stuart@laserchrom.com
4-5 Mar	**Intermediate Practical HPLC Course**	Rochester I stuart@laserchrom.com
9-11 Mar	**Practical HPLC Method Development Course**	Rochester I stuart@laserchrom.com
12-13 Mar	**Practical HPLC Troubleshooting Course**	Rochester I stuart@laserchrom.com
15-16 Mar	**Practical HPLC Troubleshooting Course**	Rochester I stuart@laserchrom.com

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 FEBRUARY 2020

Cell blocks in cytopathology: an update

Nambirajan A, Jain D. *Cytopathology* 2018; **29** (6): 505–24. Assessment No: 110819

01	The study looked at three different factors: improving diagnostic yield, CB preparation method optimisation, and looking at factors influencing ancillary testing success and validity in CB preparations.	11	P63, p40 and TTF1 ancillary tests on CB can aid diagnosis of lung carcinomas.
02	There are only two methods for preparing cell blocks.	12	The cell tube method has shown to yield up to 100 serial sections with better morphology.
03	49% of cytopathologists in the USA are dissatisfied with their current cell block quality.	13	In general, alcohol-fixed Cellient cell blocks show inferior results for hormone receptor status and *HER2/neu* CISH.
04	Exudative cavity fluids do not have adhesive properties and need an additional additive to be added (eg albumin).	14	*ALK* rearrangement in NSLC can be assessed using a combination of ICC for screening with FISH confirmation testing.
05	Plasma thrombin CB method is not ideal for cases requiring NGS.	15	EBUS TBNA are reportedly better than core biopsies for PDL1 testing as they show less crush artefact and yield more tumour cells.
06	Using a methanol-based fixative provides good morphology but gives rise to a large number of false-negative results for ICC antibodies when using the Cellient CB methodology.	16	According to current guidelines, routine testing for *EGFR* mutations along with *ALK* and *ROS-1* rearrangements are recommended for melanoma patients.
07	The colloidin bag methodology yields lower cellularity in comparison with plasma thrombin and Histogel methods.	17	DNA extracted from cytology samples is usually of better quality in comparison with histology samples.
08	LBC preparations show poor long-term DNA preservation.	18	Formalin-fixed, paraffin wax-embedded (FFPE) CBs offer the best-quality DNA.
09	Cell scrapes cannot be used for any cell block methodology.	19	The adequacy criteria for NG sequencing requires at least 20% tumour fraction in a CB measuring 3 mm or greater.
10	The principle of the AFFECT cell block method is cytocentrifugation.	20	PDL1 status can be easily assessed in serous fluid specimens.

REFLECTIVE LEARNING

01	Look into the cell block methods within your department and compare findings with the different preparatory methods reviewed in this paper.	02	Discuss the utility of cytological specimens for molecular profiling and targeted therapy.

DEADLINE WEDNESDAY 5 FEBRUARY 2020

Safety and perception: what are the greatest enemies of HPV vaccination programmes? Bonanni P, Zanella B, Santomauro F, Lorini C, Bechini A, Boccalini S. *Vaccine* 2018; **36** (36): 5424–9. Assessment No: 110619

01	The most recently available HPV vaccine is designed to protect against nine serotypes.	**11**	For people over 14 years old, a two-dose schedule for the HPV vaccine is recommended.
02	It is theoretically possible for a vaccine to produce an immunological adverse event.	**12**	The HPV vaccines currently available are subunit vaccines containing virus-like particles.
03	'Vaccine hesitancy' relating to HPV in Japan has arisen because the perceived health risk from the vaccine is more immediate than the potential for protection from HPV-related cancers.	**13**	Extensive data from follow-up studies of girls who have been vaccinated against HPV suggests that their rates of sexual activity and pregnancy are increased.
04	Adverse effects following immunisation (AEFIs) are not officially recorded.	**14**	There is a fear that HPV vaccination can cause demyelinating diseases such as multiple sclerosis.
05	One aim of a universal vaccination programme is to establish herd immunity in the population.	**15**	The Global Advisory Committee on Vaccine Safety (GACVS) is part of the World Health Organization.
06	There is substantial evidence that complex regional pain syndrome (CPRS) can arise as a complication of at least one form of the HPV vaccine.	**16**	The European Centre for Disease Prevention and Control (ECDC) issues specific information about the HPV vaccine for healthcare professionals for use in advising patients.
07	Although HPV is a sexually transmitted virus, the main aim of the vaccine is to prevent cancers.	**17**	The nonovalent HPV vaccine is mainly expected to protect against genital warts.
08	Bonanni *et al*. suggest that the nonovalent HPV vaccine should be promoted on social media only.	**18**	The first HPV vaccine was licensed in 2006.
09	When the chance of an adverse event after administration of a particular vaccine is similar to that for all vaccines, the proportional reporting ratio (PRR) will be close to one.	**19**	'Vaccine hesitancy' can be an issue among healthcare professionals.
10	In Japan, the bivalent Cervarix HPV vaccine was recommended but then withdrawn.	**20**	Mechanisms for monitoring adverse events following immunisation include the Vaccine Adverse Event Surveillance and Communication (VAESCO) network, which is funded by the Centers for Diseases Control and Prevention (CDC).

REFLECTIVE LEARNING

01	Discuss how 'vaccine hesitancy' has affected the uptake of other vaccines, such as MMR.	**02**	Evaluate the role of the routine diagnostic laboratory in monitoring the efficacy of HPV vaccination.

HERE TO HELP

HIGHER SPECIALIST DIPLOMAS PT.2

The second of two articles in which **Chris Ward**, IBMS Head of Examinations, outlines the latest developments around Higher Specialist Diplomas.

In last months' article I provided a background to the work of the Higher Specialist Diploma (HSD) review group and explained the aims, learning outcomes, eligibility criteria and portfolio requirements of the qualification. This month I will be explaining the structure of the exams, how they are marked and how candidates undertaking the HSD will be supported.

Exam Structure

Once a candidate has passed the portfolio stage of the HSD, they proceed to the exams, which take place each September. The HSD examiners reviewed the current nature of the four papers. It was recognised that the short answer question paper (Paper 1) is proving particularly problematic. The examiners also discussed the importance of ensuring that the exams are appropriate for an M-level qualification. As a result of this work, from 2020 the exams will be structured as follows:

- **Discipline-Specific Short Answer Questions** - 60 Minutes - Questions that focus on problem-solving / operational scenarios / analysis of results or quality control issues. Candidates will be expected to answer four questions in an hour. This replaces the current short answer question paper.
- **Generic Essay Questions** - 120 Minutes - This is the paper which is common to all HSD candidates, no matter their discipline. It will continue to cover laboratory management, quality and training issues that prospective Band 7 individuals should be aware of. Candidates will have one pre-released mandatory question and will also be expected to answer two further questions from a choice of four.
- **Discipline-Specific Essay Questions** - 120 Minutes – Candidates will be expected to answer two from five questions (rather than the current three from six). This will allow candidates to go in to greater detail.
- **Discipline-Specific Case Studies** - 120 Minutes – Candidates will be expected to answer three mandatory case studies, one pre-seen and two unseen.

Exam Marking and Banking of Results

Each response will be marked by two examiners, with a third examiner being involved if there is a significant discrepancy in the marks that are awarded. All four papers will continue to be equally weighted with the overall pass mark remaining at 50% across the four papers with no paper scoring below 40%. This means that candidates can pass with papers that score between 40% and 50%, provided they meet the required overall 50% average.

Up until now, candidates who were unsuccessful at their first attempt had, if they wished to re-sit the exam, to redo all four papers. As part of the review process it was agreed to change this requirement and, therefore, from the 2019 exam series candidates who fail to reach the overall pass mark on their first attempt will automatically "bank" the papers in which they scored >50%. They will only have to re-sit any papers where they score <50%. For the re-sit, the marks that the candidate achieves on each of their re-sit papers will be the ones that counts towards the overall qualification mark. This change does not dispute the fact that 40-49% is a pass mark for the paper but rather it is stating that a mark in that range is not acceptable for banking.

It is expected that this change will reduce the pressure on candidates for any re-sit. It will also reduce the costs as candidates will, for their re-sit, pay a fee per paper that they have to re-sit. The portfolio will remain valid for two attempts at the exam, so banked marks will only be available for one re-sit. If the 50% overall mark is not achieved at this point (i.e. after two

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attempts at the exam) the candidate will have to submit a new portfolio and re-sit the entire examination.

Support to Candidates

The IBMS recognises that for some the HSD will be the first qualification an individual has undertaken for some time and this can present some challenges. Even for those who have completed a qualification more recently because of its self-taught nature the HSD is a very different qualification to what many candidates will be used to.

The IBMS will be working with the HSD examiners to provide, in addition to the candidate preparation days, more support and guidance for those undertaking the qualification. This will include greater clarity in the syllabus for the generic section and each discipline so that candidates will have a better understanding of the topics that will come up in the exam. There will be more guidance on writing at this level; exemplar materials and work will also be undertaken to look at how the IBMS discussion forums can be better used as a means of support.

Past papers for the generic essays, discipline-specific essays and case studies will remain available on the IBMS website. Examples of the types of questions that will be asked in the new version of the short answer question paper will also be made available.

"It is expected that this change will reduce the pressure on candidates for any re-sit"

If you have any questions please contact examinations@ibms.org

We are looking for a Specialist Biomedical Scientist, Biomedical Scientist or Trainee Biomedical Scientist within Noble's Hospital in the Isle of Man.

Isle of Man Government

The Histopathology Laboratory is a small and busy department providing a service to the Islands hospitals and community medicine. You'll rotate through all sections of the department and must be prepared to work as part of a team.

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Interview expenses and a relocation package of up to £7000 based on receipts is available for this role. This role may also qualify for a recruitment incentive and Housing Assistance.

The closing date for this post is midnight on 22 November 2019.

For further information, please contact John Nippress on 01624 650646.

To apply online, please visit: https://bit.ly/2B9seS3 or go to gov.im/jobs and search for 9663.

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Applicants should be driven and passionate with good interpersonal abilities who wish to evolve their existing skill-set within a supportive environment. We would also be interested to hear from Biomedical Scientists (Band 5) who have at least 12 months experience and who are due to complete their IBMS Specialist Portfolio within 6 months.

ABOUT US

iPP is a wholly-owned subsidiary of SYNLAB, the European leader in the delivery of high quality pathology testing and imaging services. SYNLAB operates in 40 countries across four continents, employing more than 20,000 members of staff and conducting over 500 million tests per annum.

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- Support the selling process: develop and conduct sales/marketing and application training for our clinical insight applications.
- Support our S-RHQ MEA staff and distributors in localising marketing strategies and providing medical scientific insights.
- Scientific support of our regional and localised events, seminars and exhibitions.
- Strengthen product knowledge and maintain technical knowledge so that these can be translated and explained clearly to distributors and customers.
- Monitoring and analysis of market, product requirements and the competitive environment.

Key Skills & Competencies

- 3-5 years experience as a medical technologist or 2-3 years experience as a product specialist with a degree in medical science or similar degree.
- Expertise and knowledge in the field of haematology in a routine laboratory environment, ideally with Sysmex equipment.
- Knowledge of haematology, laboratory diagnostics market and the respective clinical relevance.
- Capability to capture complex scientific facts and to refine them in a simplified way.
- Outstanding communication, presentation, teaching skills and willingness to learn.
- Proactive team player with a highly analytical, structured, result-oriented work style with strong ability to effectively manage projects.
- Microsoft Office Suite – MS Word, Power Point, Excel, Outlook and One Note.
- Excellent English verbal and written language skills. Arabic is of an advantage.

If you feel you have the skills we are looking for and wish to apply for the position, please kindly send email with covering letter and CV to jobs@sysmex-mea.com stating your salary expectation and earliest possible starting date.

Closing date for submission Friday 22nd November 2019.

MY LAB

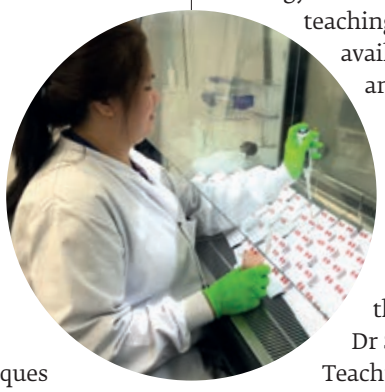
EXAMINATIONS IN PARASITOLOGY

Healthcare Scientist Specialist **Agatha Christie Santos Saez** gives a guided tour of her UK NEQAS Parasitology laboratory.

UK NEQAS Parasitology has been operating since 1986. It is a member of the UK NEQAS Consortium – a not-for-profit company and a UK-registered charity, which is this year celebrating its 50th anniversary. We provide international external quality assessment (EQA) or proficiency testing for clinical laboratories, blood banks, point-of-care testing centres and other testing sites that carry out examinations in parasitology. Various methods, including microscopic identification, serology, point-of-care and molecular testing, are catered for. Specimens are designed to simulate clinical samples and allow participants to assess their routine assays and practices. The schemes we offer are accredited for ISO/IEC 17043:2010.

We are hosted by Public Health England and operate from the premises of the Halo building in London.

We run seven parasitology EQA schemes and have at least two more in the development phase. We offer a range of techniques and sample layouts covering several parasites and techniques for detection. The range of parasites in the faecal specimens includes protozoan cysts, helminth ova, larvae and oocysts. While in the blood parasitology distributions, we include malaria parasites, microfilariae, trypanosomes and *Leishmania*. We also offer detection of malaria antigen, malaria nucleic acids, parasite serology and *Toxoplasma* serology. In addition to EQA provision, teaching programmes are also available for both blood and faecal parasites.



Our department is led by Professor Peter Chiodini, the Scheme Organiser. Other team members are: Dr Jaya Shrivastava, the Scheme Manager, Dr Samuel Boadi, the Teaching Manager, myself as Healthcare Scientist Specialist, and Ms Nikita Chauhan as the Laboratory Support Staff.

I have over 20 years of experience in clinical parasitology. I joined the team in 2004 as Laboratory Support Staff and, through various promotions, have grown within the team to my present role of Senior Healthcare Scientist. My main duties are: preparation, evaluation and internal quality control of EQA specimens for our schemes and I achieve this by applying knowledge of clinical parasitology to the design, quality control and stability of these specimens. I also help set up collaborations and field visits to the Philippines to source faecal and blood parasites. Additionally, I help with data entry, the preparation of participants' performance reports and any accompanying teaching sheets.

We are a high-performing team and pride ourselves on the quality of service that we offer to all our participants. To this effect, our work has recently been recognised via the "RCPath Excellence Awards for 2019" which exemplifies the best of pathology practice. We won the award under the Excellence in Education category. More recently, I won the best poster award at the recent IBMS Congress 2019, for presenting findings from our faecal parasitology scheme. BMS

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