CLINICAL RESEARCH

TUBERCULOSIS

Douglas Young discusses the last 40 years of work: *p.17*

BIOLOGICAL MATERIALS

MILK, SALIVA & TEARS

Could bodily secretions be used to power biomedical devices?: *p.34*

PRACTICAL GUIDANCE

QUALITY MANAGEMENT

Top tips on how to be a successful quality manager: *p.36*

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NOVEMBER 2017

A target set in stone? The latest on the ambitious budget challenges for pathology services

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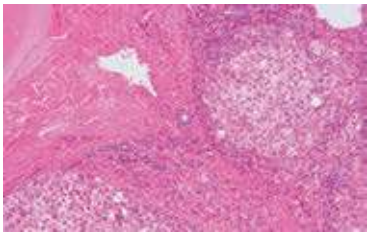

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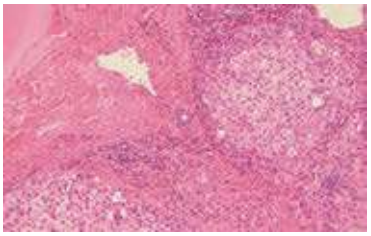

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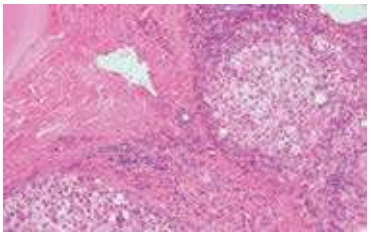

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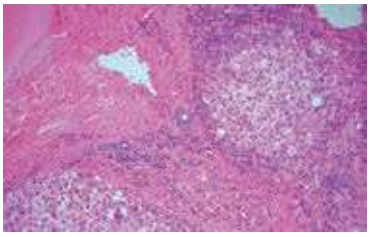

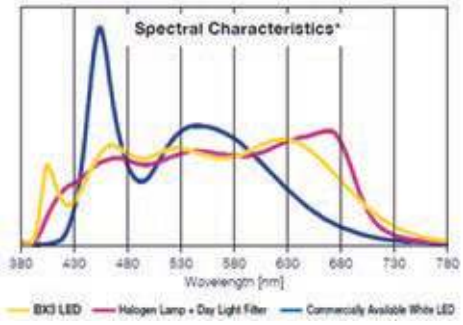

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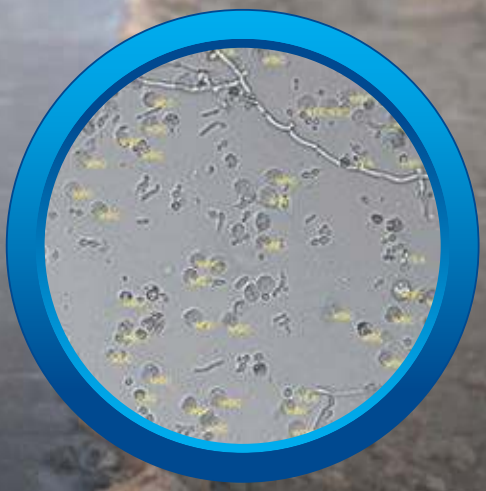

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OVER THE RAINBOW

A letter to a brave young boy, who inspired a charity that takes the fear out of blood tests.

Dear Harvey,

I wasn't at your funeral, I wasn't one of the people who cared for you while you were ill, but I met someone who did both and who is ensuring that your legacy lives way beyond the years of your short life.

Most people know all about needles and blood tests but have no idea what happens to their blood and have certainly never seen inside a laboratory. You are different, you inspired someone, a lovely kind biomedical scientist called Malcolm Robinson, to change that and to help take the fear out of blood tests. Harvey, your visit to Malcolm's laboratory has started an incredible chain of events.

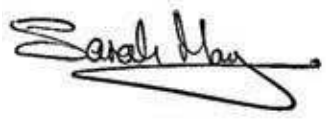
I met Malcolm for the first time last week and he told me all about you and he also told me about some of the other children that have visited his department, been given their own little lab coat and have been shown just how important their blood tests are in helping to treat them and make them feel better. Some grown-ups who also don't like blood tests have also visited the laboratory and they too don't mind them so much now that they have met the people and seen what happens to their blood.

Sometimes grown-ups can make life very complicated, so we forget that the best solution to difficult and painful problems is often the simplest one. We often say that we don't meet our patients, but maybe we need to step beyond the door of our laboratory or simply create the opportunity for a patient to see beyond the needle – just as Malcolm did for you.

Your legacy, Harvey, is a charity that is spreading across the UK and beyond. We can't stop children becoming ill but we can be a visible part of the team that helps to care for them. All the children who now visit laboratories to see what happens to their blood are members of Harvey's Gang, special people who, like you, understand the importance of what we do. I know grown-ups don't usually cry but last week in our big conference in Birmingham, when Malcolm told us about how brave you and the other children in Harvey's Gang are, it made us cry.

I hope that one day soon children will not become so ill that they need so many blood tests, but until that time comes I hope that everyone will start to see that pathology laboratories are not scary places and that the people who work there really care about their patients and want to do all they can to help them. Thank you, brave little Harvey and kind Malcolm.

Love Sarah



Sarah May
Deputy Chief Executive

"Somewhere over the rainbow" was played at Harvey's funeral

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

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CliniSys is the recognised market leader in UK pathology IT innovation; delivering reliable and highly accessible healthcare IT solutions. We understand the business of pathology.

With the ongoing formation of pathology networks and the evolving area of digital pathology, providers like you need to consider service differentiation, competitive advantage and value added offerings.

Is your pathology service empowered to manage the emerging requirements for digital imaging?

- When was the last time you were able to share key images for training and MDT purposes?
- Can you provide diagnostic quality image management?
- Are your images currently being stored outside of the LIMS creating a disconnect between event and image?
- How do you ensure patient centric images in support of data governance?
- Do you have a centralised secure image repository for retrieval of all pathology images?
- Are you able to access any medical image from any device from any location?

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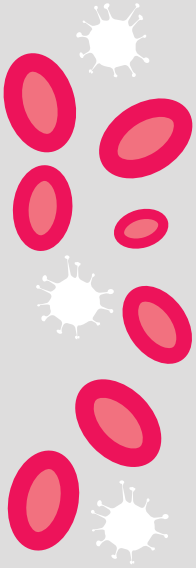
SCIENCE NEWS IN NUMBERS



The number of deaths in the UK caused by sepsis every year is

44,000

This is more than bowel, breast and prostate cancer combined. Despite this, a recent survey says

44%

of people in the UK have never heard of sepsis.

Cancers linked to excess weight make up 40% of all US diagnoses, says a new Centers for Disease Control and Prevention study. The study found that **between 2005 and 2014**, the rates of **overweight-linked cancers increased by 7%**, while rates of cancers **not associated with obesity declined by 13%**.

Hospital beds: The King's Fund has published the report *NHS hospital bed numbers: past, present and future.* It says the **total number of NHS hospital beds** in England has **decreased by more than 50%** over the past **30 years.** It has **dropped** from around **299,000** to **142,000**, while the **number of patients treated** has **increased significantly**.

41%

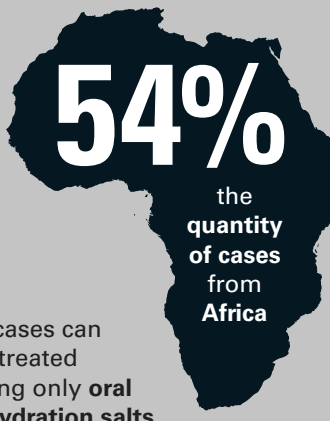
This is the reduction in the number of young women in Scotland showing early signs of potential cervical cancer, since a school vaccination programme was introduced. **The University of Aberdeen** study looked at women who had **received the human papilloma virus vaccine**.

Cholera
Health officials from around the world are meeting in France to commit to preventing 90% of cholera deaths by 2030.

WHO statistics for cholera in 2016:

132,121

The reported number of cholera cases



the **quantity of cases** from **Africa**

2420

the number of **cholera deaths**

80%

of cases can be treated using only **oral rehydration salts**

TRANSFUSION

Is older blood better?

A research trial has found the transfusion of older stored red blood cells is safe – and associated with fewer side effects.

In the TRANSFUSE trial researchers from the Australian and New Zealand Intensive Care Research Centre at Monash University in Melbourne led teams in five countries to investigate the effect of the age of transfused red blood cells on critically ill patients' outcomes.

The team demonstrated that fresher blood was no better than older blood. Unexpectedly, they also found fewer transfusion reactions, including fever, with the older blood; and in the most severely ill patients, the transfusion of older blood was associated with fewer deaths.

Lead researcher Professor Jamie Cooper said: "Older blood appears to be like a good red wine – better with some age. The findings of our trial confirm that the current duration of storage of red blood cells for transfusion is both safe and optimal."

Routine practice in Australia is to allocate the oldest compatible blood. The study has been published in the *New England Journal of Medicine*.

→ **bit.ly/BS_NovNews1**

SCIENCE NEWS

VIROLOGY

WHY VIRUSES PERSIST

New research suggests a mechanism that may explain how viruses that are considered acute can persist.

Products of viral infection, called defective viral genomes (DVGs), can kick off a molecular pathway that keeps infected cells alive, the researchers discovered.

The University of Pennsylvania study, published in *Nature Communications*, used a novel technique to examine the presence of DVGs on a cell-by-cell basis.

Author Carolina B López said: "One of the things the field has known for a long time is that DVGs promote persistent infections in tissue culture.

"But the question was – how do you reconcile that with the fact that they're also very immunostimulatory? How can they help clear a virus at the same time as they promote persistence?"

DVGs are produced in infected cells when a virus begins to replicate rapidly, leading to defective versions of itself that contain large deletions. Once thought not to have any biological function, DVGs are increasingly believed to be important components of viral infections.

→ **go.nature.com/2gyn4oO**

MICROSCOPY

NOBEL FOR IMAGING MOLECULES

The 2017 Nobel Prize in chemistry has been awarded to three scientists for improving images made of biological molecules.

Jacques Dubochet, Joachim Frank and Richard Henderson are sharing the prize.

They developed a technique called cryo-electron microscopy (cryo-EM), which simplifies the process for looking at the machinery of life.

The process made it possible for life's molecular building blocks to be captured mid-movement and allowed scientists to visualise processes that had never before been seen.

Jacques Dubochet was born in Switzerland, Joachim Frank is German and Richard Henderson is from Edinburgh.

The Nobel committee said the work had "moved biochemistry into a new era".

Committee Chair Sara Snogerup Linse explained: "Soon, there are no more secrets, now, we can see the intricate details of the biomolecules in every corner of our cells and every drop of our body fluids.

"We can understand how they are built and how they act and how they work together in large communities. We are facing a revolution in biochemistry."

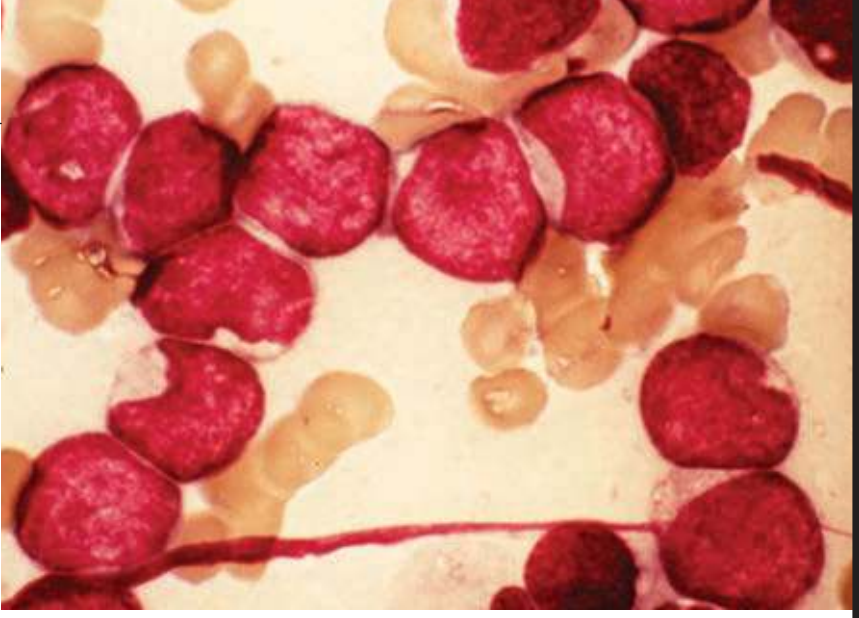
Cryo-electron microscopy has been used to capture Salmonella's "injection needle" for attacking cells, proteins involved in antibiotic resistance and the molecular structures governing circadian rhythm – the subject of this year's Nobel in medicine and physiology.

→ **bit.ly/BS_NovNews2**

CRYO-EM

THEY DEVELOPED A TECHNIQUE CALLED **CRYO-ELECTRON MICROSCOPY (CRYO-EM)**, WHICH SIMPLIFIES THE PROCESS FOR **LOOKING** AT THE **MACHINERY OF LIFE**

IMAGES: ALAMY/UNIVERSITY OF PENNSYLVANIA



LEUKAEMIA

HOW BLOOD CANCER "RECHARGES"

A new study has uncovered how blood cancer "steals" parts of surrounding healthy bone marrow cells in order to thrive.

The researchers found healthy bone marrow stromal cells were made to transfer their power-generating mitochondria to neighbouring cancer cells, effectively "recharging" the acute myeloid leukaemia (AML) and supporting the leukaemia to grow.

AML has been found to act in a parasitic way by first generating oxygen-deprived conditions in the bone marrow, which then stimulates the transfer of healthy mitochondria from the non-cancerous cells to the leukaemia cells.

The study, published in *Blood*, also identified how and why the mitochondria are transferred and discusses the potential impact this could have on future treatment and study of cancer.

Study author Stuart Rushworth said: "Our results provide a first in the study of cancer mitochondrial transfer mechanism. We have clearly shown that the cancer cell itself drives transfer by increasing oxidative stress in the neighbouring non-malignant donor cells."

→ **bit.ly/BS_NovNews3**

NHS HOSPITALS

£1BN BUILDING MAINTENANCE BILL

A news report shows that the cost of urgent repairs required to NHS hospitals is nearly £1bn.

The cost of undertaking urgent "high-risk" maintenance in hospitals has increased from £775.5m to £947.1m in the last year – a rise of 22%.

The figures, published by the NHS' statistical arm, also show the money needed has more than doubled from £458m in 2014-15.

The report says the high-risk repairs "must be addressed with urgent priority to prevent catastrophic failure, major disruption to clinical services or deficiencies in safety liable to cause serious injury or prosecution".

A spokesperson for NHS Improvement said it is working with trusts to help reduce the backlog of repairs.

→ **bit.ly/BS_NovNews4**

WHAT'S HOT AND WHAT'S NOT

HOT

BANANAS

Bananas, and other foods that are rich in potassium, may help protect against pathogenic vascular calcification, according to University of Alabama researchers.

HOT

MEDITATION

The American Heart Association has recognised meditation as a useful tool in possibly helping to prevent cardiovascular problems.

HOT

HOSPITAL DOORS

A new textile that can reduce bacteria levels by 90% has been designed for use on hospital doors, instead of the traditional aluminium door plate.

NOT

DIVORCE

Children of divorced parents have an increased chance of getting divorced and genetic factors are the primary reason, claim researchers.

NOT

WATCHING SPORTS

The heart rate of those watching live sports can increase by 110% causing more than double the cardiac stress caused by vigorous exercise.

NOT

HOUSEWORK

Using bleach once a week increases the risk of chronic obstructive pulmonary disease by a third, says the French National Institute of Health and Medical Research.

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GENOME EDITING

Human embryo development

Researchers have used genome-editing technology to reveal the role of a key gene in human embryos in the first few days of development.

This is the first time that genome editing has been used to study gene function in human embryos, which could help scientists to better understand the biology of our early development.

The team used genome-editing techniques to stop a key gene from producing a protein called OCT4, which normally becomes active in the first few days of human embryo development. After the egg is fertilised, it divides until at about seven days, when it forms a ball of around 200 cells called the blastocyst.

The study, published in *Nature*, found that human embryos need OCT4 to correctly form a blastocyst.

Dr Norah Fogarty from the Francis Crick Institute, first author of the study, said: "We were surprised to see just how crucial this gene is for human embryo development, but we need to continue our work to confirm its role.

"Other research methods, including studies in mice, suggested a later and more focused role for OCT4, so our results highlight the need for human embryo research."

→ **go.nature.com/2xB4lcp**

OCT4 THE TEAM USED **GENOME-EDITING TECHNIQUES** TO STOP A **KEY GENE** FROM PRODUCING THE **PROTEIN OCT4**, WHICH BECOMES ACTIVE IN THE **FIRST FEW DAYS OF HUMAN EMBRYO DEVELOPMENT**

MALE FERTILITY

MATURATION OF HUMAN SPERM

New research sheds light on the complex process that occurs in the development of human sperm stem cells.

This is the first study to characterise the changes human sperm stem cells undergo as they mature.

The authors claim the results, published in *Cell*, have implications for understanding male infertility, as well as cancer development. Previous studies of sperm stem cells have been limited to model systems.

This first study of developing human sperm stem cells revealed the process is much more complex in humans than had been previously understood.

The scientists used genome analysis tools to outline the multistage process that sperm stem cells undergo during their normal development.

The study examined all of the genes that turn "on" or "off" in any given cell during normal development.

Using single cell RNA sequencing analysis, they profiled cells individually, establishing the gene expression profile in human sperm stem cells.

Their findings outline four distinct cellular phases of sperm stem cells maturation, revealing how the stem cells progress from a "quiescent" state, to a "proliferation" state during which stem cells divide, to a final "differentiation" state when stem cells mature to become sperm.

→ **bit.ly/NovNews5**

UNDER THE MICROSCOPE

This month: deoxyribose-1-phosphate

What is deoxyribose-1-phosphate?
It is an intermediate in the metabolism of Pyrimidine, a substrate for Purine nucleoside phosphorylase and Thymidine phosphorylase.

OK, but what does it actually do?
It is a molecule that stimulates the formation of new blood vessels.

So what is new with it?
Scientists have discovered new insights into the molecule that could help treat non-healing wounds and injuries and reduce limb amputations.

Tell me more.
A study demonstrates that it activates the enzyme NADPH oxidase 2, which leads to the stimulation of the transcription factor called NFkB, which is responsible for turning on genes specifically involved in the formation of new blood vessels.

Go on...
Among the genes activated, the vascular endothelial growth factor receptor 2 (VEGFR2) plays a central role.This is a key target in regenerative medicine, and the team, from the University of Exeter, hopes that this discovery will provide a cost-effective treatment for manipulating blood vessel formation.

What happens now?
The researchers are planning to focus their investigation on the ability of deoxyribose-1-phosphate to stimulate skin repair by increasing the vascularisation of wounds and non-healing ulcers.

IMAGES: ISTOCK

TECH NEWS

THERMO FISHER SCIENTIFIC

LABORATORY FREEZERS

Thermo Fisher Scientific's expanded line of cold-storage products has been awarded certification for productivity and sustainability.

The company has been given the US Environmental Protection Agency's ENERGY STAR certification for its Thermo Scientific TSX Series.

These are ultra-low temperature freezers, designed to reduce energy consumption while ensuring sample protection.

Researchers can choose from the wide range of ENERGY STAR certified ultra-low freezers from Thermo Fisher Scientific.

→ **thermofisher.com**

CATAPULT

RESEARCH AND DEVELOPMENT

The Medicines Discovery Catapult (MDC) is a new, national centre of applied research and development (R&D) expertise set up to enable innovative, "fast-to-patient" precision medicine discovery approaches in the UK.

It will enable and participate in collaborative R&D projects with its community of biotech, pharma companies, charities, service providers, technologists, clinicians and translational researchers.

It is one of a network of elite, not-for-profit technology and innovation centres established by Innovate UK, as a long-term investment in the UK's industrial capability.

MDC will work in partnerships to develop new approaches for the discovery and early development of medicines – helping to transform ideas into commercial products for the wider wealth and health of the sector.

→ **md.catapult.org.uk**

SIEMENS HEALTHINEERS

IVD ANALYSERS

Siemens Healthineers has announced the CE Mark and global commercial availability of its Atellica™ Solution – flexible, scalable, automation-ready immunoassay and chemistry analysers.

The solution is now available across the globe – in Europe, the US, South America and Asia.

It features the world's first IVD analysers with a patented, bi-directional magnetic sample transport that is 10 times faster than conventional conveyors.

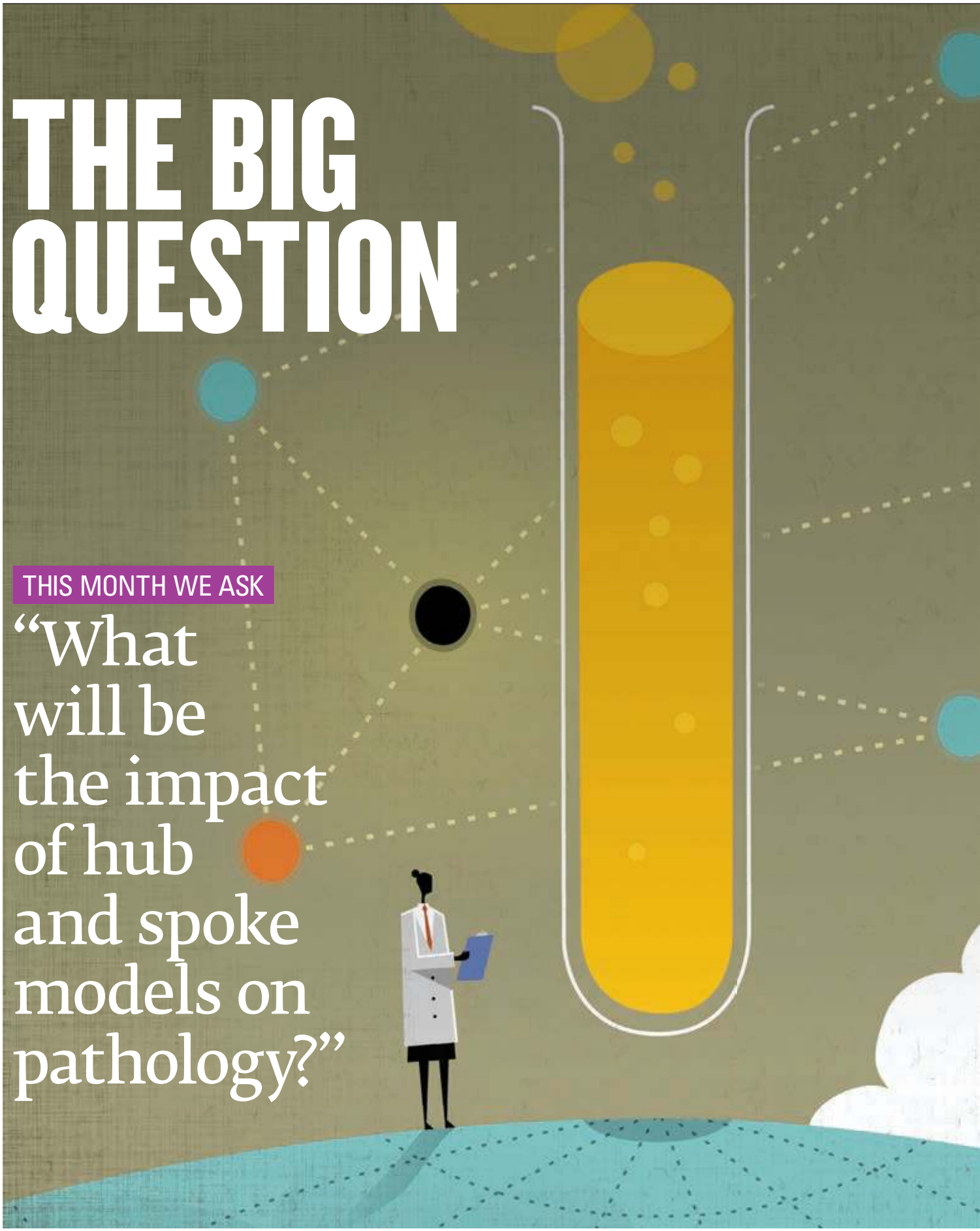
It sets a new standard in sample management and independently controls every sample, for immediate priority sample management and reduced operator intervention and fewer errors.

The immunoassay analyzer is engineered to deliver precision and can complete 440 tests per hour.

It has more than 300 customisable configurations, to adapt to changing testing needs and space constraints.

→ **healthcare.siemens.co.uk**

THE BIG QUESTION



THIS MONTH WE ASK

"What will be the impact of hub and spoke models on pathology?"

Phil Bullock

Speciality Director, Pathology
Consultant Healthcare Scientist in Cytology

The impact of hub and spoke will be dependent on the model agreed. NHSI have given three options: their model as proposed (structure unspecified), a proposed alternative model, or outsource. Efficiency for highly granular pathology services would be optimised, if delivered through a discreet single entity pathology service provider outside existing management structures. Creating a network within existing structures across multiple trusts risks significant inefficiencies around management systems, governance, IT (a single LIMS is essential), quality management and transport. This could outweigh short-term efficiency from joint managed service contracts, centralisation of high-cost low-volume specialised testing, reduction in send out cost and pooling of management expertise.

An imposed solution, which fails to take these factors into account, and does not address key issues, such as alignment with patient pathways, engagement with commissioners and STP projects, support for novel testing solutions e.g. emergency care pathways in the community, staff recruitment, retention and training. It risks imposing further stresses on pathology services, which already struggle with these key issues within existing management structures.

A final impact is for services to ensure they are engaged with trust management and commissioners – the current service provision model and efficiency must be understood and that the consequences of proposed changes are clear.

IMAGE: IKON

Angela Jean-François

Divisional Manager Infection and Immunity
North West London Pathology

For some services little impact will be seen, as some pathology services are already in networks/partnerships, while for others the impact will be bigger as services are reconfigured.

For patients, improvements can be seen in the quality and efficiency of services, enabling better demand management, standardisation of services, improving value for money and use of new technologies.

For staff, this can offer great opportunities for training and development and involvement in translational research. Logistics are key to the success of hub and spokes – with IT and transport playing essential roles.

To ensure this network operates and communicates efficiently, investment will be needed. The most obvious need is for a common IT platform

The IBMS forums are a great way to network and discuss all things biomedical science. Each month we will run a new thread based on The Big Question, asking for members' opinions to create debate. To get involved, visit the forums in your MyIBMS section of the IBMS website.

Alan Lauder

Senior Biomedical Scientist, Microbiology
Mid Yorkshire NHS Trust

Pathology networks are a fine idea in principle. Some key benefits are the advantages to be gained in procurement of goods and services, harmonisation of methods and reports for consistency across the network, increased training and promotion opportunities and increased service resilience. These factors, if astutely managed, should drive up quality. This should be accompanied by a long-term review of staff mix and plans on how to achieve this. As always, however, there is a massive BUT.

To ensure this network operates and communicates efficiently, investment will be needed. The most obvious need is for a common IT platform across the network, so that results from Lab A can be viewed, reviewed and, if necessary, have further work ordered from Lab B.

Equipment, reagents and standard operating procedures will need to be agreed upon and harmonised across the network. There will be other significant costs involved (buildings and writing off old equipment, among others) and a significant increase in the numbers of samples being transported, requiring a comprehensive sample tracking system and arguably temperature control monitoring during transport.

Having been through the trauma of a three-way laboratory merger, I can testify that it is vital that staff working are kept informed, listened to and, if possible, actively involved. Massive investment in time, money and staff will make it work... the only problem is changes seem to be driven not by quality, but by cost-cutting.

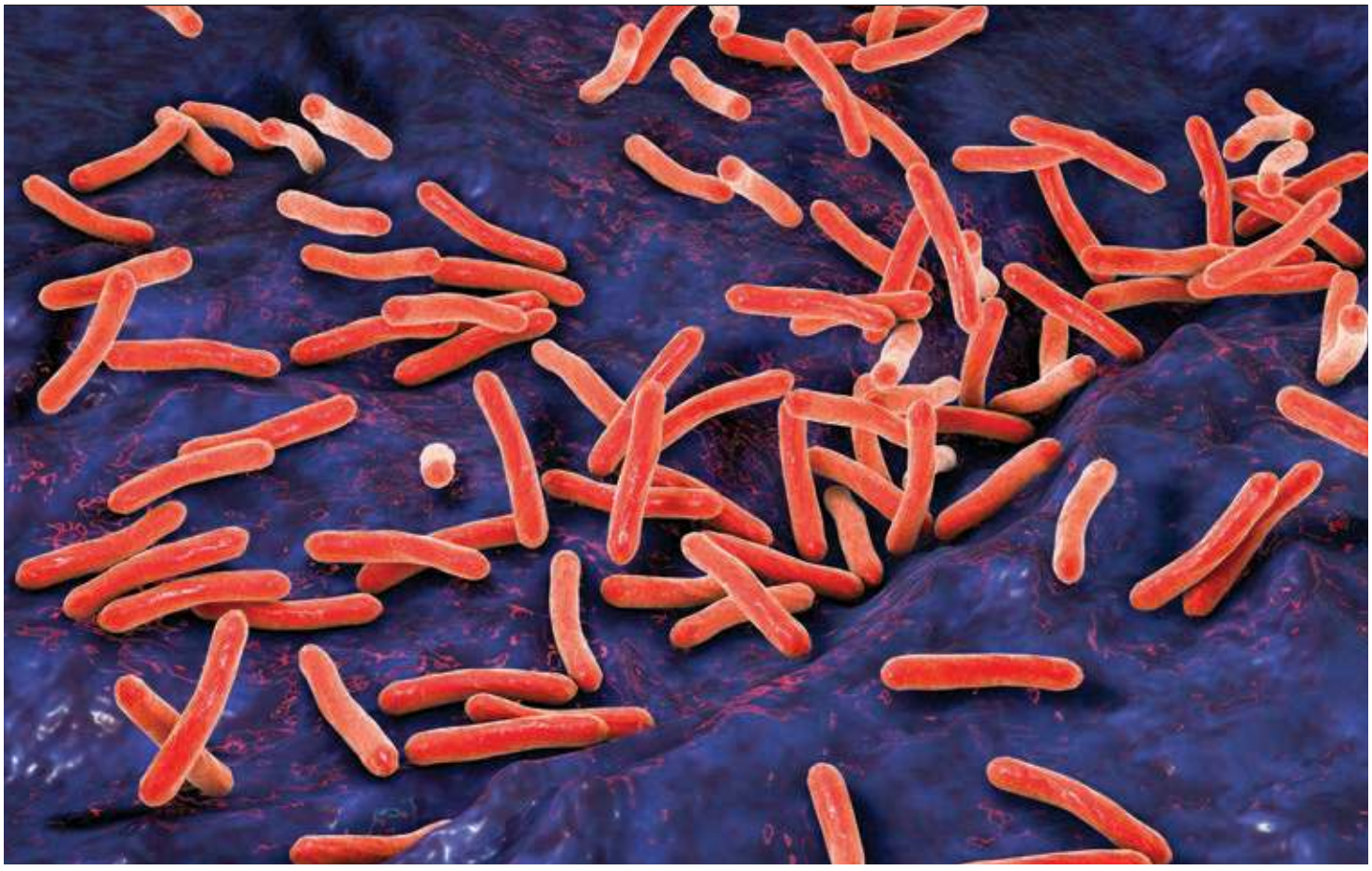


IMAGE: ISTOCK

FOUR DECADES OF TUBERCULOSIS

Professor Douglas Young discusses the last 40 years of tuberculosis research, as he hangs up his lab coat for the final time.

Ask Professor Douglas Young what inspired him to focus on tuberculosis over the course of his career, and he answers: "I had initially felt it was embarrassing that people should still be dying from a simple bacterial infection, that this just reflected selfish neglect on the part of countries with developed economies, and that the problem would be resolved by some basic appliance of science."

As he began to understand more, he adds, he felt that the idea of simple bacterial infections cured by antibiotics was misleading. The complexity of the tuberculosis infection itself highlights the underappreciation of the interdependence of humans and microbes, Douglas says.

A third of the global population is exposed to infection with mycobacterium tuberculosis, but only 10% will actually develop the disease. Whether a person develops tuberculosis or whether the bacteria stay in the body without ever causing any symptoms is the result of complex interactions between the bacteria and the body's immune system.

Evolution

Douglas is retiring from a 40-year research career (his most recent role was Head of the Division of Mycobacterial Research at the Francis Crick Institute) with an interest in studying the ways mycobacterium tuberculosis has co-evolved with humans over the last 70,000 years.

"My efforts to understand a single bacterium underwent serial expansions into questions of human physiology, evolution and society, all of which kept me interested," he says. "I continue to be surprised by the fact that all isolates of M. tuberculosis can be traced back to a single bacterial clone in the not-so-distant past. I also continue to be surprised by the fact that I am unable to say with certainty whether the not-so-distant past is about ten thousand years ago or about a hundred thousand years ago. I favour the latter."

Humans have genome sequences from very close relatives of M. tuberculosis and genome sequences from M. tuberculosis

isolates that have evolved in different populations, he explains. Genetic variation comes down to a seemingly manageable number of mutations, but it's not yet obvious which ones actually make the difference.

M. tuberculosis does not demonstrate the horizontal acquisitions of defined "virulence factors" that are reflected in the pathogenesis of some well-characterised bacteria, he adds. "The success of M. tuberculosis must lie in some more subtle combination of host-pathogen interactions that eludes our current comprehension."

Challenges

Not being able to fully answer the question of how tuberculosis has evolved with humans, and "facing the fact that 90% of what you do on a daily basis ends up going absolutely nowhere, and that the progress you do achieve appears in retrospect to be minimal in comparison to the new questions it opens up, is a bit tough", Douglas says, and something he tackled during this career by "having a few drinks with colleagues".

He has seen funding into tuberculosis increase –"albeit by orders of magnitude less than HIV" – so earlier cries that progress was stymied by neglect and rock-bottom funding became difficult to support. "We had to admit that it's a lack of knowledge and insight that's at issue."

Advances

Yet more consistent progress has been made in drug discovery and cell biology, with new imaging technologies allowing "remarkably detailed insight" into host-pathogen interactions.

Douglas' research into leprosy, undertaken during his post-doctoral fellowship at the Foundation for Medical Research in Mumbai, has also influenced understanding of tuberculosis. He worked on a glycolipid antigen of mycobacterium leprae – the leprosy-causing bacteria which is related to M. tuberculosis, and which is refractory to laboratory culture and study by microbiology.

"This provided a useful way into the microbiology and immunology of mycobacteria," he adds. "Leprosy research was really exciting in the late '70s and early '80s. This was right at the very start of the genomics revolution and we could see how access to mycobacterial DNA would provide an exciting new way to explore the biology of leprosy."

In the late '80s, cellular immunology advances – including cloning of the T cell receptor – were thought to provide an understanding of immunity and point the way to a vaccine design, Douglas says.

"However, although we have accumulated lots more T cell subsets and cytokines, it doesn't really add up to a clear understanding. Perhaps we should be thinking about immunology more as a means of maintaining homeostasis, rather than as a battleground?"

ALL ABOUT DOUGLAS

- ✔ Graduated in 1978 with a DPhil in microbial enzymology from the University of Oxford.
- ✔ Followed that with two post-doctoral fellowships, one at the Foundation for Medical Research in Mumbai, India, and one at the London School of Hygiene and Tropical Medicine
- ✔ Spent eight years as a career scientist in the MRC Tuberculosis and Related Infections Unit in London
- ✔ From 2007, headed the Division of Mycobacterial Research at the MRC's National Institute for Medical Research in London, one of the parent institutes that became the Francis Crick Institute in 2015
- ✔ Helped establish two research centres at Imperial College London
- ✔ Led a $20m international project funded by the Bill & Melinda Gates Foundation and Wellcome, which aims to develop new drugs for the treatment of latent tuberculosis.

Future direction

Like all biology, he says, tuberculosis research has been overwhelmed by host and bacterial genomics, initially in a gene-by-gene reductionist mode, now focused on a more holistic understanding.

"With a significant tuberculosis research effort in the Crick Institute, I envisage that problems in understanding and control of tuberculosis will be addressed in the broad context of human biology and evolution, rather than as a disease speciality," Douglas adds.

He would like to see future research approaches "reach an understanding with microbes, rather than just trying to kill them off", especially because M. tuberculosis demonstrates how a microbe is able to straddle the boundary between harmless commensal and deadly pathogen.

"I wonder if we shouldn't be trying to renegotiate some form of 'microbial contract' in light of antimicrobial resistance and appreciation of the pervasive influence of the microbiome," Douglas says.

A legacy

According to his peers from all over the globe, Douglas has played a major role in initiating research on disease progression that underpins current approaches to development of new drugs and vaccines for tuberculosis, shown scientific insight, leadership and influence, and clearly articulated scientific challenges with a clarity of insight and engaging writing style.

But ask him what he's most proud of about his career and he says: "The fact that I survived from one end of it to the other." BMS

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Delegates and exhibitors from the world of biomedical science joined Siemens Healthineers for the launch of the new Atellica® Solution at IBMS Congress 2017 at the ICC Birmingham. Crowds of people gathered for the unveiling, which marked commercial availability and CE Marking accreditation.

Alongside the launch, product demonstrations were also held for event attendees across the three days which proved a great success.

The Atellica® Solution is a flexible, scalable, automation-ready immunoassay and chemistry analyser, engineered to deliver control and simplicity so laboratory professionals can drive better outcomes. The new sample management technology gives independent control over every sample. It features bi-directional magnetic sample-transport technology, which is faster than conventional sample conveyors, the flexibility to create over 300 customisable configurations, and a broad assay menu.

Following the preview, Conor O'Malley, Leeds Teaching Hospitals, NHS Trust commented: "We're all about making sure that we produce the right result at the right level of quality and sometimes maintaining that level of quality is a challenge, given we have workforce issues. This system appears to remove quite a lot of those day to day headaches that we would face in terms of regulatory compliance and ease of use. So, I'm very impressed."

The Atellica® Solution simplifies laboratory operations through intelligent sample management. It can process more than 30 different sample container types, and furthermore by using the same reagents and consumables across different analyser configurations, laboratories can streamline inventory and deliver consistent patient results, no matter where patients are tested.

Addressing the crowd at the launch event, Marlen Suller, Country Business Lead for Laboratory Diagnostics at Siemens Healthineers, said: "The Atellica® Solution has been several years in the making. We did interviews and spoke to customer advisory boards to ensure this is a system which is designed by laboratory professionals, for laboratory professionals. Please join me in a toast to the future, because the future is now and it's the Atellica® Solution."

To find out more about the new Atellica® Solution, visit siemens.co.uk/healthineers

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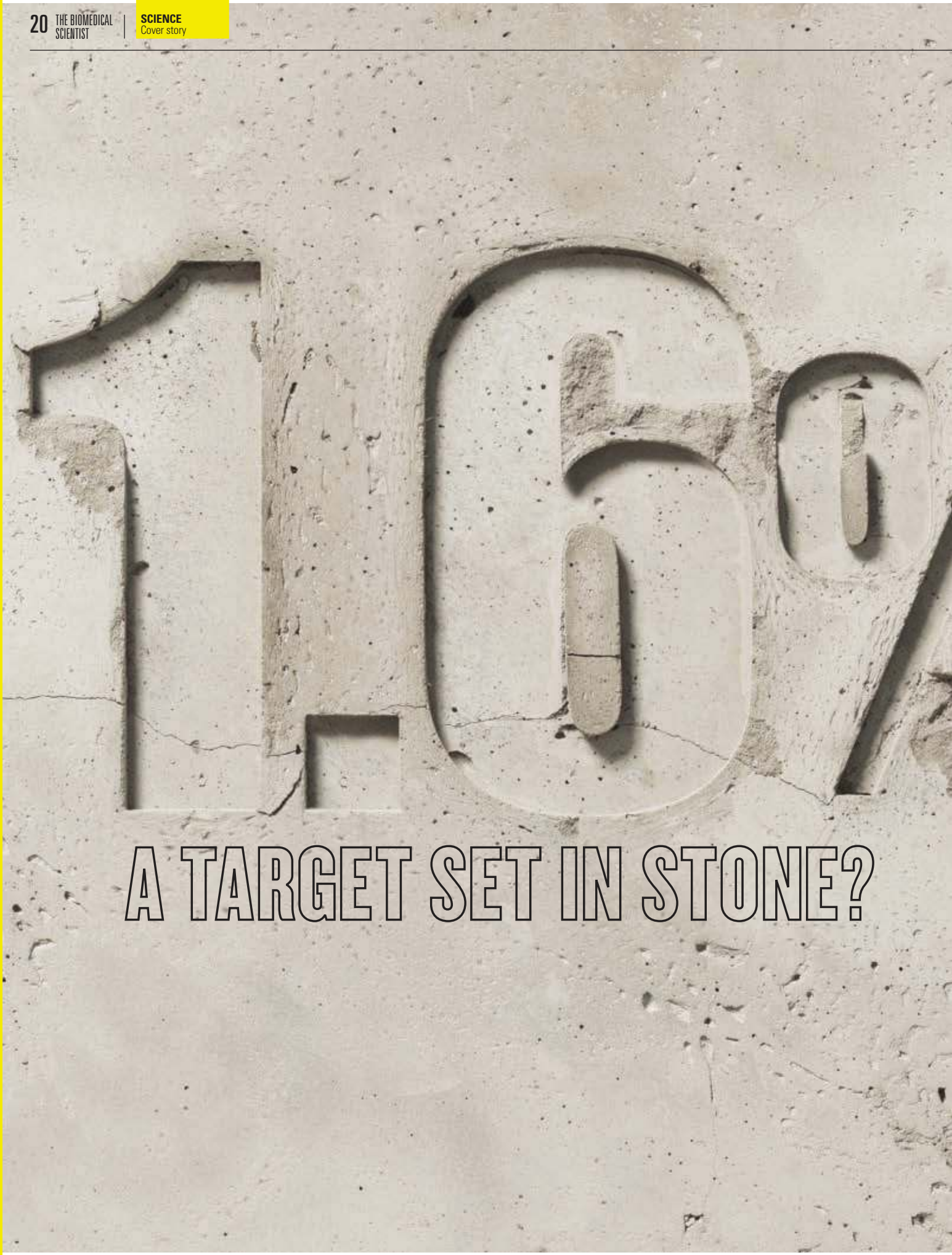
SIEMENS Healthineers



A TARGET SET IN STONE?

Almost two years have passed since **Lord Carter's** review on productivity in the NHS called for ambitious budget targets for pathology. Here we look at the progress that has been made since publication and ask if the plans have been a success.

On paper it makes total sense – when it comes to cutting costs (and to achieve pledged savings of £22bn in the NHS by 2020), no stones should be left unturned; no service is so sacrosanct that it is untouchable.

That was clearly the logic that was followed for Lord Carter's 2016 review into 156 acute hospital trusts.

So-called "unwarranted and inexplicable variation" in key areas of cost savings were looked at, compared, and contrasted, and among the many findings, one particular area was given its task – that when it comes to pathology providers, they should cost no more than 1.6% of a trust's operating expenditure.

That was the theory anyway. The report came out last year, and the deadline for meeting this target has long passed (in April 2017).

It included four recommendations for trusts to ensure that their pathology and imaging departments achieve their benchmarks, as agreed with NHS Improvement (see box, overleaf).

But not only have many not been able to achieve the budget target, plenty of questions remain unanswered, especially given NHS Improvement's recent announcement that it has gone ahead and identified 29 potential pathology networks where consolidation of pathology services should occur.

These didn't just apply to those trusts who failed to meet the 1.6% figure (as initially thought), but the detail of it even includes those that came

PHOTOGRAPHY: RICHARD GLEED

1%

Some pathology services come in at a total cost of less than 1% of a trust's operating expenditure

3%

Some pathology services come in at a total cost of more than 3% of a trust's operating expenditure

2.8

Some trusts spend around 2.8 times more on pathology provision as a proportion of operating expenditure than others

under the 1.6% threshold (and who thought there were in the clear).

Calculating costs

"The creation of the 1.6% figure always felt very arbitrary anyway; that it was the median figure of those trusts Carter looked at," says Gwyn McCreanor, Past President of the Association for Clinical Biochemistry and Laboratory Medicine and Consultant at Kettering General Hospital Foundation Trust. "But the announcement of moving into networks – well, if you look at the maps, some of them are rubbish, especially around the Midlands."

The full September networks document can be seen on the NHS Improvement website and the overall aim is to shave around £2m off the annual £2.5bn to £3bn that is estimated to be spent on pathology services in the UK annually (see box for statistics). Of the 29 potential pathology networks identified, one includes London's Imperial College Healthcare Trust becoming a hub with Chelsea and Westminster and the Hillingdon Hospitals Foundation Trust outsourcing to it. For this hub alone, NHS Improvement argues there will be around £2.5m in savings per year. But Gwyn remains unconvinced. "Some of the data is not accurate, due to lack of consistent guidance around what is required; there are errors in the calculations; to my mind it's impossible to claim the sort of savings they have."

Disgruntlement about how trusts could even identify pathology costs to the desired level was first raised when the 1.6% figure was suggested a year ago, and with the new document, this anger has clearly not abated today. At the time, Dr Suzy Lishman, President of The Royal College of Pathologists, said it wasn't possible to extract costs so easily, because pathology is a clinical, analytic and advisory service. Guidance by the Association for Clinical Biochemistry and Laboratory Medicine (ACB) has recently tried to help trusts identify which costs do, or do not, count. Those costs it says shouldn't count include the likes of blood and blood products, phlebotomy, costs associated with regional screening programmes, anticoagulation, DVT, VTE services, infection control, and also consultants (both medical and clinical scientists) and their secretaries. But now that NHS Improvement is channelling trusts into networks, Gwyn says it's simply creating more confusion. "In this hospital, we're well under the 1.6% figure as we've calculated it, but we've been asked to join up with six other hospitals."

She adds: "We were already working on our own plan, because we don't feel a hub and spoke model works. We think a more federated network model is better. It's better for logistics, and it's better for keeping work local, but it still gives us efficiency gains from better procurement and training."

PATHOLOGY NETWORKS IN NUMBER

number of disciplines within pathology

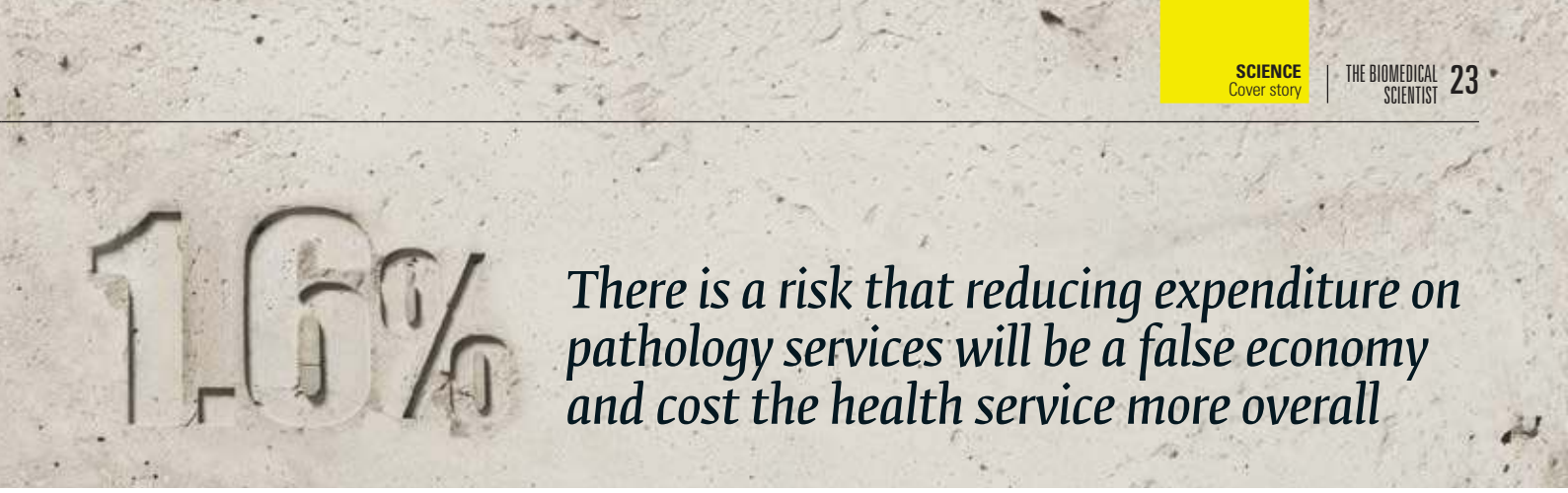
£2.5-£3bn
the estimated cost of pathology

29
the number of proposed pathology networks

105
hospitals in England provide pathology services

£200m
the expected saving by 2020-21

1.12bn
annual number of pathology tests



There is a risk that reducing expenditure on pathology services will be a false economy and cost the health service more overall

False economy

What's clear is that the solutions being suggested to trusts aren't being swallowed. At the start of the review process, there was already vocal disagreement that Carter did not appreciate the varying types and frequency of workload trusts have, especially where different hospitals will have different types of pathology services, offering different ranges of tests. For instance, specialist tests will be more expensive than routine ones and small hospitals providing expensive specialist services will appear less efficient than larger trusts providing only routine services. But now, it seems the network idea is not hitting home either.

And then, of course, there's one more nagging issue that remains – the belief still that Carter did not understand the true cost-benefit-analysis of having more pathology rather than less. "Pathology tests are an integral part of the majority of patient pathways and are particularly important in early diagnosis and screening for unsuspected disease, as well as monitoring long-term conditions and the effect of treatment," argues Suzy Lishman.

"There is a risk that reducing expenditure on pathology services [just to meet a target] will be a false economy and will cost the health service more overall, because it could have adverse consequences for patients." In other words, spend upfront in tests early on would more than pay for themselves by substantially reducing later medical costs. Hitting a 1.6% figure, she argues just doesn't look at total costs in the round.

Challenging proposals

Tim Evans, National Director for Clinical Productivity, defends the networks, saying: "Patients deserve the best quality of care at good value." He says: "By bringing these services into larger, more efficient networks, patients will have better access to innovative services and receive test results quicker."

But Gwyn McCreanor for one is already questioning this. The responses to NHS Improvement from trusts within the current East Midlands Network have requested that the plan they are already working on should be the one that moves forward. She said: "The irony is that at least with the 1.6% figure, although it did seem plucked out of the air, it's ultimate ambition was to try to create efficiencies."

Gwyn continues: "But now, with the networking model proposed, this focus seems to have been dropped, and that it no longer seems to matter how efficient you are."

The ACB isn't happy either. In a statement last month its spokesperson said: "We indicated our scepticism that it would be possible to deliver the clinical and financial benefits intended and were not consulted during the development of the proposals."

Whether Gwyn is successful in her alternative suggestion remains to be seen – she said she is still waiting for a response. It's probable other trusts will be appealing too, pushing the likelihood of achieving reduced costs (a noble aim), much further into the long grass. Although the Carter report has not been the only advocate of change Cancer Research's own study (*Testing Times to Come? An Evaluation of Pathology Capacity Across the UK*, which was published last November) also found there are "inefficiencies in pathology services that must be reduced", including more "consolidation of pathology services", it's the legacy of the Carter report that is still being debated.

The Carter report came, it saw, but didn't conquer, and now it seems, its aims will have to wait as more wrangling about the details of how to achieve savings continue to be debated. BMS

RECOMMENDATIONS FOR PATHOLOGY

- ✔ Trusts introducing the Pathology Quality Assurance Dashboard (PQAD) by July 2016 to assure themselves and others that the pathology service provided to them is and remains of appropriate quality and safety, with NHS Improvement hosting the dashboard.
- ✔ HSCIC publishing a definitive list of NHS pathology tests and how they should be counted by October 2016, with NHS Improvement requiring trusts to adopt the definitions from April 2017.
- ✔ NHS Improvement publishing guidance notes for forming collaborative joint ventures and specifying managed equipment service contracts for local adaptation by October 2016.
- ✔ NHS Improvement introducing metrics that describe relative imaging departmental productivity related to the use of equipment and workforce activity by December 2016.

Lord Carter's review, *Operational productivity and performance in English NHS acute hospitals: Unwarranted variations*, and associated documents are published online and can be downloaded by visiting bit.ly/BS_Carter_Review

CONGRESS ROUNDUP

In our final coverage of the year for the IBMS Congress 2017, we congratulate the winners of the exhibition awards and the poster competition, while paying thanks to the Birmingham branch.

CONGRESS EXHIBITION WINNERS

At every Congress, a panel of judges, including the IBMS president Ian Sturdgess, Chief Executive Jill Rodney and the Company Members Liaison Group Chairman Mark Reed, attend the opening of the exhibition.

Touring the stands across the ICC, they judge each on appearance and the welcome visitors receive.

This year's winners included Shell of the Year, which went to Aspect Scientific, who were attending for the first time, along with Stall of the Year, which was awarded to Menarini Diagnostic, who celebrated 30 years of business with a birthday cake.

BEST SHELL – ASPECT SCIENTIFIC

At their first Congress, the team at Aspect Scientific were promoting their EKF Altair 240 automated Biochemistry analyser, along with their services in providing and supporting ELISA automation systems from Dynex Technologies.

Andrea Horridge, Technical Support and Quality Manager at Aspect Scientific, said: "We saw Congress 2017 as a great opportunity to network and make many new contacts. We are proud to say it was a huge success on many different levels.

"A mixture of excitement, nerves, and awe at the scale and how impressive the exhibition looked took over as the team set up the stand. However, we soon felt at

IMAGE: PROVISIONPHOTO

BEST STALL – MENARINI DIAGNOSTICS

Menarini Diagnostics was set up in the UK 30 years ago and has been an active corporate member of the IBMS ever since. They used this milestone to celebrate in the theme of their stand design at Congress this year, including a birthday cake that IBMS President Ian Sturdgess was invited to cut.

On receiving their award, Brendan O'Dwyer, Business Unit Manager, Laboratory Division at Menarini Diagnostics, said: "We have always had a close relationship with the IBMS and were proud and delighted to be awarded as the Best Stall at Congress. The majority of our team have been, or still are, registered individual members and the company has been present at every Congress event over the years.

"This is the most important exhibition we attend – we have a wide portfolio of products and the multidisciplinary mixture of attendees at all levels of seniority and Congress presents a great opportunity to show these off.

"There is a great feeling of enthusiasm among the attendees. They are there primarily for the high-quality scientific programme, but definitely plan to enjoy themselves. We have the chance to develop relationships, give something back to our customers, and even transact some business. A fantastic event."

Ian Sturdgess, IBMS President, said:

"All of the judges were in agreement that Menarini were the worthy winners of our Best Stall award.

"Their stand, though simple in its design, was really appealing with a clinical, orderly appearance.

"The Menarini staff were also knowledgeable about the range of products they offered and always willing to engage with delegates who passed by their stall."

home, due to the welcoming and friendly atmosphere created by the organisers, exhibitors and delegates. It was fantastic to interact with so many medical diagnostics professionals on both a business and personal level.

"The icing on the cake came in the form of winning the award, presented to the team by IBMS President Ian Sturdgess. Ian, and the IBMS Company Members Committee commended the team on their approachability, product knowledge and engagement with visitors who came to the stand. It was a great surprise.

"We thoroughly enjoyed being a part of this year's IBMS Congress. A huge thank you to everyone who visited us, and to the organisers and other exhibitors for making this such a fantastic event. We will see you at the next IBMS Congress, if not before."

Ian Sturdgess, IBMS President, said: "We were warmly welcomed by the team at Aspect Scientific and their enthusiasm and willingness to discuss the range of instrumentation products they offer is what set them apart.

"It was also genuinely pleasing to see how elated they were on receiving their prize in their first year at Congress and we hope that this will be the start of a long and close relationship with the IBMS."

BIRMINGHAM BRANCH MEMBERS AT CONGRESS

The volunteers from the IBMS' Birmingham branch once again supported the functional running of this year's Congress.

On Saturday, before the event started, they enthusiastically arrived to fill 3,000 delegate bags.

On every day – including the first ever Sunday programme – they were there to "meet and greet" a total of around 300 speakers. They helped them to register, get orientated and organised for the lectures, which took place across nine streams.

The volunteers were also on hand to manage the poster competition in Hall 4, with different categories of posters each day and different judging panels.

The branch volunteers also supported the front desk, dealing with delegate enquiries each day with a welcoming smile, happy to contribute to make everyone's experience a memorable one.

Congress would not be able to run as efficiently as it does without their help. Their hard work and dedication is testament to the vital contribution that IBMS branches and networks make to the organisation. The IBMS wishes to thank them for their contributions to another successful event.

POSTER COMPETITION

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

The posters received this year for judging set a very high standard and made the judging process very difficult. With so many remarkable entries, the judges wish to thank all the poster presenters for their excellent contributions.

The IBMS wishes warm congratulations to all the poster winners (listed right), and thanks to all the poster presenters for setting a high standard at this year's Congress.

THE WINNERS

- **Chloe Jagpal**, Coventry University, Haematology: *The in vitro use of natural antioxidant oils (Cyperus esculentus, Nigella sativa) to reduce cell sickling in sickle cell anaemia*
- **Neil Kirkpatrick**, Northern Ireland Blood Transfusion Service, Transfusion Science: *A novel approach to human platelet antigen (HPA)-1 typing in the UK*
- **Jack Cowley**, Cambridge University Hospitals, Molecular Pathology and Genomics: *RNAlater as a molecular preservative for paraffin-embedded diagnostic tissues*
- **Lisa-Marie Newlove**, Cellular Pathology: *GATA3: use in triple negative breast carcinomas*
- **Mari Paul**, Antrim Area Hospital, Cytopathology: *Confirmed outcomes for HPV18-positive cases in HPV triage*
- **Paul Livingstone**, Medical Microbiology: *Isolation of bacterial predators which can kill clinically relevant pathogens*
- **Andrea Wilson**, Viapath Analytics, Virology: *Evaluation of a Mycoplasma genitalium TMA assay for diagnostic use*
- **Clare Jones**, John Radcliffe Hospital, Clinical Chemistry: *Analytical evaluation of PlGF and sFlt-1 for assessment of pre-eclampsia*
- **Charlotte Lee**, King's College Hospital, London, Immunology: *Skewed T follicular helper cell subsets in common variable immunodeficiency*
- **Vusumuzi Ncube**, Frimley Health Foundation Trust, Education and Management: *Review of post-analytic processes in a pathology network hub*

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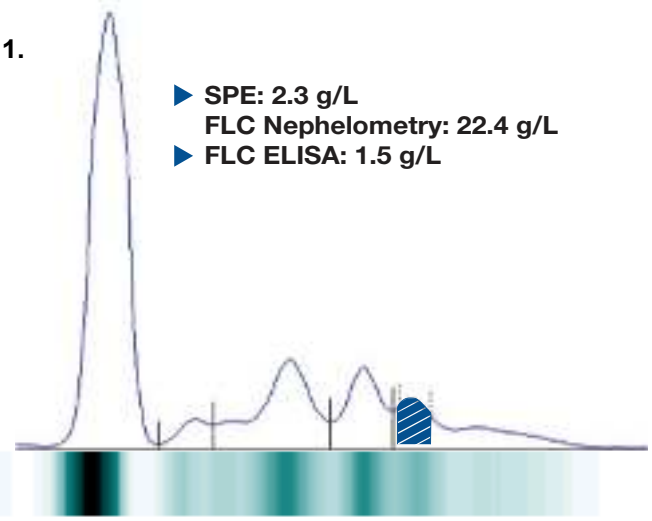

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- FLC ELISA: 1.5 g/L

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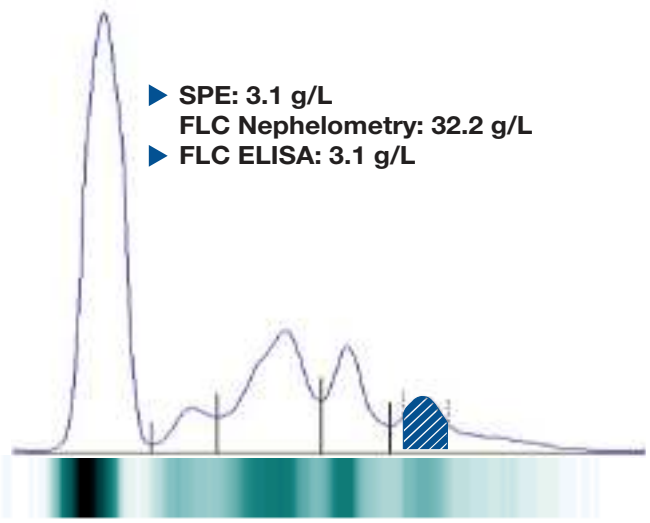

- SPE: 3.1 g/L
  FLC Nephelometry: 32.2 g/L
- FLC ELISA: 3.1 g/L

Overestimation of Serum κ Free Light Chain Concentration by Immunonephelometry
Corrie M. de Kat Angelino, Reinier Raymakers, Maria A. Teunesen, Joannes F.M. Jacobs, Ina S. Klasen
Clinical Chemistry Jul 2010, 56 (7) 1188-1190; DOI: 10.1373/clinchem.2010.143529
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CLINICAL CHEMISTRY CLASSICS

PT 4A

In the fourth of our series looking at landmark moments in clinical chemistry, **Stephen Clarke** turns his attention to cardiac markers.

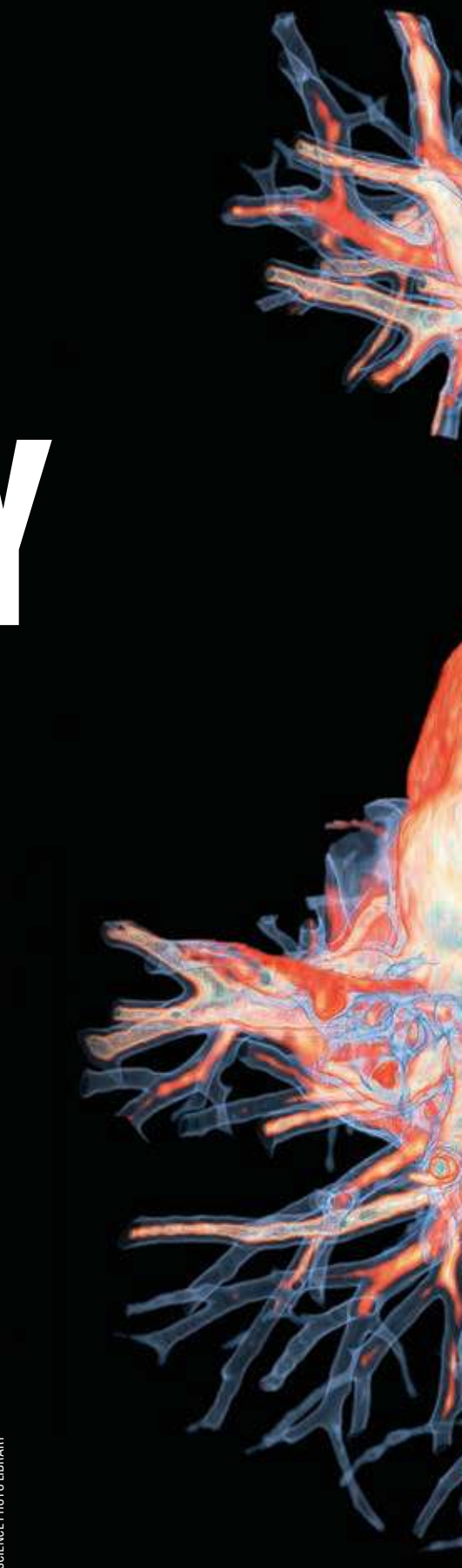
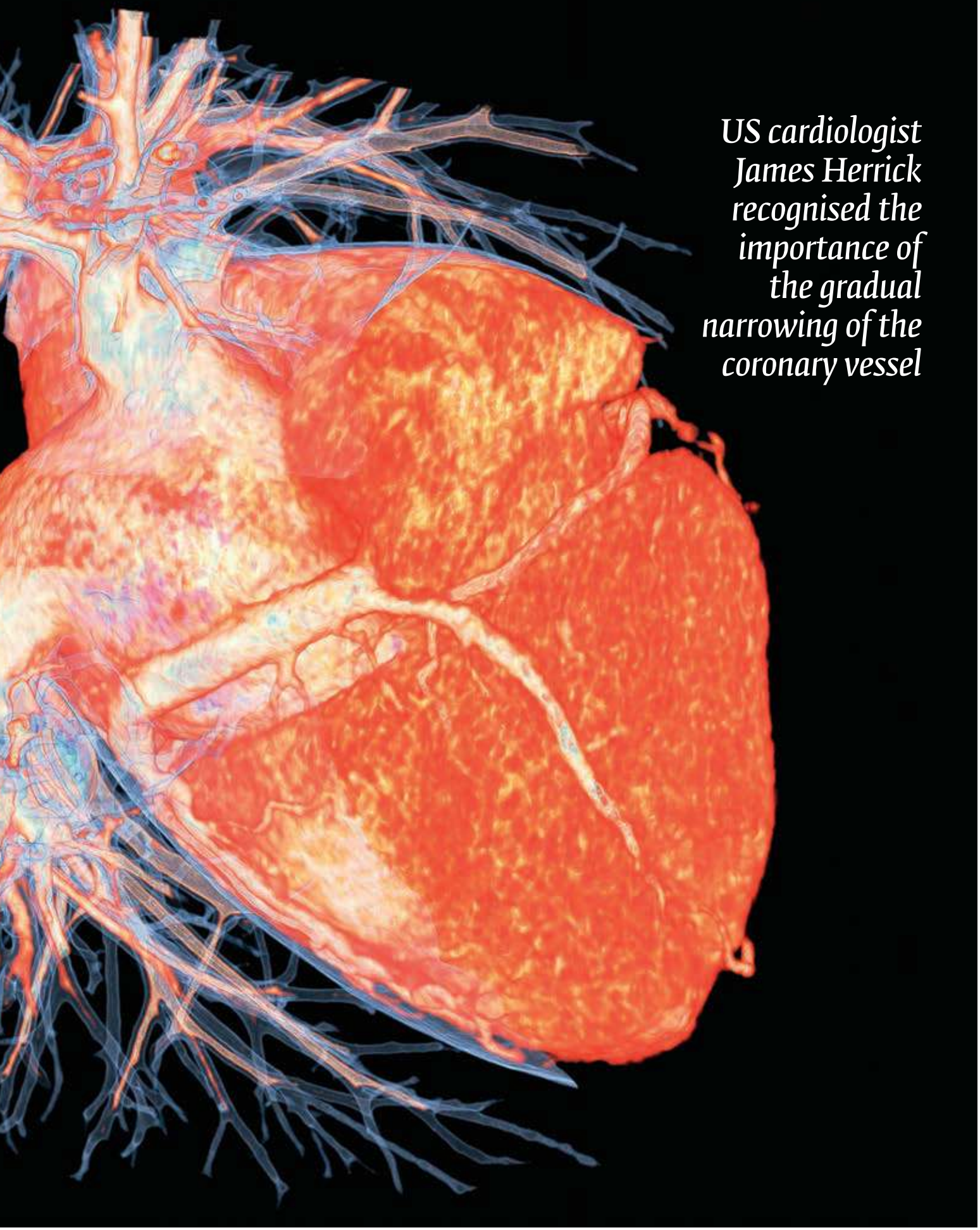


IMAGE: SCIENCE PHOTO LIBRARY

Revisiting older methodologies can help the interested reader trace the origin of current tests, learn about the author(s), the challenges they faced and appreciate the improved tests that are available today. From the vast literature, this short review selects landmark papers with background notes, paying tribute to those early pioneers who developed assays for the analysis of two early blood serum cardiac markers, for the diagnosis and investigation of cardiovascular disease, notably coronary heart disease, which may lead to life-threatening acute myocardial infarction (AMI).

Raised awareness of coronary heart disease

Evidence has been presented that atherosclerosis and vascular calcification occurred in the hierarchy of ancient Egypt, but it was only in the 18th century that blockage of the coronary arteries was first reported by the German physician Friedrich Hoffmann and later, in 1912, the US cardiologist James Herrick recognised the importance of the gradual narrowing of the coronary vessels and later coined the term "heart attack" for AMI – in 1918 he described the electrocardiographic changes on ligation of the coronary vessels. There is data to support the rising incidence of heart disease during the 20th century and



US cardiologist James Herrick recognised the importance of the gradual narrowing of the coronary vessel

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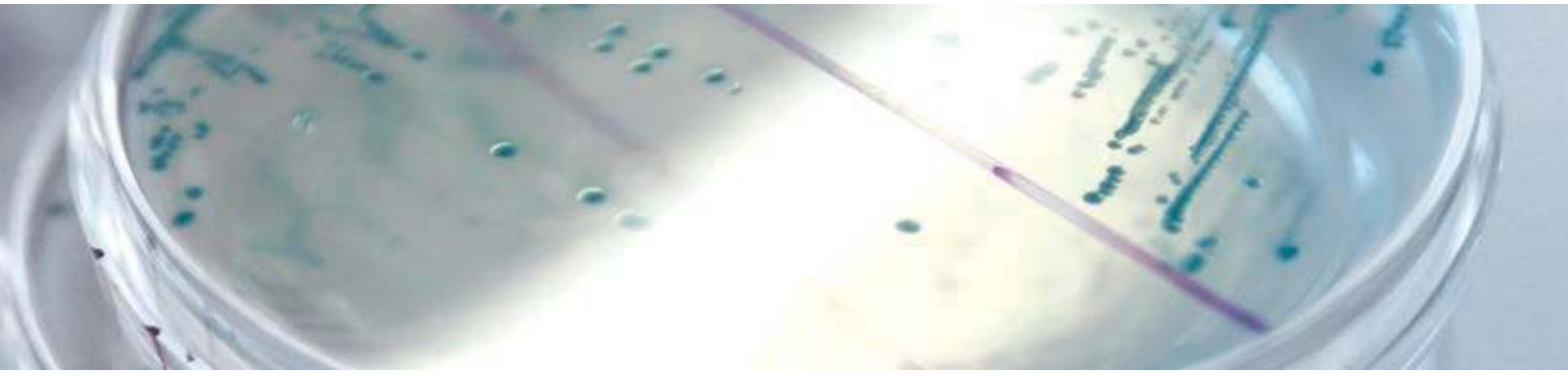

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If you missed us at IBMS Congress, we are happy to come to you and discuss how TDBactiLink may meet your requirements.

Left. Dr Felix Wroblewski (centre) and Dr John LaDue (right) working on a new blood test they devised to aid in detection of coronary thrombosis.

by mid-century it was the most common cause of death in the US, due to an increased prevalence of atherosclerosis associated with smoking and diet.

However, advances were taking place in our understanding of protein chemistry, enzyme catalysis, metabolic pathways, and the sub-cellular location of enzymes combined with improved analytical instrumentation which provided more opportunities for new approaches in enzyme assays, which previously were mainly colorimetric. In cardiology there was an increasing clinical need for a rapid, simple and reliable indicator or "marker" to confirm that the patient had suffered a myocardial infarction to improve treatment options and outcomes, particularly if the electrocardiograph findings were equivocal.

Blood serum aspartate transaminase (AST): the first cardiac marker

In 1952, a 22-year-old US medical student called Arthur Karmen undertook an extended practical project at the Sloan Kettering Institute, New York City, under the direction of cardiologists John S LaDue and Felix Wroblewski. This was to explore the possible release of a heart enzyme from the myocardium released into blood as a marker for cardiac damage. Through literature research he found others had reported a high concentration of the transaminase AST in heart muscle and demonstrated the presence of AST in serum by incubation with substrates, α-ketoglutarate and aspartate and used quantitative amino acid paper chromatography to measure the rate of glutamate produced, which was related to AST activity under standard conditions and reported a reference range.

However, the method was laborious, required technical skill and took 36 hours to complete.

In an appendix to this paper, Karmen reports an alternative quick and simple method to measure AST activity, with the oxaloacetate as substrate reduced to malate by a second enzyme malate dehydrogenase in the presence of the reduced coenzyme nicotinamide adenine dinucleotide ($NADH_2$), which is oxidised simultaneously to NAD.

This reaction was closely monitored using spectrophotometry by the decrease in light absorption at 340nm using the newly developed Beckman DU spectrophotometer for more accurate rate reaction measurements.

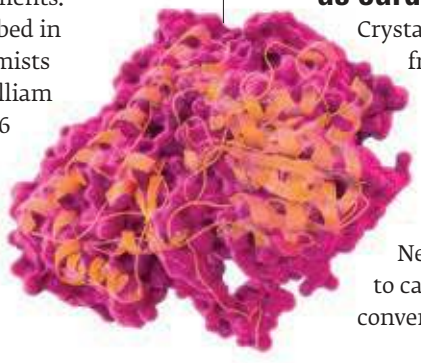
NAD was first described in 1906 by British biochemists Arthur Harden and William John Young, and in 1936 the German scientist Otto Warburg described the role of the coenzyme in hydride transfer and the nicotinamide moiety as the site of redox reactions. Further studies by Horecker and Kornberg in 1948 measured extinction coefficient of the reduced coenzyme allowing calculation of international units of activity.

This landmark paper is highly significant in the use of coupling reactions and as an early example of using the NADH/NAD redox reaction in clinical enzymology. This concept was quickly adopted for other enzymes and modifications of the original AST assay were reported by Henry in 1960 and the coupled reaction was also linked to colorimetric end point assays. A reference optimised version of the preferred spectrophotometric method was reported in 1972.

Clinical reports

In 1955, LaDue and Wroblewski performed a clinical study of induced AMI in dogs and 50 human patients post-transmural AMI and found that AST was raised two to 20 times, four to six hours after the event and remained raised for two to five days. Despite the high sensitivity for AMI, AST is a non-specific cardiac biomarker with a wide tissue distribution, notably in liver, skeletal muscle and kidney and is raised in liver disease, acute renal disease, musculo-skeletal diseases and trauma. However, it was widely used to investigate cardiac events during the following decade despite its limitations.

Blood serum lactate dehydrogenase (LDH) as cardiac marker



Crystalline LDH was prepared from heart muscle by FB Straub in 1940 and some properties and structural heterogeneity were studied by JB Neilands. LDH was known to catalyse the reversible conversion of lactate to

IMAGES: GETTY/SCIENCE PHOTO LIBRARY

pyruvate and as a key enzyme in anaerobic glycolysis to continue to produce energy, particularly during heavy exercise. It was identified in serum by Hill and Levi in 1954 in their search for a possible tumour marker using a spectrophotometric procedure.

Following their work with AST, the Sloan Kettering cardiologists Wroblewski and LaDue used the same principle to devise a spectrophotometric procedure in 1955 using the above reaction in reverse and measuring the rate of decrease in extinction of NADH2 at 340nm. Others, notably Wacker and colleagues, began with lactate as substrate and measured the increase in extinction. Once again more convenient colorimetric methods were devised, notably by John King, based on the formation of coloured pyruvate dinitrophenylhydrazine.

Clinical reports

Many studies have reported elevated results in AMI and it was used along with serum AST as a useful cardiac marker and serum LDH is raised five to 10 hours post-AMI, peaking between three and six days and may remain high for 10 days. However, LDH is present in almost all human cells and is more abundant in cardiac and skeletal muscle, liver, kidney, and red blood cells. With increased cell breakdown LDH is also raised in leukaemia, certain solid tumours, acute hepatitis and renal disease.

LDH isoenzymes

Studies were performed using electrophoresis, pioneered initially by Arne Tiselius (1931), and with more relevant advances occurring at this time notably, by the English-born biochemist Oliver Smithies, who developed the use of starch as the medium for gel zone electrophoresis in 1955. Starch block electrophoresis was used to separate serum protein fractions and LDH activity was located in three fractions by Vesell and Bearn in 1957 at the Rockefeller

Blockage of the coronary arteries was first reported by Friedrich Hoffmann (pictured above)

Institute, New York. In the same year, Wieland and Plfeiderer demonstrated five distinct zones with LDH activity in serum and most tissue extracts. Further studies demonstrated that the fastest moving isoenzyme LD1 is richest in cardiac muscle with diminishing proportions of LD2-5. Many studies have shown that LD1 is significantly increased in AMI. As isoenzymes vary slightly in their primary structure, alternative methods have been used to distinguish specific isoenzymes. LD1 has been shown to be more resistant to heat, but was relatively more inhibited by oxalate than other isoenzymes.

AST and LDH assays

Current methods for measuring both enzymes do not differ significantly from the original assays, but are obsolete in the diagnosis of AMI, with the availability of improved serum cardiac markers and imaging techniques. Serum AST is now more often used to investigate liver disease. LDH is more used clinically in the investigation of various forms of anaemia such as haemolytic anaemia and to monitor certain germ cell tumours, such as testicular cancer and leukaemia.

Arthur Karmen

Following his medical qualification, Arthur Karmen specialised in chromatography, notably at the National Heart Institute, and then was appointed the Associate Professor in Nuclear Medicine at Johns Hopkins (1963-68), later Clinical Director at New York University and finally from 1971 at the Albert Einstein College of Medicine, directing studies on therapeutic drug monitoring, kinetic enzyme assays and immunoassays. He was recognised by many awards and by the American Association of Clinical Chemistry in 1991 for "outstanding contributions in a specialised area of research".

Concluding comments

This was a remarkable decade that introduced novel spectrophotometric assays of AST and LDH to expand the range of serum enzymes, in addition to amylase and alkaline phosphatase available for clinical purposes. It inspired the development of other enzyme assays using this principle, increased the availability and use of spectrophometers in routine clinical chemistry, while further progress was also achieved by more convenient electrophoretic techniques to investigate isoenzymes and their clinical applications. The focus on heart disease remains highly topical today, with constant media attention on risk factors, improving lifestyle and new preventative treatments. BMS

Stephen Clarke is a retired IBMS fellow. He previously worked in clinical chemistry at Southmead Hospital, Bristol.

MILK, SALIVA AND TEARS

Bodily secretions could be used to power biomedical devices, according to new research.

Scientists have discovered a way to harvest electricity from tears, saliva and milk, thanks to lysozyme. This is an enzyme that generates electricity when it is put under pressure (see box). They have published a paper, which states that if we can learn to harvest it effectively, it could become a new fuel source for all kinds of implanted devices.

The researchers, from the Bernal Institute at the University of Limerick, observed that crystals of the model protein lysozyme can generate electricity when pressed.

The ability to generate electricity by applying pressure is known as direct piezoelectricity and is a property of materials, such as quartz, that can convert

WHAT IS PIEZOELECTRICITY?

The authors say: "A property of crystals and chiral molecules that originates from the absence of a centre of symmetry in their structures. When such materials are stressed, their electrical neutrality is perturbed and a net polarisation results at the surface of the material. The Curie brothers first demonstrated this property, known as the direct piezoelectric effect, in 1880. There also exists an opposite effect known as the converse piezoelectric effect; in this case, an electrical field applied across a piezoelectric material causes a mechanical strain to develop. Of the 32 crystallographic point groups, 21 do not possess a centre of symmetry and 20 of these are classed as piezoelectric."

Right. Aimee Stapleton, Irish Research Council EMBARK Postgraduate fellow at University of Limerick, Ireland and lead author of *The Direct Piezoelectric Effect in the Globular Protein Lysozyme*. Credit: Sean Curtin, TrueMedia

IMAGES: UNIVERSITY OF LIMERICK/ISTOCK

mechanical energy into electrical energy and vice versa (see box). Such materials are used in a variety of applications, ranging from resonators and vibrators in mobile phones to deep ocean sonars and ultrasound imaging. Bone and tendon are also known to possess piezoelectricity.

Aimee Stapleton is the lead author of the research and an Irish Research Council EMBARK Postgraduate Fellow at the institute. She says: "While piezoelectricity is used all around us, the capacity to generate electricity from this particular protein had not been explored. The extent of the piezoelectricity in lysozyme crystals is significant. It is of the same order of magnitude found in quartz. However, because it is a biological material, it is non toxic so it could have many innovative applications, such as electroactive anti-microbial coatings for medical implants."

The protein was once investigated by Alexander Fleming, as an antibiotic candidate before he discovered penicillin, and was one of the first proteins to ever be mapped in three dimensions.

Co-author Professor Tewfik Soulimane adds: "The high precision structure of lysozyme crystals has been known since 1965. In fact, it is the second protein structure and the first enzyme structure that was ever solved, but we are the first to use these crystals to show the evidence of piezoelectricity."

While crystals are the "gold standard" for measuring piezoelectricity in non-biological materials, this research indicated that the same approach can be taken in understanding this effect in biology.

This is a new approach, as previously scientists have tried to understand piezoelectricity in biology using complex hierarchical structures, such as tissues, cells or polypeptides, rather than investigating simpler fundamental building blocks.

The discovery could have far-reaching implications, and may lead to further research in the area of energy harvesting and flexible electronics for biomedical devices. Future applications of the discovery could potentially include controlling the release of drugs in the body by using lysozyme as a physiologically mediated pump that gathers energy from its surroundings.

Being naturally biocompatible and piezoelectric, lysozyme may present an alternative to conventional piezoelectric energy harvesters, many of which contain toxic elements such as lead.

Professor Luuk van der Wielen, who is the Director of the Bernal Institute, believes that the impact of this discovery in the field of biological piezoelectricity could be "huge". BMS

WHAT IS LYSOZYME?

The authors say: "Lysozyme is an antibacterial enzyme found in the egg whites of birds and in mammalian tears, saliva, and milk. It catalyses the hydrolysis of specific kinds of polysaccharides thereby weakening the cell wall, making the bacteria susceptible to osmotic lysis. Hen egg-white lysozyme is one of the most studied model proteins and can crystallise as tetragonal, monoclinic, orthorhombic, triclinic, or hexagonal crystals. [In our paper] we focus on the tetragonal and monoclinic forms of lysozyme which are typically described by point group 422 and point group two, respectively."

HOW TO... BE A SUCCESSFUL QUALITY MANAGER

Fiona R Denham, from Viapath Analytics, gives her top tips on how to be a successful quality manager.

It's not easy to define how to be successful as a Quality Manager, as I wouldn't necessarily refer to myself as "successful", but it's encouraging to know that others see me that way. However, here are some approaches that help me in my role.

Q Qualifications and Questions

A qualification in quality management helps with the theory to support the practical aspects of my role, and gives confidence. By asking constant questions of the team that I work with, I ensure that quality management procedures are in place in the laboratories and, most importantly, are being followed. As W Edward Deming said: "In God we trust; all others bring data."

U Understand and be Unbiased

I have experience of working in most of the disciplines that I cover and this really helps because I can better help the managers to understand how the accreditation standard applies to their service. Objectivity is vital, so I try to stand outside of laboratory operations whenever I can, so I can give an unbiased view, and better see the areas for improvement.

A Aims and Approachability

When I started in my role, I looked at where my labs stood with regards to quality management; this helped me to work out what was required to improve. I also try to be visible, and make sure all the staff know who I am and what I do. This helps to make quality management accessible.

L Learning and Leading

Almost every event provides a learning opportunity, be it an audit, an assessment, or an incident. Sharing learning with other quality managers is also vital. The managers in my area rely on me to direct and lead them before and after assessment visits and provide them with action plans.

I Improvements and Implementation

It's a significant part of my role to keep improving the

IMAGE: ISTOCK

THE ROLE

The Quality Manager role depends on their individual remit and job description, but in general, the role will include:

- ✔ Management of the QMS, including document control systems and audit schedules
- ✔ Quality improvements
- ✔ Accreditation
- ✔ Quality indicators and objectives
- ✔ Risk management and mitigation
- ✔ Incident investigation
- ✔ Clinical governance
- ✔ QMS training.

quality management system (QMS), to keep up with new learning and changes to accreditation standards. All improvement ideas then need to be implemented by the labs and unless I can convince busy teams to do this then the improvements are not worth anything.

Team and Teaching

Being part of the management team helps me to know what's going on in the service, to avoid the quality/change management aspects of any developments being overlooked. I've also got an excellent team of quality officers who support me in implementing changes and making sure compliance is maintained in the labs. I spend as much time as I can teaching on aspects of the QMS; this improves understanding across the labs and helps with compliance.

You

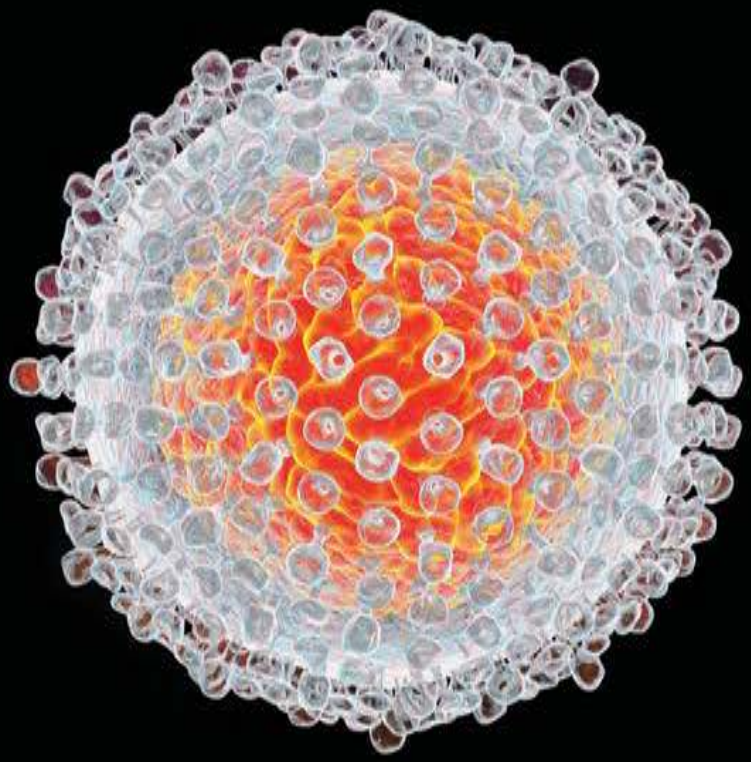
Quality managers spend a lot of their time supporting others and reviewing others' work, but I've found that it's vital to make time to complete my own work and projects. This is always challenging, but achieving my own objectives helps me to stay motivated. This puts me in a better position to motivate others, and this is essential to success! BMS

Fiona R Denham is the Tissue Sciences Quality Manager for Viapath Analytics and is based at St Thomas' Hospital, Westminister Bridge Road, London

THE TRAITS

As a Quality Manager, you need to:

- ✔ Be part of the team, but remain unbiased
- ✔ Understand the service, but be prepared to question everything you're told
- ✔ Be a leader, but also be approachable
- ✔ Be clear on where you're going and how to get there, as well as where you've come from
- ✔ Be an authority on the accreditation standards, while remembering there is more to quality management than accreditation
- ✔ Be both a teacher and a student (always learning).



British Journal of Biomedical Science Issue 4 2017: a synopsis

Issue 4 of our journal was launched in October, so hardcopy will already have landed on your doormats. However, those with access to the website will have had access to the papers for weeks, if not months. **Editor Andrew Blann** outlines the content in the latest issue.

One or more of these articles may be the subject of a Journal-based learning exercise for those seeking to improve their continuing professional development profile.

D Sanders et al. **Uncertainty of measurement in andrology: UK best practice guideline from the Association of Biomedical Andrologists.**
Although not an IBMS body, the Association is the leading UK professional group for Andrologists, and has strong links to the IBMS. Their guideline offers advice and recommendations on the assessment of semen and the viability of sperm.

CJ Donaldson & DJ Harrington. **Therapeutic warfarin use and the extrahepatic functions of vitamin K-dependent proteins.**
Although a spectacularly effective therapeutic, warfarin (in common with many drugs) has effects outside its primary function. Donaldson & Harrington review these effects, mostly on bone mineralisation and calcium homeostasis (which may lead to osteoporosis and heart valve pathology) and damage to the embryo.

AM Attallah et al. **Combined use of nuclear phosphoprotein c-Myc and cellular phosphoprotein p53 for hepatocellular carcinoma detection in high-risk chronic hepatitis C patients.**
Hepatocellular cancer (HCC, linked to c-Myc and p53) is a serious consequence of hepatitis C virus infection. Of 120 patients with this infection, of whom half had HCC, the sensitivity of serum c-Myc and p53 proteins for detecting HCC were higher than alpha feto-protein. When both gene products were combined, sensitivity was 100%, suggesting these may be a new diagnostic tool.

N Mohamad et al. **Analplastic lymphoma kinase (*ALK*) mutations in patients with adenocarcinoma of the lung.**
Lung cancer, a leading cause of cancer deaths worldwide, is linked to genes such as *ALK*. Using immunocytochemistry, our colleagues report increased tumour expression of *ALK* in women, in never-smokers, and in those with metastases, and that this method is a reliable alternative to FISH.

IMAGE: SCIENCE PHOTO LIBRARY

J Thongbut et al. **RHD-specific microRNA for regulation of the DEL blood group.**
RHD and RHCE code for RH blood group antigens. Mutations in RHD lead to a variant, DEL, resulting in 22-26 D molecules per cell, compared to 30,000 in normal D cells. Our Thai colleagues find low levels of miR-98 in DEL and D-negative samples compared to D-positive cells, but that this difference is not significant, suggesting other mechanisms must be responsible for the expression of D.

S Guo et al. **Role of miR-29 as marker of risk of acute rejection after heart transplantation.**
Despite best medical care, up to 30% of heart transplant recipients experience a rejection episode in the first year. The gold standard of myocardial biopsy is far from ideal, leading to the search for alternatives, such as troponins. This paper presents data showing that miR-29, alongside lymphocyte count, cTnI and NT-proBNP, should be considered a new marker of rejection.

Y Liu et al. **A dual-label time-resolved fluorescence immunoassay for the simultaneous determination of cystatin C and β2-microglobulin in urine.**
Our colleagues from China present data on a new immunoassay simultaneously detecting levels of two renal markers. This is possible as antibodies are labelled with europium and samarium, which fluoresce at different wavelengths. This method compares well with separate commercial assays for each marker, so may enter routine laboratory practice.

J Ewing et al. **Relative Resistance Index (RRI) – a Scoring System for Antibiotic Resistance in Pseudomonas aeruginosa.**
Antibiotic resistance is a growing problem, and accordingly the need to determine its extent is vital. This paper presents a score that determines the relative resistance of non-mucoid Pseudomonas aeruginosa to common antibiotics. Validating their score clinically (RRI correlates with lung function and the number of days on intravenous antibiotics), they suggest it may be of benefit in quantifying antibiotic resistance.

GE Orchard et al. **New embedding and staining systems PrestoCHILL and Presto stainer for application in the advancement of Mohs micrographic surgery.**
Our colleagues from London, using 279 tissue samples from 10 facial sites, report two new innovative tools that bring benefits of automation, speed and efficiency to the preparation of frozen sections with high levels of accuracy (93.5%) and precision/reproducibility (96.5%).

RS Abdul-Maksoud et al. **Serum miR-210 and miR-155 Expression Levels as Novel Biomarkers for Rheumatoid Arthritis Diagnosis.**
This paper reports low levels of microRNA MiR-210 and increased MiR-155 that correlate with TNF-α and IL-1β, concluding that these MiRs are independent markers for RA, out-performing several routine indices, and reflect disease activity. Thus miR-210 and miR-155 might serve as non-invasive biomarkers for the diagnosis of RA.

S Yang et al. **Serum micro-RNA-302b: the novel biomarker for diagnosis of acute myocardial infarction.**
The need to correctly and rapidly diagnose acute heart disease is clear, but the gold standards of CK, CK-MB and troponin are imperfect. The present paper suggests that this miRNA offers improved sensitivity and specificity, and so one day may enter routine practice.

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

MY IBMS NEWS

FUTURE OF HEALTH

IBMS RESPONDS TO PUBLICATION

The IBMS has responded to the findings from a stakeholders' survey on the future of English health and healthcare.

At the request of the National Institute for Health Research (NIHR), RAND Europe conducted a survey to gather stakeholders' views on the vision of health and healthcare in England in the next 20 to 30 years.

The research aimed to build an evidence-based picture of the future of health and healthcare needs and how it might differ from today.

Sarah May, IBMS Deputy Chief Executive, said: "The role that pathology services can and do play in healthcare is always under-represented.

"This is not just confined to the understanding of the general public but also (and more significantly) by commissioners and service providers.

"The study findings validate a number of prominent health research priorities currently visible in England, such as antimicrobial resistance, the burden of dementia and age-related multi-morbidity, digital health and genomics."

→ **The report is called *Future of Health* and can be downloaded from rand.org**

LEADER OF THE YEAR

IBMS Fellow scoops award

Adeboye Ifederu, an IBMS Fellow, has won a Great Ormond Street Hospital (GOSH) staff award.

GOSH recently held its annual staff awards, co-hosted by comedian Jo Brand, and he was presented with the prestigious Leader of the Year award.

Adeboye said: "I am delighted to receive the award and incredibly humbled by the kind words expressed in the nominations.

"The staff in GOSH Newborn Screening Laboratory are the people that really make the difference both in their enormous contribution to a highly rated service and the impact this has on patients' lives.

"I am so privileged to work with this great team. The award also represents a well-deserved recognition for healthcare scientists within our organisation."

OBITUARY

WALTER SHARP 12/5/1953 – 08/08/2017

It is with regret that we announce the death of Walter Sharp, following a brief illness.

After working in Barnsley, Yorkshire, he travelled to Jeddah in the Kingdom of Saudi Arabia, where he was Head of Haematology in King Abdul Aziz Hospital.

After working for Beckman Coulter in Dubai, he returned to laboratory life, taking over as Head of Haematology at the Sultan Qaboos University Muscat.

On returning to England, he became Head of Haematology at North Tees and Hartlepool Hospitals.

Walter will be particularly remembered for his extraordinary morphology skills. He was an active member of UKNEQAS, sitting on the General Scientific Advisory Group, covering external quality assessment for automated cell counting.

He sat on the British Society for Haematology Laboratory Science Sub-Committee.

He worked as a locum at Kingsmill Hospital, Mansfield, where he shared his morphology skills with the scientists of tomorrow.

IBMS BRANCH

WEST RIDING AGM

The West Riding Branch of the IBMS will be holding its annual general meeting on 6 November.

The event will take place at 6.30pm at the Learning and Library Centre at Leeds General Infirmary in Thoresby Place.

A series of short talks will be given on the evening.

→ **For more information, email sarah.lawson12@nhs.net**

HEALTHCARE AWARDS

IBMS sponsor category

The IBMS has sponsored an award in the 2018 Advancing Healthcare Awards (AHA).

Nominations are now open for the UK-wide awards, which are in their 12th year.

The awards are exclusively for healthcare scientists, allied health professionals and those who work alongside them in support roles.

Among the 14th awards is the newly-sponsored IBMS Award, for Inspiring the Biomedical Workforce of the Future.

The awards aim to recognise and reward projects and professionals who lead innovative healthcare practice and make a difference to patients' lives.

The closing date to enter is 5pm on 19 January 2018 and details on how to enter are published on the AHA website.

→ **For more information, visit ahpandhsawards.co.uk**

EUROPEAN CONFERENCE

Delegates attend

IBMS delegates attended the European Association for Professions in Biomedical Science conference.

IBMS Executive Head of Education Alan Wainwright and IBMS Deputy Chief Executive Sarah May visited Salzburg, Austria, to attend the conference, which is in its fourth year.

This year's theme was "Biomedical scientists adding value to the healthcare system".

The programme included a talk by Sarah May on the role of professional bodies in regulation.

PRESIDENT'S PRIZES
Continuing the coverage of winners from around the country

PRESIDENT'S PRIZE WINNERS

HIGH ACHIEVEMENT AT BRADFORD

Miriam Sadiq received an IBMS President's Prize at a University of Bradford graduation ceremony, held in July.

Miriam was the highest achieving student for the year, with a degree average of 82.7%, and she graduated with first-class honours.

Cellular science was her chosen specialism during the final year of the course.

Miriam is pictured receiving her award from IBMS Council member Joanna Andrew.

GREAT SUCCESS AT GREENWICH

Jayne Wright was this year's recipient of an IBMS President's Prize at the University of Greenwich.

Jayne joined the university as a part-time Foundation Degree student and completed her BSc this year.

While studying, Jayne worked as a medical laboratory assistant in microbiology at Eastbourne District General Hospital.

She is justifiably proud of this achievement, having had a gap in education of more than 30 years, and is hoping to continue her studies with the IBMS Specialist Portfolio and eventually a Masters qualification.

Jayne is pictured receiving her award from Dr Paul Dyer, Programme Leader, BSc Biomedical Science.

BRIGHTON BONANZA

Josh Travers is this year's recipient of the IBMS President's Prize at the University of Brighton. He undertook a sandwich degree and his placement, along with the final-year research project, was carried out in the Blood Sciences Department, Frontier Pathology, Brighton and Sussex University Hospitals NHS Trust, where he subsequently gained employment.

Pictured (l-r) are Clinical Scientists Tamsyn Cromwell and Rob Moore, Training Officer Anne Trezise, Josh, Clinical Scientist Gary Weaving, Sarah Bastow, Department Head of Services, and Jacqui Elsom, University of Brighton Academic Project Supervisor.

IBMS CPD

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

EVENTS AND TRAINING COURSES

DATE	TITLE	VENUE CONTACT
November		
04 Nov	**Preparing for life in the HPV primary screening era – BAC ASM 2017**	York I christianburt@ibms.org
07 Nov	**HPL/UHPLC column care and maintenance biocity Scotland**	Newhouse I jsumner@hichrom.com
07 Nov	**Basic concepts of HPLC biocity Scotland**	Newhouse I jsumner@hichrom.com
09 Nov	**Keele University benchmarking service – blood sciences user group meeting**	Birmingham I g.s.trigg@keele.ac.uk
14 Nov	**Keele University benchmarking service – microbiology and cellular pathology user group meeting**	Birmingham I g.s.trigg@keele.ac.uk
14 – 15 Nov	**UK NEQAS reproductive science semen analysis one-day workshop**	Manchester I repscience@ukneqas.org.u
14 Nov	**FNA cytology**	Bristol I SWRCTC@nbt.nhs.uk
14 Nov	**Big molecules – big challenges II**	Holiday Inn J10 M4 I jsumner@hichrom.com
15 Nov	**Northern autoimmunity education and quality assurance group**	Hull I fiona.nash@lthtr.nhs.uk
15 Nov	**Digestive diseases day**	Birmingham I marketing@alphalabs.co.uk
16 Nov	**Food and water microbiology proficiency testing (PT) international meeting**	London I joanna.donn@phe.gov.uk
21 – 23 Nov	**BMS/cytoscreener update 7**	London I nwlh-tr.lrctcbooking@nhs.net
27 Nov	**Non-gynaecological urine cytology for biomedical scientists**	Wakefield I kathryn.hawke@nhs.net
28 Nov	**Pathology sustainability and transformation plans**	Birmingham I nichola.cadwallader@sbk-events.co.uk
28 Nov	**If we'd known then what we know now… joint meeting of UK NEQAS (BTLP) and the BBTS blood bank technology SIG**	Birmingham I isabella.de-rosa@whht.nhs.uk
December		
1 Dec	**UK NEQAS microbiology division 2017 scientific meeting**	London I joanna.donn@phe.gov.uk
4 – 7 Dec	**British Society for Immunology Congress 2017**	Brighton I j.hemstock@immunology.org
5 – 7 Dec	**Three-day update for cervical cytology**	Bristol I swrctc@nbt.nhs.uk
6 – 7 Dec	**Update in cervical cytology**	Edinburgh I fiona.mcqueen@nhslothian.scot.nhs.uk
12 – 14 Dec	**BMS/cytoscreener update 8**	London I nwlh-tr.lrctcbooking@nhs.net
2018		
January		
15 – 19 Jan	**Biosafety practitioner Level 1 (ISTR accredited)**	Porton Down I nadp.training@phe.gov.uk
April		
23 – 27 Apr	**Introduction to the principles and practices of working at ACDP containment level 3**	Porton Down I nadp.training@phe.gov.uk
September		
21 – 22 Sept	**Advanced course in EBUS/mediastinal EUS and rapid on-site evaluation for chest physicians and cytopathology teams**	Watford I winnie.tang@whht.nhs.uk

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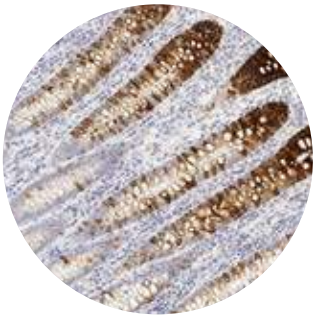

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JOURNAL-BASED LEARNING EXERCISES

IBMS CPD

Each article's contents should be read, researched and understood, and you should then come to a decision on each question. The pass mark is 17 out of 20 questions answered correctly. JBL exercises may be completed at any time until the published deadline date. Please select your choice of correct answers and complete the exercises online at: **www.ibms.org/cpd/jbl**

DEADLINE WEDNESDAY 7 FEBRUARY 2018

Diagnostic virology and patient care: from vaguely interesting to vitally important. Pitt SJ, Phillips DI. *Br J Biomed Sci* 2017; **74** (1): 16–23. Assessment No: 110617

01	The earliest noted connection made between a human disease and a "virus" that evaded filtration was for tobacco mosaic virus.
02	Damage caused by viral replication processes and the host's immune response to the infection does not lead to long-term sequelae.
03	The approximate annual incidence of human immunodeficiency virus (HIV) infection in the UK is 100,000.
04	Respiratory syncytial virus (RSV) is an important cause of severe infection in young children and the elderly.
05	During the first half of 2012, an outbreak of measles centred on Merseyside occurred, during which 1339 people were identified as possibly having the infection.
06	Worldwide, at least 600 million people are thought to be chronic carriers of hepatitis B virus and over 240,000 deaths are attributable to the consequences of infection.
07	Use of immunofluorescence-labelled antibodies to detect viruses in respiratory secretions is a relatively rapid method, but the sample must be collected appropriately.
08	It is not usually possible to identify viral species by electron microscopy appearance alone.
09	Herpes simplex virus takes about 21 days to produces its very distinctive cytopathic effect (CPE).
10	It is not possible to detect IgG and IgM separately using either radioimmunoassay (RIA) or enzyme immunoassay (EIA).
11	The EIA principle has been applied to immunochromatographic point-of-care testing (POCT) kits such as those for the rapid testing of stool samples for norovirus.
12	In general, POCT kits are inexpensive compared to laboratory-based assays, and the antigen detection formats offer ideal sensitivities.
13	In clinical samples both viral and human genomic material is sequenced and this inevitably generates a lot of data.
14	Next-generation sequencing (NGS) is being applied to sequencing HIV and hepatitis C virus (HCV) isolates to understand evolution of the virus within and between patients.
15	Qualitative methods such as TaqMan and real-time polymerase chain reaction cannot be used to measure viral load.
16	Parvovirus B19 was discovered by Dane and colleagues using EM to examine serum.
17	Enteric cytopathic human orphan (ECHO) viruses are only rarely a cause of acute, mild, self-limiting febrile illnesses.
18	It is not possible to distinguish between wild-type and vaccine-derived polio virus.
19	Polio is still endemic only in two countries, Afghanistan and Pakistan.
20	Smallpox virus and rinderpest virus are two pathogenic infectious agents that have been deliberately eradicated from the world.

Guideline for the acquisition and preparation of conventional and endobronchial ultrasound-guided transbronchial needle aspiration specimens for the diagnosis and molecular testing of patients with known or suspected lung cancer. van der Heijden EH, Casal RF, Trisolini R *et al.*; World Association for Bronchology and Interventional Pulmonology Task Force on Specimen Guidelines. *Respiration* 2014; **88**: 500–17. Assessment No: 110817

01	The number of needle aspirations with both conventional TBNA and EBUS-TBNA was found to impact the diagnostic yield, with at least two passes needed for optimal performance.
02	The use of rapid on-site cytology examination increases the diagnostic yield.
03	The recommendations for a cervical mediastinoscopy state that surgeons need to sample both contralateral and ipsilateral nodes plus the subcarinal region in every case.
04	The number of aspirates per LN affects the diagnostic yield quantity and quality of the obtained specimen.
05	The needle size affects the diagnostic yield, quantity and quality of the specimen.
06	The literature suggests that better success rates are obtained with the use of 19-gauge needles, as compared with 22-gauge needles.
07	The use of miniforceps does not seem to influence the diagnostic yield in lung cancer but may be useful in patients with suspected lymphoma or sarcoidosis.
08	There is enough evidence that two aspirations with EBUS-TBNA and four to five aspirations with conventional TBNA provide near the maximum yield.
09	There is not enough evidence to recommend for or against the use of suction with EBUS biopsies for diagnostic purposes.
10	Cell blocks perform better in terms of diagnosis of lung cancer than tissue core techniques.
11	There does not appear to be a superior method for specimen preparation.
12	Rapid on-site cytology examination (ROSE) can decrease the number of aspirations.
13	ROSE can reduce the number of additional procedures.
14	EBUS sampling must be initiated at N1 regions, followed by N2 and N3 regions.
15	The concordance rate of ROSE with the final diagnosis is low.
16	In general, the material obtained by EBUS-TBNA is suitable for molecular analysis.
17	Cell blocks and core tissue represent the best material for mutational analysis and are indispensable at the moment to assess *ALK* translocation.
18	A prospective study by Lee *et al.* of EBUS-TBNA for mediastinal staging of patients with non-small cell lung cancer (NSCLC) showed that 95% adequacy and 100% sensitivity were achieved with three aspirations per LN and did not increase with a fourth.
19	When RNA isolated from TBNA samples is used, the quality of RNA is critical and special attention should be paid to the storage of the sample to avoid RNA degeneration.
20	Conventional TBNA and EBUS-guided TBNA are used in patients with suspected lung cancer, peripheral tumours, sarcoidosis and other diseases accompanied by mediastinal or hilar lymphadenopathy.

REFLECTIVE LEARNING

01	Discuss the most effective use of point-of-care tests as part of a diagnostic virology service.
02	Discuss the applications of next-generation sequencing in diagnostic virology.

01	Discuss how ROSE at EBUS could be introduced into your laboratory. What barriers would you have to overcome?
02	Critically evaluate the use of molecular pathology to non-gynaecological cytology within your laboratory.

HERE TO HELP

TRAINEE AND TRAINER

Jocelyn Pryce, IBMS Head of Registration and Training, discusses the importance of relationships in training.

Having recently attended the IBMS Congress and given talks on a number of subjects, I thought I would use this column to answer some of the questions raised during the discussions that followed them. Although three of the four talks were very different in context, the questions raised by them have a theme. My talks included considerations when trying to train the untrainable, the ways in which training is a two-way partnership, and an update on Version 4 of the Registration Portfolio. Three very different aspects of training, but with a central core revolving around the relationship between the trainee and the trainer.

During my Trying to Train the Untrainable talk, we looked at reasons why a trainee may be struggling with the training and explored ways to ameliorate the problems. Training is a Two-Way Partnership explored what makes a successful partnership and why that can sometimes break down. The situations discussed in these talks depended on the skills of the training officer to manage the relationships and bring the training period to a successful conclusion. What was apparent from the discussions that took place was that often training officers do not have the skills which allow them to do this, or feel they are not supported.

Version 4 portfolio, with its requirement for only 30 pieces of evidence, has highlighted the need for trainers to have the skills to manage these training situations. In the past, training officers felt it appropriate to pass the responsibility of making the decisions around whether a trainee has reached threshold level to become a practising biomedical scientist (or not) to the verifier. Nowadays, the onus is on the training officer to ensure that the trainee is ready and failure to do this, with subsequent failure on the part of the trainee, can reflect poorly on the lab involved. This has meant added pressure on the training team to have the difficult conversations with trainees who are not ready. Trainees should not be put forward for verification if the training officer has any doubts, for whatever reason, and their management should support their decision based on the evidence the trainer officer has provided.

While it is the responsibility of the training team to ensure that their trainee is prepared for the verification and capable of practising at the threshold level of a registered biomedical scientist, one of the things that causes concern is whether they are then responsible for the good professional practice of that biomedical scientist once registered. There is an easy answer to this and it is "no". We have to demonstrate that we are professional practitioners in order to be accepted onto the register and it is, therefore, our own responsibility to behave in such a way as to reinforce this. The training team are the facilitators for the training period, the verifier is the gatekeeper who satisfies themselves that the training experience has been robust, the IBMS is the professional body that awards a Certificate of Competence and the HCPC makes the decision to admit the individual to the register. Each biomedical scientist has been offered the opportunities necessary to allow them to train to the threshold level, but they are the professional practitioner and solely responsible for their behaviour. IBMS

IMAGE: ISTOCK

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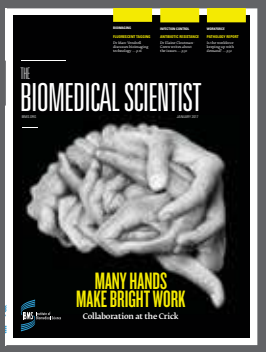

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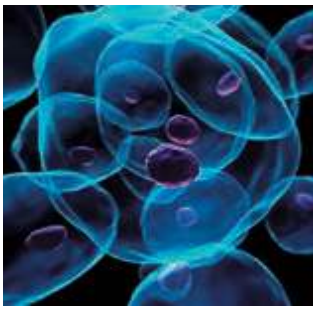

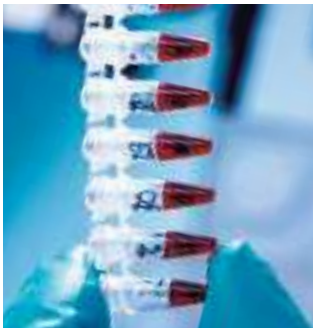

MY LAB

HEART AND LUNG TRANSPLANT

Specialist Transfusion Practitioner **Michaela Lewin** gives a guided tour of her lab at the cardiothoracic hospital in Papworth.

Although I am a biomedical scientist by profession, as a Specialist Transfusion Practitioner I get to appreciate on a daily basis the critical role biomedical science plays in clinical practice, whether its applying my biomedical science knowledge speaking to patients about why they might need a blood transfusion (or how we might help them avoid one), educating clinical staff around safe transfusion practice, auditing compliance with national standards, or trying to be a link between the laboratory and clinical areas.

In the media, positive feedback tends to focus on the frontline clinical staff. I am writing this article not to promote my role, but the fantastic work of "my lab". As a Transfusion Practitioner one could argue that the lab I'm writing about is not "my lab", but as we all work as a team, I like to think of them as "our team" – and what a great team they are!

The blood sciences laboratory is located in a pathology building separate to the main hospital, providing a 24-hour service for the patients of Papworth Hospital, which has recently been granted "Royal" status by the Queen.

Papworth, the UK's largest specialist cardiothoracic hospital and the country's main heart and lung transplant centre, treats more than 24,000 inpatient and day cases and 73,000 outpatients from across the UK each year.

It is also one of five hospitals commissioned by the National Specialised Commissioning Team to provide extra-corporeal membrane oxygenation to patients with acute respiratory distress syndrome. A specialist team is available 24 hours a day to ensure the sickest of patients can be rapidly stabilised and transferred to Papworth for this life saving very specialist treatment.

We also have a chest medical unit, treating a range of medical conditions, such as interstitial lung disease and cystic fibrosis.

To enable all of this fantastic patient care, the laboratory staff provide the usual but essential "bread and butter" blood science services you would expect a relatively small lab to provide, with the more specialist work (or work which is just simply more cost effective to be done in bulk) referred to Cambridge University Hospitals, about 16 miles down the road.

However, the pace is unpredictable; we have a 33-bed critical care unit – cardiothoracic patients are complex and know how to bleed, and when one patient bleeds, the others often decide to join in! The laboratory staff are multidisciplinary trained and well accomplished to task switching, as they have to be to keep the workflow going.

We don't have an emergency department, but this does not mean that on a "quiet night" one can sit back and relax, the lab staff have learnt to "expect the unexpected". Just like any biomedical scientist working in a hospital with acute services, they never know just what might come through the door.

It's been a challenging time for pathology across the UK, with reorganisation, modernisation and a bit more re-organisation, and Papworth is no exception. The team also has the added uncertainty that comes with working in a hospital that in 11 months time will relocate to a completely new site, with yet more reorganisation. However, despite this, in true devotion to patient care, the team makes sure the show continues to go on safely. BMS

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