MARCH 2020 # 63

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New Year, New Us

The Pathologist is changing – and we'd like to invite you along for the ride

Welcome to the first issue of The Pathologist's "Special Series" on infectious disease – a new endeavor coincidentally launched at an unprecedented time for laboratory medicine in general, and the field of infectious disease diagnostics in particular.

The aim of this "Special Series" (our first, with a second coming later this year) is to highlight an interesting, educational, or simply underappreciated area of pathology and laboratory medicine through a number of articles spread across several months. Clearly, since we originally planned this first series, the topic of infectious disease has seen a surge in awareness that few could have predicted. Certainly, infectious disease can no longer be considered "underappreciated!" But in addition to undoubted coverage of SARS-CoV-2 and COVID-19, we will also bring you planned content, including cases that will test your diagnostic strengths… opinions that will inform your approach to microbiological investigations… tips and tricks that you can apply in the laboratory… and – especially in light of recent events – articles that will change the way you think about infectious disease.

But that's not the only thing we're kicking off with our March issue. Nominations for our 2020 Power List are now officially open! And, this year, we've brought you an additional twist: instead of simply nominating individuals you think deserve to be in the "who's who" of the laboratory, we've introduced four (see page 42 for details). The Social Network (for social media influencers), A Solid Foundation (for educators and mentors), Lab Heroes (for non-pathologist laboratory medicine professionals), and Big Breakthroughs (for those responsible for techniques, technologies, and advances that have changed their fields). Nominations are unlimited – so please don't hesitate to recognize everyone you feel deserves a spot on The Power List!

We hope these will be the first of many intriguing new developments over the year, but there's one thing I want to emphasize: this is your magazine. This is a platform to make your voice heard.

Would you like to make a contribution to our infectious disease series? Email edit@thepathologist.com and we'll be pleased to work with you. Would you like to nominate someone for the Power List? You can find the form at **tp.txp.to/power/list/2020**. Or would you like to suggest something totally new? Get in touch with us – your ideas, interests, and advice are always welcome!

Michael Schubert
Editor

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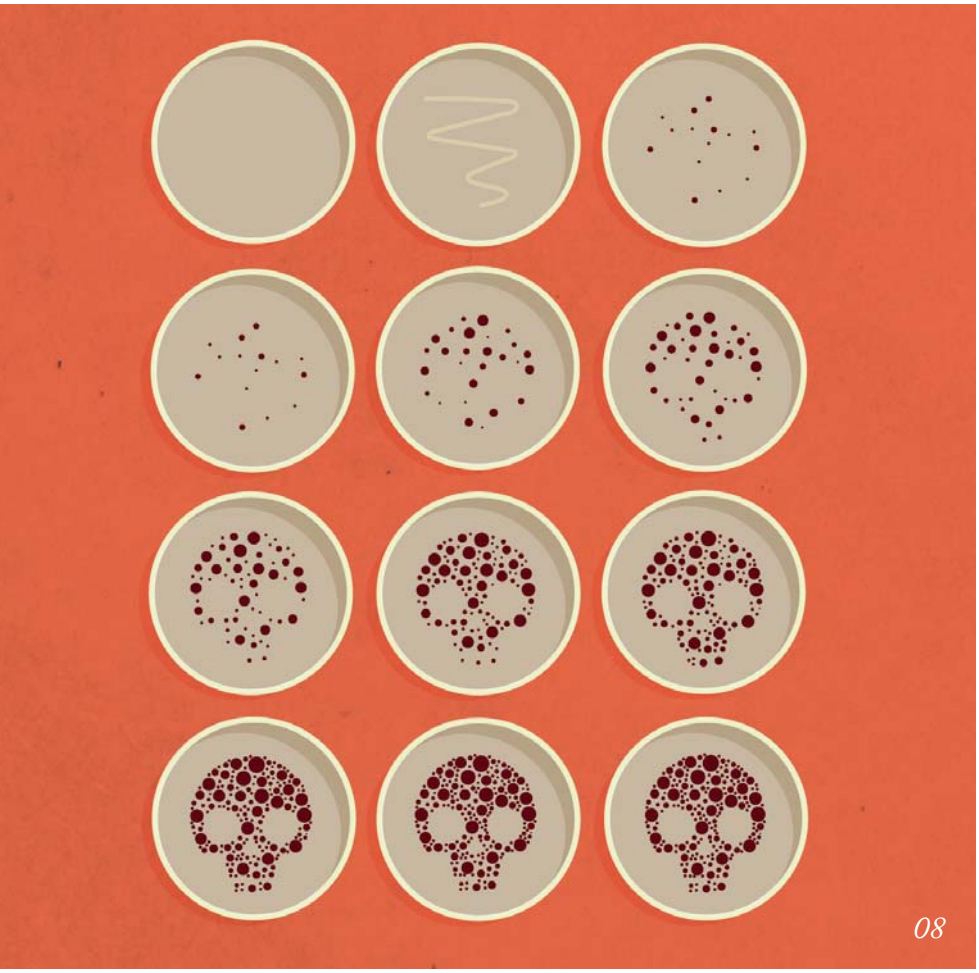

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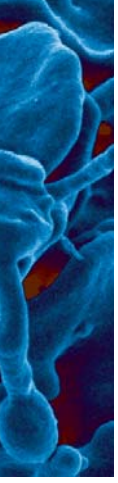
In My View

From The ASCP

On The Cover

A pathology-themed parody of a poster for the film Dr. Strangelove.

Upfront



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Feature

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Sitting Down With

the Pathologist

ISSUE 63 - MARCH 2020

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Upfront

Research
Innovation
Trends

Meddling with Nature

The benefits and dangers of human germline genome editing

Human germline genome editing (hGGE) has great medical potential, especially in preventing heritable disorders; it can delete, add to, or even replace DNA sequences that are expressed in cells and passed onto the next generation. CRISPR-Cas9, the most widely used genome editing tool, targets specific DNA sequences and cuts them using the Cas9 enzyme, allowing for changes before the cell repairs the cut.

However, a new report from the UK Parliamentary Office of Science and Technology has urged caution, calling for a full review of the potential clinical effectiveness, cost-effectiveness, and risks and benefits of hGGE before deeming it safe (1). For those with serious monogenic disorders, such as cystic fibrosis, hGGE could ensure that their children won't suffer from the same condition. But for now, at least in the UK, the Human Fertilization and Embryology Act 1990 prohibits implanting embryos with altered germline DNA inside a woman. The Human Fertilization and Embryology Authority can award licenses for research – but only for projects that involve human embryos outside the body. Safety and ethical concerns have arisen around the world; in China, for example, one scientist claimed to have edited the genome of embryos that resulted in the birth of twin girls (2).

Before hGGE can be adopted in the clinic, a number of safety issues loom large. The main concerns involve edits being made at incorrect DNA sites, or potential unintended consequences of correct edits. There's also the possibility that a cell repairs cut DNA in an unanticipated way, or that the edited DNA sequence is absent in some cells. Genome editing techniques continue to improve – but the new report calls for further advancements before hGGE could be considered safe for clinical use.

With so many unanswered questions surrounding hGGE, some scientists want a moratorium on clinical heritable genome editing until a universal framework is established (3). Several international initiatives have already tried to address the issue – and, in 2019, the WHO launched a global registry for human genome editing that aims to track all research and make recommendations on appropriate legislation (4). Watch this space…

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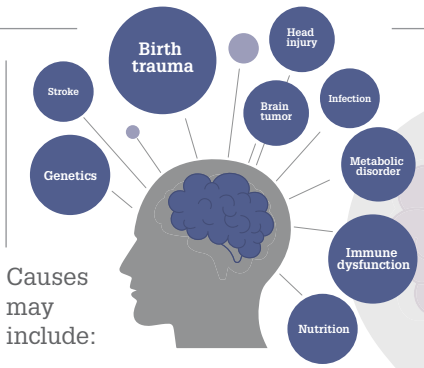
INFOGRAPHIC

Epilepsy and Neuro-developmental Disorders

The causes, genetics, and diagnostic professionals

Epilepsy and neurodevelopmental disorders worldwide

Causes may include:



BUSINESS IN BRIEF

We take a look at this month's laboratory medicine business news

Up to (Genomic) Speed

Advances in sequencing technology have produced an unprecedented amount of genomic data, now doubling every seven months. Genomic analysis is typically a computational bottleneck in the pipeline – but Parabricks has recently developed a GPU-based solution to analyze whole genomes in under a minute (1).

T In the Cloud

The FDA has awarded a five-year, US$20 million contract to DNAnexus to power the precision FDA Collaborative Omics Environment in the Cloud. Launched in December 2015, precisionFDA has led to advances in regulatory science for NGS-based drugs and devices. It unites government, academia, and industry to provide a community platform for NGS assay evaluation (2).

Standard of Care

Laboratories have a key role to play in diagnosing cases of SARS-CoV-2 – and well-defined standards are crucial for test validation. Bio-Rad Laboratories have now launched a SARS-CoV-2 Standard that contains synthetic COVID-19 RNA transcripts and human genomic DNA. This allows labs to test molecular assays, including extraction, amplification, and detection of the virus (3).

A New Horizon

The Human Protein Atlas (HPA) will use Horizon Discovery's CRISPR-edited knockout cell models in its Cell Atlas program, which aims to improve our understanding of genetic factors in disease. The new partnership will expand open-access resources and boost global genetic research (4).

A Molecular Touch

A method for rapidly detecting somatic mutations from tissue sections has proven successful in colorectal cancer. The Biocartis Idylla system runs cartridge-based assays that facilitate a "molecular-touch" preparation method in which filter paper is pressed against fresh tissue in the grossing room; it can return somatic mutation results even before the tissue has been processed (5).

References

1. *NVIDIA Developer (2020). Available at: https://bit.ly/2Sly9vy.*
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4. *Horizon Discovery (2019). Available at https://bit.ly/2UvtOZq.*
5. *MR Al-Turkmani et al., 64, 865 (2018). PMID: 29483108.*

Rapid Action Against MRSA

The increasing value of rapid, noninvasive testing

Antibiotic resistance is a growing threat to worldwide health. In the USA alone, methicillin-resistant *Staphylococcus aureus* (MRSA) is estimated to have caused 323,700 cases and 10,600 deaths in 2019 (1). As these numbers continue to rise, it's more important than ever that we detect these infections quickly so that treating physicians can make effective decisions.

At the moment, hospitals apply a "search and destroy" policy that assumes every patient is at risk of MRSA. However, effective detection of the pathogen requires rapid, accessible diagnostic technology. To this end, single-step identification of MRSA, especially from noninvasive testing, such as nasal swabs, is increasingly valuable. One such technology, presented at the recent MedLab Middle East conference (2), offers MRSA detection in just 15 minutes – a timeline that allows rapid management and the opportunity to prevent the spread of antibiotic resistance.

References

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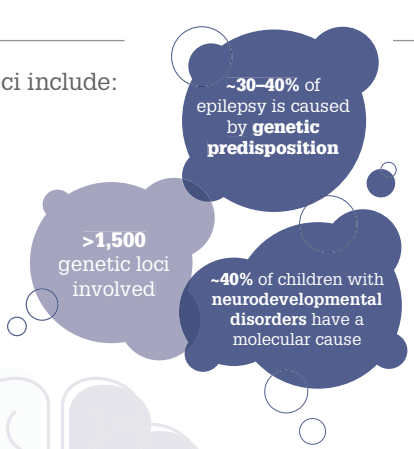
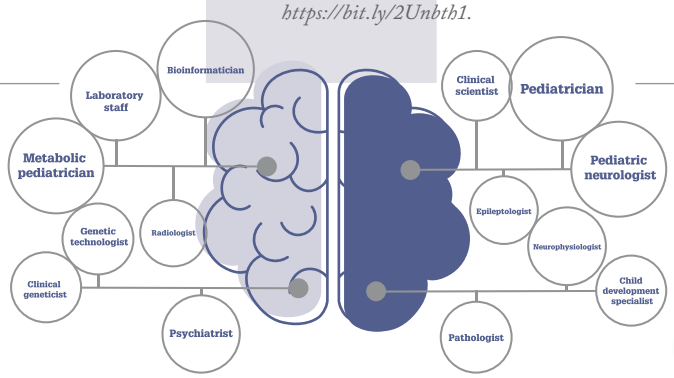
2. *Scope Fluidics (2020). Available at: https://bit.ly/2Unbth1.*

Common genetic loci include:

- *PRRT2* (Dravet syndrome)
- *SCN1A* (Dravet syndrome)
- *ANKRD11* (KBG syndrome)
- *ARID1B* (KBG syndrome)
- *KMT2A* (KBG syndrome)
- *DDX3X* (KBG syndrome)
- *ADNP* (KBG syndrome)





Professionals who may be involved in diagnosis

SPECIAL SERIES
Infectious Disease

Double Take

New figures reveal the true extent of global sepsis

The severity of sepsis is notorious. What isn't so clear is our grasp on global statistics, which inform health policy interventions, resource allocation, and clinical treatment initiatives (1). The newly published Global Burden of Sepsis study – the most comprehensive to date on the incidence and mortality of sepsis – has revealed that true global rates are over double those previously estimated. New figures put the number of cases at 48.9 million and deaths at 11 million around the world in 2017 – a far cry from the previous global estimates of 19.4 million cases and 5.3 million deaths.

But how could previous figures fall so short? We put the question to Konrad Reinhart and Niranjan Kissoon, co-authors of the new study and President and Vice President of the Global Sepsis Alliance, respectively. "We weren't surprised, because we knew that previous estimates were exclusively derived from high-income countries, where the number of deaths from infectious diseases is considerably lower than in low- and middle-income countries." In fact, the previous data came from hospitalized adults in just seven high-income countries, whereas the new study analyzed 109 million death records across 195 countries between 1990 and 2017.

In 2017, an estimated 85 percent of global sepsis cases occurred in these low- and middle-income countries – and half were in children. "National action plans must include prevention strategies, such as large-scale vaccination programs – especially for children and adults in high-risk groups – against preventable infections like pneumonia, measles, common flu, and meningitis," say Reinhart and Kissoon. The WHO designated sepsis an urgent global priority in May 2017, resolving to improve the prevention, diagnosis, and management of the deadly condition in developing countries.

However, with sepsis responsible for one in five deaths worldwide, Reinhart and Kissoon see a long road ahead: "Poor awareness among policymakers and a lack of adequate national strategies are worrying, as is the lack of education for healthcare workers and the public in terms of recognizing and treating sepsis early."

Reference

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A Body Farm First

Why Canada is opening its first human decomposition facility in 2020

They already exist in the Netherlands, Australia, and the US – but the human decomposition facility set to open in Becancour, Quebec, later in 2020 will be Canada's first. Popularly known as "body farms," these research sites play a crucial role in our understanding of the decomposition process in different environments (1). From shallow graves to empty vehicles, human bodies donated to the institution will be studied over days, weeks, and months to monitor a variety of factors associated with decay.

"Most facilities are located in very warm climates but, in Canada, we're particularly interested in understanding what happens when a body is in sub-zero temperatures," said Shari Forbes, Director of the Secure Site for Research in Thanatology, in a recent TV interview (2). Forbes aims to work closely with police and forensic services to improve the way that bodies are recovered, identified, and analyzed to estimate time since death.

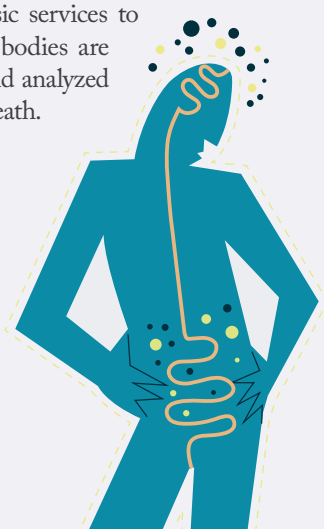

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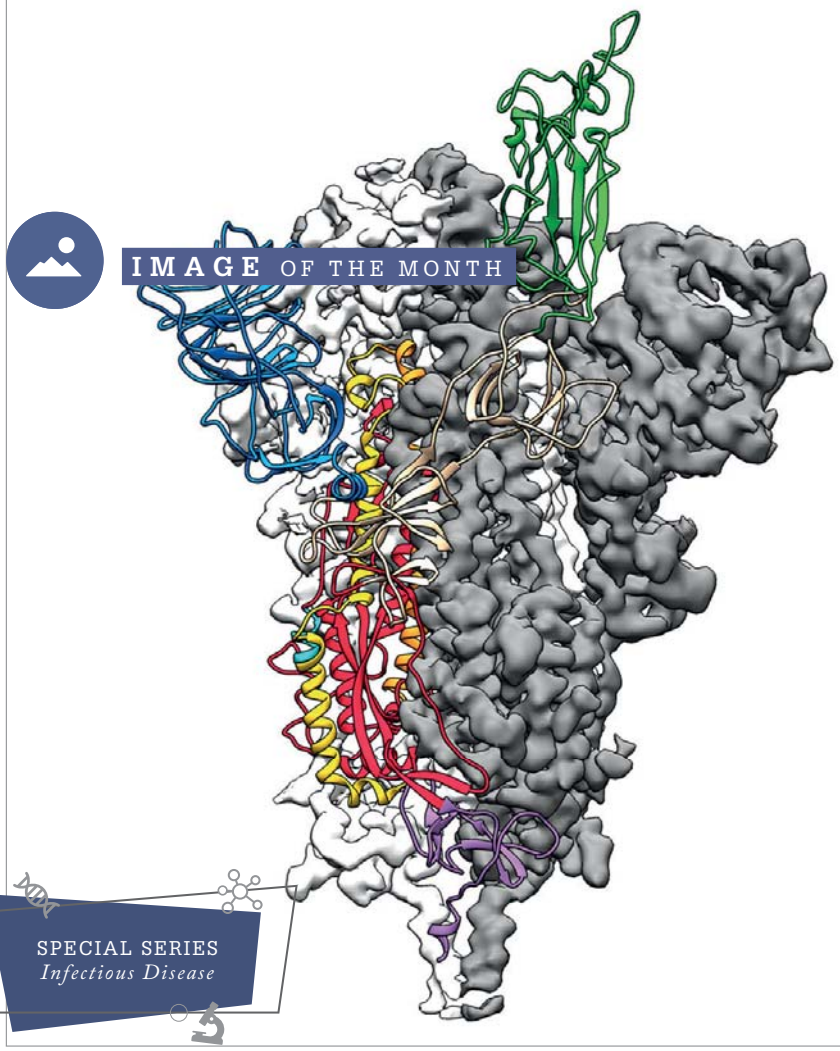
IMAGE OF THE MONTH



SPECIAL SERIES
Infectious Disease

Coronavirus in Cryo-EM

New research has revealed this cryo-electron microscopic structure of the SARS-CoV-2 spike glycoprotein trimer in the prefusion conformation.
Credit: Daniel Wrapp

Do you have a photo suitable for Image of the Month?
Send it to edit@thepathologist.com

QUOTE of the month

"With more than two million new cases identified each year and as many as one in eight women diagnosed with breast cancer, it is a disease that impacts many lives. But with more people leaving the professions that help identify cancer than joining, it is vital that we empower those left with the tools to do their jobs as effectively as possible, and AI technology can do just that."

Joseph Mossel, CEO and co-founder of Ibex Medical Analytics

Good Night!

Sleep duration and microRNA expression levels are linked in children

Sleeping like a baby is not just key to maintaining productivity, concentration, and creativity; sleep duration can also affect susceptibility to a number of diseases, especially in children. But how can we measure sleep quality? New research has found a link between microRNA levels and sleep duration in children (1). "The expression levels of circulating miR-26b-3p and miR-485-5p are different between self-reported 'short sleepers' (children averaging less than nine hours) and 'normal sleepers' (children averaging more than nine hours)" says Fabio Lauria, co-author of the study.

"The notion that some circulating miRNAs display diurnal rhythmicity in healthy humans is a relatively novel finding (2) – and this study shows that sleep duration is reflected by the profile of specific circulating miRNAs in children and adolescents," Lauria explains. With further research, this could pave the way for a simple blood test to assess sleep quality and, in turn, general health in children.

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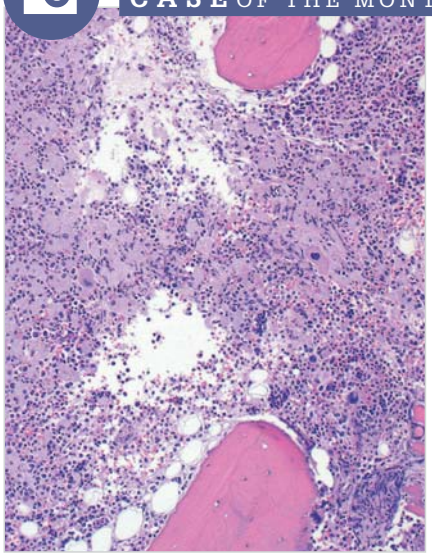
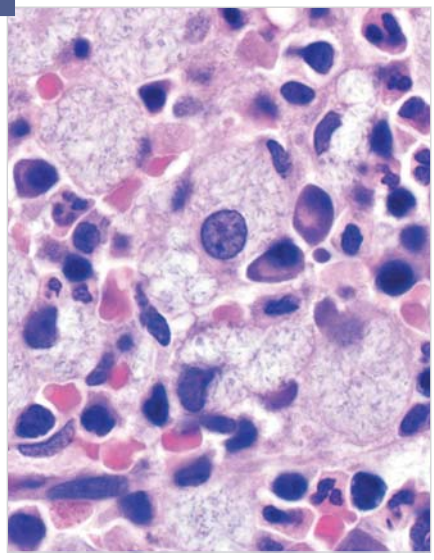
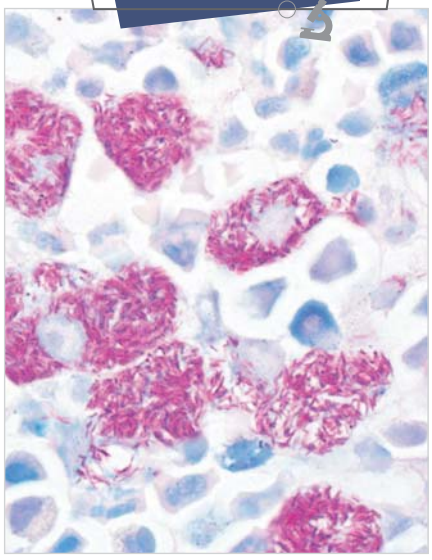
SPECIAL SERIES
Infectious Disease

CASE OF THE MONTH







A 20-year-old female presented with fever of unknown origin, normocytic anemia, neutrophilia, diffuse lymphadenopathy, and splenomegaly for several months. Bone marrow biopsy was performed.

What is the most likely diagnosis?

a) Gaucher disease
b) Myeloproliferative neoplasm with numerous pseudo-Gaucher cells
c) Mycobacterial infection
d) Crystal-storing histiocytosis
e) Niemann-Pick disease

Answer to last issue's Case of the Month…
b) Osteochondroma

Osteochondromas are benign tumors composed of bone and cartilage that typically involve the metaphysis of the femur, humerus, and tibia. They are most commonly diagnosed in the first two decades of life (1). Presentation of osteochondromas within facial bones is extremely rare (2–4). These tumors are characterized by a well-defined hyaline cartilage cap containing small, mature chondrocytes without atypia (Image 1). The chondrocytes may line up to mimic a normal growth plate. The cartilage transitions into trabecular bone via enchondral ossification, leading to expansion over time (Image 2). It is important to recognize that this lesion is not permeating bone, which is seen in low-grade chondrosarcoma (4). Instead, it is forming bone via endochondral ossification, which rules out enchondroma, a neoplasm solely made of cartilage. Chondroblastic osteosarcomas must have a malignant-appearing cartilage for diagnosis (1).

Submitted by Chelsea Styles, The University of Michigan, Ann Arbor, Michigan, USA.

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To register your guess, please go to http://tp.txp.to/0320/case-of-the-month
We will reveal the answer in next month's issue!

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In My View

Experts from across the world share a single strongly held opinion or key idea.

Consolidation Lessons Learned

How three pathology services became one – and the bumps we encountered along the way

By Simon Brewer, Managing Director, South West London Pathology, London, UK

South West London Pathology was established in 2014 to provide a single integrated pathology service for southwest London. Its founder trusts – St. George's University Hospitals, Kingston Hospital, and Croydon Health Services – could see immediately that three separate pathology services were not sustainable or affordable in the long run. In response to Lord Carter's report on pathology in 2008 (1), the National Health Service (NHS) in London had called for the creation of five pathology clusters in the capital – and South West London pushed ahead. Why? Because the chief executives at the time could see they were all facing the same issues: difficulties with recruitment, staffing, and training, and a decreasing cost base that made it difficult to invest in new equipment or technology.

The South West London Pathology business case was built around consolidation to make services more cost-effective and thus rationalize investment – so the process had to move quickly once the network was formed. The team needed to organize building work, standardize working processes, and install, test, and validate new equipment.

On day one, staff had their employment transferred to St. George's as the host trust, but nothing else happened (which was very anticlimactic!). Over the next two years, though, cellular pathology relocated to one laboratory, microbiology consolidated from three sites into one, and a blood sciences hub laboratory was created at St. George's, with spokes at Croydon and Kingston. A program of complete re-automation across all sites and all disciplines was completed and a single laboratory information system was rolled out (albeit a legacy product that would later need to be replaced).

The consolidation was completed by September 2016 – and it was a success. By the end of year three, the initial investment of £8.5 million had been repaid, and the network has delivered annualized benefits of just over £8 million ever since. There is also a robust commercial agreement in place between the partners that enables South West London Pathology to bid for and win new work. Since "go-live," South West London Pathology has picked up contracts from the Royal National Orthopedic Hospital in Stanmore and the New Victoria Hospital in Kingston – so it's clear that the network has saved money and is now competitive. Even so, we would never claim to be the perfect network; we made some key mistakes and learned some important lessons along the way.

At the start, we had three trusts that counted tests differently, called them different things, used different reference ranges, and had different platforms, preferences, and costs. I often say that pathology does the same thing differently on different sites – but we needed to create a culture in which we were all doing the same things in the same ways. Of course, everybody thought their approach was the best, so we had to win over hearts and minds. Over five years, we won some battles and lost others, but we all agreed on one thing: standardization is critical – and the sooner we get there, the better.

The next lesson we learned is that you must have a single laboratory information system. Your LIMS is your workflow; every member of staff interacts with the LIMS, so every process they perform and every change you want to make goes through the LIMS.

We are currently in the process of implementing a next-generation LIMS. The system we chose is cloud-ready, so it is not as dependent on trust IT setups. It's flexible and configurable, so we will be able to use it to further harmonize workflows and to support the network as it expands. We are supporting Epsom and St. Helier NHS Trust in rolling out the same build, so that the southwest London sector is served by a single LIMS and can work as a network across four acute trusts.

We have also learned that our staff are our biggest asset. The business plan called for a round of redundancies – something we would not do again because we lost a lot of expertise. We have also had some recruitment issues in blood services at our spoke sites (what we call "essential service laboratories"). We stripped them down too much, which has been a challenge because, if all high-end tests come to the hub, people don't want to work at the spokes because of the

reduced repertoire. We are now moving to develop a rotation for staff so that they can do core services at Kingston and Croydon and come into St. George's to conduct specialist work. We have also realized that we took our eye off training in some areas, which we are addressing.

I think there are three reasons why South West London Pathology has progressed, when other networks have not. At the outset, there was corporate buy-in; we had determined, committed agreement from the chief executives and chief financial officers. There was also strong clinical leadership – and operational ownership (because operations did the implementation). I believe that networks are the way forward; they are a much better use of resources, a much better prospect for the service, and they have a good impact on patient pathways. But they won't happen just because the Department of Health and Social Care or NHS England/Improvement say they should. You must have those three elements in place.

Networks go through phases of development. The first phase is transition, which can take two or three years. The second phase is stabilization – and we are reaching the end of that now. The third phase is delivery. Our investment in new LIMS technology will enable that – but it's our investment in staff and training that will sustain it; after all, it's our staff who deliver it.

Reference

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The Difference Between Life and Death

Pathologists' stake in the humanitarian crisis at the US-Mexico border

By Drew Bernhisel, Medical Student at Texas Tech University Health Science Center El Paso Paul L. Foster School of Medicine, El Paso, USA

On any given day, tens of thousands of immigrants and refugees are held in detention by immigration enforcement along the US-Mexico border (1). The deluge of detentions, often occurring in overflowing and inadequate facilities, has created a health crisis that has deepened the plight of this vulnerable population. For many detainees, the grating conditions of their migration and the harsh realities of their detention create the need for medical expertise in fields like clinical microbiology, transfusion medicine, and the diagnosis of surgical pathology specimens. Pathology is an essential component of this patient population's unique needs, and pathologists should be an important part of the medical voices advocating for the care of detainees' health.

As a medical student in El Paso, Texas, I have seen numerous individuals on the inpatient wards who have been admitted from detention centers and who are under supervision by immigration enforcement. The US-Mexico border is known to be home to a collection of unique health conditions and diverse pathologies. Additionally, the influx of migrants from locations throughout Latin America only increases the need for diagnoses both from the lab and under the lens of a microscope. One patient I encountered was found to be infected with Salmonella typhimurium. Another received a first-time diagnosis of leukemia in the hospital. When migrant patients receive care at the border, pathologists provide important diagnoses for a broad variety of conditions.

There are many other challenges that pathologists are uniquely qualified to address. Undocumented immigrants are vastly more likely than the average American to be victims of sexual violence and rape at some point in their lives (2). There is a great need for screenings for sexually transmitted diseases, Pap smears, and other age-appropriate cancer screening tests among migrants. This is in addition to the need for consistent screening and laboratory testing for other infectious diseases, such as tuberculosis or blood-borne pathogens.

In December 2018, a seven-year-old girl from Guatemala died while being detained at the US border. An autopsy performed by the Office of the Medical Examiner in El Paso determined that she died of sepsis and multiple organ dysfunction due to a disseminated streptococcal infection. Although she showed signs of a severe bacterial infection from the moment she and her father were apprehended, she was not hospitalized until 12 hours later. The lack of experienced medical personnel and training likely cost the child her life. The former head of the American Academy of Pediatrics called the incident "a death that could have been preventable" (3). A pathologist diagnosed her condition post-mortem but, given the chance, it's likely that another could have contributed to her diagnosis so that she

could have received life-saving treatment in the hospital. As physicians who see these challenges first-hand, pathologists should continue advocating and working for the safety of people who come over the border. Their influence could mean the difference between life and death.

Despite the fact that pathologists' work to screen, diagnose, and treat patients within the often-marginalized population in immigration enforcement custody takes place behind the scenes, they nevertheless play a decisive role in the wellbeing and even survival of thousands. As a prospective pathologist, I see these people as my future patients, and I hope to continue the essential work done by pathologists to assist some of the most vulnerable among us.

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Hidden Heroes

Medical laboratory assistants: the hidden powerhouse of lab medicine

By Bamidele Farinre, Senior Executive Officer (HCS), Clinical Services Unit, National Infection Service, Public Health England, London, UK

Many people don't realize how many different branches of pathology there are. With five main subspecialties (medical microbiology, histopathology, hematology, clinical biochemistry, and immunology) and nine smaller ones (virology, cytology, toxicology, forensic pathology, dermatopathology, and so on), the laboratory may seem like a crowded place – and that's even before counting the clinical directors, lab managers, biomedical scientists, clinical scientists, trainees, associate practitioners, healthcare assistants, and porters.

So who are these "hidden heroes?" Today, I'd like to focus on the work done by medical lab assistants (MLAs) of all grades in all laboratory settings. These members of the lab play a key role in sustaining quality diagnostic services. Their work varies, but includes receiving, sorting, preparing, and processing patient samples; maintaining stocks of consumable items; disposing of biological waste; operating and maintaining laboratory equipment; clerical tasks, such as data entry; and general housekeeping duties in the lab. There are no formal entry requirements for MLAs, although some hospitals and pathology labs require qualifications and some organizations offer training and professional development.

Sample collection for diagnostic testing is the first and most vulnerable step in a journey that will involve several hospital departments, different skilled scientists, and state-of-the-art technologies. To really understand the hard work of an MLA, it's important to have a clear understanding of this sample journey. After collection, the sample – in a colored tube that contains different chemicals and preservatives, depending on the tests to be conducted – is delivered to the pathology laboratory along with request forms that specify each test. MLAs are responsible for sample sorting – a crucial step with plenty of room for error, which is why labs employ strict quality control procedures.

Following these quality control measures, the MLAs may reject samples for a variety of reasons: inappropriate sample volume/specimen container/specimen type, sample hemolysis, incomplete or incorrect information on the request form, or lack of the requisite doctor's signature. If any of these goes undetected upon sample receipt, it may lead to incorrect results, unnecessary diagnostic procedures, increased healthcare costs, delays in diagnosis or treatment, and even physical harm. During the preanalytical phase, MLAs prepare the samples for testing. They check that patient identifiers are correct and complete, sample identifiers match those provided on the request form, that the sample type is correct, and all necessary information is available. Only then can a sample be assigned a unique laboratory requisition number and booked for testing.

Clinical pathology plays an integral role in the patient-centered approach to healthcare. Doctors rely on accurate test results for proper disease diagnosis and treatment – and patient-centered care requires effective interdepartmental cooperation. When things go awry due to undetected errors by lab personnel, it can damage the lab's reputation, diminish confidence in healthcare services, and increase in operating costs. Errors can occur at any point during patient sample journey, from the pre-preanalytical to the post-analytical phase, and it's impossible to eliminate them entirely – but compliance with best practices can significantly reduce their incidence. Responsible for the most error-prone steps in the process, MLAs deserve our thanks. Shouldering the vital task of error detection and prevention is no small feat.

SPECIAL SERIES
Infectious Disease

Winter of Discontent

Pressure on the NHS is predicted to be higher than ever this winter – and diagnostics are part of the solution

By Simon Parker, Virology Lead at Roche Diagnostics, Burgess Hill, UK

Winter is a particularly tough time for UK NHS trusts and GP practices. This year is likely to be no exception, with the British Medical Association (BMA) predicting that the NHS is "almost certain to endure the most pressurized winter on record," with increased emergency admissions, more trolley waits, and an increased number of emergency department stays longer than four hours. The BMA advises that the "government must act now to prevent an unprecedented NHS crisis" (1).

The incidence of respiratory tract infections, including those caused by the influenza virus, increase during the cold winter months. These conditions vary in severity, but are leading causes of death and disability in children and adults worldwide and place huge demands on healthcare systems. Although the UK flu season is difficult to predict, the situation in the southern hemisphere, which precedes that of the northern hemisphere, may provide clues (2). Australia has just had a notably bad flu season – with over 300,000 cases recorded for 2019 as of late November (3) – and this, given that the NHS is already under pressure following a difficult summer, is of concern to many health leaders.

"We must recognize the potential value of diagnostics in the global fight against flu and its role in supporting clinical decision-making."

Although winter projections are important for allocating resources and future planning, they are not enough to ease ongoing NHS pressures. Public Health England has recently announced that this year's flu vaccination campaign will be the biggest ever, with 25 million people offered free vaccines (4). The effectiveness of the flu vaccine varies from year to year (in the UK, last year's was 44 percent effective among all age groups), but the latest offer of free vaccines to 600,000 primary school children and a new cell-based vaccine for over-65s may provide greater protection than in previous years (5).

Improving efficiencies and productivity within the NHS may also ease ongoing pressures – for instance, by ensuring that patients flow through hospitals as swiftly and smoothly as possible. For that, we must recognize the potential value of diagnostics in the global fight against flu and its role in supporting clinical decision-making. Diagnostic tests, including point-of-care testing (POCT) devices, enable healthcare professionals to quickly test for multiple strains of influenza A and B, and to effectively triage and treat patients appropriately. A recent study evaluated the potential impact of introducing influenza POCT on operational workflow, accurate diagnosis, and potential cost savings during the winter of 2017–2018 (6). POCT adoption may lead to faster emergency department discharge decisions and avoid unnecessary isolation of suspected cases – which is estimated to have significant cost savings and may reduce the spread of the virus in hospital settings.

There is no single fix to the perennial problem of the winter healthcare crisis. Nonetheless, a better and faster understanding of a patient's diagnosis frequently leads to better decision-making on admission, better bed management, an improved clinical workflow, and more appropriate treatments. This winter may well be more chaotic than most, but in the future pressures may be eased by combining vaccination campaigns, diagnostic influenza testing, and other innovative solutions. Health services should continue to work with healthcare businesses to support the adoption of innovative diagnostic products that can help the system operate at its best when a crisis hits. This leads to better outcomes for everyone – especially the patients.

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Do Not Wait for Leaders

Finding ways to contribute to global good

By Dana Razzano, Chief Resident of Anatomic and Clinical Pathology, New York Medical College at Westchester, USA

"Do not wait for leaders; do it alone, person to person." – Mother Teresa

This call to action has always been an inspiration to me. Rather than waiting for authorities to make change and improve the world, it compels me to do something to improve the lives of others myself – one at a time, person to person. We are asked to ignore obstacles, to be tenacious, and to move forward to face challenges – alone. It's a very bold idea.

My pursuit of medicine began with a desire to work in global health. My career choice – pathology and laboratory medicine (PALM) – was a natural conclusion once I learned that it is the cornerstone of modern healthcare. It made sense to me that, globally, PALM would need to improve as we advance care for both communicable and non-communicable diseases.

As a medical student on the pathology program interview trail, my inquiries about global health opportunities in residency left me slightly dismayed. It wasn't that programs were opposed to the idea; rather, not many were aware of the concept or simply did not consider it a priority. I was naïve to the reality that roles in global health were anomalous for pathologists – a fact that, when I realized it, surprised and confused me. How could the global health community be working to improve healthcare in low-resource settings, if PALM was nowhere to be found?

As it turns out, not a single program that I interviewed with had opportunities for global health in the field of pathology – and no program other than the one I matched to was willing to explore the idea. Once residency began, my program allowed me to build a global health elective – a task I began in my first year of residency and continued at the start of my second year by completing a month-long anatomic pathology elective in a laboratory in Uganda under the supervision of a visiting pathologist from the US.

Finding that opportunity was difficult. Finding pathologists who had worked in global health was difficult. Finding out what I need to learn to lead global pathology development was difficult. I often wished that there was an easier way to make connections, learn, and get involved in the global pathology community. At the time, there was minimal information on the Internet about how to get involved as a trainee or graduate pathologist – but I had learned so much through the process of creating and completing the elective that I wanted to make it easier for any interested pathologist at any career stage to get involved in global health.

It was networking that made this dream a reality. Within weeks of my return from Uganda, I attended the 2017 ASCP annual meeting, where I met several wonderful pathologists who had also worked globally – Danny Milner, Sara Jiang, Christina Arnold, Kamran Mirza, and Jerad Gardner. We talked, brainstormed, and eventually came up with the idea to launch a webpage unique to global health opportunities. Jerad Gardner, the founder of the Pathology Resident Wiki (1), offered to host the page on that site – and that is where it all began!

The launch of the Global Health Opportunities for Pathologists Wiki page (2) has expanded the opportunities available to connect with others working in global pathology. With my colleagues' mentorship and advice from years of international pathology service, I continue to learn what it takes to improve laboratories internationally. I also had the chance to travel again to Africa in 2018 – this time as an ASCP Trainee Global Health Fellow working in a laboratory in Ethiopia – and benefited enormously by taking an active part in the ASCP's quality improvement initiatives there (3).

With every morsel of knowledge gained from my experiences both traveling internationally and seeking out opportunities to do so, I continually add to the Wiki page. There are many resources and opportunities available for both trainees and practicing pathologists, and I try to list each one of them on the site. Interested laboratory medicine professionals can also find sources of funding, education, and interviews with PALM members working in global health. And for those who are particularly enthusiastic, there's even a survey at the end of the page to learn more about your interest in global pathology!

Whatever your passion to improve the world around you, I urge you to take your ideas and turn them into reality. Do not wait for leaders – do it alone. Take charge and make changes, whether in your local community or the one you share with the world.

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Our Past Informs Our Future

Laboratory lessons from our history help us to foster forward-thinking change

By E. Blair Holladay, CEO of the American Society for Clinical Pathology, Chicago, Illinois, USA

Pathology and laboratory medicine have a rich past. Our history can be traced back to 400 BC, starting with Hippocrates and his study of the pathology of the human spine. In the centuries since the profession's original inception, our knowledge has grown and our expertise continues to expand.

As the American Society for Clinical Pathology (ASCP) approaches its 100-year anniversary in 2022, it's important to reflect on how far we've come and the impact we've had on the profession. It's important to not only see what we've done, but also use it to shape our future. Writer and philosopher George Santayana is quoted as having said, "Those who cannot remember the past are condemned to repeat it." As pathology and laboratory medicine evolve, these words seem ever more poignant to me.

Clearly, a century's worth of accomplishments can't fit onto a single page. But if we focus on just the past two decades, ASCP has made tremendous strides to benefit the profession. Here are three milestones from our recent history that have helped change the face of pathology and laboratory medicine – now and in the future.

We've shaped our mission around patient-centric care.

As health care has shifted to value-based care, we recognized that, despite a history of limited patient interaction, pathologists and laboratory scientists had to engage with patients to improve health care. It is up to us to lead this effort, and it starts with understanding the patient behind the sample. We launched our Institute for Science, Technology and Policy to foster the needed work on evidence-based practice and patient-centered outcomes. We've developed a national curriculum on cancer genomics for pathology residents. And, since its inception, we have been an active and vocal partner in the Choosing Wisely campaign, which encourages patients to be more proactive in their care. The goal is for patients to better understand their laboratory tests so they can ensure they are getting the right tests at the right times. These are just a few examples of our efforts to change the way the laboratory is viewed (and understood) by patients – and how the laboratory views itself in relation to patient health.

We've made global health local health.

Part of being "patient-centric" is recognizing that high-quality health care shouldn't be limited to a single location. It needs to be available to people across the world. Because of this, we've criss-crossed the globe to bring laboratory education to underrepresented countries, helped develop sustainable workforces, and implemented technologies in resource-limited countries to help the pathology and laboratory professionals in those areas better serve their patients. We are leading the Partners for Cancer Diagnosis and Treatment in Africa coalition to ensure patients in underserved areas have access to not only ASCP diagnostic experts from around the world, but also timely cancer reporting and clinical care. In addition, we have helped stem the tide of the HIV epidemic throughout the world and brought rapid diagnoses to patients in countries that would otherwise be devastated by the disease. By sharing our knowledge and expertise, we narrow the health-care gap and actively promote the need for improved global health.

We've built connections that serve as the foundation for growth.

There is no "I" in laboratory, and pathologists and laboratory scientists know that healthcare leadership requires macroscale teamwork – partnering and collaborating with public and private entities on national and global scales. Through these efforts, we have been able to proactively improve health care and put ourselves at the center of the change. With each connection – each bridge built – we have further solidified the importance of the laboratory, and we will continue to build on that strength.

As we move forward, what we've learned from these experiences will undoubtedly help form how we respond to challenges, as well as how we foster further change in our profession to ensure that we continue to have a significant impact on the emerging state of health care.

DR STRANGELAB...

... or, how I stopped worrying and learned to love pathology

Do you remember when you first made the decision to pursue a career in pathology? More to the point, do you remember the feedback you received from your peers and supervisors? Did they "approve" of your decision – or was it a "waste of your outgoing personality?" Were you accused of lacking an interest in patient care? All of these attitudes and more combine to discourage today's medical students from considering one of the noblest fields of medicine. And that's why a group of medical students, residents, and attending physicians with a shared interest in pathology got together to discuss the obstacles that stood in their paths, their colleagues' impressions of the discipline, and what can be done to encourage future students to consider pathology.

WHAT PIQUED YOUR INTEREST IN PATHOLOGY?

Lacey Durham: Since I was 17 years old, I had planned to go into pediatrics. About six months ago, I accidentally clicked on pathology – and when I got my schedule, I thought, "What is AP/CP?" I decided to go with it and, after one day, I realized that I had had no idea how much pathologists do. I got online and started looking up pathology, but the only information I could find was for speech pathology. I speak passionately about pathologists on Twitter because I couldn't find much information when I looked – and what I did find was all negative; everything I read said, "Don't go into pathology." And if I hadn't met pathologists and their patients in real life, I might have believed it. I think it is important that we continue to promote pathology on Twitter because I can get to know my colleagues and learn from them. All I want is more pathology online, and it's nowhere to be found – so I'm grateful to everyone who tweets cases and posts tutorials. It's my informal education.

Lily Mahler: During my first year of medical school, we had a "fundamentals block" of basic science classes in the first six months, which included a crash course in pathology. The lectures were interesting and full of good information, so I was intrigued – and then we had a resident-run session in the pathology lab with a bucket of specimens for us to pick up, look at, and learn about. The resident who taught it was really funny and down-to-earth and understood that this was all new to us. At that point, we had no idea what pathologists did, but I was interested enough to shadow some pathologists, talk to a lot of residents, and start considering a future in pathology.

Ashley Rose Scholl: I initially wanted to become a pathologist because of my interest in forensic science and my graduate studies in forensic anthropology. After my second year of medical school, I did a one-year post-sophomore fellowship in pathology at West Virginia University and I loved it. I discovered I enjoyed many more subspecialties than just forensics, and that experience showed me that the field of pathology would be an interesting and challenging way to spend my career.

Ellie Pernicone: After graduating from university and before starting med school, I got a job in a research laboratory at Beth Israel Deaconess Medical Center. In that job, I got to work with a lot of pathologists and I discovered that they were the best teachers. I also discovered that I really liked the process of research. Pathology is valuable because, without it, you don't know how to treat patients – and I think that is fascinating.

Chris Felicelli: I came from a basic science research background, so it seemed a good fit to continue along with pathology. I don't have a long story – it just happens to be super interesting to me, so I'm choosing to pursue it.

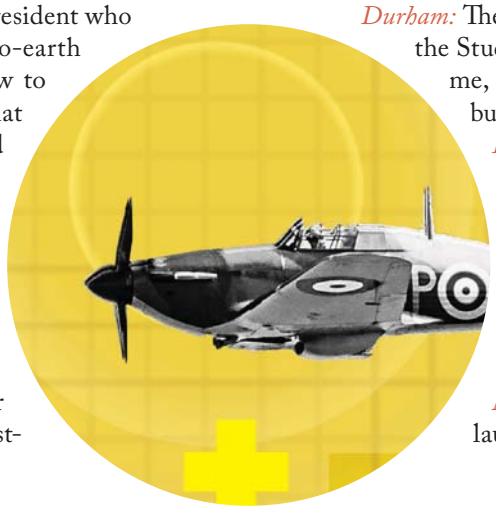
Mel Toeller-Desimone: I got interested in pathology through the Chief Medical Examiner of Milwaukee County, who inspired me to continue.

WHAT DO YOUR MEDICAL SCHOOL COLLEAGUES SAY WHEN YOU EXPRESS YOUR INTEREST IN PATHOLOGY?

Durham: They mimic the same things they read on the Student Doctor Network forums. They tell me, "Oh yeah, I thought about pathology, but the job market is so bad."

Booth: We know, of course, that that's not true. We have studies and data showing that, in fact, the job market is quite good – and we're trying to make sure that accurate information is available online so that people who might be interested in pathology can inform themselves about it.

Mahler: My classmates usually start laughing and say things like, "Really?



Pathology? That's kind of weird, isn't it?" I tell them that the people I've met in pathology – all of the residents and faculty in my program – are the nicest, kindest, most laid-back people I know. I feel like I match really well with the people I've met.

Scholl: I think a lot of people think that pathologists spend their days sneaking around in the morgue. People are confused when I tell them I'm interested in pathology, because they don't know what the profession really does.

Toeller-DeSimone: I've never hidden my interest in pathology. I have always been upfront about it, but I have seen people dismiss me when I say I'm interested in pathology. For instance, there was a surgical procedure during my nephrology rotation that involved a biopsy – so it was related to pathology – and they said, "You're going into pathology, so I guess this isn't a problem for you." They excluded me from things in which other students were included. I had to say, "This isn't a pathology rotation; this is a nephrology rotation and I would like to be treated like any other student in nephrology." And it's not just the one experience – I've had that multiple times in most departments, even though they rely on pathology.

Pernicone: When I tell people I'm interested in pathology, I usually get some expression of distaste. "You do know what pathologists actually do, don't you?"

Felicelli: It seems a lot of the responses are, "Didn't you go into med school to interact with patients and to have physician/patient relationships?" I don't entirely understand it. The same can be said to those who go into diagnostic radiology – they have as much or as little of a physician/patient relationship as we do – but they don't get that pushback…

Booth: And we don't even sit in dark rooms!

WHAT INSIGHTS CAN THE ATTENDINGS SHARE FROM THEIR OWN EXPERIENCES?

Emily Volk: What I loved about pathology was that they had all the answers. I remember Plato's allegory of the cave; the people in the cave look at the shadows and think that's the truth – and those outside it can turn around and see that the shadows are made by the sunlight and that they are only representations of reality. I feel like pathologists are the enlightened ones in medicine in that we have the privilege

THE STUDENTS

Lily Mahler (pictured left); Mel Toeller-DeSimone (pictured top right); Lacey Durham (pictured bottom right)

Lacey Durham
is a fourth-year medical student at Texas A&M University, College Station, Texas.

Christopher Felicelli
is a fourth-year medical student at Loyola University, Chicago, Illinois.

Lily Mahler
is a third-year medical student at the University of Alabama, Birmingham, Alabama.

Ellie Pernicone
is a third-year medical student at the University of Central Florida, Orlando, Florida.

Ashley Rose Scholl
is a third-year medical student at West Virginia University, Morgantown, West Virginia.

Ashley Rose Scholl
is a third-year medical student at West Virginia University, Morgantown, West Virginia.

Mel Toeller-DeSimone
is a fourth-year medical student at the University of Wisconsin, Madison, Wisconsin.

to look disease in the eye every day. Other doctors see the symptoms; we see the cancer itself – not a shadow, not a concept, but a disease that is exposed to our scrutiny.

As a Senior Vice President for a large hospital system, I can tell you that pathologists are really well-suited to taking on leadership roles in healthcare. Because we interact with so many different parts of the hospital, we understand how they all work together. Pathology has offered me a career that has been fascinating and surprising, and I'm excited to see these medical students interested in pathology.

Patrick Godbey: It took me far too long to get into pathology. I'm an obstetrician/gynecologist by training, and when I started work – at a private practice with two great partners – the senior partner said, "We just do what the pathologist tells us. If the pathologist tells us to take it out, we take it out. If the pathologist tells us to bring the patient back, we bring them back." After a few years, I decided that I wanted to be the one making those decisions! So I went back for an AP/CP residency, which took me four years, and then I returned to the same small town where I had practiced as an OB/GYN and now practice pathology.

I think the future of pathology is extremely bright. I think today's medical students are going to have all kinds of opportunities in the field, because there's an increasing shortage of pathologists and plenty for us to do. In fact, our daughter just finished her AP/CP residency and fellowship a year ago. If I didn't think our specialty had a promising future, I would have discouraged her from going into pathology – but I'm not sure I could have kept her out of it. It's such a great time to enter the field.

Anne Champeaux: When I was a kid, there was a show on TV – Quincy, M.E. He was a medical examiner with a sidekick, Sam, and I couldn't decide at the time which one of them I wanted to be. But from a very early age, I wanted to be a "lab doctor." I started actually working in a pathology lab when I was 14, so I never strayed from my path – I went to college, then to medical school, and shut out any negative comments. I'm definitely happy with my decisions, but I'm still not sure whether I'm Quincy or Sam!

Christina Wojewoda: My mom was a medical technologist growing up, so I became familiar with lab medicine early on and spent my summers working at the College of American Pathologists. Naturally, when I went to medical school, I wanted to pursue either infectious disease or pathology – and I quickly found out that pathologists are the ones with the answers. The lab tells infectious disease what the organism is and how to treat it, and that's perfect for me. I like to know things first!

I think exposure is key. Unless people are shown what pathology is – whether via television or a parent or a good experience with a pathologist – then they simply won't know. How can they consider entering a discipline they don't understand? Of course, like everyone else, I had people tell me that I was too outgoing to be a pathologist but I just said, "No, I'm the fun one that you're going to come to for all your answers." I shut down the negative stereotypes, helped people in the microbiology lab focus their microscopes, and never looked back.

Scott Anderson: My mom was a med-tech and my dad was a clinical chemist, so I must have the laboratory in my genes. Even so, when I went to medical school, I was not going to be a pathologist. I wanted a family practice in a rural setting, because I grew up in Los Angeles and never wanted to go back to the big city. But, as others have said, engagement is vitally important – and my medical school had some incredibly strong pathologists and a strong pathology course with excellent instructors. Although I was still uncertain, I decided to do the pathology department's year-long student fellowship – and it didn't take long for me to realize that this was where I wanted to be.

Even though I had made my decision, I still did a clinical intern year as well. I found it interesting because it flipped the narrative – now, I had pathologists telling me not to waste my time with a clinical internship! That year was a valuable experience and one of the better years of my training… but, in the end, I was in love with pathology.

Kamran Mirza: Now that I'm in a role where I can guide people toward pathology, I think that this conversation is highlighting the problems we have right now. There is no exposure; there is no pathology champion; you don't have a visual for "the pathologist." Our course is run by a fantastic educator who did a residency in pathology and then went

> "IF THE MEDICAL STUDENTS SEE THAT THE LAB IS NOT JUST A 'BLACK BOX' – THEN THAT COULD MAKE A HUGE DIFFERENCE IN THEIR PERCEPTION OF PATHOLOGY."

into internal medicine. In my eyes, that makes her the perfect person to run a combined course – but, when others see her, they see someone who gave up pathology and is now a clinician. That doesn't do our discipline any favors.

We don't need hundreds of students going into pathology, but I would like everyone to have it on their list. If it's on their list and they decide not to pursue it? No problem – but that's an informed decision. Right now, most students don't even take pathology into consideration. I know I didn't. I went into medical school thinking that my options were OB/GYN, psychiatry, surgery, or medicine. We need to work together to get pathology on that list, so that students have the opportunity to explore it and decide for themselves whether or not they're interested.

Jennifer Laudadio: During my second year of medical school, we had a traditional pathology course in which we attended lectures and read Robbins, but we also had small group study in which we were literally given a pot of organs. We called them "pot cases" and they came with slides and a little case history. Two of us would work the case up and present our findings to the other team members like an autopsy conference. I loved that. I loved learning about why people got sick and what it did to their bodies. I wanted to read Robbins, not clinical diagnostic books. I wanted to be in pathology, not internal medicine.

HOW CAN WE BEST REPRESENT OUR DISCIPLINE?

Yonah Ziemba: I finished medical school two years ago and went through the same challenges as you. Now, two years into my residency, I think I've found a few areas in my little world that could help other disciplines understand our field.

One is frozen section. We get a lot of third- and fourth-year medical students who come in on frozen section. As residents, we're under pressure to satisfy our attendings before we can focus on the medical students, but I keep reminding myself that, if I engage the medical students and show them a few interesting things – if they see that the lab is not just a "black box" – then that could make a huge difference in their perception of pathology.

I also try to be very sensitive with my terminology. My father is an experienced doctor of internal medicine, but he has no idea what I mean when I say "a cassette" or "I'm going to sign out." When I talk to people outside the pathology department, I'm very careful about the words I use. If the word "grossing" doesn't appear in the dictionary, then I won't use it; I won't say "accession number," I'll say "report number" or whatever it takes to communicate with them in shared language.

Finally, when I'm on blood bank and receive a question from an intern or resident, I'm very careful to be engaging and helpful. Sometimes, interns on overnight call don't know the guidelines for each product and it might be easier to just handle things on my own without explaining to them. But, if I explain to them why the situation calls for a particular response, I'm winning them over and proving that pathology is a helpful resource. Sure, it might be three o'clock in the morning and not the time that I would have chosen for this, but it's worth it.

Booth: My wife is currently a gastroenterology fellow, when she was completing her internal medicine residency, colleagues would look at her in surprise and ask, "How did you know that? How did you find that out?" She says, "I just called the lab and spoke to the pathologist." People thought she had some kind of secret insider information – but no; she just knows what pathologists do and when to ask for our help. That's one thing anybody can do: encourage people to call the pathologist.

HOW CAN WE REACH MORE STUDENTS?

Booth: We need to communicate the diversity of what we have to offer, too. If a medical student has a keen interest in computer science, for instance, informatics could be a great choice for them – and it would still allow them to be a doctor and help patients. If we can show students all of the different things the laboratory does – we're more than just autopsies! – they can make an informed decision about pursuing pathology

Mariam Molani: I agree that it's helpful to show them how broad our field is. Even my best friends have no idea that I do transfusion medicine. My husband works in the ER right now and he's ordering stuff that has been triaged through me, but his colleagues have no idea. They don't even realize that we have patient contact. Students think, "I want to do some patient care and I can't do that as a pathologist." I think we could pique more interest if we advertised our discipline better.

Volk: We are clinicians and we need to use the word "clinician." I don't know anybody named "lab," but I do know doctors who work in the lab. We are laboratory medicine specialists, and I think we need to communicate that.

Booth: Actually, I say I'm a physician. When they ask me what kind, I say a pathologist. That way, it reinforces that a pathologist is a doctor.

Mirza: When I started as an attending, I never felt the need to introduce myself as doctor – but I've since realized that, in certain settings, it's very important for people to know that I'm a physician. Medical students, for instance, need to understand that I started out where they are now, and that they could end up in my position someday.

Godbey: I think it's important to emphasize pathology's lifestyle benefits, too. I wanted to be a part of our daughter's life and I could do that a lot better as a pathologist than I could as an OB/GYN.

Booth: I love pathology and I'd be doing it no matter what, but the lifestyle is an additional benefit. I don't want to be a 65-year-old trauma surgeon working 30+ hours in a row; I want to be a pathologist who has work/life balance. And, speaking of work/life balance, I think that's a great note on which to end the discussion.

Godbey: It has been special to see everyone, particularly the medical students, express and share their enthusiasm for pathology. Thank you, Dr. Booth, Chair of the CAP Residents Forum, for organizing this meeting.

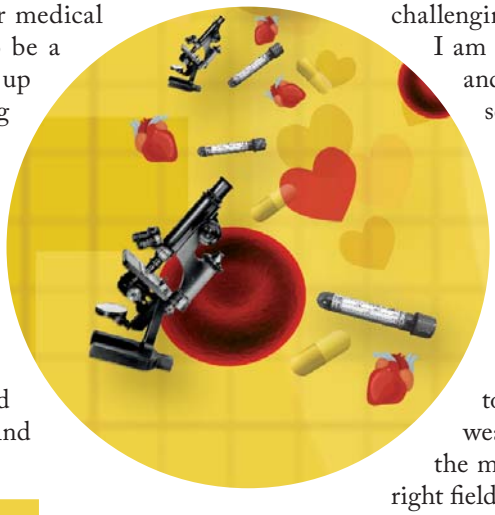
Booth: I think we came up with some good ideas and identified some gaps to work on, so thank you to everyone for your contributions to the conversation. I'm also very grateful to the Association of Pathology Chairs for facilitating this impromptu meeting of medical students, residents, and pathology leadership. The opportunity for these students to share and discuss their experiences directly with leaders in the field was powerful and illuminating for everyone in the room.

STUDENT PERSPECTIVES

Michael Schubert interviews Christopher Felicelli, Mel Toeller-DeSimone, Lily Mahler, and Lacey Durham

WHAT IS YOUR CURRENT CAREER STAGE – AND WHAT ARE YOUR PLANS?

Felicelli: I am currently a fourth-year medical student applying to pathology residency this year.
Toeller-DeSimone: I am a fourth-year medical student. I plan to study anesthesia and pursue private practice in rural areas of the Midwest.
Mahler: I am currently a third-year medical student finishing my clinical rotations. I have decided to pursue pathology as my specialty of choice and plan to have a career in surgical or forensic pathology.
Durham: I am currently a fourth-year medical student. When I grow up, I want to be a pathologist! I am currently finishing up the interview trail and I'm looking forward to seeing where I match for residency. As far as subspecialties go, I'd say I'm still… "undifferentiated." I know that I like pediatric pathology, neuropathology, and cytopathology, but I have not had enough exposure to other subspecialties to rule them out just yet. Lately, I've been thinking about bone and soft tissue pathology and forensics. But I also love the liver… And don't get me started on microbiology…



WHAT IS YOUR OPINION OF PATHOLOGY?

Felicelli: Pathology is a fantastic field of medicine with a great work/life balance. It is for those who love to solve mysteries and don't mind working behind the scenes. I did an AP/CP elective in my third year of medical school and knew it was the perfect fit for me.
Toeller-DeSimone: I love pathology; the idea of definitive diagnosis and the ability to give most patients and physicians important answers regarding their health. Pathology touches nearly every single patient, whereas most other specialties don't have that opportunity. Although I did not choose pathology for my career, it was a very difficult decision.
Mahler: To me, pathology is one of the most interesting and dynamic fields in medicine. Pathology is critical to informing clinical guidelines, understanding mechanisms of disease, and practicing medicine. The problem-solving, detailed-oriented nature of the work appeals to me and the career options within pathology are diverse and rewarding. My opinion has been informed by the experiences of pathology attendings and residents I have met, along with my own experience in the pathology department of my program. The people I have met genuinely enjoy the work they do and are excited when students are interested in pursuing pathology, which to me speaks volumes on the merits of the field.
Durham: I think pathology is the best-kept secret in medicine! I am especially drawn to the investigative work a pathologist must perform to arrive at a final diagnosis. Making the correct diagnosis is vital to finding the appropriate treatment. I like that pathologists are the ones with the answers, often at the end of a challenging clinical workup. In pathology, there are "zebras" everywhere! The rare cases make each day challenging and exciting. As a proud millennial, I am especially intrigued by how high-tech and state-of-the-art the field is. There are so many cool machines in the lab! I also enjoy how collegial and welcoming pathologists are. Pathologists spend a lot of time reviewing challenging cases together and with other medical specialists. When physicians from different departments come to the lab with their crews of fellows and medical students, pathologists are always willing to teach and review slides with them. The wealth of teaching and learning is one of the major reasons I knew pathology was the right field for me.

Unfortunately for me, my robust opinions about pathology did not occur until my third year of medical school when I did a two-week elective in AP/CP pathology. Prior to that, I thought pathology was for doctors who did not want to interact with people. I thought a pathologist was what you became if you found no other interests in medical school. I was under the impression that all pathologists spent their days performing autopsies in the basement. Like other medical schools, pathology was integrated into each system block during my pre-clerkship curriculum. My only exposure to pathology prior to my elective was during mandatory

THE FACILITATORS

Kamran Mirza (pictured left); Mariam Molani (pictured right)

Adam L. Booth
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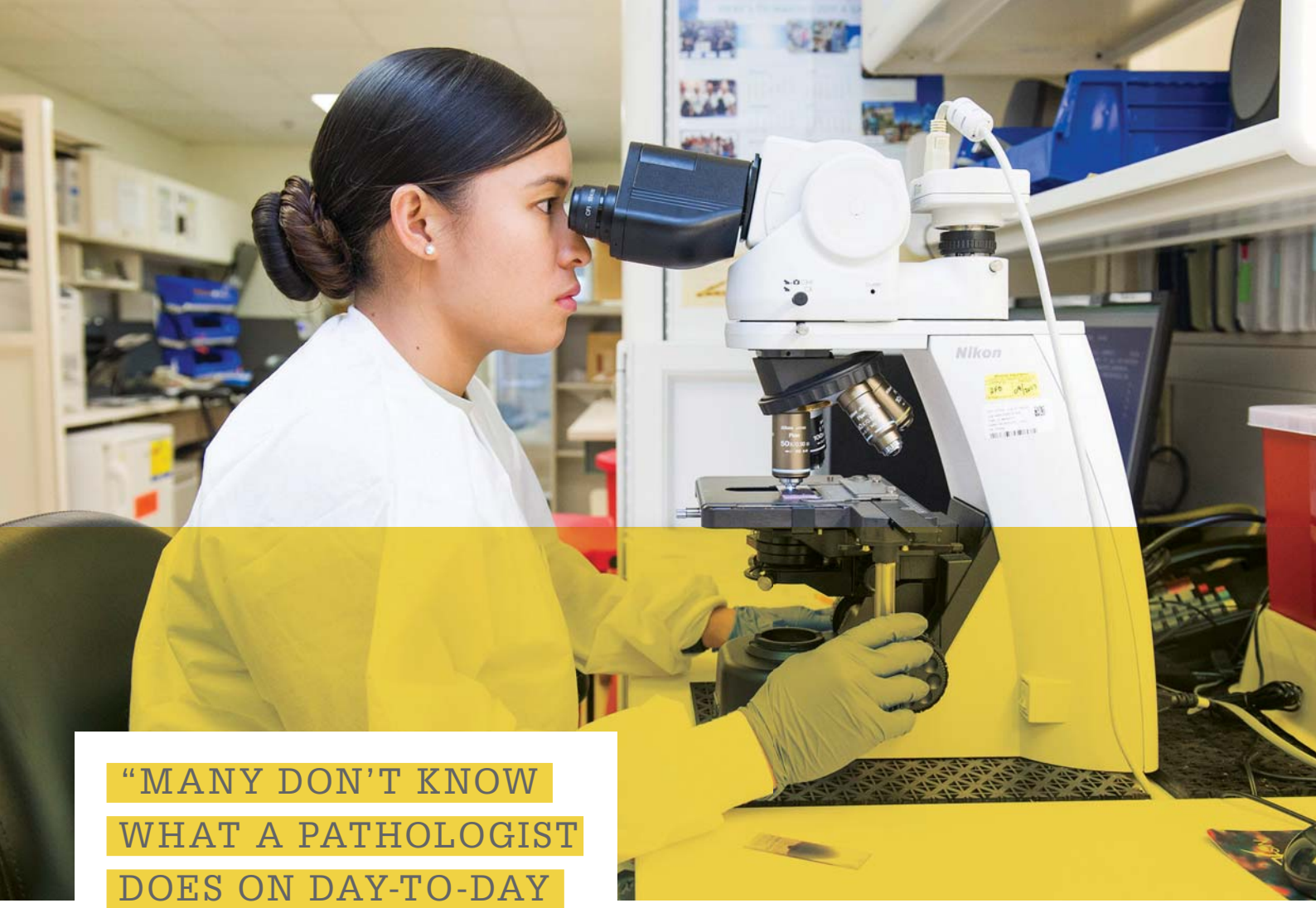
Yonah Ziemba
is a third-year AP/CP resident at Northwell Health, New Hyde Park, New York, USA.

Mariam Molani
is a third-year AP/CP resident at the the University of Texas Southwestern, Dallas, Texas, USA, and the founder and CEO of LibraMed, LLC.



"MANY DON'T KNOW WHAT A PATHOLOGIST DOES ON DAY-TO-DAY BASIS OR ARE DISSUADED BY THE MISTAKEN BELIEF THAT PATHOLOGISTS HAVE LITTLE INTERACTION WITH PATIENTS."

pathological-clinical correlate labs. During the lab sessions, my classmates and I would go over clinical vignettes with the physicians and review pathology slides together on our laptops. In other words, we would listen to the vignette, pretend to remember basic histology, and then agree with the pathologist that we were able to see whatever pink or purple dot was slightly darker or coarser or plumper than all of the others.

WHAT DO YOUR PEERS THINK OF PATHOLOGY?

Felicelli: I think most people have a negative view of pathology, mainly stemming from learning about histology and pathophysiology in their second year of medical school. This is an extremely stressful year in medical school because the big USMLE Step 1 exam is looming over everyone's head. As a result, students connect pathology with stress, leading to negative opinions.

Toeller–DeSimone: My peers think pathology is boring. They think staring down a microscope all day long is not exciting, and that you have to have a shy or bland personality to be a good pathologist. (Of course, we know that is not the case!)

In my opinion, their feelings result from a lack of exposure to pathology practice. They don't understand the diverse areas within pathology (histology, laboratory medicine, cytology, forensics, and so on). Also, other physicians don't help the matter by "specialty-bashing" pathologists, especially when they themselves don't have a strong understanding of what pathologists do.

Mahler: My peers' opinions on pathology are mixed – and most have little exposure to the discipline. Some people find it confusing and boring, whereas others enjoy pathology and like

its problem-solving nature. Many don't know what a pathologist does on day-to-day basis or are dissuaded by the mistaken belief that pathologists have little interaction with patients.

Durham: I was quite surprised with many of my friends' responses when I told them I was interested in pathology. I'll never forget how a close friend of mine, concerned for my well-being, strongly advised me to consider another specialty because he believed pathology was a doomed career choice with a horrible job outlook. He mentioned that he had briefly considered going into pathology himself, but then learned online that you had to do multiple fellowships to be hirable and that digital pathology and machine learning would make pathology obsolete. I've had countless conversations with classmates about what pathology actually is. I think many people are as surprised as I was when I tell them that most pathologists don't do autopsies in the basement all day. They are even more surprised when I tell them that pathology is a friendly and welcoming field. If I had to guess, I'd say their opinions of pathology are derived from the opinions of other physicians, the portrayals of pathologists on TV, and discussions of the specialty in online forums. It is a shame to me that so many medical students graduate without ever experiencing pathology's real-life contributions to medicine.

WHAT FEEDBACK HAVE YOU RECEIVED ABOUT YOUR INTEREST IN PATHOLOGY?

Felicelli: I have received mostly positive feedback. Sure, there are some individuals who think it is weird that a physician would "give up patient contact," but radiologists do that as much as pathologists. In the current era of medicine, with overworked, stressed, and burned-out physicians, I knew I wanted a field that has a great work/life balance and is also rewarding and intellectually stimulating. With that in mind, the negative comments have never made me reconsider.

Toeller-DeSimone: When I was interested in pursuing pathology, many residents and attendings dismissed me as someone who wouldn't be invested in a non-pathology rotation. As a result, I was sometimes denied opportunities that other students were given because they had expressed interest in other specialties. Although this was discouraging at times, it did not make me second-guess my interest in pathology. In the end, I just accidentally fell in love with something else.

Mahler: I have received mostly positive feedback about my interest in pathology. My preceptors and attendings are usually quite surprised when I mention that I plan on going into pathology and are curious as to why I chose it. I have even had a few attendings tell me that they considered going into pathology – most say that they couldn't handle the autopsy aspect of the specialty, but enjoyed the interesting subject matter and work/life balance. I did receive one offhand comment from a resident teaching me surgical/procedural skills: "I don't know why I'm teaching you this. You'll never actually do it, because you're going into pathology." I need the same education as every other doctor!

Durham: I have received an array of feedback from physicians in other fields. I went to medical school with the sole intention of becoming a pediatrician and completed a few clerkships and electives before I found pathology. When I told my attendings I was interested in pediatrics, they spoke highly of the field, which made me happy. After I switched to pathology, I still had three core clerkships, months of clinical electives, and fourth-year requirements to complete. The first time I told an attending I was interested in pathology, the response was, "So you're going to let all of the clinical skills you've learned during medical school go to waste? That's a shame." My jaw hit the floor.

I've had a handful of physicians tell me that I was too personable to go into pathology. I have explained to multiple attendings that pathologists don't actually spend their days in the basement. I really enjoyed my surgery rotation because the surgeons I worked with were happy that I was going into pathology and mentioned more than once that they couldn't do their jobs without pathologists. Many surgeons let me scrub out to carry specimens to the lab. One surgeon called me out in front of my classmates as the biggest nerd in the room. I was thrilled to reply, matter-of-factly, "You betcha!" The dermatologists and ophthalmologists I worked with were happy to hear that I was going into pathology, too, and tailored my rotations with them around reviewing dermatopathology and ocular pathology. Although I've received mixed feedback, I have never reconsidered my interest in pathology. I could not see myself doing anything else.

DID YOU FIND THE DISCUSSION GROUP HELPFUL?

Felicelli: The discussion group was a great way to network with fellow students, residents, and attendings, and to learn their stories and passions for the field. I thought it was a great impromptu event!

Toeller-DeSimone: It was helpful to know that many other students had had similar experiences to mine. They, too, noted being dismissed by others for their interest in pathology and stereotyped as someone who lacked a vibrant personality. The solidarity was very encouraging.

Mahler : I enjoyed interacting with individuals at all levels of training. I am one of the only students in my program pursuing pathology, so it was great to connect with other students who were also interested. I enjoyed hearing some of the residents' and attendings' reasons for choosing pathology – some the same as my own, which was encouraging! This discussion group and the 2019 APC Annual Meeting in general helped confirm that pathology is the best fit for me.

Revisiting the Real Impact

An oncologist's opinion on the value of fully automated NGS results in a single day

After its launch in Baltimore at the Association for Molecular Pathology (AMP)'s 2019 annual meeting, the Ion Torrent™ Genexus™ System from Thermo Fisher Scientific is catalyzing conversations in the precision medicine community. The system features a unique automated specimen-to-report workflow that delivers results economically in a single day and, in my opinion, holds unprecedented potential to advance precision medicine. Its unmatched turnaround time – as little as 14 hours to final results – is extremely appealing for clinician-scientists who are confronted with the need to make decisions fast.

To learn more about the new system's advantages from an oncologist's point of view, Luca Quagliata, Global Head of Medical Affairs at Thermo Fisher Scientific, sat down with Elena Garralda, Principal Investigator at the Vall d'Hebron Institute of Oncology (VHIO) Early Clinical Drug Development Group and Director of the Research Unit for Molecular Therapy of Cancer (UITM) "la Caixa." Garralda shares her thoughts on the benefits of obtaining a complete molecular profile of a tumor sample within a single day – both for clinical research and, in the future, for routine management of cancer patients.

What do you think of the single-day molecular testing turnaround time?
Should this claim be confirmed in a fully controlled study, it might have huge implications for clinical studies. In my experience, when sending off cases for testing, you are often confronted with long waiting times to get a full molecular report. Unfortunately, this means that, for late-stage cancer patients, you may have to make a therapeutic decision and move forward with only partial molecular information. And, sadly, it's possible that – once the full results arrive – you may discover that the first-line treatment you have already initiated is not the most appropriate therapy for that particular patient. But even beyond the implications that has on the potential outcome of treatment, I think it's important to highlight that there is also an emotional component to be considered. Waiting for results places a heavy burden on many patients, because once they have heard the word "cancer," they would like to start treatment as quickly as possible. Delays cause understandable anxiety and impatience.

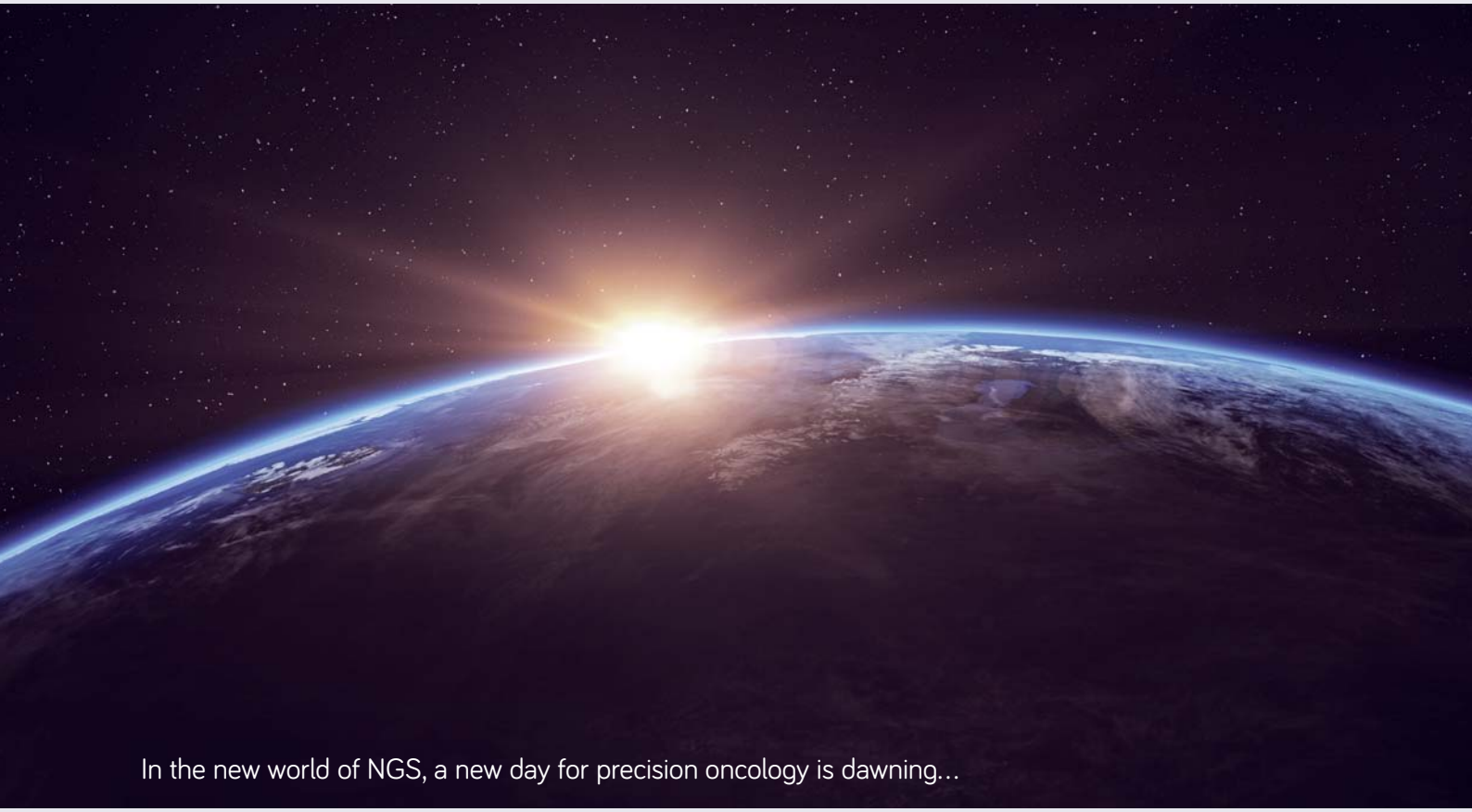
"Waiting for results places a heavy burden on many patients, because once they have heard the word 'cancer,' they would like to start treatment as quickly as possible."

What advantages would such a system bring to your clinical research practice?
From a clinical researcher's standpoint, one of the most challenging aspects of the work lies in handling patients' emotions when referring them to clinical trials. Another challenge is to pick the most appropriate trial for each patient. Having a full molecular profile in a timely manner would help with both. The oncologist's difficulties are alleviated by the ability to make rapid, appropriate treatment decisions, whereas the patient's emotional stress is reduced because the long and often excruciating wait for treatment can be significantly abbreviated.

As an oncologist, and thus the end user of the data generated by such systems, what result-reporting features would you expect?
First of all, I expect such a system to be extremely solid and reproducible in terms of data analysis reliability – that is an absolute must. In addition, I would like it to offer a great deal of flexibility in terms of content and granularity of the information. Above all, I expect it to allow the generation of a compelling, comprehensive, and plainly understandable report. Those are the features that make it easy-to-use.

For example, an ideal report would clearly display the pathogenic alterations necessary to make a timely decision – but, at the same time, it would support the visualization of genomic variants that are currently of unknown significance. Why? Because, although these variants don't currently inform treatment selection, they are often relevant for enrollment in clinical studies.

Should your institution choose to have a next-generation sequencing (NGS) system, what advantages would it have for your interactions with your pathologist colleagues?
In our multidisciplinary meetings – also known as molecular tumor boards – we sit alongside pathologists, biologists, and bioinformaticians to make decisions



In the new world of NGS, a new day for precision oncology is dawning…

about patient care. I foresee that NGS systems, especially coupled with rapid turnaround times, will allow us more decision-making flexibility when discussing patients' results. Instead of selecting treatments based on partial information, we will have all of the necessary data available at once, which will make us more efficient and effective overall.

"The less [biopsy] material you need up front, the better for everybody."

An important aspect of today's NGS-based molecular profiling is the percentage of failed tests – for instance, due to low sample quality. The Ion Torrent™ Genexus™ System holds the promise of reducing that percentage.

How could this affect your work?

From my perspective as an oncologist, it is extremely frustrating when we are told that not enough tumor content or DNA is available to generate a molecular report. This is especially true because we should avoid having patients re-biopsied to do molecular profiling; like any medical procedure, biopsies are not free from complications. Furthermore, in my role as a clinical researcher, I am acutely aware of the value of biological samples in the context of clinical trials and beyond. The less material you need up front, the better for everybody. If the sample is entirely used up in pre-screening, you have nothing left for downstream testing – and then you have to decide between putting the patient through another invasive procedure (if, indeed, a repeat biopsy is possible) or working with insufficient material to gather the necessary information. In clinical trials, it is especially important to use material wisely, because there is often a need to test additional biomarkers at a later stage of the study – so conservation is key.

How important is it for you that a platform is CE-IVD approved?

The quality assurance and robustness of the generated results, along with the trust you place in your colleagues in the laboratory, are vital to ensuring that all treatment decisions are made with full information and in the best interests of the patient.

The Ion Torrent™ Genexus™ System is for research use only.

PEER-TO-PEER,

Featuring George Lundberg

A well-known medical storyteller takes on the most difficult challenge: sharing his own story

Ivan Damjanov interviews George Lundberg

George Lundberg has a long and storied history not only in pathology, but also in medical writing. He spent 17 years as the editor of the Journal of the American Medical Association (JAMA), followed by a further decade as the editor of Medscape. Never shy of controversy, when he believes it will further the cause of pathology and laboratory medicine, he has seen plenty of career ups and downs and has emerged with his faith in the discipline intact. Here, he speaks with pathologist Ivan Damjanov about his career, his accomplishments, and his advice for those who wish to follow in his footsteps.

YOU'VE COME TO THE GOALS YOU SET AS A JUNIOR PATHOLOGIST?

As a pathology resident in San Antonio in about 1961, I was told by a staff pathologist that I had the potential to become chair of a medical school's pathology department. I felt flattered and intrigued, and I immediately established that as a career goal. When I assumed that role at the University of California, Davis in 1977, I felt fulfilled – and wildly energized.

As an associate professor at the University of Southern California, my chair told me that I had the ability to become the president of the American Society for Clinical Pathology (ASCP) and that I should think about it. As a result, I began to climb the ladder in organized pathology, serving on committees for both ASCP and the College of American Pathologists (CAP). My work with ASCP led to a position on the board of directors; my work with CAP did not. When I did ultimately become ASCP's president in 1990, I felt gratified and tried to do a good job – but the heavy lifting, and the major impacts of my work, took place on the way up, not at the top.

WOULD YOU DO IT THE SAME WAY AGAIN?

For the most part, yes; it has been a great ride! Other than deciding to become a physician at the age of five, I have done no specific career planning. The medical school I attended was the only one that both accepted me and was affordable. Internship in the Army was a preemptive strike to avoid the doctor draft, but it led to an 11-year career in Vietnam-era military pathology. My choice of a pathology residency in Texas came as a result of my need to be closer to my father (who had had a coronary) and mother (who was rattled by his illness).

"My advice is to be flexible, open-minded, and alert to unforeseen opportunities – and don't be afraid to make choices by intuition."

My professional life has largely been shaped by being open to opportunities and taking advantage of them as they appeared. I have rarely applied for jobs; most often, jobs found me and sometimes even convinced me to change career directions. My advice is to be flexible, open-minded, and alert to unforeseen opportunities – and don't be afraid to make choices by intuition.

DO YOU FEEL THAT YOU HAVE HAD AN IMPACT ON PATHOLOGY?

William Boyd taught us in medical school that cause and effect are very difficult to determine with certainty. Most outcomes are a result of myriad different forces. That said, I would like to think that my contributions had at least a small effect on the evolution of US pathology. These are specific actions I took that may have been impactful:

1. The 1975 book, "Managing the Patient-Focused Laboratory," aimed at helping to organize laboratories based on test turnaround times – not only because of technical capability, but also the need for the result to benefit clinical decision-making using patient focus committees.
2. The 1975 introduction of clinical algorithms to medicine via the regular "Toward Optimal Laboratory Use" column that ran for decades in JAMA and even resulted in a 1983 book called "Using the Clinical Laboratory in Medical Decision-Making."

In 2018, at the 50th anniversary of the founding of the UC Davis Department of Pathology. This image shows all five living chairs of the department.

WHAT WAS PATHOLOGY LIKE...

...in 1953

The autopsy was the centerpiece of the understanding and practice of pathology. It was performed on approximately half of all hospital deaths.

There was no laboratory automation.

We phlebotomists reused our venipuncture needles.

My first blood bank (in Tuscaloosa) segregated blood by race.

We used "special stains" to assist with anatomic pathology diagnosis beyond H&E.

Electron microscopes were not commonly used in medicine.

Certified medical technologists did exist within the American Society for Clinical Pathology.

Laboratory testing was expensive and sometimes difficult to accomplish.

...in 1969

The death plunge for non-forensic autopsies had just begun (2).

Technicon auto-analyzers and Coulter counters had revolutionized clinical chemistry and hematology.

Vacutainers and disposable needles were ubiquitous.

Medicare had integrated laboratories, blood banks, and hospitals – even in the South.

Histochemistry was beginning to supplant "special stains" as a diagnostic aid.

We were just beginning to use electron microscopy for kidney biopsies.

State licensing of medical technologists (in California) was an established routine.

With the debut of automation to cut costs, the growth of lab test use seemed out of control.

...Today

New technologies, such as molecular and digital autopsies, are expanding our options for death investigation.

Automation is routine in many laboratories and adoption is continually increasing.

We still use more advanced versions of Vacutainers and disposable needles.

All patients are treated equally, and discrimination is viewed negatively.

Immunohistochemistry and novel tissue biomarkers are on a steady rise.

We still use electron microscopy, as well as novel imaging technologies.

Medical technologists and other medical laboratory scientists are vital members of the laboratory medicine team.

We pay close attention to test utilization management and reflex testing so that only necessary tests are used.

"People entering pathology must recognize the vast and diverse career opportunities it offers."

3. The 1969 invention of the critical value concept of laboratory reporting that rapidly became a worldwide standard.
4. Coining the phrase "the brain-to-brain loop" for laboratory testing in 1971 to describe a global concept that is still updated 40 years later. This concept called attention to the critical pre-and post-analytical phases.
5. Placing pathologists in a position to guide physicians about what lab tests should (and should not) be ordered, and the meaning of the results, while simultaneously demanding an outcomes agenda for lab tests.
6. I first used computers in pathology in 1963, placed them into a clinical laboratory in 1966, and chaired the CAP Computer Committee throughout the 1970s – an undertaking whose effects should be obvious in today's digital age.
7. I started working in drug abuse in San Francisco in 1963. Media personality Art Linkletter's daughter died in 1969 as a result of a fall – it's believed that she jumped from a sixth-floor window in Santa Monica while high on LSD – and, at the same time, my colleagues and I were seeing up to 70 patients a day in the ER with suspected drug-related illnesses. We asked the Board of Supervisors to fund a 24/7 clinical toxicology laboratory, which became a model for the field.
8. Many of the issues we took on in my 17 years at JAMA affected the evolution of pathology. For instance, a public focus on the often-dreadful quality of physician office labs led directly to CLIA. We also led the national public health charge against tobacco and played a leading role in the international physician movement to prevent nuclear war. We converted peer review from an art into a science via the quadrennial International Congress on Peer Review in Scientific Publishing; we printed literally hundreds of articles about HIV and AIDS in the early days of the crisis; we launched the National Patient Safety movement; and we even invented open-access medical journals.
9. At JAMA in 1995 and Medscape after 1999, a group of us invented Internet medicine. Shortly thereafter, we conceived the webcast video editorial – concurrent text, audio, and video on the same web page. This was before YouTube, but everybody on the Internet uses this model now.
10. In 2010, at CollabRx, we built molecular disease models for melanoma and lung cancer and converted them into diagnostic and therapeutic decision tree web apps. In 2014, those became mobile apps ideal for use in patient-physician shared decision-making – applied precision oncology.
11. As editor-in-chief of JAMA, a position I held from 1982 to 1999, I had editorial responsibility for all the AMA journals. They wanted to discontinue Archives of Pathology and Laboratory Medicine because it was a money-loser. I fought to keep it. It was a free membership benefit for AMA members and very little money came from paid subscriptions or advertising revenue, so I convinced CAP, which did not have a journal, to subsidize the Archives and make it a CAP membership benefit. That satisfied the AMA for a few years – but some CAP leaders still wanted their own journal, so I convinced the AMA to sell the Archives to CAP for a dollar and convinced the leaders of CAP to take it over rather than found a new competitor. That arrangement is still in place today.
12. I am currently the President and Chair of the Lundberg Institute. We enjoy a terrific board of directors and advisory board and have presented a stellar annual lecture in collaboration with the Commonwealth Club of California in San Francisco for the past eight years. But we could do so much more. We have not engaged in succession planning; perhaps we should.

People entering pathology must recognize the vast and diverse career opportunities it offers. At one point, a pathologist was editor-in-chief of JAMA, another was editor-in-chief of the New England Journal of Medicine, another the Director of the National Library of Medicine, and others Deans of medical schools at Stanford and the University of Chicago. Think big!

"In the early 1950s, terms like 'quality control' and 'quality assurance' were absent."

TELL US ABOUT THE LUNDBERG INSTITUTE…

The Lundberg Institute (TLI) was founded in 2009 during the one "gap year" of my life. WebMD had laid off all the staff of the Medscape Journal of Medicine on its 10th birthday, declaring the end of a successful experiment in medicalpublishing (1). We had proven that it was feasible to create and sustain an exclusively electronic, open-access, primary-source, peer-reviewed general medical journal. It was the first such journal indexed in PubMed, Medline, and PubMedCentral – the debut of the medical Internet.

During my non-compete year, I needed to busy myself – and out of that gap came TLI. Our goal was to promote the patient-physician relationship and facilitate shared decision-making informed by the best possible evidence. The not-for-profit 501(c)(3) organization was founded by me, my spouse and former ASCP Publisher Patricia Lorimer Lundberg (who remains the CFO), Kathryn Watson (who remains the Secretary), and Peter Jensen (who remains a member of the Board of Directors). All early members of both boards were notable, and most remain to this day. Unfortunately, the initial lofty plans of TLI were truncated shortly after its founding by my taking on two serious and time-consuming jobs exactly one year after my Medscape Journal of Medicine buy-out.

The Board of Directors agreed that TLI should focus on educating the public about our mission by establishing an annual lectureship. Patti Lundberg developed relationships that opened the door to a nine-year (and counting) collaboration with the highly influential Commonwealth Club of California to host the annual lecture in San Francisco. We aim high for speakers and achieve consistent excellence: names like Don Berwick, Atul Gawande, Elliott Fisher, Leana Wen, and Ken Kizer grace the list. Who's next? As Yogi Berra famously said, "Predictions are hard to make, especially about the future." Never is that truer than when discussing TLI!

YOU'VE BEEN IN MEDICINE FOR NEARLY SEVEN DECADES. WHAT HAS CHANGED OVER TIME?

There are still buildings, patients, healthcare workers, equipment, supplies, power struggles, successes, failures, harassment, drug abuse, and administrative "processes" – but pretty much everything else has changed.

In the early 1950s, terms like "quality control" and "quality assurance" were absent. Those concepts and entities were invented and applied over the following half-century. Everything was cheap when I entered the world of medicine; there was no Medicare or Medicaid and not much private insurance. Technology was primitive and has now become overwhelmingly complex. Licensure, certification, inspections, and medical subspecialization existed, but were very early in their conception. Since then, a massive bureaucratization – both governmental and professional – has evolved. Vast riches have flowed in and been consumed by the most effective resource-trapping device ever invented: the voracious American medical-industrial complex.

Relatively small amounts of money were invested in every element of the enterprise. Over time, those dollar numbers soared. Were there population health benefits? Absolutely – but they were not proportional to the money invested. Not even close.

The notion of "medical ethics" as something distinct from common sense, the "golden rule," or other guides to behavior hardly existed. The impact of the Nuremberg War Crimes Trials had not yet entered common parlance. The Tuskegee syphilis experiment was underway. Human experimentation was common, without anything like "informed consent." This has all changed with masses of ethical writing and public laws and regulations about almost every detail of possible individual or organizational behavior. Is it now cumbersome and overwrought? Yes. But is it better? Certainly – for our patients, for us, and for our discipline.

WHERE ARE WE HEADING?

The field of pathology will continue to be "under the gun" economically, because purchasers and payors generally do not understand our value. Pathologists also tend to be soft-spoken scientist types who are not given to activism

FIFTY YEARS FROM NOW

George Lundberg's predictions for pathology in 2069

Human beings (even Americans) will still exist, having somehow escaped the seemingly inevitable nuclear war despite their consistently incompetent "leaders." We will have made major social, geographic, and economic adjustments to deal with the threat of global warming. As a result, we will be as much in need of pathology services as ever.

The autopsy – including many novel, high-tech methods – will have returned in full flower. There is no other way to close the loop for quality assessment, public health, patient safety, prudent use of resources, and precision medicine. In 50 years' time, I hope we will have realized this.

Money- and profit-driven American medicine will have been abolished many decades earlier. Health care will be an assumed right for all in developed countries – and, as a public good, we will have worked out some shifting middle ground of ethical expenditures in proportion to all other societal needs so that economics is a non-issue.

The human lifespan will have lengthened, but not by a great deal. Why? Because death will be even more accepted as normal, rather than feared and fought against. Nevertheless, preventing "premature death" will be an increasing priority. The goal will be for every person to die a natural, comfortable death.

Self-care will be the dominant approach to healthcare – and that includes self-directed laboratory medicine delivered largely through wearables. Pathologists will do constant research and development on molecular and genomic medicine. Cancer will not have been conquered, but scientifically informed prevention efforts will have superseded treatment. For those lab tests not handled by wearables, major clinical lab factories will report rapidly into seamless, interoperable, not-for-profit EMR systems – and those will not be owned or operated by any of the current capitalistic oligarchies.

Unfortunately, human behavior will continue to elude the notion of its being a "science." Obesity, sloth, diabetes, drug- and alcohol-induced diseases, violence, and sexual abuse will continue to pervade society. As a result, laboratory medicine will continue to help inform the proper handling of these maladies. Additionally, American gun owners will continue to exercise their misunderstood Second Amendment rights, so forensic examination of accidental, homicidal, and suicidal deaths will remain a major source of work for us.

These predictions may seem improbable, and it's true that they are limited. But they are also completely safe, because I won't be around to see if any of them turn out to be true – and neither will many of you.

UAB class reunion.

Bellagio, Lake Como, 1996. This image features the founders of the World Association of Medical Editors.

"To existing pathologists and laboratory medicine professionals, I say: be clinically relevant. Make a difference."

or aggressive bargaining. And, sometimes, frankly, what pathologists do may not be worth much money in the eyes of a bottom-line MBA business type – and those people tend to hold a lot of the cards – at least in American medicine. I think it would help if pathology and laboratory medicine were more visible and attractive to the next generation of physicians. To accomplish that, we need a more aggressive mindset. Don't be afraid to toot your own professional horn. If you've earned the attention, take it.

Is pathology a good career for current medical students? If they like science, the laboratory, data, diagnosis, quality assessment, quality assurance, patient safety, teaching, writing, managing people, truth-finding, truth-telling, are interested in any of the myriad subspecialty options our discipline encompasses, and have a high tolerance for administrative ambiguity, then absolutely. But just look at all those caveats…

To existing pathologists and laboratory medicine professionals, I say: be clinically relevant. Make a difference. Help clinicians help their patients. Encourage direct interaction with patients when it would be helpful. Help institutions do fewer, but more useful, lab tests. Be open to noting the clinical outcomes of performing lab tests, recognizing that most clinical lab tests do not need to be done; the results are either normal, negative, or unchanged from the previous test.

ON A SCALE FROM ONE TO 100, HOW OPTIMISTIC ARE YOU ABOUT PATHOLOGY'S FUTURE?

About 80. There is so much science of disease yet to be learned, and then applied, to improve the human condition. Pathology is at the fulcrum of all those challenges and opportunities.

I am more worried about clinical medicine in the US than I am about pathology. The forced economic industrialization of medical practice has de-professionalized medicine into almost a pure business. That condition must be temporary, because of the human need to trust learned professionals with their very lives. People know that they cannot trust businesses in the same way, which makes the present day an enormously threatening time for American physicians.

DO YOU THINK PATHOLOGISTS PARTICIPATE ENOUGH IN PUBLIC LIFE AND THE MEDIA?

Definitely not. During my time as an ASCP leader, we did organized outreach mentoring and taught lecture, radio, and TV communication skills. I am not sure whether it did any good – maybe for a few – but we should have ways to encourage pathologists and laboratory medicine professionals to reach out. We should do more role modeling and incentivize outreach.

First, though, we must endure this rough patch in the current American anti-science, anti-truth political and social environment. We can get through it by being among the leaders in speaking truth to power as our society bottoms out, recognizing the constant risk of scorn and ridicule. We can become health science advisors to our clubs and to school, town, county, state, and federal organizations. Be active in social media; become a blogger; have your own website; be available to your local public media; weigh in on discussion boards; help your local coroner's office; become an expert witness; run for elective offices; speak out; care!

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Ivan Damjanov is Professor of Pathology at the University of Kansas School of Medicine, Kansas City, USA.

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The Formalin Ban: From Lethal Threat to Unique Opportunity

How the so-called formalin ban almost caused a major patient safety issue in Europe

By Aurelio Ariza

In 2014, the European Commission upgraded formaldehyde's carcinogenicity and mutagenicity categories. Occupational safety departments started to ban formalin, leaving its future in healthcare uncertain – but swift action by pathologists and medical organizations led the European Parliament to change its outlook...

A variety of crucial issues relating to pathology and laboratory medicine are at the mercy of decisions made by European Union (EU) governing bodies. It is therefore essential to be aware of the mechanisms by which these governing bodies operate so that we can effectively safeguard the interests of both patients and laboratory personnel. An important case in point is the so-called "formalin ban."

The term itself invokes a lethal threat to the protracted intimacy between formalin and pathology. Indeed, ever since the European Commission issued a resolution that raised formaldehyde's carcinogenicity and mutagenicity levels in 2014, pathologists have felt uneasy. These changes stirred our fears of an impending mandatory end to the use of our favorite fixative. The uneasiness, however, was unevenly distributed across Europe, with perceived responses ranging from aloofness to overreaction. Once more, the rich diversity of Europe made itself fully apparent. This lack of clarity therefore begs the question: is the so-called formalin ban a myth or a reality?

Sifting fact from fiction

First of all, let's make it clear that the European Commission has never banned formalin. What the oft-quoted Commission Resolution (EU) No. 605/2014 actually did was change formaldehyde's classification as both a carcinogen and a mutagen. Specifically, its carcinogenicity was upgraded from category 2 (suspected of causing cancer) to category 1B (it may cause cancer), and its mutagenicity was newly assigned a category 2 (suspected of causing genetic defects) rating.

The EU resolution was issued mainly in consideration of furniture industry workers, who use formaldehyde at extremely high concentrations. It made no allusion to the use – much less the prohibition – of formaldehyde in the healthcare sector, where the concentrations used are much lower. In line with this, discussions in the European Parliament took place primarily in the context of the Employment and Social Affairs Committee (EMPL), and only secondarily in the setting of the Environment and Public Health Committee (ENVI).

So where did the supposed formalin ban in the healthcare sector come from? Seemingly, the formaldehyde classification changes contained in Resolution (EU) No. 605/2014 prompted occupational safety departments and trade unions to promote an across-the-board formalin ban, whose aim was to protect workers involved in any formalin-using task. Depending on the various countries' management models, however, the possibility of truly implementing a formalin ban in the healthcare sector ranged from nil (hence the cavalier attitude of some pathologists) to overwhelming (hence the alarmed reaction of many others). At the extreme end of the spectrum, countries such as France did, in fact, enact formalin-banning legislation with significant repercussions for the practice of pathology.

Pathologists strike back

Despite these differences among countries, common interest demands concerted action in an intertwined Europe where any issue rapidly spreads far and wide. Consequently, in 2016, the European Society of Pathology (ESP) and the Union of European Medical Specialists (UEMS) Section of Pathology issued a joint statement that

"The EU resolution was issued mainly in consideration of furniture industry workers, who use formaldehyde at extremely high concentrations. It made no allusion to its use in the healthcare sector, where the concentrations used are much lower."

contained stern warnings. For example, "the banning of formalin cannot be considered in the European health system without generating major harm to the quality of diagnosis for patients."

Thanks mainly to the efforts of Bernard Maillet, Treasurer of the UEMS, additional support for the ESP-UEMS joint statement was obtained from a variety of European medical organizations. These included the Association of European Hospital Physicians, the European Council of Medical Orders, the Standing Committee of European Doctors, the European Medical Students' Association, the European Federation of Salaried Doctors, and the European Union of General Practitioners (1).

Additionally, many people took strategic action that would break the stalemate and eventually lead to proper recognition by the European Parliament of formalin's role in medicine. This action was orchestrated by a number of individual pathologists – including ESP councilors, UEMS delegates, and presidents of pathology national societies – and their countries' representatives in Strasbourg. As a result, many members of the European Parliament (MEPs) – particularly those in the EMPL and ENVI committees – were made aware of the inescapable need for formalin in patient care.

An increasing amount of empathy and knowledge accompanied the subsequent discussions of the successive draft amendments, which were presented to the EMPL and ENVI committees by Spanish MEPs Javi López and Soledad Cabezón. These two members were extremely responsive to my persistent formalin-saving entreaties, which were deftly mediated by Jaime Medrano from

the International Department of Spain's Organización Médica Colegial.

The long march to a formalin-saving amendment

The following statement is part of one of the many draft amendments advocating formalin's unimpeded but judicious use: "Formalin is routinely used in healthcare facilities for standardized fixation of patients' tissue specimens, such as biopsies. The pathologist's diagnosis of a variety of diseases, including cancer, is based on the recognition of characteristic microscopic findings in formalin-fixed tissue. Moreover, criteria for the evaluation of diagnostic, prognostic, and predictive biomarkers have been progressively developed [over] many years, also in reference to formalin-fixed tissue. Validation of other fixatives putatively able to replace the crucial role of formalin in patients' care will require a number of years. Consequently, the healthcare sector must be explicitly exempt from a formalin ban that would result in multiple diagnostic errors and serious harm to countless European patients. Healthcare facilities must implement appropriate measures for keeping formalin exposure of their personnel within safe limits."

After multiple attempts and much debate, the EMPL Committee finally approved a compromise amendment in November 2018. Italian MEP Laura Agea was instrumental in reaching that groundbreaking amendment. The latter read as follows: "Formaldehyde fixatives are routinely used in European healthcare centers for the standardized fixation of tissue samples, given their convenience in handling, high degree of accuracy, and extreme adaptability, which have not been reached by any other group of fixatives so far. As a result, a pathologist's diagnosis of a variety of diseases, including cancer, is based on the recognition of microscopic traces in tissue fixed in a formaldehyde fixative. The concentrations of formaldehyde used in healthcare are minimal in comparison with those used in industry and, while healthcare centers in the Union should take all appropriate measures to keep formaldehyde exposure among their staff within safe limits, the healthcare sector should have no difficulty to respect the limit value set in the present Directive."

"The EU's recognition of the necessity and virtues of formalin, coupled with the simultaneous setting of limit values to minimize exposure, is a welcome conclusion to a five-year-long saga."

Unique opportunity

Finally, on March 27, 2019, the issue was settled by a European Parliament resolution declaring: "Formaldehyde fixatives are routinely used in the healthcare sector across the Union because of their convenience of handling, high degree of accuracy, and extreme adaptability. In some Member States, it is foreseeable that the healthcare sector will have difficulties in complying, in the short term, with a limit value of 0.37 mg/m^3 or 0.3 ppm. It is therefore appropriate to introduce for that sector a transitional period of five years, during which the limit value of 0.62 mg/m^3 or 0.5 ppm should apply. The healthcare sector should, however, minimize exposure to formaldehyde and is encouraged to respect the limit value of 0.37 mg/m^3 or 0.3 ppm during the transitional period where possible."

Following approval by the EMPL Committee, European Parliament Plenary Session, EU Council, and European Commission, the Member States have been informed of the EU's new position on formalin use and their obligation to comply. The EU's recognition of the necessity and virtues of formalin, coupled with the simultaneous setting of limit values to minimize exposure, is a welcome conclusion to a five-year-long saga. The lethal threat of a formalin ban has transformed into a unique opportunity to enhance the safety and visibility of pathology.

Such a happy outcome was only made possible by the positive response of our MEPs and the collective and personal efforts of the many European pathologists who cared enough to venture into the intricate maze of EU affairs. For the sake of European patients, let's keep engaged!

Aurelio Ariza is Secretary of the European Society of Pathology and a Professor and Senior Consultant in the Department of Pathology at Hospital Universitari Germans Trias i Pujol, Barcelona, Spain.

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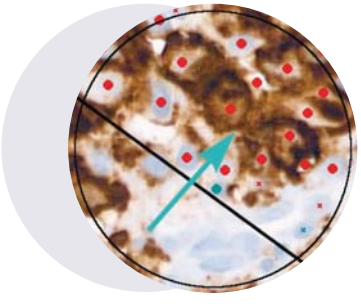

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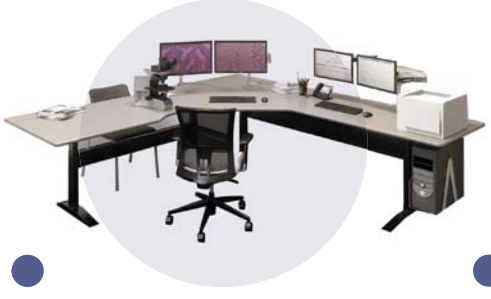

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A Digital Pathology Leader

Sitting Down With…Marilyn Bui, Anatomic/Clinical Pathologist and Scientific Director of the Analytic Microscopy Core at Moffitt Cancer Center, Tampa, Florida, USA

How did you find your way to pathology?

I became a medical doctor because it is a noble and humanitarian profession. Pathology attracted me because it is a specialty in which medicine, science, art, and humanity intertwine perfectly. Through pathology, I became a "doctor's doctor" – with the ability to leverage critical thinking, innovation, and investigational research to create new knowledge.

And digital pathology?

My first exposure to digital pathology in practice was using image analysis to interpret breast cancer immunohistochemical testing. My first experience in research digital pathology was my 2005 appointment as Scientific Director of the Analytic Microscopy Core (AMC). One of the AMC's key services is to support researchers in-whole slide image acquisition and analysis. To learn this novel technology, I joined the Digital Pathology Association (DPA), which fosters collaboration among pathologists, scientists, and industry to advance digital pathology.

For hundreds of years, pathologists' main tools were microscopes and H&E slides. The first revolution was the incorporation of immunohistochemistry into our practice; the second was molecular pathology. I am excited to practice pathology in the era of the third revolution: digital pathology and artificial intelligence (AI). I am grateful that my training, experience, and involvement in digital pathology have prepared me to embrace this transformation in research, teaching, and clinical practice.

Tell us about the Digital Pathology Association…

The Digital Pathology Association (DPA) is a nonprofit organization of pathologists, scientists, technologists, and industry representatives whose mission is to facilitate awareness, education, and adoption of digital pathology and AI in healthcare and life science. I joined the DPA to connect with other pathologists and scientists in this niche area, so that I could do a better job as Scientific Director of the AMC. After working as a volunteer board and executive committee member, I am now the association's president.

I am very proud of the DPA's members and leadership team. The talent, enthusiasm, collaborative spirit, and effectiveness are impressive for such a young society.

The DPA just hit 10 years old – how did you celebrate?

It was an honor and a privilege to cut the birthday cake for the DPA's 10th anniversary during my presidency – and I hope to continue building a successful team, fostering collaborations among members, and expanding the DPA's reach globally.

Pathology Visions is the DPA's annual showcase of technology and insightful scientific and educational presentations. The 2019 event attracted a record number of presenters, exhibitors, and attendees from around the world and featured talks on "Digital Pathology and Artificial Intelligence: The Evolution towards Digital Disruption of Diagnostic Pathology" and "Medical Artificial Intelligence at Scale: Changing Clinical Practice One Petabyte at a Time."

How does the DPA make a difference?

Through annual leadership strategic planning, our committees and task forces work to expand membership; form alliances to facilitate regulatory path clarity in computational pathology and AI applications; facilitate interoperability and connectivity; partner with allied societies in education; and expand our education portfolio. Every initiative is important, but our three most recent are the Alliance for Digital Pathology, our white papers, and the Digital Anatomic Pathology Academy.

The Alliance for Digital Pathology is a regulatory science initiative to harmonize and standardize digital pathology processes to speed up innovation to patients. The Alliance seeks participation from all stakeholders to identify key elements necessary to move the field forward.

The Digital Anatomic Pathology Academy is a free, web-based slide image teaching platform for pathology residents and fellows. It offers high-yield cases in various organ systems that trainees must know before their board certification exam. The slides can be used for unsupervised learning or incorporated into lectures. We hope the Academy will prepare the next generation of pathologists for the era of precision medicine in digital health.

Improved patient care is presumably the ultimate motivator for the digital transition…

I pursued a career as a physician to take care of patients. Being a pathologist allows me to connect with patients on a much deeper level – sometimes at a DNA level! I strive to provide the best possible care to our patients – and my recent Distinguished Patient Care Award from the College of American Pathologists reassures me that I'm on the right track!

Digital pathology and AI are here to stay. Our choice to embrace this transformative technology will extend the longevity and relevance of our specialty. With pathologist numbers decreasing and diagnostic demand on the rise, digital pathology is more important than ever – and the transition is only a matter of time. As individual pathologists, we can prepare ourselves by becoming familiar with digital sign-out and by actively engaging in the creation and validation of digital pathology applications. That way, we can oversee the safety and efficacy of computational pathology and AI – and help improve the services we offer our patients.

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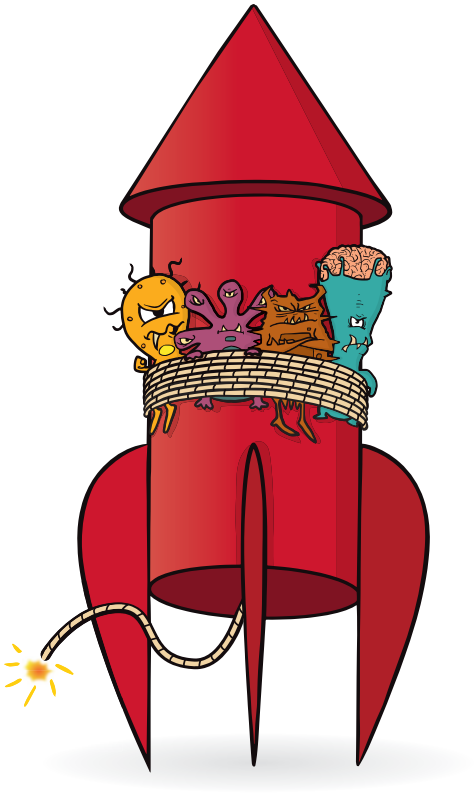

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