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COVER STORY

SAFETY

MRI SAFETY,
CREATING SAFER HEALTHCARE,
CONFRONTING RISK, DOSE CREEP,
RADIOLOGY EVENTS REGISTER,
CREATING A SAFETY NETWORK,
TELEMEDICINE DEPLOYMENT

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CREATING SAFER HEALTHCARE

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Healthcare professionals have long recognised the benefits of fostering wellness—that is, focusing on what is going right—instead of just trying to head off, or ameliorate, what might otherwise go wrong. By understanding the key determinants of good health we can keep as many patients as possible out of doctor's surgeries and hospitals, and greatly reduce the burden of preventable diseases and ill health. In patient safety, we can, and should, be doing much the same thing.

Although it may not seem immediately apparent, a similar focus on success is the best way to tackle the seemingly intractable problem of harm to patients due to adverse events in modern healthcare systems. As many as one in 10 patients in hospitals are currently harmed by care; between seven and 10 percent of patients acquire infections in hospital, and the World Health Organization estimates 20-40% of all health spending is wasted due to poor quality care.

To break this impasse we need to change how we do things. To date we have defined safety as a state in which as few things as possible go wrong, or what we call 'Safety-I'. When we do experience an adverse event or accident, we zoom in on that particular event, and work backwards to identify the exact point at which a process was derailed, often finding that 'human error' played a part. Consequently we often cast people as potential liabilities.

By isolating adverse events in this way, we assume we can both understand and learn from our mistakes and so prevent them recurring. Yet virtually no serious problem ever eventuates in precisely the same way again. Meanwhile we are overlooking what is in plain sight.

Most of the time everything goes right. But no one stops to ask clinicians "How do you manage to do that?" day in and day out, within incredibly complex systems that operate in partly degraded states under considerable pressure. Our doctors, nurses, administrators and support staff are overwhelmingly committed to their patients and to safety, and almost always pull it off.

Yet we don't invest in research that could offer us invaluable insights into how our health systems manage to get millions and millions of encounters right every day; that is, what a health system looks like when it's performing as it should, flexing and adjusting to accommodate the unexpected while still achieving its goals. Consequently, we miss the opportunity to improve safety by facilitating and supporting successes.

Our familiar but outdated Safety-I approach recapitulates the thinking in safety critical industries like aviation and nuclear power in the late 20th century, when systems were less complex. We assumed neat, stable models of cause-effect relations could be used to identify a faulty part (or player) and replace it—the so-called 'find and fix' approach. But in healthcare today, clinical work is carried out within dynamic webs of constant interaction between many different professionals and patients interfacing with increasingly complex healthcare technologies, communication systems and equipment.

In such fast moving and often unpredictable environments it is, in fact, people—individually and collectively—who are our key safety asset. The unique ability of humans to constantly adjust their performance to variable conditions and so ensure that as many things as possible go right is what we call a 'Safety-II' perspective. In a 'Safety-II' world, research seeks to reveal how things usually go right, as the basis for explaining how things occasionally go wrong.

Worldwide we have made some initial progress towards understanding success. The development of standard operating protocols and clinical guidelines and the implementation of simple but effective 'best practice' in hand hygiene, for example, has undoubtedly saved many lives. But slavish adherence to increasingly voluminous and often piecemeal guidelines is an obstacle to flexible, intuitive, effective care. Proceduralisation cannot prevent the adverse events that continue to impose phenomenal costs on stretched health budgets and unacceptable burdens on patients and their families.

We need the more holistic approach that Safety-II promises. A good starting point for this is to simply spend more time looking at what goes right as well as what goes wrong. We'll learn far more from what works well than from what fails. ■

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ESGAR 2015

A platform for personal and scientific exchange, the ESGAR Annual Meeting has become the largest and most prestigious gastrointestinal (GI) radiology meeting in Europe. With its high standard education and scientific programme it is the best place to learn about the latest advances in the fields of gastrointestional and abdominal radiology. The Annual Meeting advances the study of gastrointestinal and abdominal imaging and intervention in Europe by encouraging radiological and clinical excellence, teaching and research. It will create links with abdominal radiologists from other continents and with other Societies in the field of abdominal surgery, gastroenterology and hepatology.

The 26th ESGAR Annual Meeting and Postgraduate Course is held from June 9 – 12, 2015 in Paris, France. The ESGAR Programme Committee has put together an outstanding programme of new science in gastrointestinal and abdominal radiology.

Postgraduate Courses

The highlights of ESGAR 2015 will be the two Postgraduate Courses on Tuesday, June 09, 2015 on *Magnetic resonance of the abdomen: from the protocol to the report* and *GI oncologic imaging: from diagnosis to intervention*. Lecture sessions will address updates on rectal cancer imaging, the postoperative abdomen, inflammatory bowel disease, tumour respectability criteria, liver metastases and the paediatric abdomen.

Sessions and Worshops

There will also be interventional sessions on recent advances in hepatocellular carcinoma intervention, liver complications and management and practical biliary interventions as well as video case sessions. The programme is further enriched by interactive and innovative workshops on hot topics such as diffusion weighted imaging, contrast-enhanced ultrasound (CEUS) and CT colonography.

School of ESGAR

Another major innovation is the newly developed *School of ESGAR*. This is a comprehensive list of lectures covering the programme of the European Training Curriculum and is dedicated to those who are close to their board examination. We believe that this innovation will accompany the increasing interest of radiologists in training for attending the ESGAR Annual Meeting.

We look forward to welcoming you in Paris!

EHR Portal:
The Gateway to Integrated Care

Interview with Joost Felix, Lead Product Manager, and Jörg Schwarz, Global Business Development Director, Agfa HealthCare

With the launch of its new electronic health record (EHR) Portal, Agfa HealthCare is taking customers on a journey towards an integrated care solution. Easy to implement, yet providing a comprehensive road map, the EHR Portal integrates the experience and knowledge Agfa HealthCare has acquired in its long history, to drive towards the future of healthcare delivery with an architecture that can be extended into the entire care continuum. Co-project leaders Joost Felix and Jörg Schwarz explain:

> “All functionalities of the EHR Portal are available on mobile devices, thanks to the native mobile interfaces for Google Android and Apple iPhone mobile digital devices.”

JOOST FELIX
Lead Product Manager, Agfa HealthCare

Can you explain what the EHR Portal is?

Joost: With the Portal, all care providers – physicians, nurses, physiotherapists, etc. – as well as the patients themselves can access health information, using an interface that is easy and clear to read and is focused on the patient. It provides an overview of information coming from different healthcare sources: hospitals, laboratories, imaging centers, etc. That is what it currently does. But there is an underlying Health Information Exchange (HIE) architecture that also allows the information to be aggregated on a higher level.

Jörg: It can pull and extract the information needed from different individual records and present it together in a very user-friendly way. So if you want the history of the patient’s lipid panel, you don’t have to sift through pages and pages of lab records: you get the most recent results of whatever you are looking for. And the patient or caregiver can see all of the patient’s information in one place.
But that is just the start. This is actually the first product in a new range called ‘Agfa HealthCare 360’. This means that, while the EHR Portal provides excellent and important value now to healthcare providers, we have a planned evolutionary path that will in the future integrate all clinical players, including social services, pharmacies, etc. plus all imaging providers such as mammography and pathology.

Joost: That’s why we call the EHR Portal the ‘Gateway to Integrated Care’.

What is the technology behind the EHR Portal?

Jörg: The EHR Portal is a web-enabled software platform that can be installed either at the customer’s premises, or we can host it for the customer, with a service level agreement.

Joost: It can be integrated with both information systems like ORBIS* and HYDMEDIA** and with Enterprise Imaging. Combined with the XERO Viewer***, it provides high quality images. Radiologists want to see not only images but all kinds of information, such as lab results and patient diagnoses, which provides a greater context for the medical images. But it is up to the customer how and with what systems they want it to be integrated. That means it is scalable, too. It can be used with their current systems, and then be integrated with new products and solutions as they add them.

How is the EHR Portal answering the specific needs of hospitals and hospital groups?

Joost: Hospitals and hospital networks are asking us “How can we integrate with our referring physicians, how can we get results to them? How can we establish and strengthen our relationship with our patients? How can we keep onboard new patients more easily, for them and for us?” Hospitals don’t want departmental systems, they want enterprise-wide solutions.

Jörg: Agfa HealthCare has a lot of great IT and Imaging products and solutions. With the EHR Portal, we are providing an umbrella that brings them all together, whatever solutions the customer has or needs. But it isn’t a product that is intended to do just one thing: it has been designed to grow and evolve in order to continue the healthcare story.

Joost: And it’s not just for Agfa HealthCare products! We are known as a company that makes products supporting standards, such as DICOM, IHE, etc. that allow other vendors to integrate their products with ours. That is true for the EHR Portal, too. A non-Agfa HealthCare picture archiving and communication system (PACS) can share images, a non-Agfa electronic medical record (EMR) can send results... So it fits into any hospital, regardless of what solutions they have.

Jörg: The EHR Portal also lets hospitals realize significant cost reductions, by making all information, including imaging, available where and when it is needed, and helping to eliminate redundant procedures. To take one example: if surgeons are preparing an intervention and cannot find an image that was taken three weeks ago, they might have to order another. We have studies that show that with the EHR Portal functionality, a hospital can reduce redundant images by up to 2% of the entire imaging volume. For a high-volume imaging environment, that is an enormous savings; in some cases enough to pay for the portal itself!

Why is Agfa HealthCare the right company to accompany the healthcare provider into an integrated care future?

Jörg: With the EHR Portal, we are taking proven Agfa HealthCare expertise and experience, and turning them in a new direction for our company: a direction that our customers, the healthcare

> “The EHR Portal is a web-enabled software platform that can be installed either at the customer’s premises, or we can host it for the customer, with a service level agreement.”

JÖRG SCHWARZ,
Global Business Development Director, Agfa HealthCare

providers, both want and need. Our IT solutions are already about sharing information in multiple hospitals, in a clinical, relevant way. In imaging, we have multiple regional projects that are also about sharing. Our clinical expertise is demonstrated by the over 1000 hospitals that use our EMR and over 2500 that work with our PACS systems. With our proven experience, we have a broader outlook, vision and capability – which is what you need for integrated care.

Joost: So on the one hand it is a new product, but it is really built on all the different and proven elements and experiences Agfa HealthCare already has.

Can it be used on mobile devices, smartphones, etc.?

Joost: Absolutely! All functionalities of the EHR Portal are available on mobile devices, thanks to the native mobile interfaces for Google Android and Apple iPhone mobile digital devices. The user experience is adapted to the mobile device, but the functionality is the same. So the screen is sized differently, but the pertinent information, such as lab results, is adapted to fit.

Jörg: Some smartphones have amazing image resolution these days, great for looking at high quality images. There is also an instant messaging system that is even better than email for a mobile environment, for sending short messages and collaborating with peers.

How will the EHR Portal help lead the way to integrated care?

Joost: The first step is the total overview of the patient care, not just of what comes from the care provider’s own hospital or clinic, but all along the care continuum. This is what the EHR Portal will provide. The second step, still to come, will then be to include the activity-driven workflows.

Jörg: Then there is a third aspect: adding social care. Integrated care incorporates not only acute care, e.g., within the hospital, but also preventative and elective care. The caregiver’s goal is to improve outcomes and prevent the patient from coming back to the hospital for the same problem, and to prevent severe escalations, like emergency room visits. So the patient’s information needs to be available not just within the hospital but also to whoever will be involved in the patient’s ongoing wellbeing. This could be a home nurse, a physiotherapist, even a relative who will be making sure the patient takes the prescribed medicine, makes it to the scheduled appointments, everything.

That’s our vision of the way forward, and with the EHR Portal we and the care providers have a road map to achieve it.

The EHR Portal provides both a Patient View and a Clinical View

PATIENT VIEW:
The patient can:

- Look at their own images, results and other reports;
- Share results securely with another doctor to get a second opinion;
- Give access to their results on the EHR Portal to a caregiver;
- Upload information from e.g., wearable activity trackers or CDs provided by another doctor.

Clinical View:
Provides the clinician:

- All of the Patient View functions
- A work list with an easy overview of all patients;
- Certain key performance indicators (KPIs) based on embedded analytics;
- Peer-to-peer communication with other providers;
- A role-based framework that allows the care providers to operate within the local legislative framework and their internal processes.

*ORBIS is not available in Canada and the US.
**HYDMEDIA is not available in the US.
***XERO Viewer is pending 510(k) clearance in the US and not currently available in Canada.

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ESC CONGRESS 2015: LONDON CALLING

Bringing the fight against cardiovascular disease to the vibrant city of London between August 29 and September 2, the ESC Congress 2015 will focus on patient care this year and spotlight "Environment and the Heart" to highlight the many different kinds of interactions between the Environment and Cardiovascular Diseases.

By presenting, sharing, and debating on the latest science and research in cardiology, attendees will look at how the lives of patients can be improved with the most timely and significant advances in prevention, diagnosis and treatment of cardiovascular disease.

According to Prof. Fausto J Pinto, ESC President, and Geneviève Derumeaux, Congress Programme Committee Chairperson, the scientific programme will be practice-orientated and interactive, enabling cardiologists to equate the presented science to their professional practice.

New This Year

- The **Guidelines in Practice** sessions this year include: **My NCS@ESC**

This programme highlights the contribution of National Cardiac Societies to the ESC Congress. Seven societies have each designed their "My NCS@ESC" track – a series of 'Guidelines in Daily Practice' sessions based on the 2013/2014 ESC Clinical Practice Guidelines as well as the new 2015 Guidelines.

- Part of the **ESC Young Communities** sessions: **International Young Community**

The Cardiologists of Tomorrow as well as the Scientists of Tomorrow have prepared sessions in collaboration with the Young Community from Brazil, the Young Community from Japan as well as the British Young Community.

- Within the **Expert Sessions** series: **Science@Breakfast**

What a great way to start the day! Wake up your brain with breakfast and discussion. A unique opportunity for intense interaction between a small audience and two experts addressing a specific current issue. These sessions will take place between 07:30 and 08:15 in the Hub.

Virtual Reach

Last year's congress internet statistics are impressive, with close to 195,000 online live views on the ESC website and a social media reach of almost 30 million people. The dedicated ESC Congress 365 section received over 808,000 page views in 2014 and, based on that success, it will continue to feature prominently during the London event and beyond as a gateway to thousands of webcasts, slides, abstracts and reports. No subscription needed!

Exhibition and Industry

The ExCeL's exhibition space will welcome over 200 international companies. They will present the latest, greatest and most cutting-edge in cardiovascular therapies, technologies and related services in an animated, educational exhibition area.

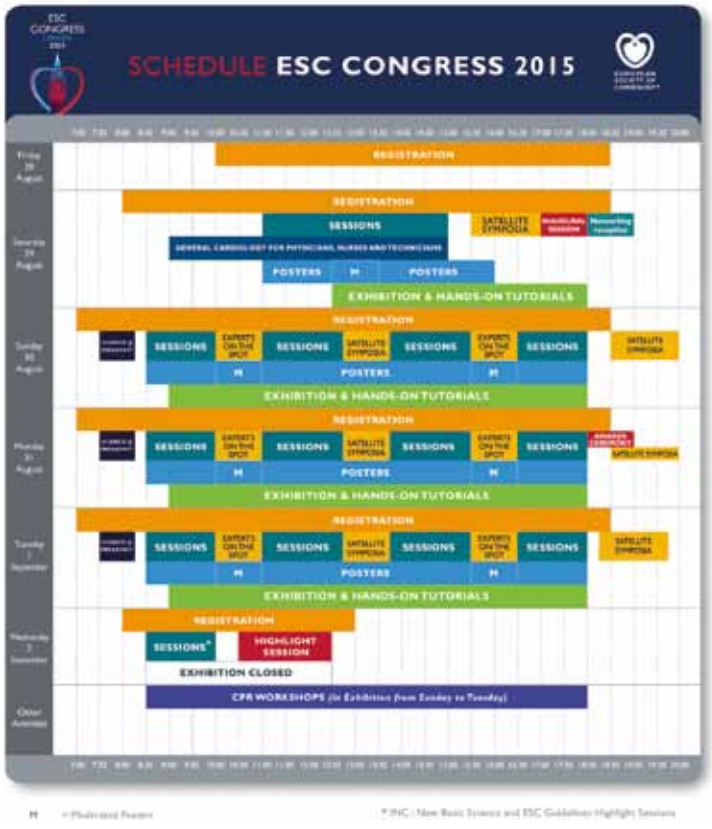
Industry-sponsored sessions are approved by the ESC Congress Programme Committee, and will offer key insight into the latest scientific developments for cardiovascular care.

The hands-on tutorials are organised by supporting companies (also approved by the ESC Congress Programme Committee). These intensive practical tutorials will allow attendees to gain first-hand knowledge by learning from industry experts on imaging and device techniques relevant to them.

Interaction between experts and delegates is ensured in the 'Experts on the Spot' Satellite Symposia.

Advance Programme

The 2015 advance programme is online; scan this QR code to see what's on at the ESC Congress 2015:



eHEALTH WEEK 2015 & WoHIT

More Than Two Events in One

The High Level eHealth Conference is the largest pan-European conference of its kind: an all-encompassing event focusing on leadership and the continuum of care – healthcare from the home to the hospital.

It is organised by the Latvian Ministry of Health and the Latvian Presidency of the Council of the European Union, and scheduled alongside WoHIT - World of Health IT Conference & Exhibition, which is organised by HIMSS Europe. Both events take place in Riga's International Exhibition Centre Kipsala from May 11 to 13, 2015.

Attracting over 2000 international delegates and 75 exhibitors, the congress will welcome global decision makers from public and private healthcare sectors, clinicians, hospital and IT managers and VIP guests.

Apart from an industry exhibition that includes country pavilions from all over the world, endless international networking opportunities can also be had at these events:

mhealth Summit Europe 2015

Monday, 11 May, 9:00 - 14:15 and **Tuesday, 12 May, 9:00 - 12:00**

Reflecting the fact that mHealth and eHealth will be coming together in the near future, this summit is now an integral part of the main event. It represents a unique opportunity to learn about the latest advances in health IT and how mHealth fits into the bigger picture. Focusing on "Energising the mHealth Agenda in Europe", some highly anticipated topics include:

- mHealth and Big Data – how can we unite all patient data to accomplish personalised care?
- mHealth in Europe – one size does not fit all?
- Who apart from patients has interest in using mHealth? Who should be driving and paying for mHealth?

(mHealth Summit Europe requires additional registration and is available at an additional fee).

EU SME eHealth Competition

Monday, 11 May, 09:00 - 13:00

A satellite event of the conference and endorsed by the Health and Wellbeing Unit of the European Commission, the eHealth Competition is an initiative that rewards the best eHealth/mHealth solutions produced by European SMEs. It recognises the best eHealth SMEs and supports their business success by giving them visibility together with marketing opportunities to attract customers, partners and external capital (registration required).

Joint HL7-EFMI Workshop

Monday, 11 May, 12:30 - 14:15

"Interoperability in Action: Information + Integration = Innovation?"

A debate on how rethinking interoperability standards and continuing education can bridge divides, change cultures, and open markets. Perspectives from health management, education, industry, government and standardisation present challenges and opportunities, as liberation of data drives social and technological innovation.

Workshop from Garage to Market

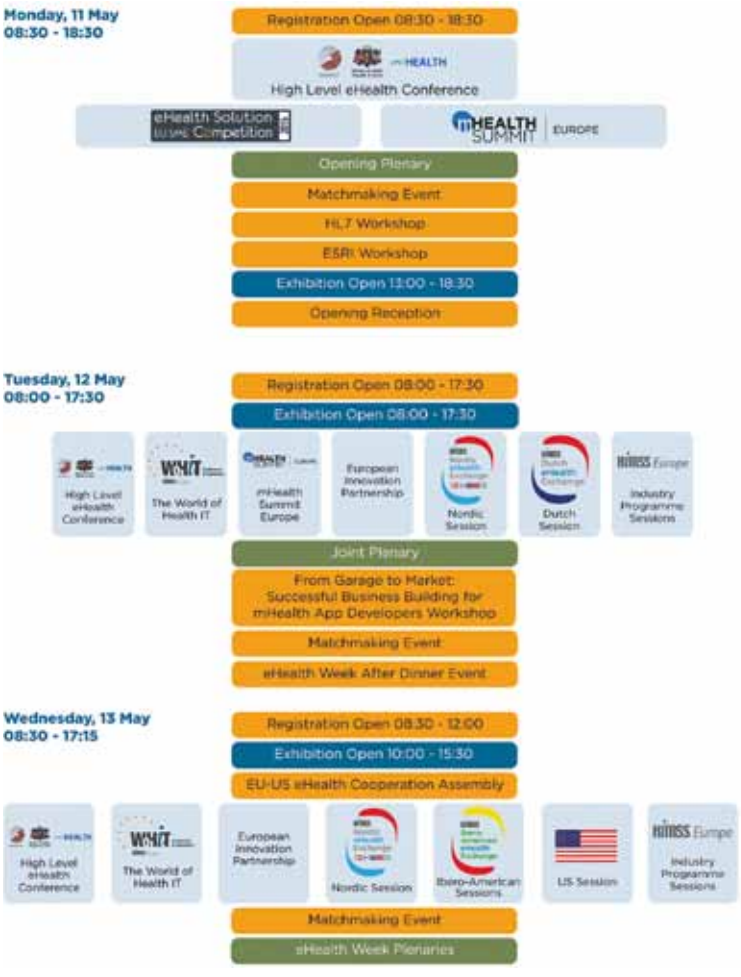
Tuesday, 12 May, 13:00 - 17:00

The overall objective of the workshop is to enable participants to develop successful go-to-market and business development strategies, including legal requirements and implications. Adopting the perspective of mHealth app and device developers, the first part will show pathways to approval in the European Union and in the US. The second part of the session will examine and discuss how to create sustainable mHealth commercial cases, which meet the needs of patients, clinicians and providers (registration required, €80.00 additional fee applies).

EU-US eHealth Cooperation Assembly

Wednesday, 13 May, 10:45 - 16:00

The 6th eHealth/Health IT Cooperation Assembly will give participants an opportunity to hear at first hand about the progress of the Roadmap to strengthen transatlantic cooperation in eHealth/Health IT. The event will focus on two work streams of the Roadmap - interoperability and standards for Electronic Health Records and Healthcare Workforce Skills. ■



TOMOSYNTHESIS FOR BREAST CANCER SCREENING PROGRAMS

MANAGEMENT FACTORS

Early adopters of digital breast tomosynthesis in Spanish and Italian breast cancer screening programs are confident that potential organisational limitations can be overcome in order to maximise the benefits of increased cancer detection rate and reduced recall rates.

Dr. Marina Álvarez
Reina Sofia Hospital
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Dr. Daniela Bernardi
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Key Implementation Factors

- Impact of organizational changes
- Technology feasibility in the screening program
- Costs/replacement cycle for mammographic units in the screening program
- Acceptance by the medical team
- Acquisition time
- Reading time
- Results in sensitivity and specificity
- Acceptance by the patient

The Spanish experience

Dr. Marina Álvarez
Reina Sofia Hospital
Córdoba, Spain

Dr. Sara Romero
IBIDIC

The Andalucía region of Spain set up its mammography screening program in 1995, achieving full coverage in 2005. Screening is offered to a population of 650,000 women between the ages of 50 and 69, every two years, and independent double reading is standard. The centre in Córdoba serves a population of 75,000 women.

The Cordoba centre recently installed a Hologic tomosynthesis unit in order to perform research and demonstrate that it is feasible screen with tomosynthesis with the same level of security and results, or probably better, than with mammography.

While the clinical benefit of tomosynthesis is clear, introducing the equipment was not without its barriers for our program.
We made organisational changes, provided training for the radiographers and radiologists, and offered special information for the women coming for screening.

Results

Once we complete our research study, we will publish our results. The implementation has shown that radiographers have accepted the technique, radiologists have adapted, and 98% of women agreed to participate. Radiation doses are within the admissible limit and our results in sensitivity and specificity are promising.

	N. cancers	CDR %	p	↑ DCR% related to 2D/3D
Overall (7294 screens)				
2D alone	39	5.3 (3.8-7.3)		
2D/3D	59	8.1 (6.2-10.4)	<0.0001	2.7 (1.7-4.2)

Table 1. Results from the STORM trial
Source: Ciatto et al. 2013.

The Italian experience

Dr. Daniela Bernardi
U.O. Senologica Clinica e Screening mammografico
Dipartimento di Radiologia
Trento, Italy

The Screening with Tomosynthesis OR standard Mammography (STORM) trial compared two different screen reading modalities used sequentially: 2D mammography alone and integrated 2D/DBT mammography.

Using integrated 2D/3D mammography to screen 7294 women we detected 59 cancers, 20 more cancers compared to 2D mammography alone, an increase in cancer detection rate of 2.7 per thousand (Table 1). Before introducing DBT to our screening program we needed to overcome the limitations, namely increased acquisition times, increased reading time and higher radiation dose to the breast.

Acquisition Time

We evaluated the impact of DBT on the radiographer's activity and compared it to the time needed to acquire 2D mammography images (Table 2). We calculated that the time increases by 26%. However, this included the time for women to get undressed prior to the examination and dressed afterwards. Further calculations showed that the realistic impact is 10% more time to do a combo mammogram, which in the context of a screening program is not so significant.

ACQUISITION TIMES
7 expert radiographers, based on 20 screening examinations
Selenia Dimensions (Hologic, Bedford, Mass) DBT system

TSRM	Tempi medi
2D	3' 13"
2D + 3D	4' 03"
≠ 2D + 3D vs 2D	+49"
≠ % 2D + 3D vs 2D	+26%

Table 2.
Source: Bernardi et al. 2012

"Things are going well"

Dr. Marina Álvarez

Reading Time

We calculated that reading 2D + 3D images takes double the time compared to 2D mammography. Our results were similar to those reported in the Oslo trial (Skaane et al. 2013) (Table 3). This compares to the study by Dang et al (2014), which reported an increase in reading time of less than 50%. We consider 50% more time is realistic, because we radiologists experience a learning curve, and after gaining experience we are able to reduce the reading time for DBT. There were similar initial increases (+75%) in reading time when services moved from screen field mammography to digital mammography (eg. Ciatto 2006).

READING TIMES

- 3 dedicated screening radiologists (> 50,000 read)
- 100 cases (negatives seeded with cancers, 9:1), 2D and 2D + 3D
- four sets of 25

Radiologist	A	B	C	Average
2D	41' 28"	45' 32"	76' 10"	54' 23"
2D + 3D	133' 06"	100' 11"	150' 16"	127' 51"
≠ 2D + 3D vs 2D	91' 38"	54' 39"	74' 06"	73' 28"
≠ % 2D + 3D vs 2D	+220%	"120%	+97%	+135%

Table 3.
Source: Bernadi et al. 2012

Radiation Dose

The dose administered during the DBT mammography projection is equal to the dose administered during 2D Mammography in the same compression. So using integrated 2D/DBT mammography gives the patient double the dose.

There are two possible solutions. The first is to acquire DBT Mammography alone, and the second, possibly more realistic, solution is to use reconstructed 2D images from the data acquired during the DBT exposure. Thus the first software gets a pseudo 3D reconstruction of the breast with the reconstruction of the different slices of the breast, and the second software gets the reconstruction of synthesized 2D mammography using C-view™ software. We are running the STORM 2 trial to compare the results of the different reading of 2D + DBT Mammography and synthesized 2D + DBT mammography, with double blind and sequential reading by four readers. The preliminary results showed an increase in the proportion of cancers detected of 22% (6/27), with no statistical significance.

Screening Program Re-Organisation

The Trento mammographic screening service started in October 2000. Women aged 50-69 are invited to one of seven screening centres. Initially the dedicated technicians travelled from the main centre in Trento to the peripheral sites. All readings were centralized in the Trento screening unit and performed by fully dedicated breast radiologists using double blind reading.

When our service started we installed analogue mammography units, and switched to full-screen digital mammography in Trento and indirect mammography using CR systems in the peripheral sites in 2005. In 2011 we installed our first DBT unit. By 2014 we needed to change the analogue mammography units, and we decided to install DBT on the basis of our own interim results and the Oslo trial.

With the cost of installing DBT there was a risk of underutilisation of these hi-tech machines if we installed DBT units in all 7 screening centres. Therefore, we decided to adopt only 3 DBT units across the service. The radiographers no longer have to travel to all the peripheral sites, and the women are invited to the two main centres. The radiographers' shifts were changed from one shift per day to two. Now we work from 7:30 in the morning to 7:30 in the evening. This optimised the use of the DBT units and extended the time for women to have their appointments.

DISCLOSURE:
"Point-of-View" articles promote Leadership Engagement and they are part of the HealthManagement.org Corporate Engagement Programme

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"The safe modality." That's what MRI is frequently referred to as. In a profession (and larger populace) focused on ionising radiation risks, MRI's exclusive use of non-ionising magnetic fields and radiofrequency energies makes it an appealing alternative to many x-ray based imaging modalities, particularly for young and repeating imaging patients. However, the absence of ionising radiation in MRI does not equate to an absence of risks to patients (or radiographers).

MRI Adverse Events

As anyone who has worked in MRI for any length of time can tell you, there is no shortage of anecdotes about MRI accidents or injuries: from cryogens, magnetically-induced projectiles, or burns. There do appear to be a small number of touchstone anecdotes, such as the oxygen tank fatality of a young boy in the U.S. in 2001, or much more recently the four-hour entrapment of two hospital employees in India (again, involving another ferrous oxygen tank), but other accident accounts are often dismissed or diminished as oral tradition legends, embellished for the retelling. The lack of knowledge of the actual risks of MRI, and the diminution of the validity of retold accounts of accidents, stem from a lack of data about MRI accidents.

Regulatory accident reporting regimes are frequently based on the notion that approved radiological devices are only able to cause harm if the device malfunctions, or is improperly administered during the exam. For MRI, however, the risks of projectiles, burns, or hearing damage are inherent to the proper operation of the MR scanner equipment. Does a flying ferromagnetic projectile represent a malfunction when the MR scanner's magnetic field is designed to be 'always on'? Widely acknowledged to be profoundly under-representative of the actual number of MRI accidents and injuries, regulatory reporting remains our best resource for assessing the effectiveness of safe MR practices.

Perhaps the most accessible adverse event data for MRI comes from the U.S. Food and Drug Administration (FDA). The FDA makes their reported approved-device-related incidents available online (**www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM**), and a year-over-year review of MRI accident data suggests that, over a 13-year period, MRI accident rates in the U.S. have plateaued at a rate that has grown nearly five times the rate for overall utilisation from the year 2000 (see Figure, p. 100).

While generalised MRI accident growth should be a cause for alarm in the industry, it is the nature of the specific accidents that reveals the keys to prevention.

With regard to accident prevention, MRI accidents and injuries reported in the United States are exceedingly rarely attributable to the MRI equipment malfunctioning. Like any

machine, MRI systems do experience errors, breakage, or malfunction that can cause harm, but when looked at in the context of the total number of adverse events, it is clear that other aspects of bolstering MR safety will have more substantive positive effects on reducing accidents.

When evaluating two years of FDA MRI device injury accident reports, it was discovered that more than 85% of all reported injuries stemmed from RF burns, ferromagnetic projectiles, and hearing damage (**youtube.com/watch?v=c-iMRYXhlzg** - recorded research presentation to 2012 RSNA Annual Meeting, entitled "MRI Accidents & Adverse Events: Empirical Analysis of Frequency, Type, Severity, Trends, and Preventions"). In the overwhelming majority of cases of injury studied from that two-year period, existing best practice standards guiding operations and patient care would have prevented the injury, had they only been followed. In short, the phenomenon of MRI injury accidents is one of "pilot error," and not equipment malfunction, that is responsible for the overwhelming majority of injuries in the MRI setting.

Regulatory Background

Disturbingly, while there are established best practice guidance standards available for MRI that have provisions that can be shown to reduce accidents and injuries when followed, these standards have failed to be incorporated in many regulatory, licensure, or accreditation programmes for healthcare providers. In this instance, the moniker of "the safe modality" may have led governing boards and bodies to believe that requirements haven't been necessary to prevent MRI injury. After all, how could "the safe modality" possibly produce injuries?

Those regulations that do exist largely don't appear to be specifically shaped by the occurrence of injury accidents that continue to happen. Take, as an illustration, the single most substantial piece of MRI safety regulation to have been proposed anywhere in the world in the past decade, the EU's Physical Agents (EMF) Directive.

EU Physical Agents (EMF) Directive

The Physical Agents (EMF) Directive, while not targeted specifically towards MRI, purported to be safety legislation intended to diminish occupational exposure to non-ionising radiation. The effects of the EMF Directive on MRI, as originally proposed, would have been to substantially curtail the allowable working hours of MR radiographers, radically shifting the cost structure of providing MR services.

"REGULATORY REPORTING REMAINS OUR BEST RESOURCE FOR ASSESSING THE EFFECTIVENESS OF SAFE MR PRACTICES"

It was later revealed that the EMF portions of the Directive were not based on acute health risks, as originally stated, but rather were intended to be precautionary, based on small studies that weren't immediately relevant to the conditions found in clinical MRI. During the effort to postpone (and ultimately obtain an exemption for MRI from) the implementation of the EMF Directive, nearly a decade passed where the only regulatory effort of the EU purportedly on behalf of MR safety required the concerted effort of medical physicists, trade organisations, and healthcare providers themselves, to beat back service-impairing regulation. In short, fighting the EMF Directive stole nearly a decade of resources that might otherwise have been directed at the actual sources of MRI injury.

Accreditation

Accreditation regimes promote themselves as being overseers of both quality and safety, but the "safety" half of this promise is often not met for MRI. In the U.S., where accrediting agencies compete for healthcare providers' business, there are inherent disincentives to enacting new unilateral requirements (and thereby making competing accreditation organisations appear 'less onerous'). This is further complicated when an accreditation organisation simultaneously serves as a professional society for radiologists who have ownership interests in imaging facilities, equipment, and practices. The standards of practice described in the four-times published American College of Radiology's Guidance Document on MR Safe Practices (Expert Panel on MR Safety 2013) are not (as of the date of this publication) requirements of the ACR's own MR accreditation programme.

Prevention, Professionals and Credentialing

So, if one were to specifically target the source(s) of contemporary MRI accidents and injuries in order to better prevent them, where would one focus their efforts? Western MRI equipment is already profoundly reliable, and existing means of oversight of a healthcare enterprise or the image quality of a piece of MRI equipment neither seem effective nor practical routes towards enhancing safety, given the inherent conflicts of interest. If MR accidents and injuries could be prevented with existing best practices, and are - nearly universally - the result of lapses at the point of care, perhaps the focus on reducing MRI accidents should be directed to the MR professionals directly responsible for patient care.

Individually, and in groups, organisations within the MRI industry have begun by seeking to standardise definitions of the specific MR safety duties and knowledge attributed to radiologists, researchers, radiographers, and medical physicists responsible for the safety of patients or research subjects. The Medicines and Healthcare Products Regulatory Agency (MHRA), the Society of Radiographers (SOR), the British Association of MR Radiographers (BAMRR), and the Institute of Physics and Engineering in Medicine (IPEM) individually sought to codify these roles and responsibilities, with some agreement, but also significant conflicts, among their preliminary standards.

While international efforts are presently afoot to reconcile the different nomenclature and standards defining MR safety roles, the recently formed nonprofit American Board of Magnetic Resonance Safety (ABMRS), which was formed for the specific purpose of credentialing MR professionals in matters of safety, is both participating in the international effort, and already looking beyond it to what can be done with standardised MR safety roles.

While standardised definitions and roles will go a long way to shaping the future structure of MRI safety, unified terminology itself won't improve safety at the point of care. ABMRS seeks to turn these shared positions into actionable standards. Within a few months, ABMRS intends to begin a credentialing process, certifying MR safety professionals.

The ABMRS MR Safety Certified™ (MRSC™) credential will demonstrate a diplomate's competency within a range of MR safety topics, and to levels commensurate with

his/her role in responsibility for safety at the point of care. The organisation has published a syllabus/outline of the subject areas that will be subject to examination (http://abmrs.org/Syllabus.php). The exams are slated to present a mixture of didactic and scenario-based questions, intended to test a candidate's mastery of the science underpinning MR safety considerations, as well as their ability to translate scientific information into practical application.

This year, ABMRS will offer MR Safety Certified™ credentialing for three positions: MR Medical Director/Physician (MRMD), MR Safety Officer (MRSO) and MR Safety Expert (MRSE).

The MR Medical Director will be the only position with a prior credential requirement. Candidates for the MRMD exam must have, at the time of examination, either an MD or DO. This is due to the particular fiduciary and legal obligations specific to the physician's duty to the MR patient.

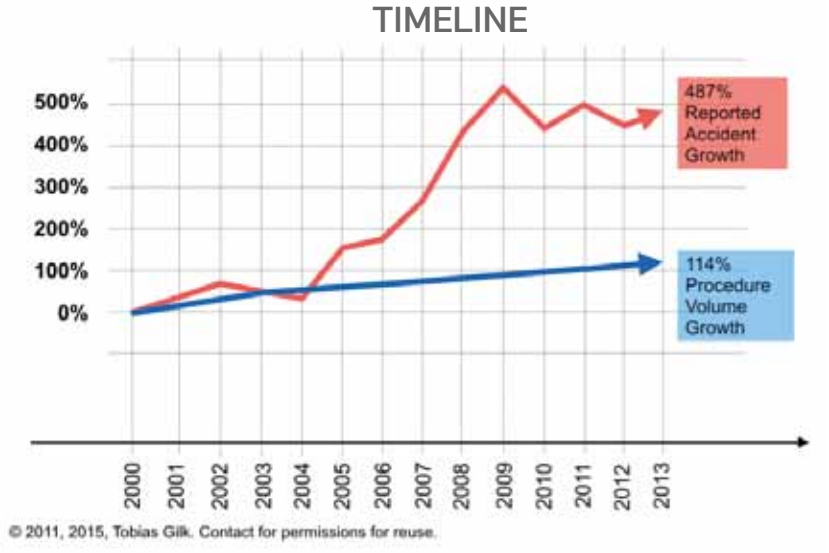
The MRSO and MRSE credentials will have no prior credential requirement. The MRSO examination will focus more on the specific application of MR safety knowledge in a direct patient care setting, and will be closely aligned with the responsibilities of an MR radiographer. The MRSE credential will weigh more heavily on the scientific aspects of MR safety, such as the physics of RF heating, and will be more aligned with the responsibilities of a consulting MR physicist.

ABMRS is planning to administer the exam twice this year, both times in the U.S., but the organisation's Board is already discussing the establishment of an international body. Dr. Emanuel Kanal, President of ABMRS, asked the nearly 300 attendees at a recent MR safety seminar in Sydney, Australia, about their personal interest in accreditation, and nearly every attendee indicated that they would seek it out, if available. Even should the formation of an international version of ABMRS take time to establish, discussions are already underway about offering the ABMRS credentialing exams outside the U.S.

It is the stated goal of the new organisation that every MR patient's exam should have the benefit of an MRSO overseeing the unit's delivery of care, an MRMD setting the policies and standards for clinical MR safety, and an MRSE to serve as a reference to both the MRSO and MRMD.

It is expected that providers of MRI services will begin to train and credential radiologists, lead researchers, radiographers, and medical physicists to help assure the appropriate knowledge assets are applied to enhancing safety in the MRI environment.

Based on what we know of the causes and preventions of MRI accidents, MRI is certainly capable of living up to its moniker of "the safe modality." We know that it is entirely possible to prevent the overwhelming majority of MRI injury accidents with existing best practice knowledge. The twin efforts of developing an international consensus on MRI safety roles and responsibilities, and credentialing those who fill those roles, offer the promise of even safer MR imaging in the years ahead.



"THE PHENOMENON OF MRI INJURY ACCIDENTS IS ONE OF 'PILOT ERROR,' NOT EQUIPMENT MALFUNCTION"

Key Points

- ✓ While generalised MRI accident growth should be a cause for alarm in the industry, it is the nature of the specific accidents that reveals the keys to prevention.
- ✓ More than 85% of all reported injuries stemmed from RF burns, ferromagnetic projectiles, and hearing damage. The phenomenon of MRI injury accidents is one of "pilot error" and not equipment malfunction.
- ✓ Established best practice guidance standards for MRI have provisions that are shown to reduce accidents and injuries when followed, but these standards have failed to be incorporated in many regulatory, licensure, or accreditation programmes for healthcare providers.
- ✓ The recently formed nonprofit American Board of Magnetic Resonance Safety (ABMRS) has been formed for the specific purpose of credentialing MR professionals in matters of safety.

Further Information

American Board of Magnetic Resonance Safety http://abmrs.org ■

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DELIVERING ON DOSE REDUCTION PROMISES

Dr Steven Mendelsohn, Chief Executive Officer/Medical Director of Zwanger-Pesiri Radiology, New York, explains his commitment to dose reduction and why he believes a change in attitudes will be driven by patients rather than radiology professionals.

Steven L. Mendelsohn, M.D.

With more than 60 years' experience in the field of Radiology, Zwanger-Pesiri is one of the largest non-hospital based radiology practices in the US today. Its staff of 60 radiologists comprises a number of specialties including Vascular Imaging, Interventional Radiology, Neuroradiology, Musculoskeletal Imaging, Abdominal Radiology, Cardiovascular Radiology and Breast Imaging.

With such a diverse and large patient base, and so many radiologists to manage, workflow is a key consideration, which is why the DX-D 300 DR system, with its Cesium Iodide detector technology and immediate image availability, was its solution of choice.

Workflow rather than dose reduction the initial driver

"We installed our first Agfa HealthCare DR solution, the DX-D 300, in our Elmont site in August of 2013. We chose it primarily because the workflow was so efficient, it was very easy for the technologists to set up and the images were quickly available. At the time, Agfa HealthCare was telling me about its dose reduction capabilities, but, to be frank, I didn't really believe them. But they kept on telling me about it so we decided to set up a study to compare the results.

"We had two competitive units from other suppliers available on the same site, so that provided the ideal opportunity to test out what we were being told."

The study parameters

The study sought to determine if the DX-D 300 required less exposure and patient dose versus two other systems in use at Zwanger-Pesiri Radiology. It also compared the doses used to those used for similar examinations in other facilities, based on available published studies[1]. It comprised PA Chest, Lateral Skull and AP Hand exposures taken on phantoms used to simulate patient exposures. In each case the phantom was positioned just as a patient would be and the standard exposure made.

Average dose reductions of 41% achieved

The results showed that while the amount varied depending on the type of exam, the average dose on most was 41% lower with the Agfa HealthCare system versus the other systems – an admittedly unexpected result for Zwanger-Pesiri.

Says Dr Mendelsohn, "Much to my surprise, the DX-D 300 was able to provide high image quality at a lower dose. For me, that's great in one way and possibly bad in another. It's good because we can promote our commitment to dose reduction to our patients and now have the figures to prove it, but," he adds laughingly, "it could possibly be bad because Agfa HealthCare will want to raise the price we pay! Although, to be honest, I would be prepared to pay a little more for the level of dose reduction we achieved. Agfa HealthCare has done a really wonderful job with it."

Dose reduction has become a compelling story

And dose reduction is a subject on which Dr Mendelsohn believes patients are becoming increasingly well-informed.

"Dose reduction has become a very compelling story; all radiologists need to be cognitive of patient dose and aware that patients are becoming better informed and will increasingly ask questions. But, change will ultimately be driven from the grass roots rather than by the radiologists themselves because our financial model does not currently place a premium on it."

The best of both worlds

Dr Mendelsohn does acknowledge, however, that with the advent of Cesium Iodide phosphor detectors and MUSICA imaging processing software used as part of the DX-D 300 solution, Zwanger-Pesiri is now able to achieve the best of both worlds – significant dose reduction while still achieving the high quality images that radiologists have come to expect and are more comfortable working with.

"With so many sites and such a large population to serve, our biggest challenge is one of workflow," says Jeanine Sartorelli, Zwanger-Pesiri's Chief Technical Officer. "To meet demand, we have a lot of teams that rotate across our sites, so ease of use when switching between solutions is paramount."

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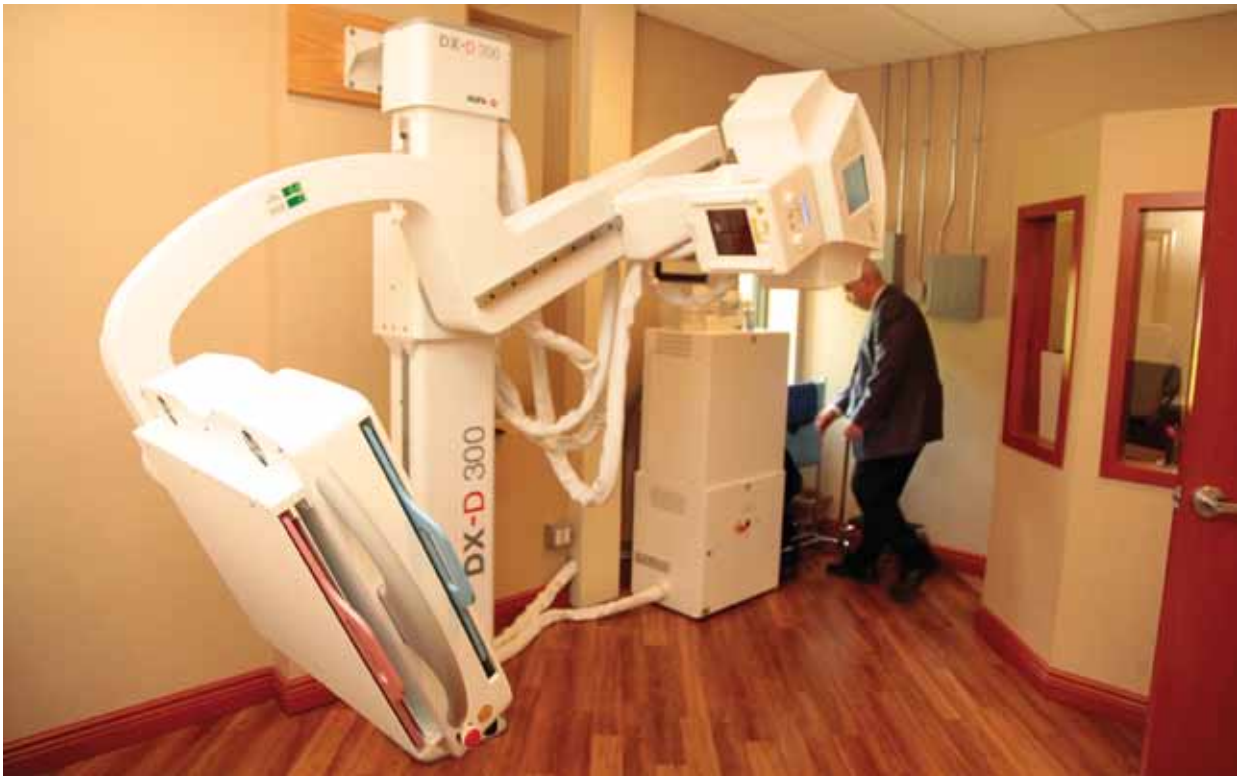
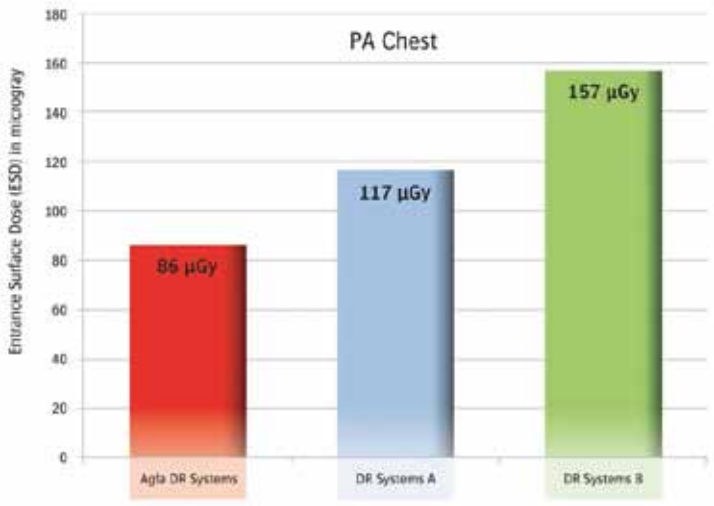


A happy patient is Zwanger-Pesiri's ultimate aim, as Jeanine explains, "With the advent of Google and other information sites, patients are becoming more knowledgeable and more prepared to question their dose exposure. It's great to be able to say that we are using the lowest possible dose for their images. With the automation and accuracy offered by the DX-D 300 with Cesium Iodide detectors and MUSICA, we can speed them through the process and make it easier for referrers to access their information."

"Ultimately, it's all about delivering better quality care for our patients." ■



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CONFRONTING RISK

REGULATORY EFFORTS AND INFORMATIONAL CAMPAIGNS SEEK TO STRENGTHEN RADIATION SAFETY IN MEDICINE

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That the use of ionising radiation for medical purposes holds both tremendous potential and entails serious risks is not a new insight. The first resolution aiming to protect individuals from excessive exposure through x-rays was adopted a full one hundred years ago by the British Roentgen Society. However, various developments have lent new urgency to, and sparked renewed interest in, the issue, and both regulatory bodies and professional societies are seizing the opportunity to push for greater vigilance.

A Growing Problem

Today's practitioners rely on a dizzying array of imaging modalities for both diagnostic and treatment purposes, several of which – including projection radiography, computed tomography (CT), fluoroscopy and positron emission tomography (PET) scans – use ionising radiation to generate images. As a result, medical procedures have become by far the main artificial source of radiation exposure to the general population.

Such exposure can trigger both stochastic and non-stochastic, or deterministic, effects. Stochastic effects are more likely to result from increased exposure, but are not necessarily more severe as a result of higher exposure. These include a higher risk of cancer. While the doses emitted in diagnostic and interventional radiology may increase that risk, sound estimates of radiation-induced cancers remain elusive. By contrast, non-stochastic or deterministic effects, which generally result from short-term exposures to high radiation levels, do become more severe with increased exposure, and often appear quickly. Examples include burns and radiation poisoning.

Technological advances have both alleviated and exacerbated these risks. While innovative devices now include features that facilitate intelligent dose customising, for example, technological progress has also resulted in the introduction of new medical procedures that rely on the use of ionising radiation. In addition, sophisticated health services are increasingly widely and readily available across the globe, meaning that both cumulative radiation doses are increasing, and that more patients, practitioners and medical staff are at risk of suffering negative side effects.

The growing use of CT is particularly striking. The modality entails notably high radiation doses compared to traditional radiography, accounting for only a fraction of total exams performed (under 15%), but for a large percentage (around 65-70%) of imaging radiation (Voress 2007). Nonetheless, thanks to its ability to provide cross-sectional views of organs, it is an immensely popular tool, and its use has multiplied significantly since the early 1990s. In English hospitals, for example, the number of CT scans performed per year rose from around 1 million in 1997 to almost 5 million in 2013 (Elliott 2014). In Germany the number increased by 130% between 1996 and 2010, with around 4.88 million patients receiving at least one CT scan in 2009 (Federal Office for Radiation Protection 2014). The trend is even more dramatic in the United States, where the threat of litigation may be pushing practitioners to err on the side of ordering more exams: fewer than 19 million CT scans were performed there in 1993, while 85 million were carried out in 2012 (IMV 2012).

Fluoroscopy is another modality that has triggered considerable debate on balancing risks and benefits. Its ability to provide real-time imaging of internal organs has revolutionised medical treatment, particularly by making possible a variety of interventional radiological (IR) procedures that permit patients to forgo invasive surgery. But its use is also associated with significant radiation doses. Complex IR procedures that involve long exposure times are of particular concern, with embolisation (especially in the brain), the creation of transjugular intrahepatic portosystemic shunts (TIPS), and percutaneous transluminal coronary angioplasty often singled out for entailing high doses. Dose reduction is especially vital for practitioners and other staff members who are chronically exposed. Interventional radiologists, for example, have been found to face an elevated risk of developing radiation-induced cataracts.

Concerns about exposure have already spurred some improvements. Publicity about the increase in CT use did impel manufacturers to lower the dose emitted per scan, resulting in significant reductions. But with reliance on imaging for both diagnostic and therapeutic purposes continuing to expand, heightened awareness is crucial. A recent flurry of initiatives, both at the regulatory and professional society levels, is aiming to achieve that result.

Directing Change through Regulation

The European Union has long immersed itself in radiation protection, both by way of regulatory efforts and by issuing non-binding guidelines. Its latest measure on the issue is Council Directive 2013/59/Euratom of 5 December 2013, laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. Also referred to as the Basic Safety Standards Directive, it came into force in February 2014. It consolidates and updates a group of previously applicable rules, and member states have until February of 2018 to comply with its requirements.

The Directive reiterates the EU's commitment to two main principles often invoked in radiation protection efforts in the medical context: the "justification principle", which requires that decisions that introduce changes in radiation exposure result in more good than harm,

CIRSE's radiation protection campaign highlights the risk of eye disease for interventional health professionals.

viewed either from an individual or a societal perspective; and the "optimisation principle", which mandates that exposures are to be kept as low as reasonably achievable. Also referred to as the ALARA principle, this concept acknowledges that worse can actually be better, with practitioners encouraged to aim for images that are adequate for diagnosis or intervention, and not necessarily for maximum precision, which generally entails higher exposure levels.

The instrument is comprehensive in scope. Emphasising communication with patients, it obligates physicians to inform patients about the benefits and risks associated with examinations before these take place, and requires resulting reports to include information on patient exposure. Recording and communicating dose information is also a central element of the sections targeting medical equipment. Amongst other things, these require equipment used for IR procedures to provide information about the radiation quantity produced during the procedure. In addition select equipment, including CT, must be able to produce parameter information, based on which practitioners can assess patient dose at the end of a procedure, and transfer this information to examination records. (Equipment installed before the Directive enters into force may be exempt from parts of these requirements.)

"RADIATION PROTECTION EFFORTS ARE GAINING MOMENTUM"

Incorporating new epidemiological insights about the effects of exposure on specific tissues, especially on the lens of the eye, an issue highlighted by the International Commission on Radiological Protection in 2011, the Directive also lowers applicable occupational dose limits. Previously capped at 150mSv per year, the equivalent dose limit for the lens of the eye is now set at 20mSv per year, averaged over 5-year periods, during which the dose may not exceed 50mSv in any single year.

In addition the Directive seeks to harmonise and strengthen radiation protection education and training efforts across the EU. Having introduced requirements for such training in medical school curricula in the late 1990s, the new rules emphasise continuing education, obliging governments to ensure that post-qualification education and training is provided to all individuals involved in the practical aspects of medical radiological procedures. The Directive also specifically notes that where new techniques are introduced, targeted training that covers radiation protection aspects must be provided.

Enhancing Safety with Professional Society Initiatives

While legislative efforts can play important roles in prompting change, these will have little impact if a proper safety culture is missing in day-to-day practice. A genuine appreciation of the risks involved is vital for creating such a culture. Several professional societies have recently stepped up efforts to foster such awareness, and are leading a variety of initiatives that address several of the priorities emphasised in the new Basic Safety Standards Directive.

The Cardiovascular and Interventional Radiological Society of Europe (CIRSE) is strongly committed to ensuring comprehensive and up-to-date radiation protection training. This is reflected in the European Board of Interventional Radiology, an exam offered to physicians seeking to certify their IR expertise. The EBIR, which is based on *CIRSE's European Curriculum and Syllabus for Interventional Radiology*, requires trainees to build on radiation protection education received during diagnostic radiology training and to achieve numerous specific learning outcomes, including being able to estimate effective doses from IR procedures and determining the best compromise between the risks and benefits of specific approaches.

The society was also one of the six professional organisations that contributed to the Medical Radiation Protection Education and Training (MEDRAPET) project (**www.eurosafeim-aging.org/medrapet**), an EU-funded initiative conducted between late 2010 and early 2013, which included a study exploring the status of radiation protection education and training of medical professionals within the EU.

The European Commission has incorporated insights obtained from that study into new guidelines issued in 2014, *Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union, Radiation Protection No. 175* (European Commission 2014), which outline a framework on which future curriculum development efforts for several different professional groups can be based.

In addition CIRSE is pushing practitioners to embrace the protective measures available for reducing the risk of developing lens opacities, associated with reduced contrast sensitivity as well as declined visual ability. Its first Radiation Protection Pavilion, launched at CIRSE 2014 in Glasgow, featured eye exams, informational material outlining practical advice and tailored industry exhibits. CIRSE 2015 in Lisbon will feature a new, expanded edition of the pavilion.

The European Society of Radiology has also been an active advocate. In 2014 it launched its EuroSafe Imaging Campaign (**eurosafeimaging.org**), which aims to spread awareness both amongst the medical community and amongst patients. In addition, it is coordinating the European Diagnostic Reference Levels for Paediatric Imaging (PiDRL) project (**eurosafeimaging.org/pidrl**), which strives to better protect children from radiation exposure by developing and promoting the use of European diagnostic reference levels for paediatric imaging, focusing on CT, interventional procedures using fluoroscopy and digital radiographic imaging.

Paediatric radiation exposure is also getting more attention in the United States, where the Image Gently® campaign has urged caution since 2008 (**imagegently.org**). With children at heightened risk both because their developing organs and tissues are more vulnerable, and because of their longer life expectancy, such efforts are particularly vital.

Encouragingly, recent reports indicate that awareness is not just rising, but is also resulting in reduced exposure at individual hospitals. For example, Yale-New Haven Children's Hospital reports curtailing the number of CT scans performed on children by 50% since 2003, thanks to both advances in scanner technology that have facilitated adjusting doses for younger patients, and to increased mindfulness, with practitioners paying more attention to alternative options, such as MRI and ultrasound, or resorting to watchful waiting (Bessinger 2013). Cincinnati Children's Hospital Medical Center recently announced that it has developed protocols that cut the radiation dose for paediatric digital subtraction angiography procedures by up to 95% without sacrificing image quality (Casey 2015).

Gaining Momentum

Such reports suggest that radiation protection efforts are gaining momentum. Administrators can help the medical community to capitalise on this renewed surge of interest in the issue in myriad ways. Tangible investments in relevant equipment, ranging from sophisticated imaging devices to surprisingly simple protective gadgets for both health workers and patients, are vital, but devices are only part of the equation. Administrators can also make crucial contributions by fostering a workplace culture that genuinely values and prioritises vigilance and diligence with respect to limiting exposure, as well as by facilitating access to accurate and up-to-date information amongst patients, practitioners and medical personnel alike. ■

Key Points

- ✓ Cumulative radiation doses are increasing, and patients, practitioners and medical staff are at risk. Complex IR procedures that involve long exposure times are of particular concern.
- ✓ A recent flurry of initiatives, both at the regulatory and professional society levels, is aiming to heighten awareness.
- ✓ Key EU documents are the Basic Safety Standards directive and the Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union.
- ✓ Several professional societies have initiatives underway to improve radiation protection education and awareness, including the Cardiovascular and Interventional Radiological Society of Europe, which included a Radiation Protection Pavilion at its 2014 congress for the first time.

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DOSE CREEP

UNNOTICED VARIATIONS IN DIAGNOSTIC RADIATION EXPOSURES

ECRI's Top 10 Health Hazards 2015 (ECRI 2014) lists at no. 7 "dose creep", which is a pattern of radiation exposure levels (ie, dose) being increased by clinicians over time in an attempt to achieve better image quality in diagnostic radiography. Although it is unlikely to result in immediate harm, it's an insidious problem that can have long-term consequences and that, over time, can affect many patients. Fortunately, tools are now becoming available to help healthcare facilities combat this hazard.

In many ways dose creep is an unintended consequence of the progress from film to the use of digital detectors in diagnostic radiography.

With any imaging technology that uses ionising radiation, exposures to higher doses are associated with greater risks to the patient (eg, an increased long-term risk of developing cancer). Thus, standard practice specifies that technologists use a dose that is "as low as reasonably achievable" (ALARA) to acquire the desired diagnostic information. In other words, the dose should be neither higher nor lower than is necessary to obtain a diagnostic-quality image.

In film-based radiography, exposing the patient to radiation levels that were too high or too low carried a built-in penalty: The resulting film would be unusable (either overexposed or underexposed). Thus, wide variations from the optimal exposure parameters would be noticed.

Digital detectors, by comparison, are more forgiving. Because they have a much wider dynamic range than film, they can tolerate a significantly wider range of exposure parameters and still return a usable image. One advantage of this wider dynamic range is that it reduces the likelihood that an imaging exam will need to be repeated—which would expose the patient to additional radiation—if a higher- or lower-than-optimal exposure is used.

One downside, however, is that the wider dynamic range creates an environment in which radiographic technologists can adjust exposure parameters away from the recommended levels—sometimes making changes little by little over time—without there being an obvious indication of the change. That is, deviating from the recommended exposure would not typically be evident by looking at the resulting digital image.

In fact, with digital detectors, the quality of the image generally improves as the dose increases. Thus, there is a natural tendency to nudge the dose higher to get better-quality images. Repeated adjustments in this manner over time can lead to the use of exposure factors that vary substantially from the "usual" exposures for a given study, without users being aware that dose levels have crept upward.

The consequence is that patients may routinely be exposed to unnecessarily high levels of ionising radiation during exams. While any increase in dose for a single exam is likely to have a negligible effect, the cumulative effect on patients subjected to multiple studies during the course of their treatment—particularly neonatal patients—can become significant.

Recommendations

- ✓ If your digital diagnostic radiography systems are not already equipped to use the standardised EI—as developed by the International Electrotechnical Commission (IEC 62494-1) and the American Association of Physicists in Medicine (AAPM TG-116) and as implemented by device manufacturers—investigate whether a software upgrade is available to add this capability. For new equipment purchases, incorporate EI capabilities into your request for proposal.
- ✓ After it has been incorporated into your imaging systems, use the EI to estimate the patient dose and exposure on the detector.
- ✓ Take the steps necessary to display EI values to radiographic technologists as part of their routine workflow. This may require a software upgrade or configuration change.
- ✓ Install software tools that automatically import and analyse EI data.
- ✓ Define responsibilities for tracking and analysing the EI data for the whole department.
- ✓ Work toward defining acceptable EI values and ranges for commonly performed radiography studies.

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With digital imaging, the only objective way to identify whether the optimal exposure factors are being used consistently (ie, for all studies or in all care areas) is to review the exposure indicators provided by the imaging system. Previously, the practice of comparing exposure indicators across imaging systems or care areas was complicated by the lack of a standardised approach: Each imaging system manufacturer defined its own numerical indication of the radiographic exposure to estimate the dose delivered to the detector. Now, however, manufacturers are increasingly adopting the standardised exposure index (EI), established by International Electrotechnical Commission (IEC) standard 62494-1. This means healthcare facilities can begin using the EI (on appropriately equipped systems) to track the exposure factors that are used and to identify trends that might indicate variation from the optimal values.

Newer imaging systems are now beginning to incorporate EI capabilities. And for existing digital radiography systems, it may be possible to add this capability through a software upgrade. In addition, software tools are becoming available to facilitate the tracking of EI values. To make effective use of the EI, radiology managers, possibly in consultation with medical physicists, will need to define acceptable values for specific studies and patient types, track the variation, and find ways to efficiently identify poor practice. ■

Source: ECRI (2014) Top 10 health technology hazards. Health Devices, November. Available from: https://www.ecri.org/Resources/Whitepapers_and_reports/Top_Ten_Technology_Hazards_2015.pdf

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THE RADIOLOGY EVENTS REGISTER (RaER)

THE ROLE AND VALUE OF INCIDENT REPORTING IN RADIOLOGY

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Incident reporting is a key safety tool in high-risk industries and is now widespread in healthcare. Many reporting systems are designed for health systems and do not cater for medical specialties such as radiology.

Incident Reporting

Harm in Healthcare

A systematic review has shown that 9.2% of hospital inpatients experience harm from their care, with a median percentage of preventability of 43.5% (De Vries et al. 2008). Over half (56.3%) of patients experienced no or minor disability, whereas 7.4% of events were lethal. Operation- (39.6%) and medication-related (15.1%) events were most prevalent (De Vries et al. 2008). Many more patients are subject to near misses, with estimates ranging from 3 to 300 times as many near misses as adverse events (Barach and Small 2000; Runciman et al. 2007).

What is a Safety Incident?

A patient safety incident, (ie an 'incident'), is defined as "an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient" (Runciman et al. 2009). Incidents comprise both adverse events (in which a patient suffers physical or psychological harm, for example, a patient suffering stress from a misdiagnosis, or a reaction to intravenous contrast media) and 'near misses' in which the incident does not 'reach' the patient and no harm occurs. Near miss examples range from double-checking a patient's identifier details on the request form with hospital records indicating a mix-up between two patients prior to imaging being conducted, or where a patient needs a right-sided nephrostomy, but is admitted and prepared for a left-sided nephrostomy with the error detected before commencement of the procedure and the correct side is treated. Near misses may not progress to adverse events, because they are intercepted by, and/or harm is mitigated by, systems containing many cross-checks and redundancies or vigilant people (eg discovering an incorrect procedure was planned during a surgical time out) or by chance and good luck (eg the radiologist did not read the referral with the incorrect side noted and performed the procedure on the correct side despite this not being what was requested) (Runciman et al. 2007). While comparison of near misses and adverse events may be confounded by hindsight bias, it is generally considered that the underlying systems failures for near misses are the same as for actual adverse events (World Alliance for Patient Safety 2005).

In the field of patient safety errors are defined as unintentional consequences of either failure to carry out a planned action as intended, or application of an incorrect plan (Runciman et al. 2009). Errors may occur by doing the wrong thing (an error of commission) or by failing to do the right thing (an error of omission) at either the planning or execution phase (Runciman et al. 2009). James Reason has described the occurrence of errors in a range of settings, including healthcare, aviation, mining and nuclear power plants, by categorising errors as either latent (embedded within the system) or active (occurring at the level of the operator) (Reason 2000). These two types of errors can reduce the effectiveness of the different layers of defences designed to protect a system from loss. Most incidents are the result of a sequence of events where each event in isolation would not cause harm. Harm occurs when the flaws in the defences, usually both active and latent errors, momentarily align in such a way that hazards are brought into damaging contact with victims. Reason's widely used Swiss cheese model (see Figure 1) argues that focusing on active errors is flawed because systems weaknesses can recur time and time again regardless of the operator (Reason 2000).

Why Reporting Incidents is Important

Incident reporting, when done well, can detect near misses and events where harm occurs (Anderson et al. 2013; World Alliance for Patient Safety 2005). Other safety tools and data sources may not capture near misses. The advantages of knowing about near misses include:

1. Near misses account for the majority of incidents;
2. They can act as an 'early warning system';
3. Information about how the incident was detected and mitigated before patient harm occurred can be obtained.

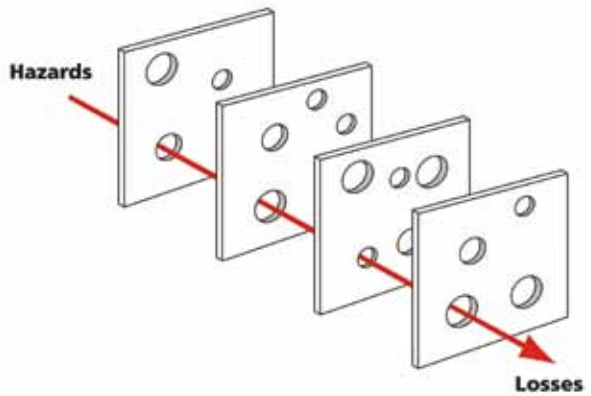

Figure 1. The Swiss Cheese Model
Source: Davidmack (Own work) [CC BY-SA 3.0 (http://creativecommons.org/licenses/by-sa/3.0)], via Wikimedia Commons.

The cheese slices represent the defences instituted to prevent errors and harm occurring. The holes in the cheese are the weaknesses of the defences that may allow harm to occur. Most incidents are prevented by one or more of the defences but occasionally all the defences fail and harm occurs (ie the holes in the cheese slices line up and the incident occurs)

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Incident data from near misses and adverse events can be useful in identifying risks that may allow harm to occur and in developing effective mitigation strategies to prevent similar events happening in the future.

Another benefit of incident reporting is its role in the development of a safety culture (World Alliance for Patient Safety 2005). The process of reporting is reflective, and this reflection on what happened, what could have happened and what stopped it being worse is important in creating a safety culture, ie one where actions are seen through a system 'safety lens' and staff are cognisant of safety in everything they do. Embedding vigilance about safety is an important distinguishing feature of high reliability organisations like nuclear aircraft carriers, nuclear power plants and air traffic control centres (Reason 2000). Such organisations are preoccupied with error and safety, and expect their staff to make errors, and therefore train their workforce to recognise errors and how to recover from them.

Characteristics of an Incident Reporting System

For an incident reporting system to be effective it needs to be easy and quick to use (World Alliance for Patient Safety 2005; Anderson et al. 2013). Reporting must be supported and encouraged by the organisation. In particular, reports are more likely to be submitted where the culture is just, ie non-punitive but accountable, key attributes of a safety culture (Reason 2000). Doctors are less likely to report when their identities are known, and this has been found to be due to fear of punishment; of being held responsible; or losing face to peers and seniors (Waring 2005). Making a reporting system anonymous and confidential encourages reporting. Having the incident reporting system managed by an organisation that is not a regulator or employer is reassuring to reporters and more likely to elicit information that will be helpful (Runciman 2002; Smith and Mahajan 2009).

A common language, or taxonomy, is helpful for classification, analysis and dissemination of findings. The World Health Organization's International Classification for Patient Safety (ICPS) (World Alliance For Patient Safety Drafting Group et al. 2009) (see Figure 2) provides a conceptual framework suitable for: comparing patient safety incident data across disciplines and between organisations on local, national and international levels; trending patient safety incident data; investigating patient safety incidents and identifying patient safety issues in different areas of care; examining the roles of system and human factors in patient safety; determining the applications and limitations of existing strategies to reduce risk to patients; identifying potential patient safety issues through evidence-based research; and developing priorities and preventative and corrective strategies.

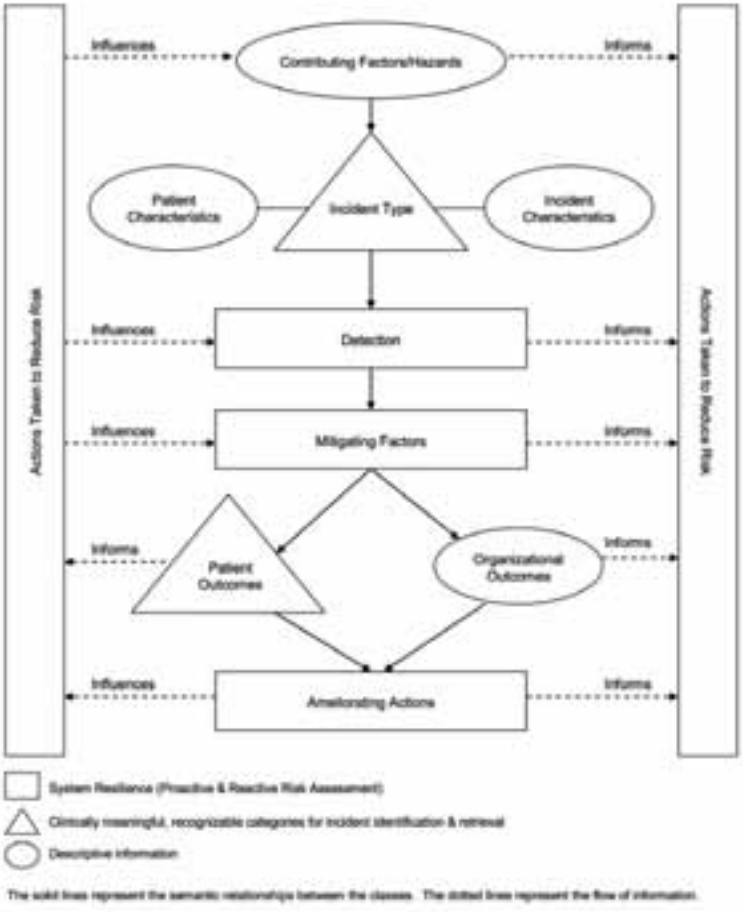

Figure 2. WHO Conceptual Framework for the International Classification for Patient Safety

Reproduced by permission. Source: World Health Organization (2009) Conceptual framework for the international classification for patient safety: version 1.1: final technical report. Geneva: WHO, p.8. [Accessed: 22 April 2015] Available from http://www.who.int/patientsafety/implementation/taxonomy/icps_technical_report_en.pdf?ua=1

Using an online reporting system saves costs in transcription and allows easier searching of data. Online forms can be adapted to elicit specific information depending on the data entered and 'pick lists' can simplify the process. Reporting is easier if there is ready access to the internet. Paper forms are still used by some agencies and have a role where internet access may not be available. Whatever system is used, data security is critical.

"A DEDICATED RADIOLOGY INCIDENT REPORTING SYSTEM SUPPORTS THE APPROPRIATE FORMAT, CLASSIFICATION AND ANALYSIS OF PATIENT SAFETY DATA"

Open access to reporting enables anyone to report, not just radiologists. Nurses, radiographers and clerical staff all play an important role in patient safety, and their knowledge of incidents is invaluable in making patient care safer. Access for referring clinicians, patients and family members to report gives other insights into how healthcare can be improved. As patients rarely speak up during care (Weingart et al. 2005; Kinnunen and Sarantob 2013), having access to incident

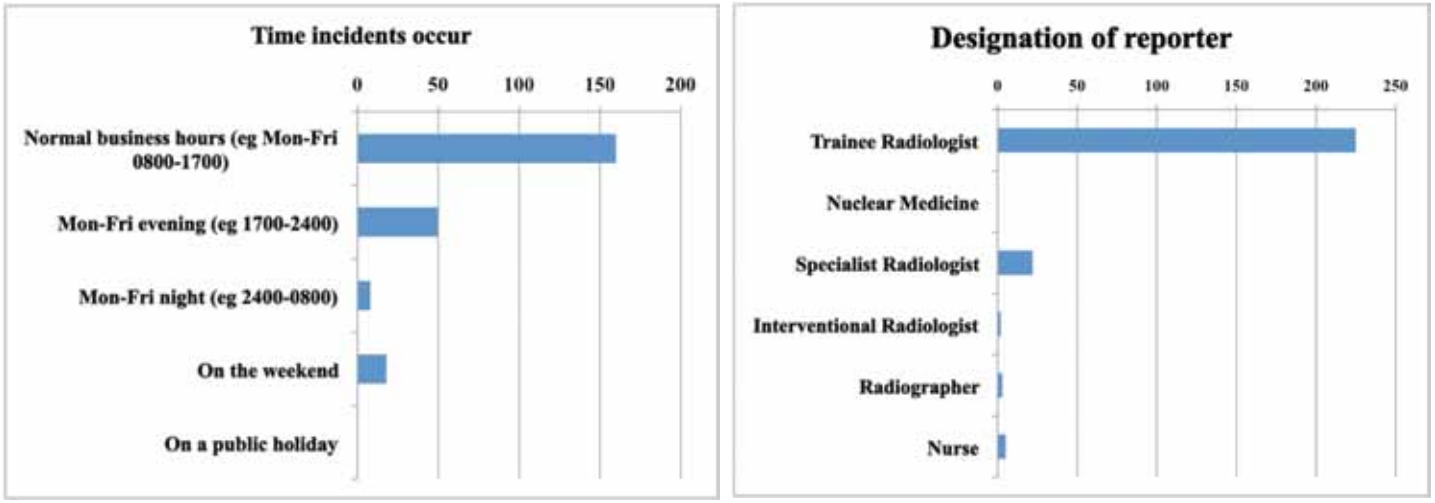

Figure 3. Typical graphical presentation of data seen by the person who has reported an incident (i) time when incidents occur (ii) designation of reporter

reporting may be the only way to capture data from a patient perspective.

Ideally collaboration between organisations and sharing of de-identified data will allow incidents to be entered once and distributed to the reporting system where the expertise is greatest.

Whilst much reporting is voluntary, some reports may be mandatory such as wrong patient, side or site procedures (Australian Government Department of Health 2012), or where significant harm results from the incident. In a safety culture there is a great willingness to report incidents, even if seemingly trivial, as the benefit of reporting is widely understood and valued by management.

Reporting alone is not enough. A feedback or response system, ie classification of incidents to enable analysis and the development of alerts, warnings and solutions to prevent recurrence or mitigate the risk, is essential for an incident reporting system to be effective (Anderson et al. 2013). Timely feedback at the end of entering a report is also helpful in keeping those entering reports engaged.

Effective incident reporting results in safer care, better patient outcomes and cost savings as care is provided more efficiently and money is not spent on rectifying errors and treating harm.

Having a dedicated radiology incident reporting system supports the appropriate format, classification and analysis of patient safety data, and this allows the collection and understanding of information relevant to imaging. The outputs, such as alerts and warnings, will be relevant, practical and capable of being implemented and, therefore, more likely to be effective.

The Radiology Events Register (RaER)

The Radiology Events Register (www.raer.org.au) is the first national or international dedicated radiology incident reporting system. It was founded in 2006 by the Royal Australian and New Zealand College of Radiologists (RANZCR), and was funded by the Federal Government of Australia as part of the RANZCR's Quality Use of Diagnostic Imaging Program (QUDI) (Jones et al. 2010a). Currently RaER is funded by the RANZCR, and the Australian Patient Safety Foundation (APSF) is contracted to manage RaER. This provides independent management and housing of the data (thus reassuring and protecting the reporters), and expertise in classifying incidents using a validated patient safety classification. The data is subject to qualified privilege (statutory immunity) under relevant legislation in both Australia and New Zealand, meaning that it cannot be used in legal proceedings even if it could be identified. Although set up in Australia and New Zealand, there is no geographical restriction on reporting. RaER is not, however, a substitute for mandatory reporting in hospitals and practices.

To date we have over 4000 incidents from direct reports and data sharing with health departments, medical defence organisations and radiation regulators. The biggest hurdle for RaER is to encourage reporting. Doctors are not inclined to enter incidents into RaER or elsewhere and, as workloads are increasing, radiologists have little time to do anything other than report the radiology studies in front of them.

In order to encourage reporting, RANZCR has mandated incident reporting as part of the clinical radiology training programme and provides points for continuing professional development (CPD) for qualified radiologists. Incident reporting meets the requirement for reflective elements in CPD. Instant feedback is provided at the end of entering each case by means of a set of graphs showing a real-time summary of the types of incidents entered into RaER (see Figure 3).

Part of the data collection includes identifying where in the imaging cycle (see Figure 4) each incident is initiated and where it is detected (see Figure 5). This helps to identify the stages in the patient journey that are of higher risk (Jones et al. 2010b).

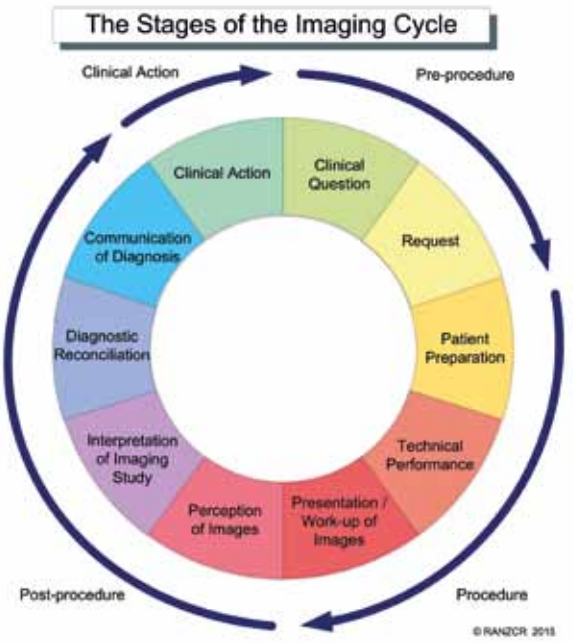

Figure 4. The imaging cycle showing the stages involved in imaging from formulating a clinical question that could be answered by medical imaging to the clinical action resulting from the radiologist's report of the imaging.

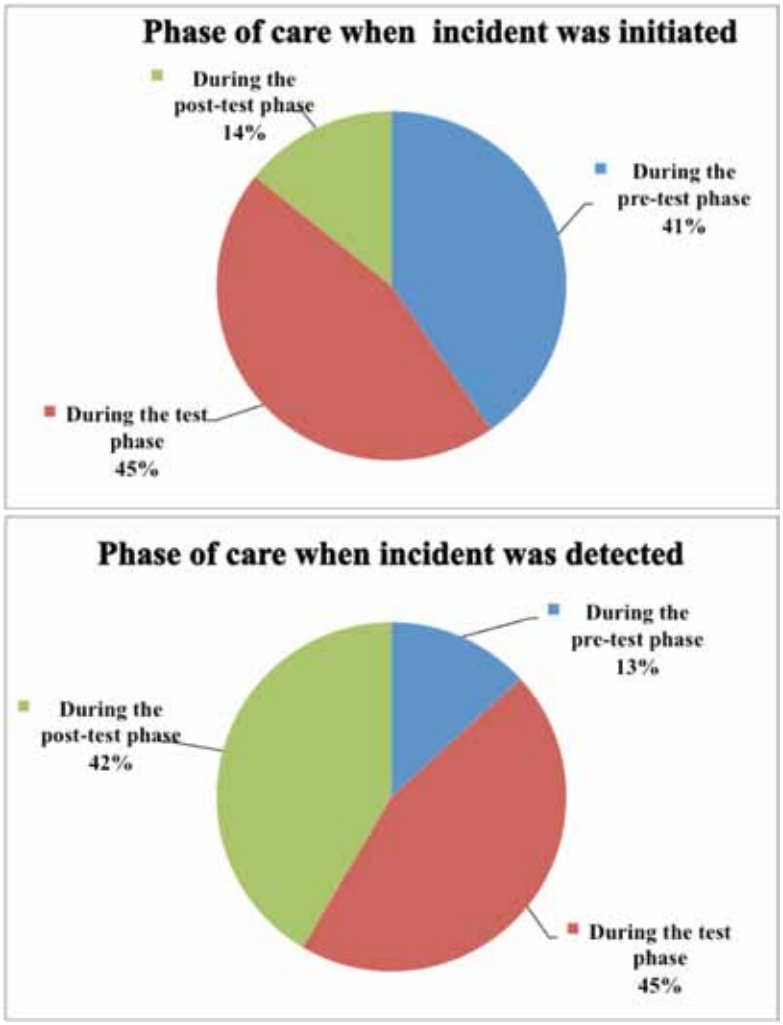

Figure 5. Phase of care where incidents were (i) initiated and (ii) detected

Key Points

- ✓ The Radiology Events Register (RaER) (www.raer.org.au) is the first radiology-specific incident reporting system to be established.
- ✓ Its purpose is to provide a platform to improve safety in radiology by recording, classifying and analysing incidents in a way that is relevant to radiology and that can result in education, alerts and other notices to raise awareness and help improve practice and safety in patient care.

We have analysed reports to look for common causes and patterns that may be able to be mitigated. To date we have issued case reports with analysis of incidents and suggested risk mitigation strategies, and published papers in the peer-reviewed literature looking at errors in handover and communication. Papers on when and where errors occur and errors in neuroradiology have been presented at national and international conferences. The case reports published in RANZCR's Inside News (**www.ranzcr.edu.au/resources/newsletters/611-current-edition**) are popular and widely read. A full list of publications and presentations is available at **www.raer.org.au/publications-presentations.html**

Additionally, APSF convenes a multidisciplinary biennial conference, the Australasian Conference on Error in Medical Imaging, which promotes best practice and error reduction. These conferences are held in November, and include experts from radiology, patient safety and healthcare human factors.

Conclusion

Incident reporting is a key patient safety tool. RaER is at the international forefront of incident reporting in radiology, and the combination of radiologist expertise and the APSF's skills in patient safety and human factors means that RaER outputs are a combination of best practice in patient safety and relevant and practical in radiology. The biggest challenge is increasing reporting rates. Experience in other industries shows that this is a matter of time, effective and continuous promotion and clearly demonstrating the benefits of reporting. ■

For further information please go to **www.raer.org.au**

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INSTITUTE FOR SAFE MEDICATION PRACTICES

TARGETED BEST PRACTICES OUTLINE TOP MEDICATION SAFETY ISSUES

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Hospitals and health systems around the globe that are deciding what to focus their medication safety efforts on can gain input from the Institute for Safe Medication Practices (ISMP). In 2014 ISMP celebrated the 20th anniversary of its founding, and reflected on the feedback that it has received through its voluntary national reporting programme on medication errors and hazardous conditions, and what lessons can be learned from that information.

Certain medication errors that cause harm or are fatal to patients continue to recur in the United States and around the world, despite repeated warnings from ISMP and other organisations. ISMP launched the 2014-15 Targeted Medication Safety Practices for Hospitals to identify, inspire and mobilise widespread national and international action to address these recurring problems (ISMP 2013a).

The 2014-15 best practices identify a group of key safety issues, and provide realistic, high-leverage strategies for error prevention. ISMP intends implementation of the best practices to be a collaborative effort at hospitals; success hinges on cooperation between health professions. While they are primarily targeted for the hospital-based setting, some of the best practices may be applicable to other healthcare settings.

The 2014-2015 best practices have already been adopted by many U.S. healthcare organisations (ISMP 2015). Following are those that are most applicable to the European healthcare community.

Best Practice - Vinca Alkaloids

Dispense vincristine (and other vinca alkaloids) in a minibag of a compatible solution and not in a syringe.

Rationale

The goal of this best practice is to ensure that vinca alkaloids are administered by the intravenous route only. Vinca alkaloids (vinBLAStine, vinorelbine, vinCRIStine, and vinCRIStine liposomal) can cause fatal neurological effects if given via the intrathecal route instead of intravenously. VinCRIStine is particularly problematic, and the most frequently reported, because it is often ordered in conjunction with medications that are administered intrathecally (eg methotrexate, cytarabine, and/or hydrocortisone). When vinca alkaloids are injected intrathecally, destruction of the central nervous system occurs, radiating out from the injection site. The few survivors of this medication error have experienced devastating neurological damage. The U.S. product labelling also carries a special warning ("For Intravenous Use Only—Fatal If Given by Other Routes"). Despite this warning and repeated warnings by various national and international safety agencies, deaths from this type of error still occur.

An effective prevention strategy that reduces the risk of inadvertently administering vinca alkaloids via the intrathecal route is to dilute the drug in a minibag that contains a volume that is too large for intrathecal administration (eg 25 mL for pediatric patients and 50 mL for adults) (Polovich et al. 2014).

Many U.S. healthcare organisations, including paediatric hospitals, have successfully switched to preparing vinca alkaloids in minibags, overcoming concerns of extravasation and other complications. There have been no reported cases in the U.S. of accidental administration of a vinca alkaloid by the intrathecal route when dispensed in a minibag. It is important to note that this best practice is supported by the World Health Organization (2007).

Best Practice - Oral Methotrexate

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.

- For manual systems, require verification of an appropriate oncologic indication before dispensing oral methotrexate for daily administration.

b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

- Ensure that written drug information is given to patients that contains clear instructions about the weekly dosing schedule.
- Explain to the patient that taking extra doses is dangerous.
- Have the patient repeat back the instructions to ensure that the patient understands the weekly dosing schedule and that the medication is not to be used "as needed" for symptom control.
- Provide the patient with a copy of the free ISMP high-alert medication consumer leaflet on oral methotrexate (ISMP 2014).

Rationale

The goal of this best practice is to prevent errors involving inadvertent daily dosing of oral methotrexate both in the inpatient setting and after discharge. Since early 1996, and as recently as 2013, fatal errors have been reported to ISMP about the accidental daily dosing of oral methotrexate that was intended for weekly administration.

Methotrexate is a folate antimetabolite used to treat different types of cancers. Since the drug's introduction, its labelled indications in the U.S. have expanded to include non-oncology uses. It is now used to treat a variety of autoimmune diseases (eg psoriasis, severe rheumatoid arthritis, lupus) and other disorders. In the U.S., many hospitals have reported to ISMP that the non-oncology use of this product is greater than its use for oncological indications. It should be noted that this best practice still applies to hospitals that specialise in cancer treatment only, since patients may still receive this drug for non-oncological reasons.

When used for immunomodulation to treat disorders such as rheumatoid arthritis, the drug is administered weekly or twice a week. Prescribing errors occur when physicians, who are familiar with prescribing many medications for daily administration, erroneously

prescribe this medication daily instead of weekly. Dispensing errors occur in much the same way, when pharmacy technicians and pharmacists inadvertently select/approve daily instead of weekly administration during order entry or order verification.

Best Practice - Oral Liquids

Ensure that all oral liquids that are not commercially available as unit dose product are dispensed by the pharmacy in an oral syringe

- Use only oral syringes marked "Oral Use Only."
- Ensure that oral syringes used do not connect to any type of parenteral tubing used in the hospital.
- Use of an auxiliary label "For oral use only" is preferred, since the print on the oral syringe is small, if it does not obstruct critical information.

Rationale

The goal of this best practice is to prevent the unintended administration of oral medications via the intravenous route. ISMP continues to receive reports in which patients were inadvertently given an oral liquid medication intravenously. This happens most often when an oral liquid is prepared extemporaneously or dispensed in a parenteral syringe that connects to vascular access lines. Such errors have resulted in patient death.

Fatalities have also occurred when the contents of liquid-filled capsules (eg niMODipine) were withdrawn for oral administration via a nasogastric or other tube with a parenteral syringe and then inadvertently administered intravenously. The oral syringe tip is designed to be incompatible with vascular lines so it cannot be inadvertently attached.

It should be noted that the key feature of this best practice is to dispense this product in unit dose, rather than in bulk dosage forms, so nurses will not draw up the oral solution using a parenteral syringe. Dispensing the product in unit-dose cups or bottles from the pharmacy is acceptable, although the use of an oral syringe is preferred. Oral solutions should never be dispensed from the pharmacy in a parenteral syringe.

"CERTAIN MEDICATION ERRORS CONTINUE TO RECUR DESPITE REPEATED WARNINGS"

Best Practice - Glacial Acetic Acid

Eliminate glacial acetic acid from all areas of the hospital.

ISMP recommends removing and safely discarding this product from all clinical areas of the hospital (including the pharmacy, clinics, and physician office practices), and replacing it with vinegar (5% solution) or commercially available, diluted acetic acid 0.25% (for irrigation) or 2% (for otic use). Laboratory use could be excluded if the lab purchases the product directly from an external source.

Rationale

The goal of this best practice is to prevent harm from the use of glacial acetic acid applied directly to patients (ISMP 2013b). The use of hazardous chemicals in pharmacy compounding, or for special therapeutic procedures and diagnostics, is common in many U.S. hospitals. Patient harm has occurred when toxic chemicals have been misidentified as oral products, or when a very concentrated form of a chemical has been erroneously used in treating patients.

Of particular concern is glacial acetic acid. Accidental topical application of "glacial" (greater than or equal to 99.5%) acetic acid has repeatedly resulted in serious patient harm, including severe pain and serious tissue damage, third-degree burns, and in one case bilateral leg amputation. Often in these cases, this item was either accidentally purchased or used in place of a much more diluted form of acetic acid, such as vinegar or a commercially available 0.25% acetic acid solution.

Based on comments ISMP has received from U.S. hospitals, there is rarely any requirement for pharmacy to have to compound a strength of acetic acid from glacial acetic acid. If required, there should be an investigation of the evidence demonstrating the true need for that particular strength.

Conclusion

ISMP strongly encourages adoption of these practices in all hospitals. The Institute has conducted baseline surveys to determine how they are being incorporated and to collect information on any potential barriers.

ISMP plans to release its 2016-17 Targeted Medication Safety Practices for Hospitals at the end of 2015. A survey of the implementation status of the current set of best practices in U.S. hospitals will be conducted in the late summer of 2015 to help determine which will be continue to be highlighted and how many new practices will be added. ■

For more information or to download a complete copy of ISMP's 2014-15 Targeted Medication Safety Practices for Hospitals, go to: **www.ismp.org/tools/bestpractices**

Key Points

- ✓ ISMP's Targeted Medication Safety Practices for Hospitals provide consensus-based strategies for issues that continue to cause fatal and harmful errors.
- ✓ Topics for the 2014-15 best practices include safe use of IV vinCRIStine, oral methotrexate, oral syringes, and glacial acetic acid.
- ✓ For more information or to download a complete copy, go to: www.ismp.org/tools/bestpractices

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CREATING A SAFETY NETWORK FOR USE IN A CLINICAL ENVIRONMENT

DEVELOPING MEDICAL DEVICE PLUG-AND-PLAY INTEROPERABILITY TO IMPROVE PATIENT SAFETY AND HEALTHCARE EFFICIENCY

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Need For Interoperable Devices

Medical devices are essential for the practice of modern medicine. However, unlike the interconnected "plug-and-play" world of modern computers and consumer electronics, most medical devices used for the care of high-acuity patients are designed to operate independently, and do not employ open networking standards for data communication or for device control. For years we have benefited from integrated systems to enhance the safety of potentially hazardous activities. For example, safety interlocks that require stepping on the brake before putting your car in gear, or having a clear alarm sound in the cockpit, if the landing gears are not deployed when a plane descends for landing, add "error resistance" to potentially hazardous equipment. This solution is not yet easily achievable in a cross-vendor device integration scenario to implement error resistance in operating rooms (ORs) and other clinical environments today.

The absence of an intranet-like ecosystem for interconnecting medical devices and clinical information systems is a fundamental impediment to realising the use of comprehensive, accurate, electronic medical records and healthcare information technology (HIT) systems to improve the quality and efficiency of healthcare. Interoperability of devices and IT systems in clinical environments will permit mixed-vendor data transfer, comprehensive secure data acquisition and safety-enhancing capabilities, such as safety interlocks and closed-loop device control. Medical device interoperability will enable innovations to improve patient safety, treatment efficacy and workflow efficiency, reducing medical errors and healthcare costs to the benefit of patients throughout the continuum of care – from the home to out-of-hospital transport, and to clinical areas as diverse as the OR, intensive care unit (ICU) and general hospital ward. Moreover this will facilitate regulatory compliance.

Medical Device Interoperability Examples

Below are some examples of how medical device interoperability would aid in a clinical setting.

Patient-Controlled Analgaesia (PCA) Pump

While on the PCA infusion pump, the patient is monitored with a respiration rate monitor and a pulse oximeter. If physiological parameters move outside the pre-determined range, the infusion can be stopped, and an alarm sent to notify the clinical staff and restart the infusion if appropriate. The use of two independent physiological measurements of respiratory function (oxygen saturation and respiratory rate) enables a smart monitor to optimise sensitivity to detecting respiratory compromise while reducing false alarms.

X-Ray Capture During Lung Ventilation

The x-ray and anaesthesia machine-ventilator are synchronised, so that the x-ray is taken at the desired phase of ventilation, such as end-inspiration or end-expiration. When the technician pushes the exposure button, the image is taken at a synchronised point, triggered by the respiratory waveform. If necessary, the ventilator is instructed to supply a brief breath hold. The ventilator was not stopped for the x-ray, so the patient was never in danger from hypoventilation.

Home and Remote Monitoring for Elderly Patients

For patients with chronic illnesses a doctor may prescribe wearable and monitoring devices for disease management at home. In an emergency the patient's body worn devices (eg ECG, blood pressure monitor, and continuous glucose monitor) are connected to the ambulance monitoring system for en route management. The devices can also be queried to obtain patient ID and recent data history. This information is transmitted to the managing emergency physician en route, and the data provenance is included in the EMR. Additional data from the remote disease monitoring service is made available to the physician.

Continuum of Care - Workflow Support

In order to improve the handoff process for a patient being transferred between an operating room (OR) and an intensive care unit (ICU), it is necessary to automatically push patient data and device settings from the OR to the ICU. This proposed state would enable a system in the OR to communicate with a system in the ICU in order to assist with setting up devices, and to enable a system readiness checklist. This is a dynamic and interactive checklist that maintains near real-time updates of the patient's status, required devices, physicians' orders and necessary supplies, depending on the patient's history, current status and physician's orders. It would also provide the OR with a continuous assessment of the state of the ICU.

Quarantine Environment For Infectious Disease Care and Monitoring

Interoperability can be used for sensor integration and data acquisition to improve disease screening, monitoring and diagnosis. Remote control, closed loop control, and remote data access could improve patient care and reduce the exposure of hospital personnel to infected patients by limiting the number of times caregivers enter the patient's intensive care environment to change device settings.

Our Programme

The Medical Device Plug-and-Play (MD PnP) programme, established in 2004, is accelerating the adoption of medical device interoperability to enable the creation of complete and accurate electronic health records and the cost-effective development of innovative third-party medical apps for diagnosis, treatment, research, safety and quality improvements, equipment management, and adverse event detection and reporting when using networked medical devices for clinical care.

The programme is affiliated with the Massachusetts General Hospital (MGH), CIMIT (Center for Integration of Medicine and Innovative Technology), and Partners HealthCare System, with additional support from TATRC (the U.S. Army Telemedicine & Advanced Technology Research Center). Having evolved from the OR of the Future program at MGH, the MD PnP programme remains clinically grounded.

Our team has been developing shareable databases, tools and applications that will enable a broader community of researchers and manufacturers to implement medical device interoperability. We have taken a multi-faceted approach to begin addressing key barriers to achieving interoperability, including the development and support of suitable open standards and the elicitation, collection and modelling of clinical use cases and engineering requirements for the Integrated Clinical Environment (ICE) platform and "ecosystem".

Our interdisciplinary, multi-institutional programme team collaborates with diverse stakeholders (clinicians, biomedical and clinical engineers, academic engineering programmes, healthcare delivery systems, regulatory agencies, medical device vendors, standard development organisations).

The CIMIT MD PnP Lab provides a vendor-neutral "sandbox" to evaluate the ability of candidate interoperability solutions to solve clinical problems, model clinical use cases (in a simulation environment), develop and test related network safety and security systems, and support interoperability and standards conformance testing.

"MEDICAL DEVICE INTEROPERABILITY WILL ENABLE INNOVATIONS TO IMPROVE PATIENT SAFETY, TREATMENT EFFICACY AND WORKFLOW EFFICIENCY"

Our Key Work

Establishment of Engineering Requirements Needed to Overcome Current Barriers to Interoperability

Using our Clinical Scenario Repository we have elicited and analysed clinical scenarios at the level of detail needed to inform interoperability solutions and to derive engineering requirements. We have performed detailed workflow analysis of use cases with a team of collaborators (including multiple device companies), and analysed the ability of existing standards (ISO/IEEE 11073-1048:2014) to meet these requirements (gap analysis), yielding important understanding of the capabilities and limitations of existing interface standards. Our team is developing detailed requirements (ie clinical, functional, non-functional, safety) for safe and effective networking of heterogeneous (multi-vendor) medical devices to implement our use cases.

Medical Device Interoperability and Integration Software and Architecture

Using the requirements mentioned above, we are developing architecture and software to implement our use cases to enable improvements in patient care through the safe, reliable integration of medical devices and information technology.

We have developed a prototype healthcare intranet with an open ICE platform and tools to ensure safe and effective connectivity of medical equipment and decision support for clinical care. This open prototype research platform could support evaluations by the U.S. Food and Drug Administration (FDA) of interoperable medical device systems, and serve as a generic model that could be shared with other organisations developing open device software adapters and reference architecture.

OpenICE is an initiative to create a community implementation of the ASTM F-2761 standard for the ICE (ASTM International 2013). The initiative encompasses not only software implementation of those functionalities described in the standard, but also architecture for a wider clinical ecosystem that incorporates seamless connectivity to increase patient safety.

We have also created demonstration implementations of clinical use cases, in which integrating the clinical environment will improve patient safety. We have created data visualisation apps and apps that reduce alarm fatigue or use intelligent algorithms to produce smart alarms (eg x-ray/ventilator synchronisation and safety interlocks for patient-controlled analgaesia medication delivery).

Development of Suitable Open Standards For Integrated Clinical Environment (ICE)

We have created a new open standard for a patient-centric "Integrated Clinical Environment" (ICE) to define the conditions under which interoperability can enable device integration to create new medical device systems with greater safety and performance capabilities than any individual device – Part I of the ICE standard was published as ASTM F2761-09, and is providing a valuable framework for further defining the vision and clinical content for other standards. The figure below shows the functional model of ICE as described in the ASTM F2761.

Test and Validation Tools

We are also developing a suite of software tools to test and validate that system interface software meets requirements for functionality, accuracy, timeliness, security, safety, consistency and completeness. Test tools are used both for component development and for validating compliance to design guidelines.

Accelerating the Adoption of Medical Device Interoperability

We have created a Medical Device "Free Interoperability Requirements for the Enterprise" (MD FIRE) whitepaper, which includes a sample request for proposals and contracting language (MD FIRE Contracting Language Medical Device Free Interoperability Requirements for the Enterprise 2012). Healthcare delivery organisations can use relevant sections to procure interoperable devices, convey the importance of interoperability to manufacturers and learn more about manufacturers' involvement with interoperability efforts.

The simplest path to interoperability is through the manufacturer. If a product has been built to be interoperable, the manufacturer has addressed regulatory issues. If a hospital needs to write an integration program for a medical device, it may need to handle FDA regulatory issues. The more hospitals and clinical organisations get involved and clarify the potential benefits of Medical Device Interoperability (MDI), the easier it will be for manufacturers to understand the opportunities and provide these products.

We are also working to define a safe regulatory pathway for patient-centric networked medical devices, in partnership with the FDA.

The Path Forward

The barriers for widespread use of interoperability today are:

- Low market need for interoperable platforms and medical devices due to lack of awareness by healthcare professionals;
- Unclear regulatory path;
- Proprietary nature of currently available medical devices.

We believe that, given the right cause and motivation, we can bring medical device manufacturers on board to jointly explore the possibilities of interoperability. This would mean improvements for both patients and caregivers with easier to use apps and visualisation tools, improved quality of monitoring and detection, and easier access to data and diagnostics. Open sourced interoperability allows use to create collaborative technology, which no single manufacturer could do on their own. We believe the power of the community is greater than the power of a single product.

The MD PnP programme aims to create knowledge that will spark in the healthcare industry the creation and adoption of innovative healthcare applications, systems, and medical devices, which enable safer and more effective care through medical device interoperability. Success will not be achieved solely by our project, but in conjunction, partnership, and cooperation with the healthcare and related industries and the extensive activities of project collaborators. ■

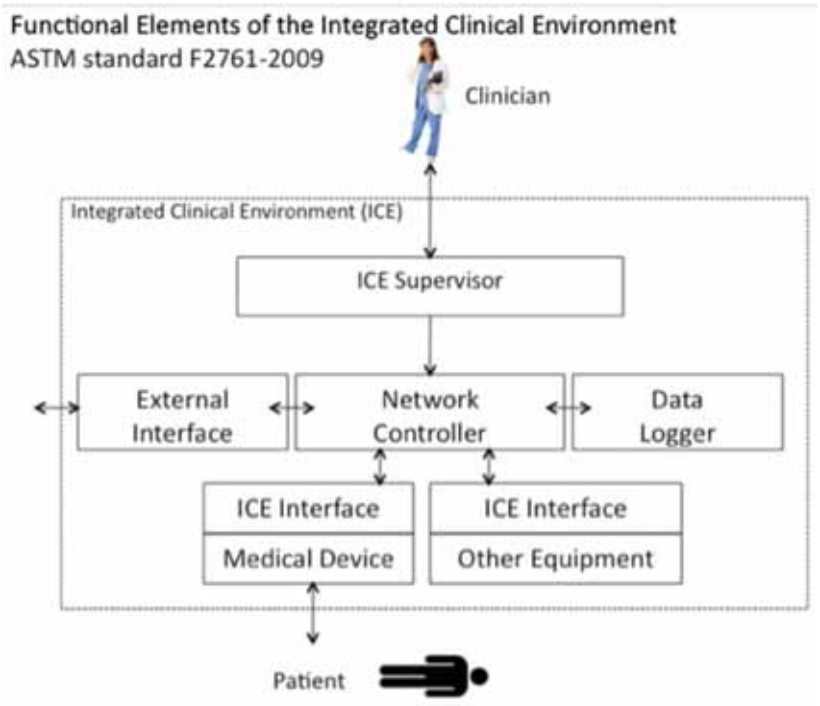

Figure 1. ICE Functional Model, redrawn from ICE Part I (ASTM F2761-2009)

Key Points

- ✓ Medical device plug-and-play interoperability can enable many improvements in safety and workflow surrounding patient care.
- ✓ The MD PnP programme for the last 10 years has taken a leadership role in the academic and industrial environment, to drive forward development and deployment of this technology.
- ✓ We have developed open source software to enable cross-vendor device integration and interoperability, and created open standards to accelerate adoption.

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EUROPE'S MOMENTUM TOWARDS TELEMEDICINE DEPLOYMENT

CRITICAL SUCCESS FACTORS RELATED TO LEGISLATION, REGULATION AND SECURITY

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The MOMENTUM thematic network was a European Commission-funded initiative aimed at encouraging the sharing of knowledge about introducing telemedicine services into routine care (**telemedicine-momentum.eu**). The people involved in the network were telemedicine practitioners or "doers": health authority personnel, decision-makers in healthcare payer organisations eg, insurance funds; hospital and clinical administrators; clinicians; business executives, and managers.

MOMENTUM has confirmed that a set of critical success factors is extremely important to guaranteeing the success and growth of such initiatives. One area on which to concentrate is the legal, regulatory and security issues relevant to telemedicine.

Approach

During 2012-2013, MOMENTUM undertook an analysis of telemedicine-related legal, regulatory and security issues. The study was based on an in-depth assessment of almost 30 telemedicine services integrated into routine care in different regions in Europe. MOMENTUM was able to describe the work of services up-and-running in a variety of regions around Europe. All the service owners responded to a detailed questionnaire survey on the work undertaken on their site. From an overview of the sites, it quickly became evident that 18 critical success factors have been of prime importance to the deployment activities on the sites. These factors were validated and fine-tuned with numerous stakeholders during 2014-2015 (**telemedicine-momentum.eu/project**). In February 2015, they materialised in a blueprint of telemedicine guidelines (**telemedicine-momentum.eu/news**)

Critical success factors relating to legal, regulatory and security issues

Four critical success factors were identified in the legal, regulatory and security field.

- Assess the conditions under which the service is legal.
- Identify and apply relevant legal and security guidelines.
- Involve legal and security experts.
- Ensure that telemedicine doers and users are "privacy aware".

These critical success factors were validated against the descriptions of seven telemedicine cases, which offered a representative set of the diversity of telemedicine applications. The cases range over telemedicine initiatives in Denmark, Sweden, Germany, Israel, Norway, and Spain. The site leading the work on legal, regulatory and security matters was the National Centre for Telemedicine (NST), which had particularly good connections with their Norwegian colleagues (**telemedicine-momentum.eu/wp-content/uploads/2014/09/D6.2_MOMENTUM_SIG3_v12.pdf**)

All the cases reported certain similar observations. At different stages of deployment, they all investigated the circumstances under which the service could be legally established. They all took into account and applied some form of guidelines – they mentioned both clinical guidelines and legal and security guidelines. Legal and security expertise was drawn on in at least four of the cases for various purposes and at diverse stages of the development and implementation process. Training in "privacy awareness" and various aspects of patient consent were important areas of concern.

Important challenges

Stakeholders

A wide range of stakeholders undertake deployment initiatives in the telemedicine field. These stakeholders include clinicians, hospital managers, entrepreneurs, vendors, and public administrators.

Competence

Competence in legal and security matters is not always easily available to them when it is needed during the process of setting up and deploying a telemedicine service.

The whole process

It is, however, critical for those involved in the successful deployment of a telemedicine service to pay attention to legal, ethical and security issues throughout the whole telemedicine deployment process. This is necessary whenever a new telemedicine service is developed, implemented, scaled-up, or put into operation. Sound, legal services founded on the legislation and regulations in the field are a prerequisite for the development of high-quality health services that are fit for large-scale implementation.

Codes of conduct and practice

Considerations in the legal and security field also involve discussions about codes of professional conduct and about ethical principles.

Privacy awareness

When it comes to legal and security issues, it is important to bear in mind that initiatives in this area are intended for the benefit of both patients and telemedicine doers. Hence, concerns with regard to the privacy of patients lie in the focus of both health professionals and patients. Privacy awareness is therefore often discussed when legal and security matters are on the agenda.

Discussion and conclusions

The first three of the MOMENTUM critical success factors on legal, regulatory and security issues are closely related:

- Assessment of the conditions under which the service is legal;
- Identification and application of relevant legal and security guidelines;
- Involvement of legal and security experts in the legal, regulatory and security fields.

Giving a high level of attention to these factors could help telemedicine doers to take all the relevant legal and security aspects into consideration when deploying and scaling-up their initiatives.

When applied together, the critical success factors contribute to create sound and sustainable telemedicine services. They offer guidance that helps to make sure that the services under development are legal, safe and secure.

All of these issues are to be borne in mind in an era in which there is growing awareness of public health needs, gathered through open data, big data and the cloud, and their implications for telemedicine and beyond.

The MOMENTUM Blueprint is available at: **http://telemedicine-momentum.eu** EHTEL is a multi-stakeholder platform, described as the eHealth focal point in Europe: **http://www.ehtel.eu** ■

Key Points

- ✓ Assess the conditions under which the service is legal.
- ✓ Identify and apply relevant legal and security guidelines.
- ✓ Involve legal and security experts.
- ✓ Ensure that telemedicine doers and users are "privacy aware".
- ✓ Help make services under development legal, safe and secure.

ULTRASOUND

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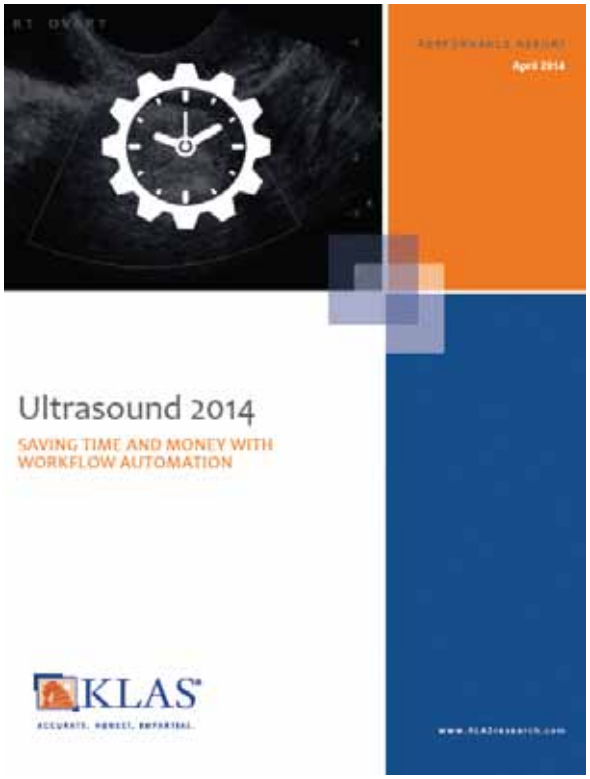
Ultrasound is a popular modality, widely used in healthcare, and there are a host of vendors in the market. For their *Ultrasound 2014: Saving Time and Money with Workflow Automation* report KLAS Research interviewed 178 healthcare providers to find out their opinions on which ultrasound vendors deliver when it comes to providing best value and saving time. To quote one sonographer, "Every minute we save is a minute we can use for another patient."

Performance

The vendors included were GE, Philips, Siemens and Toshiba. GE's LOGIQ E9 ranked top: providers were satisfied with the scanner's reliability and GE's account management. The Philips iU22 virtually tied with GE in this study. GE customers save an average of almost seven minutes per scan, across all scan types. Philips, Toshiba and Siemens customers save just over five minutes per scan. Providers save the most time on abdominal scans, regardless of vendor.

Top performer GE Healthcare, with the LOGIQ E9 with XDClear, found favour with its Scan Assistant tools and ergonomic features, including the ease of raising and lowering the monitor. The six providers who rated it gave an average score of 96 out of 100. Users of the Philips iU22 with xMatrix saved time with the organ identification tool, and found the automation tools and touchscreen user interface intuitive.



Price

GE came in at the lowest average per unit in this report. Philips is the most expensive, based on information from those who reported pricing. Philips customers noted that extra charges for service were an annoyance. However, Philips was praised for its technology and providers felt that it is worth the expenditure. Toshiba is second most expensive on average and several providers felt that they were not getting their money's worth as the technology is not the same standards as other vendors. Some Siemens customers felt they were not getting their money's worth due to reliability challenges in the initial rollout of the S2000. Some were pleased that they were able to trade in their S2000 for an S3000

The full report *Ultrasound 2014: Saving Time and Money with Workflow Automation* is available from KLAS Research, **www.klasresearch.com**

About KLAS Research

KLAS works with over 30,000 people in 5,000 hospitals and nearly 3,000 ambulatory organisations. KLAS sources its information predominantly from the United States. KLAS data and reports represent the combined opinions of actual people from provider organizations comparing how their vendors, products, and/or services performed when measured against participants' objectives and expectations.

KLAS findings are a unique compilation of candid opinions and are real measurements representing those individuals interviewed. ■

LEADERSHIP IN HEALTHCARE

A REVIEW OF THE EVIDENCE

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The delivery of clinical care is based on careful research to determine the most effective way of providing care for patients. At the same time the UK National Health Service (NHS) spends huge amounts on leadership development without a clear understanding of what kind of leadership and leadership development has most impact on patient outcomes.

The Leadership Task

The leadership task is to ensure direction, alignment and commitment within teams and organisations (Drath et al. 2008). Direction ensures agreement among people in relation to the organisation's vision, values and strategy. Alignment refers to effective coordination of the work. Commitment is manifested by everyone in the organisation taking responsibility and making it a personal priority to ensure the success of the organisation as a whole, rather than focusing only on their individual or immediate team's success in isolation.

Research Evidence

Despite thousands of publications on the topic of leadership in healthcare, a recent review (West et al. 2015) reveals relatively little research conducted to a high academic standard. In addition, much of what is written about leadership and much effort on leadership development in the NHS is based on fads and fashions rather than theory-driven evidence. Moreover, successive government reviews often fail to draw on the evidence base, only adding confusion via strong opinion to the vast body of writing on what constitutes good leadership in healthcare. The evidence is clear though: leadership at every level – from frontline leadership in wards, primary care and community mental health teams, to board leadership in trusts, to national leadership in overseeing bodies – is influential in determining organisational performance. The evidence points towards the need for what we call collective leadership. Collective leadership is characterised by shared leadership, where there is still a formal hierarchy, but power is more dependent on who has the expertise at each moment. Leadership is most effective when all staff, especially doctors, nurses and other clinicians, accept responsibility for their leadership roles. Collective leadership is characterised by leaders working together to nurture a shared culture, adopting leadership styles that are consistent across the organisation, and cooperating and supporting each other across boundaries within the organisation to deliver continually improving, high quality and compassionate patient care.

"THE LEADERSHIP TASK IS TO ENSURE DIRECTION, ALIGNMENT AND COMMITMENT WITHIN TEAMS AND ORGANISATIONS"

We conducted a literature review across a large number of databases, including Business Source Complete (EBSCO), Web of Science, British Nursing Index (BNI), CINAHL (Cumulative Index to Nursing and Allied Health Literature), and JSTOR. We limited our search terms to articles published in the last 10 years, in English, and peer-reviewed. A separate review was conducted, which looked at the grey literature and trade press. Below, we briefly summarise some of the evidence we found from our review, in relation to key leadership groups.

Nurse Leaders

Nurses prefer managers who are participative, facilitative and emotionally intelligent, and such styles are in turn linked to team cohesion, lower stress, and higher empowerment and self-efficacy. Effective nurse leaders are characterised as flexible, collaborative, power-sharing, and as using personal values to promote high quality performance. Van Bogaert et al. (2010) examined the effects of nursing environments and burnout on job outcomes and quality of care. Nursing management was positively related to perceived quality of care and staff satisfaction in this study, while other studies found relationships with medication errors and staff levels of well-being, burnout and turnover intention. In their literature review Wong et al. (2013) also note a relationship between nurses' relational leadership styles and lower levels of mortality rates and medication errors.

Katrinli et al. (2008) examined the quality of nurse managers' relationships with their staff, nurses' organisational identification, and whether job involvement mediated any relationship between these factors. When nurse leaders gave nurses opportunities for participation in decision-making, nurses reported high levels of organisational identification and job performance as a consequence. Empowerment of nurses to bring about quality improvement emerges from the literature as a possible key factor. Wong and Laschinger (2013) describe how authentic leadership can influence job satisfaction and outcomes through empowerment. Authentic leadership is characterised by honesty, altruism, kindness, fairness, accountability, and optimism; authenticity implies consistency with values of providing high quality and compassionate patient care.

Medical Leaders

In a large scale review of medical leadership models Dickinson et al. (2013) found that medical or clinical leadership varied across the case study sites they assessed. There were reported variations both between and within organisations in the extent to which doctors felt engaged in the work of their organisations. Those organisations with high levels of medical engagement performed better on available measures of organisational performance than others. In an earlier study Hamilton et al. (2008) found that in high-performing

trusts, interviewees consistently identified higher levels of medical engagement. Additionally, Veronesi et al. (2013) examined strategic governance in NHS hospital trusts, and found that the greater the percentage of clinicians on governing boards the better the performance, patient satisfaction and morbidity rates (inversely) were.

Team Leaders in Healthcare

Effective team working is an essential factor for organisational success, frequently cited in the grey literature. The largest study to date used team member ratings of leadership in an NHS sample of 3,447 respondents. The results revealed that leadership clarity was associated with clear team objectives, high levels of participation, commitment to quality of care and support for innovation. Where there was conflict about leadership within the team, team processes and outcomes were poor. However, more recent meta-analyses of research consistently indicate that, across sectors, shared leadership in teams predicts team effectiveness (eg D'Innocenzo et al. 2014; Wang et al. 2014). These findings are not inconsistent, because having a clearly designated team leader may be associated with less conflict over leadership and as a consequence the enhanced ability of team members to smoothly assume leadership roles and responsibilities when their expertise is relevant.

Organisational Leaders

In one of the few studies examining the relationship between leadership and organisational outcomes in healthcare, Shipton et al. (2008) investigated the impact of leadership and climate for high quality care on hospital performance. The research revealed that top management team leadership predicted the performance of hospitals. Specifically, top management team leadership was strongly and positively associated with clinical governance review ratings, hospital 'star' ratings, and significantly lower levels of patient complaints.

Leadership, Culture and Climate in Healthcare

In the largest study of culture in the English National Health Service (NHS), Dixon-Woods et al. (2014) concluded that six key elements were necessary for sustaining cultures that ensure high quality, compassionate care for patients: inspiring visions operationalised at every level by leaders; leaders ensuring clear aligned objectives for all teams, departments and individual staff; supportive and enabling people management; high levels of staff engagement; leaders focused on ensuring learning, innovation and quality improvement in the practice of all staff; and effective team working.

Another large scale, longitudinal study, involving all 390 NHS organisations in England, identified a link between aspects of climate (eg working in well-structured team environments, support from immediate managers, opportunities for contributing toward improvements at work) and a variety of indicators of healthcare organisation performance (West et al. 2011). Climate scores were linked to outcomes such as patient mortality, patient satisfaction, staff absenteeism, turnover intentions, quality of patient care and financial performance. The results revealed (among many other relevant relationships) that patient satisfaction was highest in organisations that had clear goals, and whose staff saw their leaders in a positive light. Staff satisfaction was directly related to subsequent patient satisfaction.

Leader and Leadership Development

Leader and leadership development are vital for healthcare, with considerable resources dedicated from budgets always under great pressure. In the UK, NHS England has invested many tens of millions of pounds through the NHS Leadership Academy in order to increase leadership capabilities across the NHS. Summative figures for local and regional investment are lacking, but estimates are between 20 and 29 percent of an organisation's training and development budget is dedicated to leadership development.

One approach relies on the definition of leadership competencies. Numerous competency frameworks, competency libraries and assessments are available off-the-shelf, and organisations have been using them for many years to map the leadership competencies required for the success of their organisations. The UK NHS competency orientation derives from the multiple and overlapping competency frameworks and career structures developed over recent years. A wide range of programmes based on these competency models have been delivered, and varied instruments are used to underpin these competency frameworks, with the majority having, at best, poor psychometric properties and unclear theoretical underpinnings. Consequently there is little evidence that the use of these competency frameworks translates into improved leader effectiveness or evidence about which framework is most appropriate. The research literature on leadership generally does not yet show that competency frameworks are potent in enabling leaders to improve their effectiveness.

Evidence of the effectiveness of leader development in healthcare mainly derives from research with medical and other clinical leaders. One-off programmes generally do not provide the sustained support and continual improvement in leadership training likely to be necessary to ensure impact on key outcomes, such as quality of care. However, there are examples of more successful programmes from within the NHS such as the Royal College of Nursing Clinical Leadership Programme (CLP), which has been offered since 1995, and which has been shown as successful in improving nurses' transformational leadership competencies. There is no evidence of benefits to patient care, however.

In comparison with the focus on leader development, leadership development – the development of the capacity of groups and organisations for leadership as a shared and collective process – is far less well explored and researched. However, as previously noted much of the available evidence, particularly in the NHS, highlights the importance of collective leadership, and advocates a balance between individual skill-enhancement and organisational capacity building. Research evidence suggests the value of this, particularly at team level: meta-analyses demonstrate that shared leadership in teams predicts team effectiveness, particularly, but not exclusively, within healthcare.

The need for leadership cooperation across boundaries is not only intra-organisational. Health and social care services must be integrated in order to meet the needs of patients, service users and communities both efficiently and effectively. Healthcare has to be

delivered increasingly by an interdependent network of organisations. This requires that leaders work together, spanning organisational boundaries both within and between organisations, prioritising overall patient care rather than the success of their component of it. That means leaders working collectively and building a cooperative, integrative leadership culture – in effect collective leadership at the system level.

The implication of this new understanding of leadership is that our approach to leader and leadership development is distorted by a preoccupation with individual leader development (important though it is), often provided by external providers in remote locations. Developing collective leadership for an organisation depends crucially on context and is likely to be best done 'in house' with expert support, highlighting the important contribution of Organisation Development and not just Leader Development.

Evidence-based approaches to leadership development in healthcare are needed to ensure a return on the huge investments made. It remains true that experience in leadership is demonstrably the most valuable factor in enabling leaders to develop their skills, especially when they have appropriate guidance and support. Focusing on how to enhance such learning from experience should also be a priority.

National Level Leadership

National level leadership plays a major role in influencing the cultures of NHS organisations. Many reports have called for the bodies that provide national leadership to develop a single integrated approach, characterised by a consistency of vision, values, processes and demands. The approach of national leadership bodies is most effective when it is supportive, developmental, appreciative and sustained; when health service organisations are seen as partners in developing health services; and when health service organisations are supported and enabled to deliver ever improving high quality patient care. The cultures of these national organisations should be collective models of leadership and compassion for the entire service.

Conclusions

The key challenge facing all NHS organisations is to nurture cultures that ensure the delivery of continuously improving high quality, safe and compassionate care. Leadership is the most influential factor in shaping organisational culture, so ensuring the necessary leadership behaviours, strategies and qualities are developed is fundamental. There is clear evidence of the link between leadership and a range of important outcomes within health services. The challenges that face healthcare organisations are too great and too many for leadership to be left to chance, to fads and fashions or to piecemeal approaches. This review suggests that approaches to developing leaders, leadership and leadership strategy can and should be based on robust theory with strong empirical support and evidence of what works in healthcare. Healthcare organisations can confidently face the future and deliver the high quality, compassionate care that is their mission by developing and implementing leadership strategies that will deliver the cultures they require to meet the healthcare needs of the populations they serve. ■

Key Points

- ✓ Leadership in NHS organisations needs to ensure direction, alignment and commitment to the core task of developing cultures that deliver continually improving, high-quality and compassionate patient care.
- ✓ Leaders need to work together, spanning boundaries within and between organisations, prioritising overall patient care rather than the success of individual components, and to build a cooperative, integrative leadership culture – in effect collective leadership.
- ✓ Developing collective leadership for an organisation depends crucially on local contexts and is likely to be done best 'in house' with expert support, integrating both organisational development and leadership development.
- ✓ Evidence-based approaches to leadership development in healthcare are needed to ensure a return on the huge investments made.

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PRACTICE MANAGERS

OVERLOOKED AND UNDERNOURISHED?

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General practice will not remain "the jewel in the crown of the National Health Service", as it is often described, without change. Indeed, given the onslaught of criticism directed at this health sector by the media in recent times, it might appear that it has already lost much of its sparkle and will soon be neither fit for purpose nor sustainable.

The need for change was set out by NHS England in its March 2014 report, *Improving General Practice - A Call to Action* (NHS 2014). The drivers were identified as an ageing population, growing co-morbidities and increasing patient expectations, resulting in a large increase in consultations; increasing pressure on NHS financial resources, which will intensify further from 2015/16; growing dissatisfaction with access to services; and persistent inequalities in access and quality of primary care.

The argument for providing more personalised, accessible community-based services for patients to help improve community health and reduce avoidable pressures on hospital resources has been persuasively made, and the challenges faced in making this vision a reality widely acknowledged. It is currently high on the political agenda. But one of the many questions that remains unanswered is this: how engaged and supported are the workforce who will help deliver the new agenda?

The GP recruitment crisis has hit the headlines with increasing regularity over the past two years. In phase 1 of Call to Action, NHS England pointed out that while the numbers of full-time equivalent GPs had increased over the past ten years, the GP workforce had grown at only half the rate as other medical specialties and had not kept up with population growth.

Furthermore, a gradual increase in the proportion of GPs working part-time was creating longer-term sustainability pressures: the peak age band for female GPs leaving the workforce then was 35-39 years, whereas the peak age band for males leaving was 55-59 years. Within the wider general practice workforce there had been only a marginal increase in the number of practice nurses.

What was missing from this analysis was recognition of the difficulties also being faced in recruiting a significant group of people working in GP practices: the practice managers.

The role of the practice manager has never been more important. Their responsibilities, covering practice development and clinical governance, managing partnership issues, managing finance of the practice, patient and community services and human resources, put them at the centre of ensuring a quality primary care experience for patients.

In summer 2013 a survey of 471 practice managers undertaken by recruitment agency First Practice Management (2013) revealed that a high percentage of practice managers were considering a new career. The survey found that 44% had already considered applying for a new job, 65% of whom said they would be seeking out a new career. Over two-thirds (68%) of the practice managers surveyed said they were feeling demotivated.

More than one in five of the managers surveyed cited workload as their biggest concern, with the remainder citing "too much change", "a lack of support" and "too much bureaucracy".

Over the past year the Institute of Healthcare Management (IHM) has been running a series of focus groups with practice managers across England, and has found the situation largely unchanged. Perhaps unsurprisingly the results show that the main issue impacting on GPs - overwork - is also having a marked effect on practice managers' job satisfaction and commitment to stay in this area of healthcare management.

As one practice manager put it: "In other organisations, HR, finance, premises management etc. would all be separate departments but we have to be 'jacks of all trades'. It's hugely difficult to keep abreast of all the changes - payroll developments such as real time monitoring; structural changes to finance and how payments are made; and developments in IT, which are supposed to help but often hinder us - to name but a few. Many of us are now working 12-hour days and at weekends. A decent work/life balance is simply unachievable."

Another said: "Historically general practice has been good at getting a lot done for less and that's how we've shot ourselves in the foot. The government thinks we can deliver so much with so little. There has been a lot of goodwill around with doctors, nurses, practice managers and other staff all chipping in and doing extra. But if people are not enjoying their job, that goodwill diminishes - and it has."

Among other common problems identified by focus group participants was a lack of understanding from NHS England "about what primary care really do" - the relationship between the two was described by many as "dysfunctional at best"; lack of leadership and/or support from the GP partners; demoralising attacks from the media; and lack of time or opportunities for training.

Perhaps most dispiriting was the perceived impact on patient experience. Time constraints, practice managers reported, meant that they had fewer opportunities to build relationships with patients.

Institute of Healthcare Management

The good news is that overall satisfaction with general practice services remains high – 86 percent of respondents to the *GP Patient Survey* (Ipsos MORI 2013) say that their overall experience is good or very good. However, the Care Quality Commission (CQC) points to the Chief Inspector of General Practice's comments in December 2013 that there is a "small minority" of practices where there are serious failings in the provision of care, notably around access (NHS England 2014). A quarter of patients did not rate the overall experience of making an appointment as "good"; 26 percent of people did not find it easy to get through to the surgery by telephone, and this figure varied from 8 percent to 48 percent in different parts of the country (NHS England 2014).

So inspection of GP practices is now under way and the pressures on practice managers continue to build.

IHM is responding to the need for greater training opportunities to meet the challenges head on. Its starting point is a pilot programme for practice managers, run in partnership with the Primary Care Development Centre in Nottinghamshire. The programme has been developed from the Institute's successful Vocational Training Scheme for practice managers in Scotland and the previous practice management programme in England.

The 14-week, blended learning model is designed to provide practice managers and aspiring practice managers with the essential skills and behaviours required to manage and deliver a great service. The programme is underpinned by the IHM Professional Practice Framework, and covers topics including managing finance, setting budgets, systems for funding health and social care, delivering the service, business and service planning, managing teams and team performance.

The programme will give practice managers a firm foundation of management skills and knowledge, which will enable them to support and sustain the delivery of high-quality healthcare services, demonstrating an awareness of current and emerging trends in healthcare and the importance of incorporating the needs of patients in service design and delivery.

There is a clear need for more programmes and initiatives like this if practice managers across the country are to be expected to carry forward the vision of improved, extended and sustainable primary care services. They are the lynchpin of the complex health system and deserve more recognition and support for their efforts. ■

Practice managers' focus group, conducted by the IHM

"PRACTICE MANAGERS PLAY A VITAL ROLE IN ENSURING A HIGH QUALITY PRIMARY CARE EXPERIENCE FOR PATIENTS BUT OFTEN RECEIVE LITTLE RECOGNITION"

Key Points

- ✓ Overall satisfaction with general practice services remains high, but there are increasing problems around access.
- ✓ GP practices lie at the heart of a new vision of improved, extended and sustainable healthcare services.
- ✓ Recruitment of both GPs and practice managers looms large as workloads increase.
- ✓ Practice managers often feel disenfranchised and overwhelmed by change.
- ✓ More training and support needs to be available to practice managers to help them face the challenges ahead.

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COMPETITION IN THE UK NATIONAL HEALTH SERVICE

HAS IT LED TO THE PROGRESS WE HOPED FOR?

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Over the last two decades, successive policies have aimed to increase competition within the UK National Health Service (NHS) with the aim of improving outcomes and efficiency. This article reviews the successes and failures of these reforms, to assess whether the introduction of competition in the NHS has resulted in the progress hoped for by policymakers.

The private sector has long been viewed as a beacon of efficiency by public policymakers. Within healthcare, initiatives have been introduced in many systems that have aimed to use private sector practices to improve efficiency and outcomes. Of these, the introduction of competition has played a prominent role. The NHS is the largest public sector organisation in the UK and its sustainability is an issue that has remained at the heart of British politics since its inception. Increasing demands on its services have led to the adaptation of various policies to improve efficiency and ensure sustainability. There are few public sector bodies in the world that better exemplify the conflict between the challenges faced by the public sector and the attempts to rebalance with private sector initiatives.

Analysis of NHS policy over the last 30 years demonstrates that successive governments have introduced various reforms that have aimed to reproduce private sector practices with the aim of improving efficiency. The most common recurring theme has been an emphasis on introducing competition within the NHS to "eliminate inefficient providers and provide incentives for the adoption of productivity enhancing techniques" (Dawson et al. 2001).

However, there still remains uncertainty as to whether these reforms have led to the outcomes that were hoped for. The Health and Social Care Act (UK 2012) was widely criticised as a bill which aimed to privatise the NHS. However, evaluation of previous initiatives demonstrates that this was not the first time that policy had been redesigned to encourage competition in the NHS. Since the 1980s consecutive Conservative and Labour governments introduced private sector initiatives. These initiatives and policy changes are analysed below.

The Internal Market

The creation of the NHS internal market in 1991 led to the introduction of full price costing for healthcare. The aim was to increase efficiency through introducing a purchaser provider split to stimulate provider competition and improve productive efficiency (Propper and Söderlund 1998). Providers would develop contracts priced on cost so that these prices reflected resource use. Purchasers would then be guided by these prices to choose the most efficient provider. It was hoped that introducing price competition would tackle the inefficiencies that had resulted from the monopoly power of purchasers and providers, eventually leading to price reductions.

A number of problems arose through the internal market, on both practical and conceptual levels. For price to truly function as an indicator of comparative performance, accurate costing practices had to be in place. Little of this information was available when the internal market was introduced. In 1991/1992, a survey of hospitals in the West Midlands revealed vast variations in speciality prices between hospitals. Despite the development of guidelines (NHS Management Executive 1993), a repeat survey did not show real improvement (Ellwood 1996). This highlighted the difficult nature of costing healthcare, an essential component of competition in the free market.

The evidence regarding productivity in the internal market is mixed. Söderlund et al. (1997) did not find a significant increase in productivity secondary to competition in the first three years of the internal market. Maniadakis et al. (1999) did demonstrate improved productivity, but felt this was due to technical changes rather than efficiency gains.

So why did competition fail to yield the productivity gains expected? It has been proposed that full price NHS costing was unrealistic due to the very nature of the market itself. The number of purchasers and providers steadily decreased after the introduction of the internal market, leading to the formation of local monopolies, which dampened incentives to compete on price (Dawson et al. 2001). Inter-organisational bargaining became the main approach to contract negotiation instead of selective contracting based on full price costing. Listed prices became irrelevant, as they did not reflect true negotiated prices. The lack of transparency regarding these negotiated prices was particularly pertinent in the NHS, due to the absence of an external regulating body to monitor competitive behaviour and monopoly pricing. The internal market had been structured so that the NHS Management Executive could regulate monopoly pricing through monitoring listed prices. As these prices did not reflect the prices actually negotiated, their relevance was doubtful (Ellwood 1996).

Although the internal market was eventually disbanded, arguments have been made in its favour. Whilst the effects were not immediate, the introduction of competition led to lower prices for some low cost procedures (Propper and Söderlund 1998). Opponents of the internal market argued that inter-organisational bargaining undermined the value of

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listed prices. However, if the internal market was modelled to reflect the private sector, then these private negotiations were perhaps inevitable. Indeed, a dynamic market does not actually require open information on prices. Propper and Söderlund (1998) argued that listed prices were still a useful indicator of the impact of competition on prices, especially in regions where there were a large number of providers.

It is argued by many that the internal market did not stimulate significant competition or create effective incentives for hospitals (Cooper et al. 2010). Whilst its successes and failures continue to be debated, it undoubtedly had a key role in shaping future policy. Certain regions experienced a significant reduction in provider price due to the monopsony power of single purchasers in these locations (Propper and Söderlund 1998). The pricing power of a single purchaser over multiple providers is a tool that has subsequently been adapted in health reforms, including the current Health and Social Care Act (2012). However, perhaps the biggest impact of the internal market was to put the doctrine of cost transparency into the public arena and consciousness of policy makers.

Reference Cost Indexing

The new Labour government largely abandoned the internal market in 1998. It introduced radical NHS reforms through a new white paper, describing the internal market as "distorting incentives to such an extent that unfairness and bureaucracy became its defining features" (Department of Health 1997). Whilst the purchaser provider split remained, reforms aimed to encourage collaboration, "moving away from outright competition." Buyers and sellers now negotiated on price, quality and volume through negotiated annual bulk contracts.

However, promoting efficiency remained a key objective. Whilst encouraging collaboration would no doubt improve certain aspects of healthcare, there was no evidence to suggest it would incentivise hospitals to reduce costs (Dawson et al. 2001). Potential inefficiencies were therefore tackled through introducing a reference costing system. Reference Cost Indexing (RCI) aimed to show an organisation's aggregate activity compared with the national average cost. It aspired to overcome the inadvertent disincentives produced by the efficiency targets of the Internal Market. To meet these previous targets, hospitals had to reduce their costs from the previous year. Successful hospitals faced the same efficiency targets the following year, leading to disincentives for cost reduction (Appleby 1996). RCI was introduced in the hope that through comparing a hospital's performance to that of other providers, these disincentives would be overcome. It was modelled on 'yardstick competition,' which had been used in the U.S. to stimulate indirect competition and drive down prices.

It was argued that comparing the performance of institutions with each other or benchmarking was essential to recreate a public sector results-driven culture similar to the private sector to improve efficiency (Dixon 2004). Advocates of RCI emphasised that purchasers would have enhanced power over providers due to the availability of detailed costing information (Northcott and Llewellyn 2003). Proponents also argued that it would result in the sharing of best practices, leading to better quality care (Department of Health 1997).

However, the effect of RCI on efficiency has been strongly debated. The availability of cost information per se will not reduce costs unless incentives exist for providers to respond to this information. Under RCI reforms, incentives were targeted at individual hospital managers who lost their jobs if targets were not met. These reforms were flawed on two levels: through incentivising managers, a 'them versus us' culture developed between clinical and management staff. A perception that hospital managers were following a political rather than clinical agenda led to a natural distrust between clinicians and managers, with inevitably negative consequences on institutional reform (Garelick and Fagin 2005). Secondly, whilst managers developed strategies to help hospitals meet targets, there was little incentive to perform beyond set targets (Dawson et al. 2001). Indeed, the use of averages to produce targets led to a lack of a true benchmark or gold standard. Northcott and Llewellyn (2003) argue that these targets led to complacency rather than performance improvement.

There were also practical problems with RCI and block contracting. Variations in clinical coding practices led to difficulties in comparing institutional efficiency (Dawson and Street 1998; Northcott and Llewellyn 2003). RCI was modelled on yardstick competition which is effective in per case reimbursement, not bulk contract negotiation (Dawson et al. 2001). Although RCI information was available to purchasers, it was not linked to provider payment. Whilst purchasers could technically use the RCI database to challenge provider costs, in practice they were relatively weak in negotiating with hospitals. The terms of a block purchaser provider contract often depended on the negotiating skills of a purchaser and led to national variations in provider payments for the same services (Dawson et al. 2001). Purchasers were, to a certain degree, at a natural disadvantage as the choice of secondary care provider was often limited.

Although direct competition had been abandoned, the importance of comparing institutions with one another was still recognised. RCI was used to 'name and shame' poorly performing NHS trusts and hospitals (Northcott and Llewellyn 2004). Despite questions about the sustainability of this approach, publicly outing poorly performing healthcare organisations has remained an attractive political tool (Wright 2012). Whilst the impact of introducing RCI on efficiency and quality may be debatable, the comprehensive data collected has played a key role in shaping future health policy. The data gathered through the National Costing Exercise allowed the development of an 'average tariff'. This would pave the way for Payment by Results (PbR) and patient choice (NHS Executive 2000).

Payment by Results

The Labour government introduced a seismic shift in health policy by introducing activity-based financing through PbR in 2002. Although RCI

was intended to improve efficiency, it became apparent that the concomitant use of block contracts often resulted in inefficiency and poor quality care, as providers could quality skimp or avoid high-risk patients. True efficiency gains and cost containment were the main motivations behind linking payment with activity (Farrar et al. 2009).

PbR was introduced to reward efficiency, reduce negotiating disputes and pay NHS providers on a 'fair and transparent basis.' Block agreements where funding was fixed regardless of activity were abandoned (Department of Health 2002). An 'average tariff' was developed through the collation of previous cost data. For the first time hospital income was directly linked to activity. Patient choice was also introduced where a patient had a choice of up to five providers for elective secondary care: providers were now in direct competition to attract patients.

As well as reintroducing competition, PbR was a huge stride in modernising costing. Paying providers on a per case basis incentivised them to increase revenue through treating more patients. For the first time, a hospital's income was directly linked to the number of patients treated and complexity of cases. PbR incentivised good performance through withholding some payment until results were delivered (Audit Commission 2012). The average tariffs more accurately reflected workload and forced providers to optimise information collection (Dixon 2004). Prices were designed to change practice, with incentives for hospitals to undertake work in cheaper day case settings (Street and Maynard 2007). The success of this was demonstrated in a study showing reduced unit costs and length of stay. (Farrar et al 2.009).

However, PbR was not without its own problems. Its structure led to incentives for 'gaming' by providers. Rogers et al. (2005) found that PbR-reimbursed hospitals had a disproportionate increase in short stay admissions through using more complex healthcare reference groups (HRGs) to increase revenue. The use of average cost to determine reimbursement has been criticised due to the variations in hospital performance. It is questionable whether averages truly reflect the performance of most hospitals. As with RCI, it has been argued that providers are encouraged to become average performers rather than truly excel.

The impact of PbR on quality has also been debated. Opponents argued it encouraged providers to increase profit through quality skimping. The DoH sought to address this through the introduction of patient choice as a means to encourage non-price provider competition. As prices were fixed, it was intended that providers would compete on non-price factors such as quality. The evidence on the impact of PbR on quality is mixed. Farrar et al. (2009) analysed mortality and readmission rates and found no significant impact of PbR on quality. However, a later study by Gaynor et al. (2010) did demonstrate improved quality outcomes (mortality and length of stay) through PbR and patient choice.

What is the true impact of PbR? It may still be too early to assess whether it has been successful. On balance, there is a general consensus that it has led to the achievement of preset performance targets. Its effects on overall health expenditure are, however, less clear. Its use in primary care led to £200 million extra spending due to the achievement of performance targets (Timmins, 2005). PbR has accelerated the expansion of HRG codes which have increased in number from 48 to 1400 (Health and Social Care Information Centre n.d.). The expansion of HRGs and the use of PbR have undoubtedly played an important role in the current healthcare reforms underway in the UK.

"FEW PUBLIC SECTOR BODIES IN THE WORLD BETTER EXEMPLIFY THE CONFLICT BETWEEN THE CHALLENGES FACED BY THE PUBLIC SECTOR AND ATTEMPTS TO REBALANCE WITH PRIVATE SECTOR INITIATIVES"

The Health and Social Care Act

The 2011 budget of the current UK government saw NHS cuts of almost £1bn (Campbell, 2011). Against this backdrop of financial austerity, major NHS reforms were introduced in the 2010 White Paper (Department of Health 2010). These centred on expanding patient choice, introducing price competition between providers and giving GPs responsibility for commissioning healthcare. The White Paper proved extremely controversial, with opposition from healthcare professionals (Royal College of Nursing 2011). After extensive media coverage and political debate, the Health and Social Care Act was passed in 2012.

The impact of these reforms remains to be seen, but there is little doubt that they have had a divisive effect on public opinion. Prior to its passing, the Bill was one of the most scrutinised in the last decade. Its advocates highlight that competition can stimulate innovation and increase productivity, as previous evidence has demonstrated that competition can lead to improved outcomes in mortality (Cooper et al. 2010). Quality improvement has thus been emphasised as a major driver behind the reforms, and quality indicators have been incorporated into payment incentives (Department of Health 2010). However, as is the case for healthcare systems across the world, effects on quality are difficult to measure, raising questions about the true value of this evidence (Söderlund et al 1997).

Conclusion

The last four decades have seen a number of NHS reforms with varying degrees of success. The introduction and failure of the internal market demonstrated the importance of accurate costing and accounting. Subsequent reforms have only been

possible through the development of these practices. The collation of cost data has enabled the quantification of inputs and outputs, providing a measure of efficiency.

However, various considerations need to be made before introducing new reforms. Cost containment and efficiency measures are viewed with suspicion by healthcare professionals, who are trained to treat patients without consideration of cost (Kurunmäki and Miller 2008). The sustainability of any reforms will depend on cooperation with health professionals. It is also important to understand the differences between the private and public sector to assess which practices can be successfully adapted.

Has the introduction of competition improved NHS performance? In an assessment of seven nations, the NHS scored highly on efficiency, equity and quality (Davis et al. 2010). Whilst it is difficult to assess the impact of individual reforms, it can be argued that the NHS is a successful public sector organisation, which has improved its performance over the last four decades, during which time reforms to increase competition have been gradually adapted.

The future of the NHS in light of the current reforms remains to be seen. Given the consistent improvements in NHS performance, major restructuring may be inappropriate. Successful organisations focus on consistency in strategy and stable leadership rather than repeated policy change (Dixon and Ham 2010). This may go in some way to explain the divisive public reaction to the current reforms. However, the majority of arguments against the reforms are more ideological. The NHS has a unique position in the British psyche. Public misgivings are rooted in the distrust of using a private sector tool to improve a hugely important public sector organisation. As such, any reforms to improve performance need to be considered in light of political and public opinion. ■

Key Points

- ✓ Private sector practices have been introduced to the UK NHS to improve efficiency and increase competition.
- ✓ The 2012 Health and Social Care Act was viewed by some as an attempt to "privatise" the NHS.
- ✓ Review of the effects of attempts by governments since the 1980s to introduce competition to the NHS.

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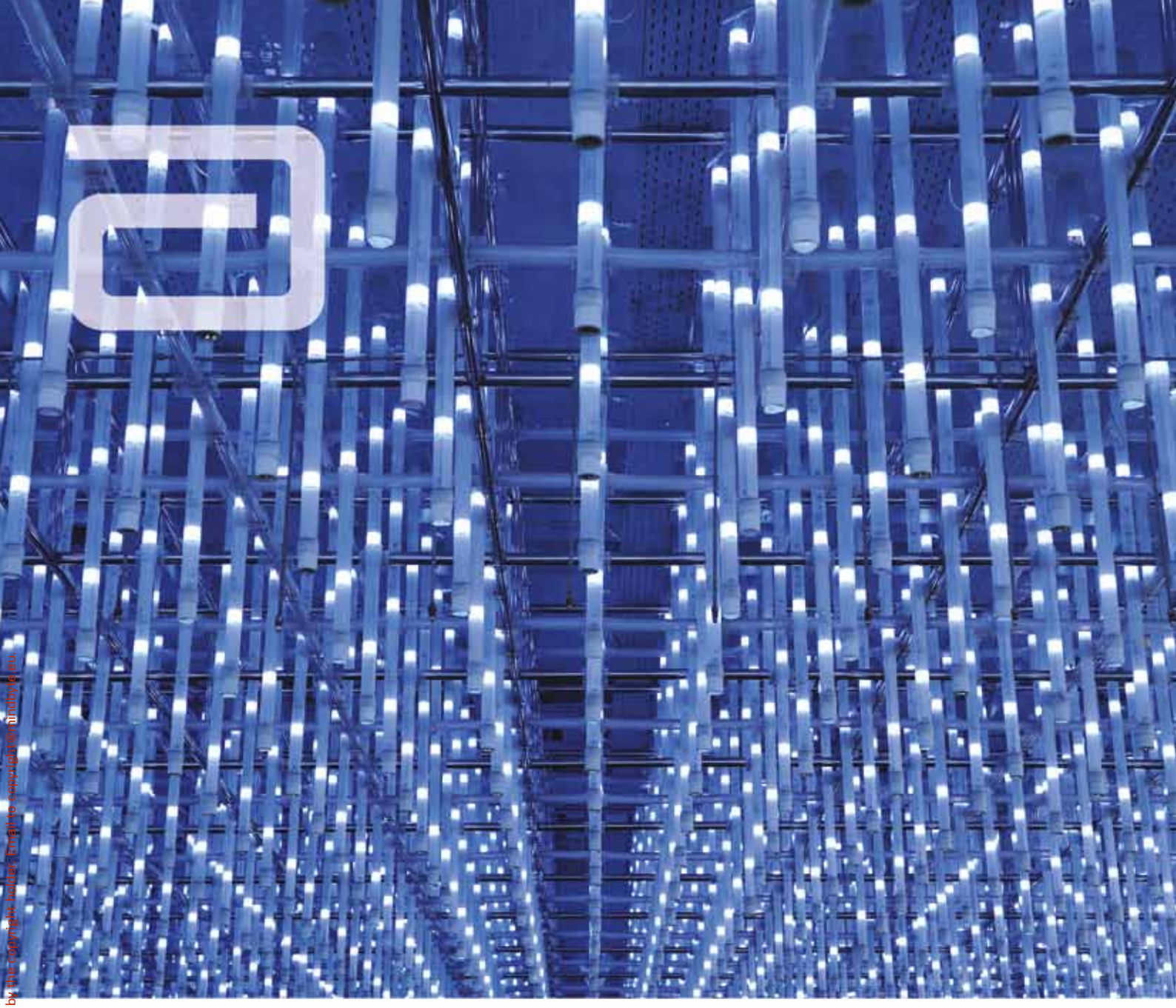

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TWO PATHS FOR MEDICAL DEVICE APPROVAL

FDA VS. CE

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Several factors influence the length of time it takes for a medical device, particularly a new device, to reach its end user. One is the time it takes medical manufacturers to navigate regulatory demands, proving a device's safety and effectiveness before it gets to market. In terms of these demands, companies routinely face one simple but weighty decision: should they seek the United States' Food and Drug Administration (FDA) approval or the European CE mark?

Two Approaches

The choice is not necessarily an either/or, of course, but many companies don't have the resources to pursue both approvals at once. The differences between the two approaches stem from a central divide: the U.S. approach assesses the device's effectiveness as well as its risk of harm; the CE mark, on the other hand, affirms simply that the product "meets high safety, health and environmental protection requirements" (European Commission 2015). Ideally then the U.S. approval would ensure not only that the product poses no harm to consumers, but also that it does what it claims to do. Critics of the FDA system argue instead that this goal adds time and unpredictability to the approval process without in fact establishing the effectiveness of the device.

Measurable Differences

Congress established the framework of the FDA's current regulatory system in the Medical Device Amendments of 1976, with major modifications occurring in the 1990s (Rados 2006). However, the last major change to the medical device review, the Medical Device User Fee and Stabilization Act (MDUFSA) of 2005, merely added the requirement of a fee for medical device manufacturers seeking FDA clearance. The proceeds of the fee were meant to hire additional staff to improve the process (Rados 2006). Critics say it is overdue for reform.

For medical devices, the FDA assigns new products a classification of I, II or III, with Class III devices requiring a far more stringent trial process, the Premarket Approval Process or PMA than those in Class I or II. The classification is based on the degree of harm the device might pose and the specificity of its indications for use (U.S. Food and Drug Administration 2014a). However, only the truly novel device will require a PMA. If the manufacturer can prove "substantial equivalence" to a product already on the market, the device needs only to gain a less rigorous form of clearance, the 510(k).

Timeframe

With its many exemptions and various tracks, the FDA's approval process is widely considered more cumbersome and less clear than the CE marking process. A 2012 report by the Boston Consulting Group quantified as much, analysing approvals "for the most innovative and potentially risky medical technologies" (those requiring PMA) from 2000 through 2011. They concluded that "the same devices have been approved and made available to patients in Europe three or more years before devices are approved in the U.S" (Boston Consulting Group 2012).

"FDA'S APPROVAL PROCESS IS CONSIDERED MORE CUMBERSOME AND LESS CLEAR THAN CE"

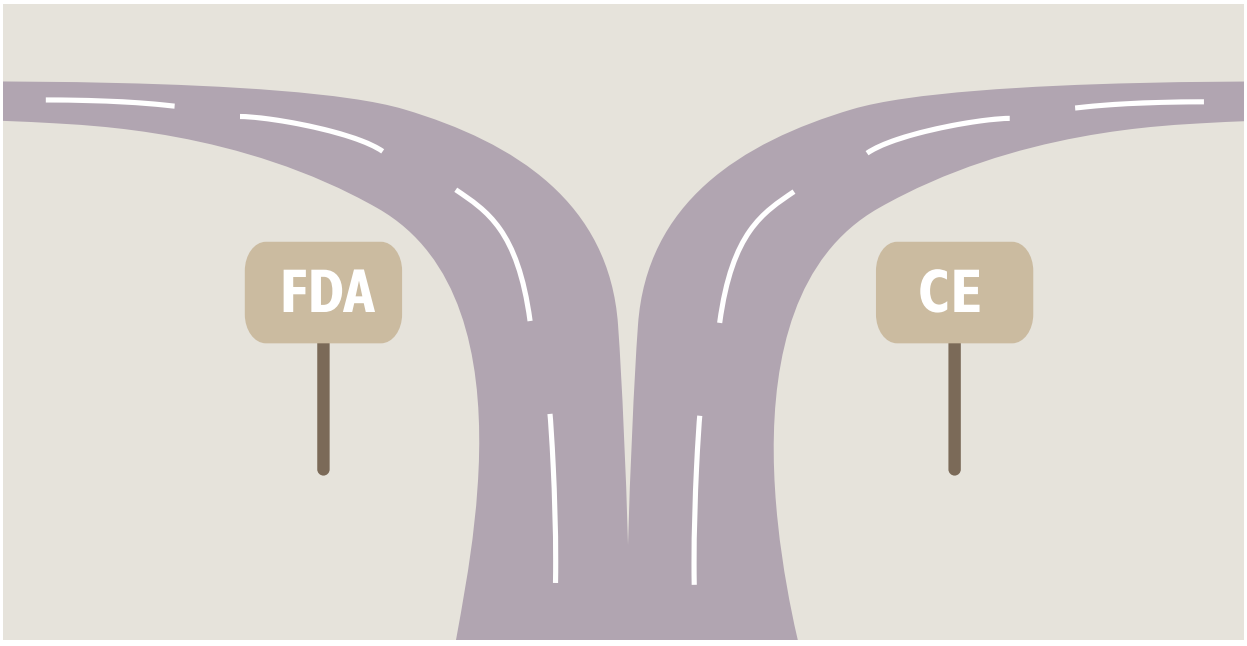
A 2014 paper in the *Journal of the American Medical Association (JAMA)* called out as well an "underexamined third way for a device to reach the market [is] via the 'supplement' process, used for modifications of devices originally approved through a PMA" (Rome et al. 2014). They found that most "new device models are deemed safe and effective without requiring new clinical data", even when those new models "involve significant design changes" (Rome et al. 2014).

Indeed, a 2011 Institute of Medicine committee recommended that the FDA eliminate the 510(k) altogether: "Rather than continuing to modify the 35-year-old 510(k) process, the IOM concludes that the FDA's finite resources would be better invested in developing an integrated premarket and postmarket regulatory framework that provides a reasonable assurance of safety and effectiveness throughout the device life cycle" (Institute of Medicine of the National Academies 2011).

Effects

Calling the FDA approval process for Class III devices "confusing and repetitive," the study's authors identified a troubling trend for the U.S. population: "sustained approval differences are encouraging companies to favour innovations that will serve European markets and reducing the incentive to innovate for the specific needs of the U.S" (Boston Consulting Group 2012).

This very outcome has been tacitly acknowledged by the FDA. On 22 April 2014 the FDA proposed an expedited premarket approval process for devices addressing unmet medical needs (U.S. Food and Drug Administration 2014b). The FDA's Medical Device Reimbursement Task Force, created in December 2013, shares the goal of promoting innovation and getting important devices to market. The group aims to "shorten the time medical-device manufacturers wait before health plans will pay for products after



they're approved"—a critical barrier that manufacturers face even after completing their FDA submissions. "We recognize that the mere fact the FDA approves or clears a device is not equivalent with patients getting access to that device," said Murray Sheldon, associate director of technology and innovation at the FDA (Dickson 2013).

Additional Considerations

Still, while the CE mark is less onerous to obtain, it is a less powerful certification. FDA approval means that the device is approved for use in all parts of the world, while the CE mark has restrictions, sometimes even within the EU. As one medical device company founder says of the CE marking, "there is no guarantee that the device will be widely accepted by physicians or reimbursable by the government in each European country" (Chi 2012).

It is possible too that the FDA's strictness is seen as safer for consumers. Some argue that the breast implant scandal of the early 2000s, in which the French company PIP sold silicone implants, which were not medical grade, wouldn't have happened in the U.S. Indeed, the FDA announced a moratorium on silicone breast implants in 2000. A recent paper in *JAMA* challenges that confidence, noting that less than 1% of medical devices approved by the FDA have undergone Premarket Approval (PMA), the most rigorous path to market (Rome et al. 2014).

Remaining Questions

A medical company's decision to pursue one approval over the other has ramifications extending beyond its own bottom line. Indeed, the advantages and disadvantages of each system translate directly into which population—American or European—gains access to new medical technologies.

With this in mind, the question remains: is the extra expense and cost (human as well as financial) in the FDA's longer timeframe and more intricate process balanced by the presumed assurance of effectiveness that the EU's approval system lacks? ■

Key Points

- ✓ Overview of how the U.S. Food and Drug Administration's approval processes for new medical devices varies from the European CE marking process.
- ✓ While the CE mark takes less time to obtain and devices may be available earlier than in the U.S., the FDA's strict procedures may be seen as safer for consumers.

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RADIOLOGY AND PATHOLOGY AND FINLAND AND ESTONIA

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Sometimes insights, hitherto unperceived can be gleaned by finding points of connection between seemingly disparate pairs of organisations. The power of an apt metaphor can serve to transcend differences in focus and mission by bringing to the fore mutualities of concern and opportunity. In this regard, two small countries in Northeastern Europe—Finland and Estonia—have much in common with two relatively small medical specialties-Radiology and Pathology.

By many measures in the past 35 years Finland and Estonia have been very successful. Finland has a higher per capita income than Estonia, but both are near or at the top in global rankings of political and press freedoms, a sense of contentment or happiness felt by their citizens and diversification of their economy despite each being relatively resource-limited. Their intellectual achievements are noteworthy. For instance, in music, both popular and classical, they each "punch above their weight". Estonia has been called the most "wired" country in the world, while Finland has been heralded for having the best system for primary and secondary education.

Radiology particularly has grown in the same period, through the impress of technological advances in diagnosis and interventional procedures. Pathology perhaps to a lesser degree has nevertheless prospered technically, and is poised to pursue further initiatives through the advent of personalised medicine using genomic and cellular-based therapies.

Estonia and Finland have very similar languages and are situated near to each other with their capitals only 38 miles apart. Hospital-based Radiology and Pathology departments are also often positioned in close proximity. Both use visual representations as their "lingua franca" whereas other specialties can claim hegemony by the inherent advantage of the clinical "intimacy" of the doctor-patient relationship. Such a setting in the delivery of care is outside the domain of much of radiology and pathology practice, as each are largely confined to more remote sites within a hospital. Finland and Estonia are situated at a similar distance away from the geographic centre of Europe and hence at the margins of the world stage. By dint also of their small size and population they have limited power to direct global trends by themselves. The focus of both is on regional issues. They have each joined continent-wide organisations such as the EU and the euro zone to protect their interests and project some influence.

Technological process is the forte of each pair. For example Skype was developed in Estonia and electronic innovation is a hallmark of Finnish industry.

Today all four entities have to confront continuous challenges and expectations. Finland has successfully overcome the economic disruption caused by the recent difficulties of Nokia, a signature company identified with the country. Estonia now must protect itself from hostile murmurings from its neighbour Russia, which 75 years ago invaded and conquered it, forcing many of its citizens into forced labor imprisonment in the gulag.

Radiology, having passed beyond its 40-year golden age (1970-2010), must now face the need to be more judicious in its application of the technology within its purview. To make the necessary adjustments, outdated habits of utilisation must be discarded or modified to respond to imaging wisely initiatives. And at the same time it must confront the likelihood that some examinations will not just be computer-assisted but really computer-determined, thereby constricting the repertoire of tests it controls. Like many other forms of intellectual work, it must face the prospect of dislodgement by technologies, once its servant and soon to be its rival. Estonia and Finland have already shown the suppleness to reorient their economies away from a dependence on meeting Russian needs and wants in order to satisfy the demands of new trading partners, ie Sweden, Germany, and the rest of Europe. Can Radiology and Pathology reposition themselves so readily in light of new realities?

Patterns of convergence seem to be emerging between these two specialties. Joint projects in functioning imaging on a microscopic scale can be accommodated within the scope of expertise of both Radiology and Pathology, with them functioning as partners rather than as competitors. Some might claim that there are advantages in creating a so-called unified Department of Imaging services. In such a scenario the two specialties would have one leader to administer and strategise. Could this work? Perhaps? Despite their propinquity, similarities of language, commitment to the structure and function of democracy, the maintenance of social welfare programmes and education, there is no call at present for each of the two Nordic nations to forgo their independence to create a conjoined new country. Instead both have made a commitment to European integration rather than any other political arrangement.

Similarly, Radiology and Pathology could perhaps try to best meet the threats and challenges that technology will present by working toward shared investigational, educational, and clinical goals within the larger arena of Medicine in general.

Then how should such an anticipated conjunction of interests be accommodated? Finland and Estonia have needs in common to be sure, but they are still independent polities, each with a distinct history and a unique culture. On specific initiatives they are apt to be partners, but retaining always their de jure and de facto nationhood. Similarly Radiology and Pathology will do well to seek shared purposes and pursue opportunities for research, education, and political viability within Medicine. But for the near and medium terms, at least, these goals can be better realised by collaboration rather than confederation. ■

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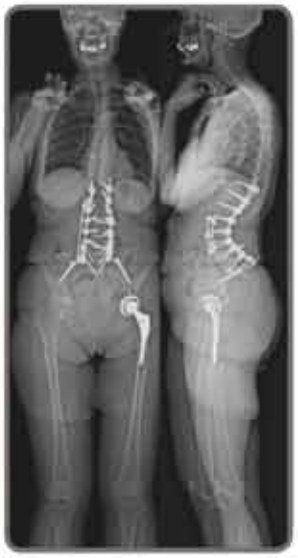

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American College of Radiology Head Injury Institute

Traumatic Brain Injury (TBI) is a major societal issue that has recently captured a progressively greater degree of public attention. TBI occurs across a spectrum of mild to severe disease with outcomes that range from transient symptoms to lifelong disability or death. The initial clinical presentation of TBI does not necessarily clearly predict outcome in all cases. As such there is an increased sense of urgency in defining the role of imaging in the management of this disease process. Realising this trend, in May 2013 the American College of Radiology (ACR) launched the Head Injury Institute (HII) to help drive progress and demonstrate leadership in head injury imaging. The HII works with TBI researchers and caregivers, leveraging and combining both science and practice information to create a shareable message for practising radiologists. The objective is to improve patient care as a broad and practical translational effort. To achieve these goals, the HII focuses on three domains:

1. **Standardisation:** this includes standardising terminology and descriptions applied to TBI imaging, in addition to standardised clinical and scientific imaging protocols (Maas 2011);
2. **Knowledge sharing:** this includes creating and managing information exchanges involving not only scientists but also clinicians, and
3. **Research to practice:** facilitating and organising efforts to move research initiatives into the practice setting.

A key focus of the ACR HII is to address barriers that limit the role of imaging in patients with mild traumatic brain injury (mTBI). The vast majority of patients with head injury experience the mild form of this condition (mTBI). Though many mTBIs may be transient in nature with complete resolution of symptoms, this condition may also be associated with lifelong morbidity that includes difficulties maintaining employment and interpersonal relationships, particularly in sports or military populations with an increased environmental risk for subsequent exposures. MTBI in its uncomplicated form is defined by the lack of any observable imaging abnormalities using current clinical techniques. Although neuroimaging is of great utility in identifying moderate to severe injuries that may require acute neurosurgical or intensive care management (Kim 2011), imaging has a very limited role in helping elucidate subtle diagnostic features that may help to predict prognosis on the milder spectrum of this disease process.

Neuroimaging

Recent population-based research studies have demonstrated that advanced neuroimaging techniques may be capable of identifying the structural and functional changes that are known to occur in mTBI (Eierud 2014). These advanced techniques may include functional connectivity magnetic resonance imaging (MRI) (McDonald 2012), spectroscopy (Yeo 2011), white matter-sensitive techniques such as diffusion tensor imaging (DTI) or diffusion spectrum imaging (DSI) (Shenton 2012; Grossman 2010), cortical volumetric techniques (Wang 2014), and/or positron emission tomography (PET) molecular imaging using TBI-specific ligands (Ramlackhansingh 2011). These advanced neuroimaging techniques are presently used to detect statistically meaningful differences in scientific exploration, but are of limited use in helping to inform the real-time clinical management of patients with TBI. Although many of these techniques can be acquired using current clinical scanners, the abnormal signal reflective of mTBI is often diffuse and difficult, if not impossible, for a neuroradiologist to qualitatively describe. Discernible changes from normal on imaging studies often can only be revealed using quantitative, computer-assisted techniques. However, validated quantitative diagnostic tools to interpret advanced neuroimaging techniques and achieve a diagnosis of mTBI within a single patient do not exist. In many cases, the lack of 'normal' comparison values that are readily measurable on clinical scanners further impedes the implementation of advanced imaging tools.

The ACR HII recognises that the future of neuroimaging for mTBI will likely require some combination of computer-aided diagnosis (CAD) and qualitative interpretation by a practising radiologist. Therefore the HII is actively involved with helping to bridge the gap between the prevailing clinical neuroimaging of TBI and the disruptive potential of advanced neuroimaging for the management of this disease condition. Through multiple ACR-supported conferences that have assembled many of the thought leaders and policy-makers in the neuroimaging of TBI, a pathway forward has been defined which includes:

(i) Collection and aggregation of large-scale data from TBI clinical trials and from age-stratified

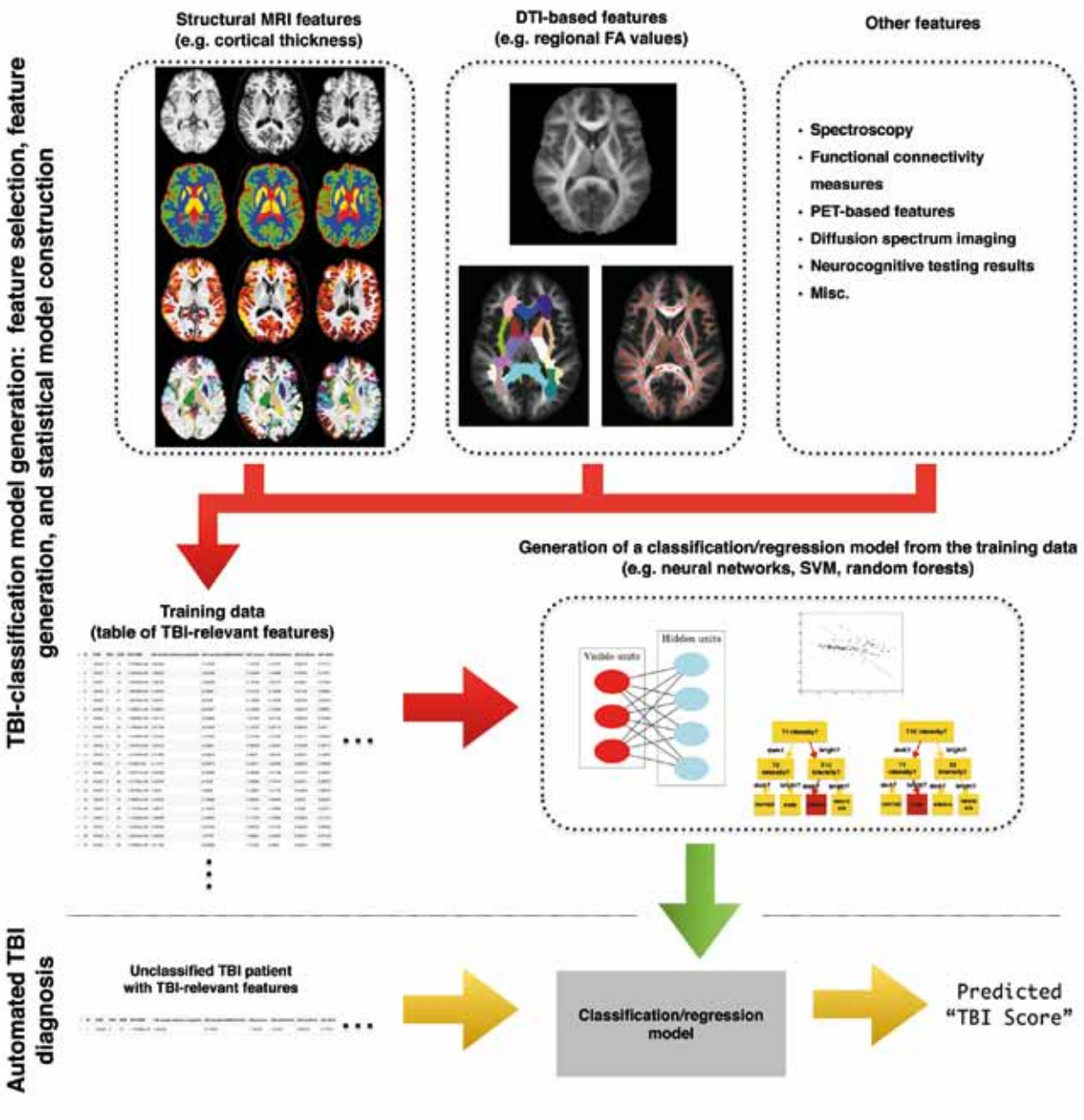

Figure 1

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normal controls employing standardised techniques and standardisation between imaging equipment; (ii) Identification of clear imaging features that are diagnostic for TBI and demonstrate value in assessing injury severity and outcomes, and (iii) Development of practical image-based tools and the requisite statistical framework to determine a diagnosis and prognosis for individual patients with TBI. This final goal may include the use of such contemporary tools as machine-learning algorithms that can learn from large volumes of patient data where such knowledge is encapsulated in statistical classification/regression models, which can then be used for TBI prediction in individual patients (see Figure 1).

"BRIDGE THE GAP BETWEEN PREVAILING NEUROIMAGING OF TBI AND THE DISRUPTIVE POTENTIAL OF ADVANCED NEUROIMAGING"

Data Archive and Research Toolkit

The ACR HII acknowledges that to realise these ambitious goals, "big data" initiatives are required, and the Data Archive and Research Toolkit

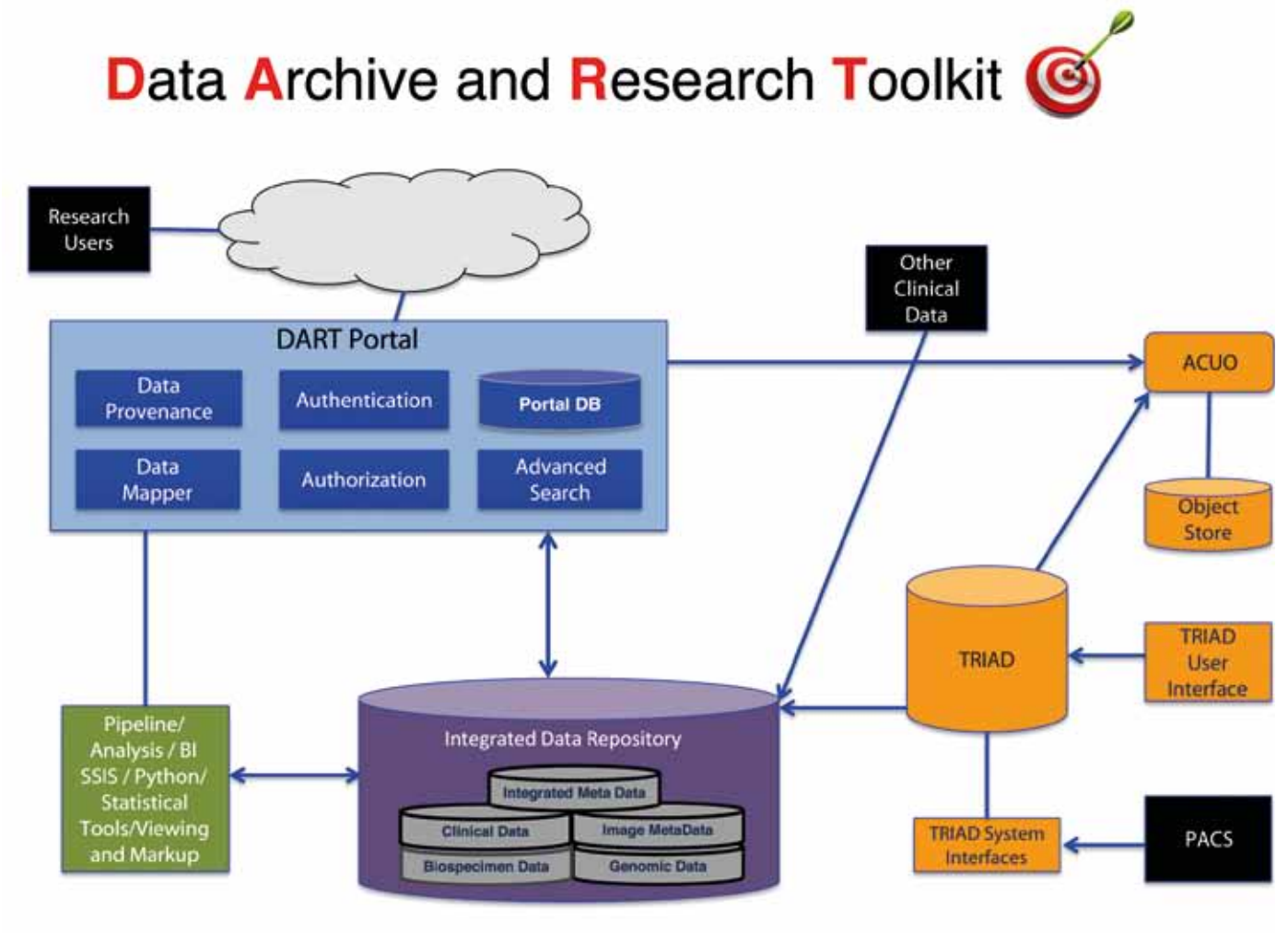

Figure 2

(DART) was developed in response to this. DART is both an IT infrastructure and analysis platform. It was built to support clinical researchers (internal and external) from a central point permitting access, query, visualisation, and analysis. DART was configured to provide data querying and access with sufficient flexibility and range to allow for a variety of researcher needs. DART empowers researchers to create harmonised datasets, perform analyses and develop algorithms which can be 'published' and shared with other researchers. DART is designed to be adaptive, serving as a multi-source research data warehouse that eases cross-trial, cross-discipline research specifically designed to promote the discovery and elucidation of biomarkers and clinical patterns (see Figure 2).

"A 'BIG DATA' APPROACH IS KEY FOR THE DEVELOPMENT OF CLINICALLY USEFUL TOOLS"

DART evolved from an ACR legacy Clinical Data Warehouse. DART's predecessor was an archive of clinical images and associated clinical data collected utilising ACR's TRIAD (Transfer of Images and Data) software. DART goes beyond the capabilities of the Clinical Data Warehouse, and supports new classes of research data extending well outside the traditional imaging range. Such additional data found in DART includes digital pathology images, bio-specimen/bio-repository information and operational research reports. With TRIAD as the data transfer component, the DART ecosystem is able to handle specialised workflow and requirements, including de-identification, integration with other clinical trial systems, flexible access and robust and highly customised federated searches.

DART's architecture includes a streamlined tool-building environment that encourages researchers to create harmonised datasets from clinical data, and to also perform post-processing of images in a transparent and consistent manner. The DART-supported tools will allow for assessing complex data

sets via a group of specialised software, generally third-party packages, but may also include custom programs. Examples of third-party packages supported by DART include quantitative computational methods such as cortical thickness heterogeneity measurement. Given the germinal nature of much of the related research and development efforts to date, both the lack of universally accepted algorithms and critical preprocessing components are strong deterrents to the widespread use of these algorithms.

As a corrective measure, DART tools will significantly ease the use of established and well-vetted imaging pipelines. Common pipeline elements for structural (eg T1-weighted) MRI include inhomogeneity correction (Tustison 2010), brain extraction (or skull stripping), prior-based n-tissue segmentation (Avants 2011) and cortical thickness estimation (Tustison 2014). Diffusion-weighted measures provided as part of the DART framework include mean diffusivity (MD), fractional anisotropy (FA), axial diffusivity (AD), and radial diffusivity (RD) maps with the potential inclusion of additional modalities. An additional benefit to the average researcher is that these pipelines have been tuned by knowledgeable developers in terms of the governing parameters, which are known to affect performance and quality of results, but are often omitted in traditional publishing venues (Tustison 2013). DART will include these processing parameters as part of the metadata. The ability to use complex pre-processing and processing algorithms, in addition to building a platform for comparison to 'normal' data, will greatly expedite the use of these important techniques in clinical practice.

This DART platform may serve to aid the convergence and utility of open science elements in a mutually beneficial way. The cloud-based environment will provide a platform for storage of image data and will facilitate method-driven contributions from developers. These efforts should enable cross-availability, ie cutting-edge processing methods, to neuroscientists and a large-scale vetting platform for developers.

TBI has a relatively heterogeneous imaging signature (Eierud 2014), which complicates tailored strategies for individualised disease characterisation. Thus a "big data" approach is key for the development of clinically useful tools whereby multimodality imaging features (Van Horn 2014), generated from DART processing, are supplemented by clinical and neuropsychological data from large cohorts demonstrating a range of TBI diagnoses. These large feature-sets can then be used as input to powerful machine learning techniques (eg support vector machines, random forests, neural networks), which generate diagnostic models for determining clinically relevant parameters (Lui 2014). Not only is it possible to use these models for predicting individual TBI classification or regression, but certain machine learning techniques can be used to provide feedback as to which details are most relevant for the diagnostic task thus potentially providing new research avenues for further exploration.

Conclusion

Utilising the above roadmap, it is hoped the coming years yield a comprehensive quantitative description of the imaging aspects of TBI, particularly mTBI, that span injury severity and multiple imaging modalities by capitalising on large scale TBI and population-based normal datasets. It is believed these key data will inform advanced analytical tools that may serve as a core for next generation clinical computational platforms to diagnose this condition. Development of this capability will provide leading-edge, powerful tools to clinicians caring for patients suffering from TBI. This platform, built on shared understanding and learning, could ultimately provide an objective tool for measurement of a patient's present disease state and prognosis. The objective measurement tools in neuroimaging facilitated by this effort will prove to be a critical component in the development of large-scale individualised treatment programmes for TBI. ■

Key Points

- ✓ The American College of Radiology (ACR) launched the Head Injury Institute (HII) to help drive progress and demonstrate leadership in head injury imaging.
- ✓ A key focus is to address barriers that limit the role of imaging in patients with mild traumatic brain injury (mTBI).
- ✓ Imaging currently has a very limited role in mTBI.
- ✓ The future of neuroimaging for mTBI will likely require some combination of computer-aided diagnosis (CAD) and qualitative interpretation by a practising radiologist.

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EUROPEAN HEART AGENCY

THE ESC AT THE HEART OF EUROPEAN POLITICS

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The European Heart Agency was opened two years ago as the Brussels office of the European Society of Cardiology (ESC) and is located in the centre of the city close to the European Commission. It has three branches: European Affairs, the European Heart Health Institute and the European Heart Academy.

ESC Immediate Past President Professor Panos Vardas, Managing Chair of the European Heart Agency, says: "By establishing the European Heart Agency the ESC now has a position near the heart of European politics. We will use this vantage point to promote policies and actions to prevent cardiovascular disease and encourage equal access to treatments."

European Heart Academy

The mission of the European Heart Academy is to champion academic excellence by fostering future leaders in cardiovascular medicine. It does this by organising courses around relevant cardiovascular topics together with an excellent European university. Each course leads to a university degree.

The **Master of Sciences (MSc) in Health Economics, Outcomes and Management in Cardiovascular Sciences** launches in October 2015 for a maximum of 30 students. The European Heart Academy has teamed up with the London School of Economics to teach students a unique skill set combining world-class expertise in health economics and in cardiovascular disease management.

Professor Paulus Kirchhof, Head of the University Courses Unit at the European Heart Academy, says: "Leading economic and cardiovascular disease experts teamed up to design this course which is the first of its kind. There are many health economics courses but none have a cardiovascular focus."

Economic evaluation has become a central part of leading departments and hospitals, and the course was created in response to this development. "These skills are not covered by current medical school curricula and are usually not taught in a formal way during specialisation, but they increasingly shape the way that we practise medicine," says Kirchhof. "This is especially the case in cardiovascular medicine where we have sophisticated interventions that prolong life but have high demands on technology, skills and expertise, and are therefore costly."

He adds: "The overall mission of the ESC is to reduce the burden of cardiovascular diseases in Europe. The ESC recognises that this has to be achieved in an environment where resources are limited. We think that the people who come out of this course will have the best training and education to make informed decisions about how to deliver optimal healthcare."

The programme is expected to attract two types of students. A large number are likely to be cardiologists, who are on the road to becoming department leaders or hospital leaders in the future.

Health economists who want to specialise in cardiovascular health economics are also potential applicants. Kirchhof says: "Students will come out of the course not only with a first-rate understanding of health economics but also with a profound insight into best practice in cardiovascular medicine."

To help students participate in the course, the ESC will offer a limited number of scholarships. ESC members who apply for the course and are offered a place can apply for one of the scholarships, which will fund the full course fees. Scholars will pay travel and accommodation costs for on-site activities.

The European Heart Academy is less than two years old but is set to release its first graduates this October. Some 50 cardiologists with a special interest in heart failure have nearly completed the **Postgraduate Course in Heart Failure**. The programme was designed by the Heart Failure Association (HFA) of the ESC in collaboration with Zurich University and the Zurich Heart House in Switzerland and leads to a Certificate of Advanced Studies.

Two more courses are on the way. The **Advanced Course in Cardiac Arrhythmias** focuses on another subspecialty of cardiology and is designed for 30 students. Set to start in 2016, it aims to educate the future leaders in electrophysiology. The course was designed by the European Heart Rhythm Association (EHRA) of the ESC in partnership with Maastricht University in the Netherlands and leads to a Diploma of Advanced Studies.

Also planned for 2016 is the **MSc in Translational Cardiovascular Medicine** which was planned together with the German Centre for Cardiovascular Research (DZHK) and the University of Hamburg in Germany. The programme is aimed at cardiovascular clinicians and researchers and expects to enrol 20 students.

All the courses intend to train future leaders in cardiovascular medicine and the themes therefore reflect upcoming hot topics in the field. Heart failure is a growing problem in Europe due to an ageing population, improved survival from cardiovascular diseases and increasing risk factors including obesity and diabetes. It is a costly disease largely because of hospitalisations.

Leaders are needed in the area of arrhythmias since atrial fibrillation and sudden death are two of the big unsolved cardiovascular health problems in Europe.

"The courses on heart failure and arrhythmias will give participants world-class training in important areas of cardiovascular medicine where novel therapeutic options are entering clinical medicine," says Kirchhof. "The management of patients in both subspecialties is changing with the emergence of electronic diagnostic tools, telemedicine and hybrid therapies that combine drugs and interventions."

Leaders at the ESC and the European Heart Academy firmly believe that some of the solutions to current chronic cardiovascular diseases will be found

in developing novel personalised or stratified therapies. Kirchhof says: "We expect that this development needs a new generation of clinician scientists who have an understanding of clinical cardiology and of modern approaches to the biosciences and to research. We hope that the MSc course will train future leaders in translational cardiovascular medicine."

All the courses are executive style and allow students to continue work while they study. A few weeks each year are dedicated to on-site training. Good use is made of online teaching, self-learning assignments, and online evaluation.

An **alumni forum** has been established for students and graduates of the European Heart Academy to encourage networking among the future leaders in cardiovascular disease. The group will operate through an online forum and yearly meetings at ESC Congress, starting this year in London, UK, at the end of August.

Kirchhof says: "We have come a long way in the last 18 months, but we still have to fully establish the European Heart Academy as a fully recognised place to train cardiovascular leaders of the future. Ultimately we will demonstrate this when graduates become leaders in their respective subspecialties."

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ESC Brussels Office

European Heart Health Institute

The European Heart Health Institute is in charge of new ESC activities including clinical trials, personalised medicine, novel technologies, quality assessment, health economics and healthcare management.

It is compiling the *ESC Atlas of Cardiology*, a unique database on healthcare systems, provision and services in cardiovascular medicine in the 56 ESC member countries. "The Atlas is an ongoing project but the plan is to map in a credible way the costs of cardiovascular diseases in different parts of Europe," says Vardas, who is Acting Chair of the European Heart Health Institute. "It will also describe the differences in cardiovascular disease burden and inequalities in availability of treatments."

Vardas adds: "The European Heart Health Institute is set to become a reliable source of information on the costs of cardiovascular diseases and the cost-effectiveness of diagnostic tests and treatments in Europe."

European Affairs

The European Affairs division works with European Union (EU) and national policymakers, European advocacy groups and medical associations to promote policies that favour cardiovascular health. It provides the secretariat for the Members of the European Parliament (MEP) Heart Group which hosts awareness raising activities in Brussels such as Cardiovascular Health Week. The division also provides the secretariat for the European Chronic Disease Alliance (ECDA). Another activity is CardioScape, a project which conducted a survey of the European cardiovascular research landscape using funding from the European Commission's Seventh Framework Programme (FP7). ■

Key Points

- ✓ The European Heart Agency is the Brussels bureau of the European Society of Cardiology.
- ✓ The three branches of the European Heart Agency are European Affairs, the European Heart Health Institute and the European Heart Academy.
- ✓ The European Heart Academy is training future leaders in cardiovascular medicine.
- ✓ The European Heart Health Institute aims to provide reliable information on the cost-effectiveness of cardiovascular treatments in Europe.
- ✓ European Affairs works with EU and national policymakers, European advocacy groups and medical associations to promote policies that favour cardiovascular health.

CURRENT DEVELOPMENTS IN THE EUROPEAN PERCUTANEOUS CORONARY INTERVENTION DEVICES MARKET

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Coronary artery disease (CAD) is one of the major causes of death worldwide affecting both women and men. Sedentary lifestyles along with hereditary factors are some of the major reasons for deaths due to CAD (Antman et al. 2008). Mortality due to these conditions has increased to the extent that it is attracting attention the world over, resulting in concentrated efforts to curb it. This has led to a huge number of surgeries and preventive treatments being performed. European healthcare systems are increasingly opting for treatments that are effective and less time-consuming, and have shorter recovery times with regards to CAD. As a consequence, healthcare across Europe has evolved from corrective bypass surgeries to interventional procedures. Over the last decade, there have been huge investments in research to discover innovative and minimally-invasive methods to treat CAD, as these minimally-invasive interventional procedures are not only less time-consuming, but are also cost-effective.

With minimally invasive technology becoming a well-established treatment for CAD in Europe, percutaneous coronary intervention (PCI) has become the standard when compared to surgery (Anderson et al. 2007). PCI usually involves inserting catheters and guide wires through the groin or arm to deliver stents and balloons to the narrowed coronary arteries. It is estimated that in 2014 alone more than 1.3 million PCI procedures were performed in Europe* (Frost & Sullivan 2015). The number of PCI procedures performed is expected to grow steadily due to better reimbursement, increased diagnosis and awareness among patients.

Percutaneous Coronary Intervention Segmentation

The PCI market is segmented into coronary stents, catheters, accessories, and embolic protection devices (EPD) (see Figure 1) (Frost & Sullivan 2015). The coronary stents segment includes drug eluting stents (DES), bare metal stents (BMS), and bio-absorbable stents (BAS). Catheters for angiography, percutaneous transluminal coronary angioplasty (PTCA), thrombectomy, atherectomy and ablation are included in the catheter segment. Guide wires, introducers and stand-alone balloons form the accessories segment (see Figure 1).

Current Market Scenario

The Western European** PCI market was estimated to be U.S. $2,038.3 million in 2014 (Frost & Sullivan 2015). It is a mature market and is expected to grow at a compound annual growth rate (CAGR) of 1% in the next five years. An ageing population, associated with increased incidence of CAD, drives the uptake for PCI procedures. There is also a growing interest among patients about their wellbeing, and they are seeking to aggregate information from various sources about their condition. This change in patient attitude is also expected to drive the PCI market.

The coronary stent segment accounted for almost 56.2% of the PCI market. Within the coronary stent segment, DES contributed to a majority share due to its increased penetration

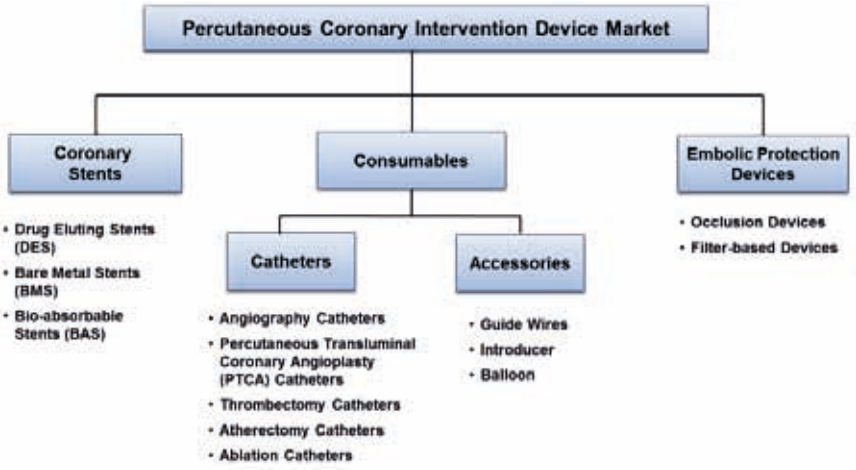

Figure 1. PCI Market: Segmentation, Western Europe, 2014

EuroEcho2015 Imaging

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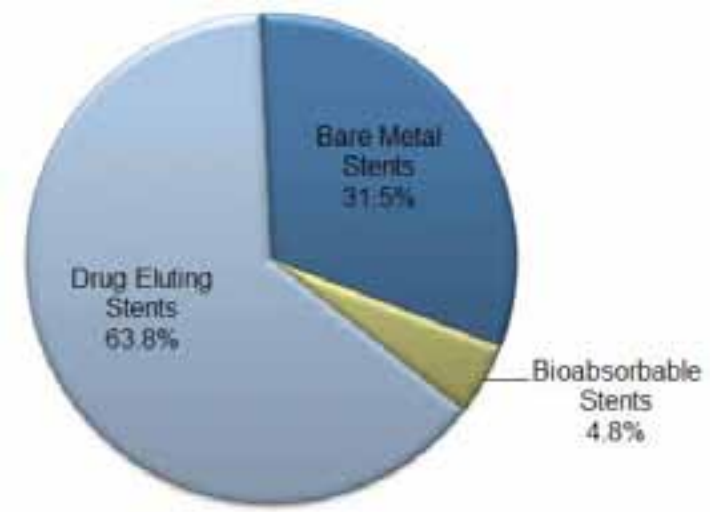

Figure 2. Coronary Stents: Percent Sales Breakdown by Sub-segments, Western Europe, 2014

within hospitals. BMS accounted for most of the remainder of the pie, while BAS represented a very small share in this segment (see Figure 2).

The use of coronary stents in PCIs has risen rapidly in recent years. Studies show that more than 90% of PCI procedures in Europe involve a coronary stent, as it has shown remarkable improvements in restenosis rates (Steinhubl et al. 2002). primarily driven by the high volume of PCI as well as diagnostic procedures carried out throughout Europe. Guide wires and introducers are required for every interventional procedure, thereby making procedures the principal catalyst in unit and subsequent revenue growth. As the number of PCI procedures increases, the average number of guide wire and sheaths per procedure will also increase,

"OVER THE LAST DECADE, THERE HAVE BEEN HUGE INVESTMENTS IN RESEARCH TO DISCOVER INNOVATIVE AND MINIMALLY-INVASIVE METHODS TO TREAT CAD"

While the number of coronary stenting procedures performed across Western Europe is expected to grow, the average selling price (ASP) of stents is declining, resulting in a significant reduction in the coronary stents segment. However, the exception to the decline in the coronary stents segment will be BAS, which are expected to be increasingly adopted in the coming years due to better prevention of stent thrombosis found in DES.

The European consumables segment, consisting of catheters, guide wire and introducer sheaths, accounted for around 40% of the revenue generated within the PCI market in 2014 (Frost & Sullivan 2015). The catheter segment is thus driving market revenue. However, opposing this growth is a decline in ASPs, due to the increasing commodity status of these simple devices.

Embolic protection devices (EPDs) are devices that can minimise or eliminate the risks and complications of embolism. This device safely traps and removes much of the debris that may be dislodged during interventional procedures. The Western European EPD segment accounted for 3.7% of the revenue generated within the PCI market in 2014 (Frost & Sullivan 2015). The EPD segment is currently dominated by filter-based systems (70%) when compared to occlusion-based systems. Technological advancements and therapeutic effectiveness, along with growing acceptance, aid in greater uptake of EPD.

Germany remains the market leader amongst Western Europe, and accounted for almost 30% of revenue generated within the PCI market. In the past 10 years, the number of catheterisation laboratories in Germany has dramatically increased, along with coronary angiography rates, which have quadrupled, resulting in almost a 10-fold increase in the number of PCI procedures performed. The United Kingdom and France occupied the second and third position and accounted for 38.2% in terms of revenue generated for the PCI market. Increased awareness about CAD and PCI treatment is driving patients to undergo diagnostic checkups that could lead to interventional follow-up, thus aiding the market revenue within these countries.

Industry Challenges

One of the major factors that has had a significant negative impact on all PCI segments is decreasing ASP. Industry participants have been aggressive in their use of pricing as a competitive tool, especially in the coronary stents segment, to gain increased penetration. Due to this heightened competition, ASPs of stents are decreasing swiftly, as manufacturers further employ discounting and bundling tactics to gain greater market share, thus affecting market revenue.

Another major reason contributing to the reduction in ASPs is the lack of overwhelming innovation in the market to stabilise current prices. Although competitors continue to roll out new-generation stents and balloons, major differences between products are difficult to distinguish. Due to this, many products such as balloons, guide wire, and introducers have become more commoditised, inciting greater price competition amongst the numerous competitors in the market.

Lack of reimbursement in certain PCI segments such as EPD further restrains the PCI market. The cost of adding an EPD to the PCI procedure cost is significant, and its usage is affected by current reimbursement policies. In many cases reimbursement of EPD has been a little difficult, as they are not part of the devices implanted in the body. Securing adequate reimbursement and recognition of the device as a necessary part of

the procedure still remains a challenge. Reimbursement is further affected by budget restrictions within hospitals, and hinders the acceptance of an additional product as part of the procedure.

New Developments in PCI Devices

One of the limitations associated with DES is the increased risk of late stent thrombosis, as they remain within the artery wall, which can be a source of chronic vessel wall inflammation, and in turn may interfere with the endothelial function. To counter this, BAS and drug eluting bio-absorbable stents (DEBAS) were introduced, as they are absorbed by the body without compromising the integrity of the vessel. Products such as ABSORB® BVS from Abbott Vascular (CE mark in 2011) and DESolve® BRS from Elixir Medical (CE mark in 2014) fall under this category.

Additionally, in recent years drug eluting balloons (DEBs) and drug-coated balloons (DCBs) have emerged as potential alternatives to effectively combat restenosis. DEB technology has demonstrated safety and efficacy in patients with in-stent restenosis. DEB is still in its nascent stage; however, it is expected to grow substantially. DEB is expected to affect not only the standard PTA balloon market, but also to threaten the stent market. It is predicted that in the coming years DEBs have the potential to be considered the gold standard of treatment by providing an effective and cost-saving solution. Medtronic plc is one of the leading market participants in the DEB segment.

Competitive Environment

The PCI market in Western Europe had more than 40 active participants in 2014, and this number is expected to increase with new participants entering the market every year. The top three PCI participants contributed to around 64% of total market revenue (Frost & Sullivan 2015). Currently, Boston Scientific is the market leader in terms of revenue generated in the PCI devices market. Its broad product portfolio and good research and development budget are some of the critical factors for its effective penetration across all regions in Europe. Its recent acquisition of Bridgepoint Medical (2012) is aiding combating coronary chronic total occlusions (CTOs) by providing novel solutions for its treatment.

Medtronic and Abbott Laboratories occupy the second and third position, respectively, and have almost similar market shares. Medtronic has leveraged its established infrastructure and market presence to gain business in the PCI segment. Its introduction of the export advance aspiration catheter for thrombus removal in 2013 is expected to have a big impact on its revenue.

The Cordis Corporation, due to the discontinuation of its DES products in 2011, has lost its market share. However, with the recent (2015) acquisition of Cordis by Cardinal Health, Cardinal Health is expected to garner market shares from Boston Scientific and Medtronic and remain one of the top three players in the PCI market.

Conclusion

With the PCI market in a mature stage, companies are continuously trying to differentiate themselves from their competitors in order to increase their market share. Factors such as brand identification and loyalty retention measures are expected to significantly drive companies to realise this. Increased brand loyalty through a better relationship with end users and a more effective post-sales service will be the motto for companies to maintain advantage.

Western Europe is an ideal place for the PCI devices market, as there is an ever-increasing demand for more sophisticated products to tackle complex conditions. This is an ideal opportunity, which small manufacturers could leverage on and develop expertise in that field, giving them a competitive advantage in the market over established participants for complex coronary conditions. Exploitation of new markets is expected to drive sales for small manufacturers and help them to establish a concrete brand name and loyalty associated with their products.

The full report is available from **www.frost.com/sublib/display-report.do?id=MA97-01-00-00-00** ■

Key Points

- ✓ The Western European percutaneous coronary intervention devices (PCI) market is in its mature stage.
- ✓ The current focus is on innovations like bio-absorbable stents and drug eluting bio-absorbable stents that have the potential to drastically influence the stent segment.
- ✓ Decreasing average selling price, seen in every segment within the PCI market, restrains revenue growth significantly.

NOTES

* Europe includes Germany, UK, France, Spain, Italy, Benelux (Belgium, the Netherlands, and Luxembourg), Scandinavia (Norway, Sweden, Finland, and Denmark), Bulgaria, the Czech Republic, Hungary, Poland, and Romania.
** Western Europe includes Germany, UK, France, Spain, Italy, Benelux (Belgium, the Netherlands, and Luxembourg) and Scandinavia (Norway, Sweden, Finland, and Denmark).

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GUIDING POPULATION HEALTH STRATEGY WITH VISUAL DATA

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An emerging management approach in healthcare delivery is that of a migration towards comprehensive examination of chronic diseases, and entire populations as a whole instead of the individual. In essence, slowly moving from episodic-quantity care to population-quality care. Managing the overall wellness or health status of an "assigned" risk pool or population of patients has been a constant for third party insurers for many years, but only more recently has it emerged on the provider side of healthcare delivery. Examination of the health status or wellness of a defined population can provide valuable insights, and is the premise behind our recommendation in harnessing visual data as an effective tool for providing healthcare services not only more cost efficiently, but at a same or higher quality and for greater populations.

The field of epidemiology has historically demonstrated that a person's health can be markedly affected by the place or region where they are born or live. When basing a person's health on only one factor of the social determinants of health, healthcare professionals are not necessarily garnering a complete picture. In order to effectively forecast health conditions it is essential to look into a community's social, environmental and cultural factors. In a population healthcare delivery climate, the use of epidemiological metrics in a visual rather than numerical fashion may allow for more timely strategic decision-making.

As we begin to migrate towards new delivery models, and to harness new techniques for more effective strategic planning, it is prudent to examine some of the key terms and concepts in population health management.

Population Health

Population health is an up-and-coming real delivery model in the healthcare industry, and has been identified as a top strategic initiative (Punke 2013). With the shift in focus from episodic care to looking at the health of a population as a whole, organisations have to begin to think about how to take care of the patient across the continuum. Managing the overall wellness and health status of an assigned risk pool of patients is the primary goal of population health.

What exactly does population health and visual mapping have to do with strategy and planning? To truly understand their patient population, organisations must first understand who their population is. Many of the social determinants of health, such as social, environment, cultural and physical factors, are largely impacted by where the patient lives. Visual mapping should be utilised to develop a better understanding of not only who your patients are, but also what the day-to-day factors are that influence their healthcare needs. Understanding these interactions can lead to better decision-making.

Accountable Care and The Medical Home

Accountable Care Organisations (ACOs) and The Medical Home (Agency for Healthcare Research and Quality n.d.) must take a look at the entire population and their needs in order to align best with payment and care. Technology associated with population health will aid ACOs and The Medical Home. It is possible to see health status from state down to zip code, population growth, and three-dimensional rankings of chronic diseases by state, timelines of disease progression by state, hospital inpatient discharge data by disease, ambulatory surgery case data, emergency visit data and more. With this information you can start to predict what health conditions will arise from the state to the city level. This will aid organisations in tailoring their specialties to provide the specific services that are needed.

Bundled Instead of Episodic Payments

Providers assume any cost that exceeds the fixed rate with bundled payments; essentially the provider has the financial risk. To help keep costs down providers can work to reduce episodes by connecting patients to prevention and care management programmes. In looking at what episodes to bundle, regional and statewide trends are assessed. To determine what acute or chronic conditions to bundle, the current "assigned" population is assessed and the episodes selected. Population health's effect on bundled payments is that it requires clinicians to think beyond their patient encounter. For example, surgeons must think past the operating room and consider the total impact and need for follow-up care. With bundled payments, clinicians are encouraged to emphasise prevention strategies, begin with conservation treatment, and work to enhance patients' understanding of diseases, treatments and prevention.

It is also prudent to note that growing debate exists regarding the educational infrastructure and ability to provide clinical services in a population health climate with nursing and physician shortages.

Looming Shortage of Essential Personnel - Physicians and Nurses

With the looming shortage of essential clinical personnel those in the field will need to be better utilised. This means strategically placing physicians and nurses in the communities they can best serve. Using population demographics to place physician practices the community can be better served with the appropriate number of clinicians. With a potential shortage coming physicians must be placed as efficiently as possible.

Strategic Planning and Visual Mapping

Strategic planning is a critical component for every healthcare provider, and

Figure 1. Example of Microsoft Power Maps

healthcare is truly location dependent. Executives can better understand where their patients come from in order to figure out what types of services to focus on, as well as where to place facilities for future growth. Some examples of useful visual mapping data include patient age, zip code, county, health status and diagnosis code. Other important data that could be utilised visually are 3D rankings of chronic disease, population growth, hospital inpatient discharge data, and also ambulatory surgery case data.

As far as visual mapping resources go, Google Maps API (**developers.google.com/maps**) and Microsoft Power Maps (Part of Microsoft's Business Intelligence Solutions - **www.microsoft.com/en-us/powerBI/solutions/capabilities/mapping-software.aspx**) are two examples of affordable software. These software packages allow for dataset uploads, and commonly allow Microsoft Excel spreadsheets as well as other database sources. There are numerous online tutorials for visual mapping, which allow for a wide range of users. Visual mapping resources provide numerous opportunities not only for the executive management team, but also frontline managers.

While commercial data analytics are key to understanding where key patients are located, it is crucial that organisations leverage their own electronic health record (EHR) systems within their organisation. Many different analyses can be done within an EHR, such as viewing patient encounters and admissions in order to compare what chief complaints patients are visiting the facility for. Some of the other metrics that can be leveraged through an EHR are patient locations based on zip codes and patient demographic profiles, such as age, sex and ethnicity.

Use of an organisation's own EHR would better help them to understand and assess their patient population in order to better understand the diseases that affect those individuals. With the use of an EHR, the ability to gain an understanding of patient disease states greatly improves and helps to better combat different episodes of care. Each patient and each patient disease requires significantly different methods of treatment and disease regulation.

Not only can leveraging an organisation's own EHR be a useful strategy, so can using public and proprietary available resources. Often these resources are not leveraged to their fullest potential. Some of these resources include healthcare websites, Hospital Association data resources and advisory board data statistics. These data can be obtained through manual or automatic data pulls, home build or commercial products and SQL databases. This data can be used to strategically plan and manage the care provided to a patient population.

"MANY ORGANISATIONS USE VISUAL OVERLAY-MAPPING AS A STRATEGIC AND OPERATIONS PLANNING TOOL"

Conclusion

With use of these various data sources, many organisations have now been utilising visual overlay-mapping as an effective tool for strategic and operations planning and to look at the current state and future state of opportunities within a market area. By using these maps, organisations are able

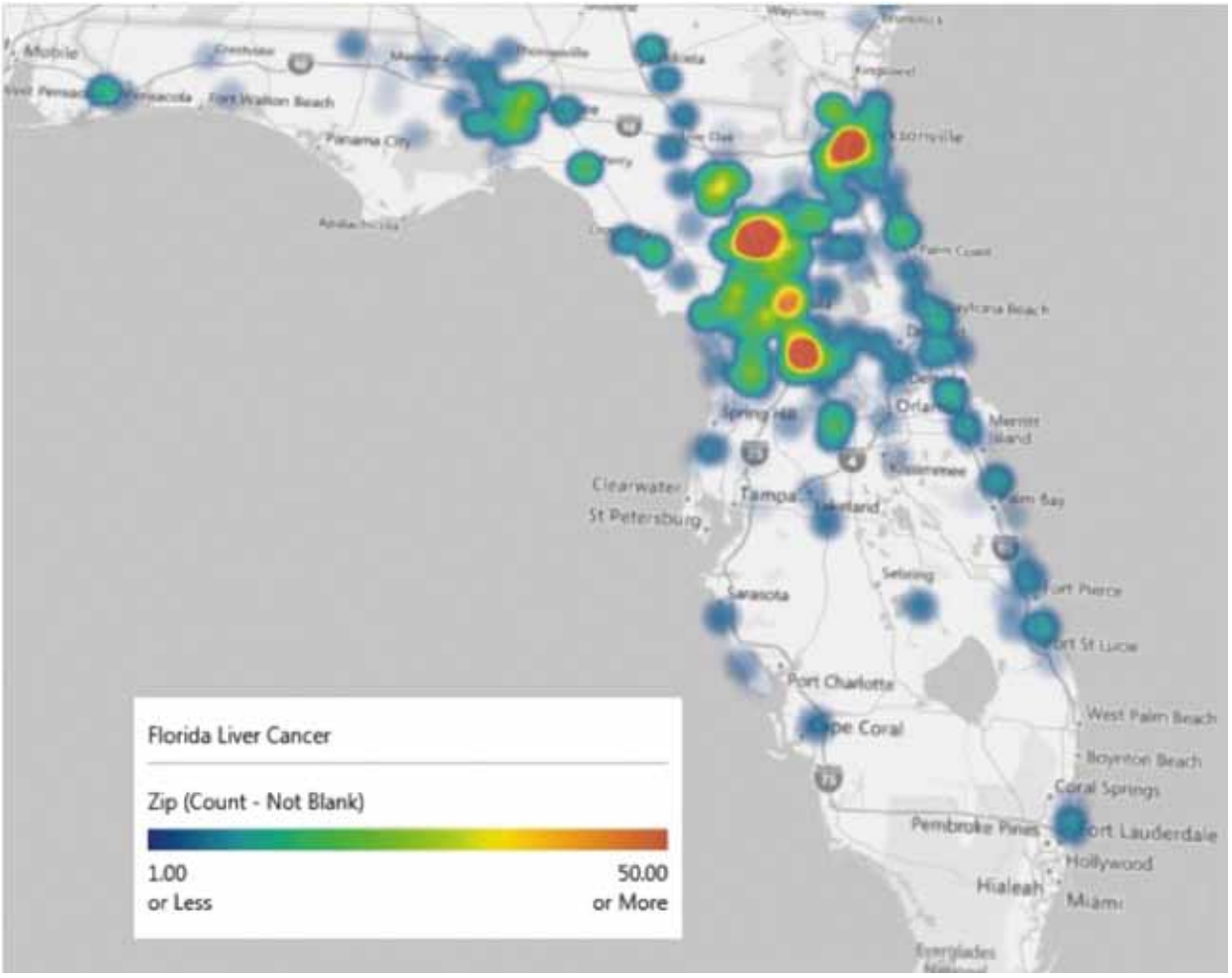

Figure 2. Microsoft Power Maps Example Showing Liver Cancer Incidence

to help better maximise resources such as clinicians, supplies, mobile outreach, physical space, etc. While maximising resources is key, it is also crucial that these maps can pinpoint patient populations in order to help better manage new payment modelling systems for the organisation in the future.

Key Points

- ✓ Healthcare delivery is moving from episodic care to a population health model.
- ✓ Managing the overall wellness and health status of an assigned risk pool of patients is the primary goal of population health.
- ✓ Use of epidemiological metrics in a visual rather than numerical fashion may allow for more timely strategic decision-making data.
- ✓ Data sources include organisations' own electronic health records as well as publicly available and proprietary resources.
- ✓ Maps assist in maximising resources and pinpointing patient populations in order to help better manage new payment modelling in future.

Suggested Resources

Below are a few resources that have been utilised by numerous organisations in order to take advantage of visual mapping tools. We are not in any way affiliated or compensated with these resource providers.

1. Caradigm Population Health Software Vendor provides great resources
   a. **www.caradigm.com/en-us/resources**
2. Microsoft Power BI - Includes Power Maps
   a. **www.microsoft.com/en-us/powerbi/default.aspx**
3. SmartDraw Software
   a. **www.smartdraw.com/software/map-software.htm** ■

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GETTING STARTED WITH A HEALTH BLOG

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The Internet is full of blogs. They are multi-themed sites, self-managed by the authors and demonstrative of, and only limited by, the authors' level of creativity. They are potentially accessible to anyone and everyone. There are numerous health blogs, but the proportion of health professionals who are bloggers is low. Having a blog is a cost-effective option to share health information, to promote interaction between professionals and patients, and for global communication.

What is a Blog?

A blog is a website whose owner can edit and share the contents easily. The term 'blog' is a derivative of the original 'weblog', taken from 'web' (network) and 'log' (diary, daily account of events), whose publications are logged in chronological order. The owners of different blogs are known as bloggers.

Advantages

- Advanced computer know-how is not a requirement.
- It is the easiest way to have a digital presence.
- It can be run at minimum cost or even at no cost at all.
- Text, audio, video, attached files, presentations, and/or images can be shared.
- It allows interaction with readers through free comments or through the author's supervision.
- Readers can subscribe and receive information published in their email or via a content aggregator programme.

Before Starting a Health Blog

It is essential to work up a basic blog design before opening it, and to be able to answer the following questions:

- What is my reason for writing a blog about health issues?
- Who is my target audience?
- What information do I want to share?
- How often will I publish?
- How much of my time do I want to invest in this endeavour?
- Do I want to or can I provide this blog in other languages?

How to Start a Blog in a Minute

There are many tools to create a blog, both free and at a cost. At the present time, two tools stand out above the rest: Blogger and Wordpress

Blogger is perhaps the most widespread free tool. The owner doesn't need to buy a web domain or hosting package. It has the advantage of integration with other services offered by Google.

WordPress is constantly updated and very easy to use. It is chosen by many bloggers. It has a free version and has advanced options of payment also. There is an advanced platform that can be installed on private servers to which many services and applications can be added. It is very versatile.

Living with a Blog

The first bit of advice: once you have it opened and running, you need to write or share content frequently and regularly. A blog that does not publish content on a regular basis fades away and dies from lack of followers. Good quality content, interesting and reliable data ensure that your blog will be visited and endure over time.

If you want your blog to be known, you must share your posts on different social networks (Facebook, Twitter, LinkedIn, Google+).

Dealing with your Followers

You can decide whether to receive comments or not to your blog; whether they are published automatically as they reach you or supervised by you prior to publication. It may be advisable to establish a policy for publication of comments to orient the reader.

Good Reasons for Starting a Health Blog

Having a health blog benefits the health professional by allowing him/her to share and discuss health and medical issues with colleagues or patients.

Our professional visibility increases as we share content. By posting resources, quoting other websites, and referencing prestigious journals, we will be positioning ourselves higher in the rankings for the issues we discuss.

A good reputation on the Internet translates into greater confidence from patients and professionals. The confidence in the blog will increase as well, not to mention your reputation as an expert in your field.

A blog means connecting easily with other bloggers to exchange ideas, and to deepen your understanding on a specific topic, while providing a platform for the continuing education of its authors and readers alike.

Health Blogs Are Useful

- **For professionals:** as a training or educational tool, to share knowledge and experiences on different topics.
- **For patients:** as a health education tool; to take health questions and advice out of the limits of the family doctor´s office, ambulances or hospitals.
- **For government institutions:** to disseminate health contents for the population.
- **For networks of patients:** to offer information and support to other patients, based on personal experience.

What Can Go Wrong With a Blog?

- Excessive time spent.
- Too much visibility.
- Errors and opinions are misinterpreted.

In our opinion...

Having a blog is a personal choice. If you like to write, if you feel that your voice needs to be heard and you want to reach a lot of people (professionals, patients, family), do not hesitate: this is your tool!

PROYECTO HU-CI
HUMANIZANDO LOS CUIDADOS INTENSIVOS

The IC-HU Project: Humanizing Intensive Care
www.humanizingintensivecare.com

La consulta del Doctor Casado www.doctorcasado.es

Salud conectada www.saludconectada.com

"YOU NEED TO WRITE OR SHARE CONTENT FREQUENTLY AND REGULARLY"

The authors of this article have become known thanks to our respective health blogs, three of the most popular blogs in Spain. As a result, communication between the different levels of public healthcare in Spain has increased.

Health Blogs We Read:

1. Kevin MD (English) **www.kevinmd.com/blog**
2. Open Innovation and Co-Creation in Health(Bilingual) **https://healthco-creation.wordpress.com**
3. Neuronas en crecimiento (Spanish) **http://neuropediatra.org**
4. Enfermería basada en la evidencia (Spanish) **http://ebevidencia.com**
5. The BMJ blog (English) **blogs.bmj.com/bmj**
6. 33 Charts (English) **http://33charts.com** ■

GETTING STARTED WITH TWITTER

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If you want to know how we practised medicine 5 years ago, read a textbook.

If you want to know how we practised medicine 2 years ago, read a journal.

If you want to know how we practise medicine now, go to a (good) conference.

If you want to know how we will practise medicine in the future, listen in the hallways and use FOAM.

— From International EM Education Efforts & E-Learning by Joe Lex 2011

The growth of social media for medical CPD has been astronomical over recent years. More and more healthcare professionals are taking to Twitter to share useful papers and educational resources. The emphasis on encouraging Free Open Access Medical Education (FOAM) is embedded throughout these interactions. We have no intention of reinventing the wheel with this one, but have tried to combine the wealth of information already out there with a few of our own experiences. Hopefully this will help newcomers to Twitter, and perhaps persuade those still resisting to come on board.

What is Twitter?

- Online social networking/micro-blogging platform enabling users to send and read text-based messages ('tweets').
- Limited to 140 characters [see highlighted text below to see how long that is!].
- Photos can be tweeted.
- You only read tweets of people you follow.
- Anyone can follow you, although you can block them if you wish.

Benefits

- Global conversation with like-minded individuals interested in the latest medical practice and literature.
- It's acceptable just to watch if you prefer.
- Follow conferences even if you are not there.
- Social networking and friendships develop and can be consolidated at conferences, with colleagues across the globe.

What does it mean to follow someone on Twitter?

This means that you've chosen to subscribe to their Twitter updates. You can unfollow them at any time. Similarly, anyone is able to follow you. If you decide that you do not wish for them to do this, you can always 'block' them. You can easily see who is following you.

Figure 1. Twitter Discussion

Who should I follow?

Have a look at someone you know, who is already using Twitter for medical education purposes, and look at their list of people they are following. You will quickly learn to recognise the Twitter characters who are reliable and useful, and after a period of Twitter interaction, you should start building up your own following.

What's @ and # all about?

@TwitterID directs your message to that person. You can add other names if you want to send to multiple, but beware the character limit. If '@' appears at the start of the tweet it will go to that person AND anyone who is following both you and them. If '@' appears later in the tweet, it will go to that person and ALL of your followers.

To illustrate this, if you send the following tweet '@avkwong this blog is rubbish' - I will receive this message and anyone that is following both of us. If you send 'This blog is rubbish @avkwong' or 'This blog by @avkwong is rubbish' - I will receive this message and also ALL of your followers – thanks!

A Direct Message (DM) This is a private message and visible only to you.

 # (hashtag) is used to mark keywords or topics in a tweet. Anyone can make a hashtag at any time, simply by typing a phrase of the form '#topic' in a tweet (again no spaces). This creates a page specific to that hashtag and whenever someone tweets and includes this hashtag, it will be visible on this page as well as to anyone who follows them.

Many hashtags have already been created, and medical conferences will advertise the ones they are using e.g. #isicem15 (International Symposium on Intensive Care and Emergency Medicine 2015), #ISCSOA2015 (State of the Art Meeting, ICS 2015) and #smaccUS (Social Media and Critical Care Conference 2015). The days of writing notes at conferences (if you did in the first place) have also gone if the conference is well covered by avid Twitter users. Photos of conference slides, posters and equipment at trade exhibitions can also be tweeted and shared.

What's Twitter not so good for?

Apart from your social life, it is not a great platform for having extensive discussion and debate. This often is difficult to fit in 140 characters, and results in huge number of tweets about one topic, and the context of these key messages can often be lost in translation.

A word of caution with using Twitter

You should comply with the General Medical Council (UK)'s 'Good Medical Practice' (**www.gmc-uk.org/guidance/good_medical_practice.asp**) or equivalent in your country, and it is worth having a look at the brief GMC regulations (**www.gmc-uk.org/guidance/ethical_guidance/21186.asp**).

Personal experience

We have found Twitter a fantastic vehicle for learning, sharing and discussing the latest literature, resources and details at conferences. It still amazes us that we were able to have discussions about the TTM trial on Sunday 17 November 2013 as it was being discussed in Dallas (have we decided yet 33°C or 36°C?!). Access to information, working collaboratively and encouraging each other in a really friendly and supportive way must be credited to Twitter and all the incredible FOAMites involved (see Figure 1). Join now!

Summary

- Register at Twitter.com
- Install the App on your mobile device(s)
- Follow users and hashtags (#)
- No, you DO NOT have to contribute
- It is OK to watch

The original article in our sister journal *ICU Management* included Twitter suggestions specific to intensive care medicine. These are the *HealthManagement* team's suggestions.

HealthManagement.org
@ehealthmgmt
Latest developments in healthcare management, leadership, patient and staff safety, best practice, economics, industry developments and much more.

JAMA
@JAMA_current
The Journal of the American Medical Association, published since 1883, is an international, peer-reviewed medical journal published weekly.

IHM
@IHM_tweets
The Institute of Healthcare Management is the leading independent membership organisation for health and social care managers.

NHSLeadershipAcademy
@NHSLeadership
Our purpose is to develop outstanding leadership in health, to improve people's health and their experience of the NHS.

WHO
@WHO
Official Twitter account of the World Health Organization, the United Nations' health agency.

ECDC
@ECDC_EU
The European Centre for Disease Prevention and Control (ECDC) is an EU agency aimed at strengthening Europe's defences against infectious diseases.

European Society of Cardiology
@escardio
The European Society of Cardiology aims to reduce the burden of cardiovascular disease through congresses, surveys, journals and clinical practice guidelines.

Radiopaedia.org
@Radiopaedia
Free online collaborative radiology resource with frequently updated articles covering all aspects of medical imaging, a huge case library and much more...

ECCO
@EuropeanCancer
Raising awareness to improve prevention, diagnosis, treatment and care of cancer patients.

EU Medicines Agency
@EMA_News
Latest news from the European Medicines Agency, the European Union agency responsible for the evaluation and supervision of medicines.

European Society of Radiology @myESR
ESR is the largest radiology society in the world, dedicated to promoting and coordinating the scientific, philanthropic, intellectual and professional activities of Radiology in all European countries.

PART 2: BEYOND THE BASICS - CPD RECORDS

The world of medical education is changing. Gone are the days of textbook learning. Medical developments and practice are evolving so quickly that print as a medium is becoming obsolete. So you've read the first part of the guide and are really enjoying the newfound source of information and education. You've even started communicating and engaging in lively discussions with colleagues from all corners of the globe.

You now need to convince your colleague/manager/organisation of its value. Despite the social media label, this is far from being a plaything, and is actually educational and relevant. The fact that it is fully electronic makes compilation of evidence and/or records possible. As part of the appraisal and revalidation process, doctors and other healthcare professionals must now provide evidence that they are keeping up with the latest medical developments. The GMC UK has defined five domains in the Duties of a Good Doctor document (**www.gmc-uk.org/guidance/good_medical_practice/duties_of_a_doctor.asp**).

In this section we suggest a few ways of expanding the use of Twitter to support continual professional development beyond a simple reading list and conversation tool.

Figure 2. JAMA Twitter page

Figure 3. Screenshot of Tweetdeck

Journal Alert – the "ex-" Printed Press

We are expected to keep up-to-date, and reading journals has traditionally formed a large part of it. The more diligent amongst us may keep a record of the articles that we read. Some publications also have a short quiz accompanying the article in order to test understanding and act as proof that the article has indeed been read.

The Internet has revolutionised the spread of information. Traditional

medical journals are now available online in addition to their printed forms. The use of smartphones, tablets and other mobile devices is now common in the medical workplace.

For the reader, articles can be downloaded and read whenever convenient. Such is the impact of social media, journals and professional societies/organisations now have their own Twitter accounts (see Figure 2). By following these accounts, you can access the articles immediately, and some of the latest articles are available online even before the printed edition. Greener colleagues amongst us would also welcome the paperless option.

The digital format means you can easily generate an electronic record of your activity. As evidence for keeping up-to-date, this is more credible and permanent than a written record (see Figure 2).

The Conference Hashtag

From our initial guide, you've managed to follow the conference. At last year's European Society of Intensive Care Medicine (ESICM) LIVES congress, results of five major ICM trials were presented and discussed on Twitter by colleagues across the world. The use of social media at medical conferences has been increasing. Most major conference organisers have dedicated hashtags which are promoted to encourage delegates (and indeed non-delegates) to engage with colleagues and presenters. ISICEM 2015 had the hashtag #ISICEM15. The upcoming ESICM LIVES 2015 Conference in Berlin had the hashtag #ESICMLIVES2015, Social Media and Critical Care #smaccUS, and the ICS State of the Art Conference in London is #ICSSOA2015.

It's now time to put it all together as your record of the conference. You might want to share your notes with colleagues within the department. The organisers have even written a blog of the day to add to the myriad of tweets by delegates. You could use a pen and paper, but given that all of this is online and digital, there can be an easier way to compile this information.

The search function on Twitter can be used to produce a list of tweets with the appropriate hashtag. The Symplur website (**www.symplur.com**) allows you to find relevant healthcare conference hashtags in your field of expertise. Most of us already use word-processing software to compile our notes. It is then a simple matter of reviewing the tweets, cutting/pasting and formatting. It does require a certain degree of discipline to look through the list of tweets, but it does provide insight from multiple delegates. Appraising the presentation/publication is immediate and of obvious value when compiling such notes. You no longer have to wait for next month's issue to read the correspondence section.

We have no doubt that as technology evolves methods of compiling notes will evolve. Last year's ESICM LIVES conference app had a note section, recorder function, etc. in addition to conference planning tools. It was a 1.0 form but a clear indication of future direction. Mobile apps for conferences are becoming a common occurrence – download them and see what you think.

Maintaining a CPD Diary

Electronic logbooks are common across a variety of specialties. These include simple procedural logbooks to more detailed diaries of meeting activities, teaching activities, courses and conferences. The Royal College of Anaesthetists in the UK has an online CPD diary for members who use their educational portal.

Cloud-based storage allows access to these regardless of location and device, provided there is online access. The record can be updated from your conference laptop or tablet device on the journey back home.

As an example, after your attendance at a conference, the following could form part of your appraisal portfolio:

- Conference attendance certificate;
- Conference handbook;
- List of tweets contributed, which may include analysis of retweets;
- Notes compiled from various online sources – tweets, blogs, article references.

Apps at Your Service

In addition to an Internet browser and word processor, there is a myriad of tools/apps to help you work more efficiently/smartly.

Cloud Storage

From tablets to smartphones, netbooks to desktops, we're using more devices on a daily basis than ever before, and toggling files between each of these devices can be cumbersome and complex. Not so with online storage services. You can access your account from any Internet connection, whether you're on a mobile browser or your work computer. Other advantages include:

- Syncing – all files automatically updated across your devices;
- Sharing/collaboration;
- Recovery/back-up.

Cloud services include iCloud (**www.icloud.com**), Dropbox (**www.dropbox.com**) and GoogleDrive (**www.google.com/drive**).

Online Organisers

Being an organised professional, we are sure that you already have your own way of organising your digital resources and files. Software such as Evernote (**www.evernote.com**) works on a variety of devices and complements the benefits of cloud storage.

3rd Party Twitter Tools

There is nothing wrong with the official Twitter app or website. However, apps such as Tweetdeck (web.tweetdeck.com) (see Figure 3) allow a greater degree of flexibility and an enhanced experience. Features include the ability to view multiple accounts at the same time and a dedicated column for each hashtag (especially useful during conferences).

We hope you have found this article useful. If you have any comments, we would love to hear from you. See you out there on the Twittersphere. ■

THE UK RADIOLOGICAL CONGRESS

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UKRC 2015 PROGRAMME

The UKRC programme once again brings together an impressive and diverse range of high-profile speakers, keynote and 'state of the art' lectures from the UK, Europe, North America and the Far East. The 3 day event offers 8 specialist streams; eponymous lectures from SCOR, IPEM and BIR; interactive voting; OsiriX workstations and FRCR VIVA tutorials, along with exciting new features for 2015.

Along with interactive and informative sessions in a range of presentation styles, this event is less than 2 months post a UK general election, therefore our plenary sessions will also address the key controversial questions and provide a glimpse of the future and ideas on evolving practice.

The exhibition complements the main programme, bringing the top companies in the industry to showcase the latest developments and technical updates; a full programme of satellite sessions; CPD NOW education on the stands; poster displays, ePoster consoles and much more, making this the largest clinical imaging exhibition in the UK.

There is truly something for everyone at UKRC 2015!

HIGHLIGHTS

Inspiring keynote and 'state of the art' lectures:

- **Internationally renowned speaker Prof Sir Muir Gray** who will deliver the opening plenary lecture on **'From quality to value - population and personalised imaging'.**
- **Join the Question Time debate! - 'Is outscourcing the silent killer of the NHS?'** Discussed by a top panel, including Dr Clive Peedell and Pam Black, taking questions from the audience
- **Prof David Townsend** who will deliver a plenary session on cutting edge imaging titled **'PET/CT where did it come from and where might it be going?'**
- **One of the inventors of the CT scanner Prof Willi Kalender** from the University of Erlnagen, Germany who will discuss the **'CT: even faster, even more resolution'.**

EXCITING NEW FEATURES FOR 2015

In addition to the streams, interactive workshops and plenary sessions, we aim to evolve the programme based on your feedback – we are delighted to include these new elements into the programme and exhibition.

Drop-in programme - 'Know your Rs from your elbow!'
Informal drop in sessions covering the basic terminology of PACS, RIS & VNAs for radiologists.

A giant PACS touchscreen tablet
A giant touchscreen MDT table to look at use for anatomical teaching, hands-on PACS review and demonstrations in MDT meetings, pre-operative planning, medical education and presenting clinical case studies.

A directory of exhibitors by product and/or service to help you identify organisations you wish to engage with, along with a discussion zone for procurement managers and exhibitors to meet

For all programme updates, view the live interactive programme planner at www.ukrc.org.uk

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#UKRC2015

The congress app **'UKRC2015'** will be available to download closer to the event, where you can view the full programme and build your own event itinerary.

SINGAPORE

FOCUS ON ELDERCARE

Dran Coronado

Regional Editor, APAC HealthManagement

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Singapore's transformation from a low-income country to a rich, developed economy within a span of five decades is truly remarkable. The country's GDP per capita of US$55,182.5 (World Bank 2015a) is currently among the highest in the world. This is in contrast to US$516 GDP per capita in 1965, the year Singapore became independent after seceding from the Federation of Malaysia.

Equally remarkable is the city-state's performance in the field of healthcare. The country has achieved extraordinary results in the high quality of its healthcare system, having established the world's fourth best healthcare infrastructure (IMD 2010) while spending less than four percent of GDP on healthcare. The standard of medical practice also ranks among the best in the world. The Joint Commission International (JCI), which has set up its Asia Pacific headquarters in Singapore, has accredited 11 hospitals and three medical centres in the host country (Singapore Economic Development Board 2014).

Singaporeans Living Longer

Data from the World Health Organization show that Singapore is now among the top countries in the world in terms of life expectancy at birth. A Singaporean woman can now expect to live until 84 (vs. 66 in 1960). Singaporean men also live longer — up to 80 years (vs. 62 in 1960).

Similar to many developed countries, Singapore is seeing a rapid increase in the proportion of elderly citizens to total population. Today, seniors aged 65 years and up number 430,000 (out of Singapore's total resident population of 3.87 million); this figure is expected to more than double to around 900,000 in 2030. By then, one in five Singaporeans will be 65 and older, compared to one in nine today.

"Singapore is ageing not only because of falling fertility rates, but also because achievements in public health and healthcare allow us to live longer as individuals," according to Mr. Gan Kim Yong, Singapore's Minister for Health. "Fifty years ago, a person at age 65 years could expect to live some 8 years more. Today, a person who is 65 years old can expect to live another 20 years. And we can expect life expectancy to increase even more in the next 50 years" (Ministry of Health 2015a).

Care for the Elderly: An Integrated Approach

An ageing population leads to higher demand on healthcare and aged care services, and new challenges in the delivery of care. Singapore has embarked on a careful planning and implementation effort involving all government ministries — ie, a total government effort. The government has even formed a Ministerial Committee on Ageing to coordinate ageing issues across all government agencies.

"HELPING SENIORS REMAIN IN THEIR HOMES AND WITH THEIR FAMILIES"

Ministerial Committee on Ageing

Formed in 2007, the Committee on Ageing coordinates efforts by the various ministries charged with addressing the needs of the elderly and creating an environment for successful ageing. The Committee's strategy for seniors is divided into four initiatives:

1. Allowing seniors to stay on the job, drawing salaries and remaining financially independent;
2. Enabling the elderly to age in their own communities in a barrier-free environment and with a transportation system that allows them mobility;
3. Maintaining a healthcare system that gives seniors access to care for their particular needs at an affordable price; and,
4. Promoting active ageing by encouraging physical and mental well-being and the ability to continue to contribute to society.

The government is particularly interested in helping seniors remain in their homes and with their families — families taking care of an elderly parent at home could see their monthly cost of care go down from S$1,400 to S$700 per month (Haseltine 2013). Additional incentives include an S$120 grant to hire a maid to help with care of a senior and a new subsidy to install elderly-friendly features in the home. As Minister Gan has pointed out: "The best medical care in an institution cannot replace a family member's love and support" (Haseltine 2013).

Community-based care for the frail elderly is another initiative and an alternative to nursing homes. Called the Singapore Programme for Integrated Care for the Elderly, it combines public and private support through rehabilitation centres and day care centres. It allows the frail elderly to receive the continuing care they need while living in their homes and communities, and with their loved ones, instead of in a nursing home.

An S$500 million project to expand eldercare facilities is underway. Its target is to build 10 nursing homes, 21 Senior Care Centres and 45 Senior Activity Centres by 2016. The additional nursing homes will add over 3,000 beds to Singapore's nursing home capacity, bringing the total number of beds to over 12,000.

Regional Health Systems for Holistic and Integrated Care

Realising that effective eldercare requires an integrated approach to infrastructure, the country's policymakers have restructured its healthcare system towards an integrated care model to provide patients with holistic and integrated care. The healthcare system is divided into six Regional Healthcare Systems, anchored by a regional hospital working with a variety of facilities in the primary, intermediate and long-term care sector and support services to deliver patient-centric care. The aim is to build a strong primary and community care sector that delivers preventive care and comprehensive disease management.

The Agency for Integrated Care (AIC) was set up in 2009 to effect this integration of primary, intermediate- and long-term care sectors. AIC coordinates and facilitates placing of elderly sick into nursing homes, with community providers and in day rehabilitation centres. It also handles discharge planning and transition of patients from hospitals to long-term care facilities or to their own homes.

Community Functional Screening Programme

Implemented by the Health Promotion Board, the programme aims to help seniors (60 and above) detect early signs of functional decline. The screening focuses on mood, hearing, vision, oral health, continence and physical function. Seniors found to have problems in any of these areas are referred to the proper medical personnel for follow-up testing and treatment.

Some changes in life such as retirement, loss of a loved one, and worsening health may induce depression, hence screening is provided for early detection of depression symptoms, and enables a medical follow-up.

The physical function test aims to detect disability and risks for falls. Seniors with low physical function are referred to family physicians for medical follow-ups, and are also invited to a 12-week programme designed to help them improve their strength and balance.

The screenings are followed up by a nurse counsellor on the same day on site. The results are interpreted and the participants receive guidance on the appropriate medical follow-up and healthy lifestyle practices.

Helping Elderly Pay for Care

Singapore spends less than four percent of GDP on healthcare, which is the lowest figure among all other high-income countries in the world. The United States, by contrast, spends nearly 18 percent of GDP annually (World Bank 2015b).

The government's creative use of the Central Provident Fund (CPF), a mandatory savings plan for workers primarily to fund their retirement, has been a key factor in controlling healthcare costs. The CPF's medical savings component, called Medisave, enables Singaporeans to pay for much of their own medical care. Other systems have been put in place, including a low-cost medical insurance programme (MediShield) and a social safety net (Medifund). The 3Ms - Medisave, MediShield, and Medifund - play an integral role in the success of the system.

"Indeed, with the 3M system, most Singaporeans fork out little or no cash payment for hospitalisation. Moreover, since Medisave is our own money, available for use for oneself or one's family, many would take care to ensure that it is spent wisely. This makes our healthcare financing model affordable and sustainable," says Senior Minister of State Dr. Amy Khor, who has also been designated as Chief Health Ambassador by the Health Promotion Board (Khor 2012).

The initiatives for the elderly Singaporeans seem to support the notion that the system is well-managed and responsive to changing conditions in the environment. As Health Minister Gan Kim Yong has said, "Not only does a rapidly ageing population challenge the way we organise services, it also requires a rethink of the mix of healthcare professionals we need, and how we finance health and aged care. Even as we build infrastructure and enhance affordability under Healthcare 2020 master plan, we are looking ahead and studying ways to articulate and expand the role for Regional Health Systems to promote health and to integrate care for all in different regions in Singapore" (Singapore Ministry of Health 2015b). ■

Singapore Statistics	
Total population (2013)	5,412,000
Gross national income per capita (PPP international $) (2013)	76,850
Life expectancy at birth m/f (years, 2012)	80/85
Probability of dying between 15 and 60 years m/f (per 1,000 population, 2012)	68/42
Total expenditure on health per capita (Intl $, 2012)	2,881
Total expenditure on health as % of GDP (2012)	4.7

Source
World Health Organization (2013) Singapore Country Statistics http://www.who.int/countries/sgp/en/

Key Points

- ✓ Singapore has built a world-class health system while spending less than 4% of GDP on healthcare.
- ✓ The country's life expectancy at birth is among the highest in the world—up to 84 years.
- ✓ By 2030, 1 in 5 Singaporeans will be 65 or older, compared to 1 in 9 today.
- ✓ Committee on Ageing: Government is addressing the needs of the elderly.

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"The truth is rarely pure and never simple."

DR. NICOLA STRICKLAND
CONSULTANT RADIOLOGIST

Dr. Strickland is a consultant at Imperial College Healthcare NHS Trust in London, UK, and is an esteemed member of HealthManagement's Editorial Board.

1. What are your key areas of interest and research?
Imaging information technology; chest and oncology imaging.

2. What are the major challenges in your field?
- Lack of interoperability of digital systems in imaging IT. Unwillingness of vendors to introduce proven technology and standards which would enable seamless interoperability between digital imaging systems in healthcare, which is very detrimental to patient care.
- Lack of scientific understanding of the pathogenesis of fibrosing lung diseases.
- Lack of easy imaging-based measurement of the bulk of oncological disease, and its current 'sledge-hammer treatment'.

3. What is your top management tip?
- Don't be afraid to tell the truth and to advocate what is best ultimately for the healthcare of the patient.
- Limit unnecessary bureaucracy, "management speak" and pointless administration.

4. What would you single out as a career highlight?
Being the first person to appreciate the need for, and design "DDPs" default display protocols (hanging protocols): software for the automatic display of current with relevant historical imaging studies on PACS, and seeing this now available in every PAC system worldwide.

5. If you had not chosen this career path you would have become a...?
Graphic art designer, or a wildlife conservation worker.

6. What are your personal interests outside of work?
Nature and wildlife, mountain hiking, water sports.

7. Your favourite quote?
"The truth is rarely pure and never simple." uttered by the character Lady Bracknell in Oscar Wilde's play, The Importance of Being Earnest.

"It is not how you get knocked down, but how you get up..."

PROF. HANS BLICKMAN
PAEDIATRIC RADIOLOGIST

Prof. Blickman is Vice Chair, Department of Imaging Sciences at the University of Rochester's Medical Center and Radiologist-in-Chief at the Golisano Childrens Hospital in the USA. He is a valued member of HealthManagement's Editorial Board.

1. What are your key areas of interest and research?
- Paediatric imaging: trauma, gastrointestinal, genitourinary;
- Management of imaging departments.

2. What are the major challenges in your field?
- Decreasing reimbursements;
- Commoditisation of imaging;
- Part-time workforce.

3. What is your top management tip?
"Your people should come to work with a smile on their faces, and, if you do it right, leave with a smile on their faces at the end of the day."

4. What would you single out as a career highlight?
Nearing completion of designing/building and opening my third department of academic (paediatric) imaging at the Golisano Children's Hospital in Rochester, New York, USA.

5. If you had not chosen this career path you would have become a...?
No idea!

6. What are your personal interests outside of work?
Running, yacht racing, classical music and reading historical tomes.

7. Your favourite quote?
"It is not how you get knocked down, but how you get up..."

The full Zoom Ons can be found online at www.healthmanagement.org or scan the QR codes

LAB SUPPLEMENT

HEALTHMANAGEMENT VOLUME 15 ISSUE 2 (2015)

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EUROMEDLAB 2015

WHO, WHAT, WHEN

EuroMedLab 2015, organised by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), will be held in Paris from 21-25 June 2015. EuroMedLab is one of the most important and influential European events in laboratory medicine.

The motto of the conference is R-evolution in Lab Medicine, and the goal is to emphasise the importance of lab medicine in patient care and wellness.

The conference has a high quality scientific programme based on topics and discussions of direct relevance to modern clinical chemistry and laboratory medicine.

Scientific Programme

The scientific programme will comprise symposia, educational workshops and interactive poster sessions. The discussions will focus on the link between laboratory medicine and clinical medicine and the role they play in dealing with public health challenges.

Opening Ceremony

Sunday, 21 June 2015

Master of Ceremony: **Prof. Damien Gruson**

Organisers' Welcome
Dr. Bernard Gouget
Chair, Congress Organising Committee
Euromedlab Paris 2015 Co-President

Prof. Maurizio Ferrari
President, International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)

Prof. Mauro Panteghini
President, European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)

Prof. Joëlle Goudable
President, Société Française de Biologie Clinique (SFBC)
EuroMedLab Paris 2015 Co-President

Dr. François Blanchecotte
President, Syndicat des Biologistes (SDB)

Opening Remarks

Prof. Philippe Gillery
Chair, Scientific Programme Committee
EuroMedLab Paris 2015 Co-President

Opening Lecture

Sunday, 21 June 2015

Innate Immunity: from Insects to Humans.
Prof. Jules Hoffmann - France

Plenary Lectures

Monday, 22 June 2015

Using Laboratory Science to Individualise Care in Diabetes
Andrew Hattersley - United Kingdom

Tuesday, 23 June 2015

Laboratory Medicine in the New Health Environment
Mauro Panteghini - Italy

Wednesday, 24 June 2015

Challenges in Infectious Diseases
Didier Raoult - France

Thursday, 25 June 2015

Molecular Medicine Revolution - its Impact in the Clinical Laboratory
Marc Delpech – France

Symposia

17 symposia will take place over the duration of the Congress on the following topics:

Monday, 22 June 2015

- Engaging Patients with Laboratory Medicine
- Assessing Cardiovascular Risk: Beyond LDL Cholesterol and APO B
- Quantitative Analysis of Peptides and Proteins in Clinical Chemistry by Targeted Mass Spectrometry
- Exosomes and Other Extracellular Vesicles as Disease Biomarkers
- Adding Value to Laboratory Tests

Tuesday, 23 June2015

- Diagnostic Errors: A Challenge for Laboratory Medicine
- New Biomarkers of Vascular Damage
- Metabolomics Perspectives in Diagnosis
- Microbiome

Wednesday, 24 June 2015

- Quality in Laboratory Management in Europe: Impact of Future Trends on Labs Daily Routine
- Glomerular Filtration Rate - Linking Clinical Chemistry and Nephrology
- Systems Pharmacogenomics
- Autoimmune Diseases

Thursday, 25 June 2015

- Rare Diseases - A Call for European Cooperation
- The New Oral Anticoagulants: A Challenge for the Laboratory
- Biomarkers - Key to Personalised Medicine
- Biology of Addiction
- Harmonisation of Clinical Laboratory Practices: A Need for Reference Intervals Utilisation

European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Symposia

Monday, 22 June 2015

Adding Value to Laboratory Tests

Tuesday, June 23 2015

Next Generation Performance Criteria for Laboratory Tests

Wednesday, June 24 2015

Guidelines - A Call for Cooperation between Laboratory and Clinical Societies

International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Symposia

Monday, 22 June 2015

Improving Patient Outcomes through Assay Standardisation

Tuesday, 23 June 2015

The IFCC e-Academy

Wednesday, 24 June 2015

Value and Impact of Laboratory Medicine in Patient Care: What is the Evidence?

Other Symposia

Monday, 22 June 2015

German Society for Clinical Chemistry and Laboratory Medicine (DGKL) Symposium
Current Status of the Internal and External Quality Control in Laboratory Medicine Exemplified by Diabetes Mellitus

Wednesday, 24 June 2015

The Joint Committee for Traceability in Laboratory Medicine (JCTLM) Symposium
Metrology and Standardisation in Laboratory Diagnostics

Wednesday, 24 June 2015

IFCC-TF-Pharmacogenetics Symposium

Workshop

Tuesday, 23 June 2015

Clinical Chemistry Workshop on Publications Ethics and Scientific Writing
Publication ethics **N. Rifai** - USA
Guide to scientific writing **T. Annesley** - USA

To view the complete EuroMedLab 2015 schedule, please scan the QR Code or visit **http://www.paris2015.org/documenti/scientific-programme.pdf**

THE R-EVOLUTION IN LABORATORY MEDICINE

THE NEED FOR A NEW MEDICAL PARADIGM

Prof. Damien Gruson
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EuroMedlab 2015
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The EuroMedLab Congress this year aims to offer insight into the direction of Laboratory Medicine in the 21st century. On the agenda is the role this field can play in a fast-changing health environment and the medical and scientific innovations that continue to take place.

In an exclusive interview with *HealthManagement*, Prof. Damien Gruson shares his thoughts about the goals of EuroMedLab 2015, the future of laboratory medicine and the role it will play in the years to come.

The motto of the EuroMedLab 2015 is R-evolution in Laboratory Medicine. What does that mean?

R-evolution refers to the different revolutions ongoing in laboratory medicine and impacting healthcare at large. There is the revolution from the clinical angle and the rise of molecular medicine and nanotechnologies and how laboratory medicine is now directly contributing to personalised care and precision medicine. There is also an ongoing revolution in laboratory structures and management, with laboratories becoming more and more consolidated and automated. In the meantime, laboratory medicine is also engaged in the revolution of communication and mobile health. Laboratory specialists are becoming counsellors for physicians and are assisting them in choosing the best tests and the most suitable testing procedures. This enhanced communication plays a very important part in improving patient care. The entire dynamic in laboratory medicine - communication between researchers, laboratory specialists, physicians and between physicians and patients - is fundamental.

In the congress invitation, it is mentioned that there is a need for a new medical paradigm. Would you care to elaborate on that?

The paradigm is shifting in many different ways. Science; more personalised tools and molecular medicine tools are being used because of the role of laboratory medicine in precision medicine. Mobility; nanotechnologies; point-of-care testing and the use of information and communication technologies are contributing to mobile health and the continuous monitoring of patients. Process and controls; lean, automation and ISO standards are changing the game of laboratory operations and quality.

What does the translational nature of laboratory medicine mean?

The translational nature of laboratory medicine refers to the integration of innovation from basic research and research and development as well as the transfer of information. It refers to the interrelation needed between researchers, laboratory and professionals of the in vitro diagnostic industry to facilitate the access of patients and physicians to innovation. It also refers to the challenge of financing innovation in difficult economic climates.

What are some of the primary goals of EuroMedLab Congress? Will there be a discussion on any new initiatives or breakthrough ideas?

There are different objectives focusing on continuing education of all laboratory stakeholders in laboratory medicine, clinical chemistry, haematology, microbiology, molecular medicine and patient safety. EuroMedLab 2015 in Paris is designed to facilitate networking among the different players in laboratory medicine and caregivers. At the same time EuroMedLab and the JIB exhibition will discuss the latest innovations in laboratory science and will allow IVD manufacturers and companies to showcase their latest products and technologies,

"THE PARADIGM IS SHIFTING FOR SPECIALISTS IN LABORATORY MEDICINE AND THEY ARE NOW COUNSELLORS FOR PHYSICIANS"

Diagnostic errors are an unfortunate reality. What role can laboratories play to prevent this?

This is a very good and up-to-date question. There is a specific session in the programme regarding diagnostic errors and several other workshops and posters will be centred on this subject. The prevention of diagnostic errors

[Cont. p. 6]

POINT OF CARE: INTEGRATED TESTING SOLUTION

Point-of-Care testing offers not only a smart way of increasing patient safety, but also enables restructuring staff working patterns. If done in the right way, both are more than likely to increase the quality of care delivered, or efficiency and staff morale.[1a 1b]

Cardiac surgery is increasingly being performed on patients who are 70-80 years of age. However, alongside the increase in age comes also an increase in the burden of comorbidities.[2] The complexity has also increased with operations on sicker patients and performance of multiple concomitant procedures. Cardiopulmonary bypass (CPB), which is usually an essential ingredient for these operations but it causes physiological and metabolic changes, all of which require regular monitoring at short intervals.[3]

During most low-risk, single-procedure cases, an average of five arterial blood samples have to be processed and analysed (blood gases, electrolytes, haemoglobin and blood glucose, etc.): once prior to induction of anaesthesia; every 20-30 minutes while the patient is in CPB; once prior to separation from bypass and at least once before the patient leaves the operating room. Often times when an arterial sample is taken, the activated clotting time (ACT), the test to monitor the appropriate effect of heparin on coagulation must be taken and testing can require one to five blood samples per surgical case. The ACT is measured in the operating room, next to the CPB machine, but traditionally carries with it a coefficient of variation of up to 25%. Many other blood analyses are traditionally processed outside the operating room. For example, blood gas analyses are routinely available in a central location outside of the theatre. However, queuing and delays can result, due to calibration and sample integrity issues (i.e. blockage by a poor sample).

This traditional way of working has implications for patient safety at crucial times such as at point of induction of anaesthesia, and again at the separation from CPB), when the anaesthetic assistance leaves the operating theatre to process the sample. In addition human error (documentation and patient identification errors) may impact safety.

True bedside testing at the point of care presents a number of obvious advantages, including minimization of transcription errors, faster delivery of results possibly leading to more timely treatment, and an operating theatre team that remains intact at crucial times during the procedure.

In addition, there are the economic benefits to be derived from the use of point-of-care testing, including the optimal utilization of highly capable and trained professionals.

Emergency medicine

In a recent article, Eichler and Jarvis have described how the introduction of point-of-care testing at their site has help provide timely, high-quality care and a reduction in emergency department overcrowding.[5]

Increased numbers of patients attending emergency departments cause significant logistical issues, including overcrowding and[6] the lack of sufficiently trained staff. Point-of-care testing may help alleviate overcrowding by reducing the amount of time a patient will spend in the emergency department from the drawing of blood to the results being interpreted by the clinician. Point-of-care testing allows the analysis to be performed immediately at the patient's bedside by a healthcare professional. The results are displayed and recorded electronically on the hospital's server, which minimizes human error.

The operating theatre and the emergency department are just two of the settings in which point-of-care testing may help improve patient safety, provide a more time-efficient service, and allow optimal use of valuable resources.

ACCELERATING PATIENT CARE DECISION MAKING PROCESS

"When it comes to clinical decision-making, time is often critical," said Dr. Florian Falter, a consultant anesthetist at Papworth Hospital in Cambridge, United Kingdom.

"Wireless point-of-care technology improves our team's ability to have fast access to blood test results and will help doctors act quickly to determine the best course of treatment. Being able to act without delay is especially important in high-risk and intense situations."

In busy health care environments, the speed of a wireless system can improve efficiencies for clinicians and their health care systems by simplifying the testing process. Additionally, as electronic medical records are being introduced more widely as standard practice, a wireless system such as the i-STAT® 1 can also automatically transfer patient's results to this record without a person having to enter the details, reducing the risk of human error.

POINT OF CARE

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in laboratories relies on the improvement of pre-analytical phases (outside the laboratory) as well as the peri-analytical processes. More automation, more process control and accreditation are also important in the recipe.

What are some key measures that you believe could help improve lab efficiency? Are there any specific technologies that you recommend?

Laboratory efficiency relies on different factors, but I think that more process control, automation and implantation of lean culture can have a significant impact on e-lab operations, the turnaround time of analysis and, in effect, patient care. In the same way, the accreditation of laboratories represents another opportunity for the improvement of laboratory efficiency. Furthermore, communication with caregivers is central nowadays. Lab efficiency is also driven by the performances of the IT solution(s) used.

What measures can help to ensure optimal use of laboratory testing? How can you add more value to laboratory tests?

The paradigm is also shifting for specialists in laboratory medicine and they are now counsellors for physicians. They are also adding a lot of value for the interpretation of results, test selection and control of an efficient test ordering.

What do you think the future of laboratory medicine holds?

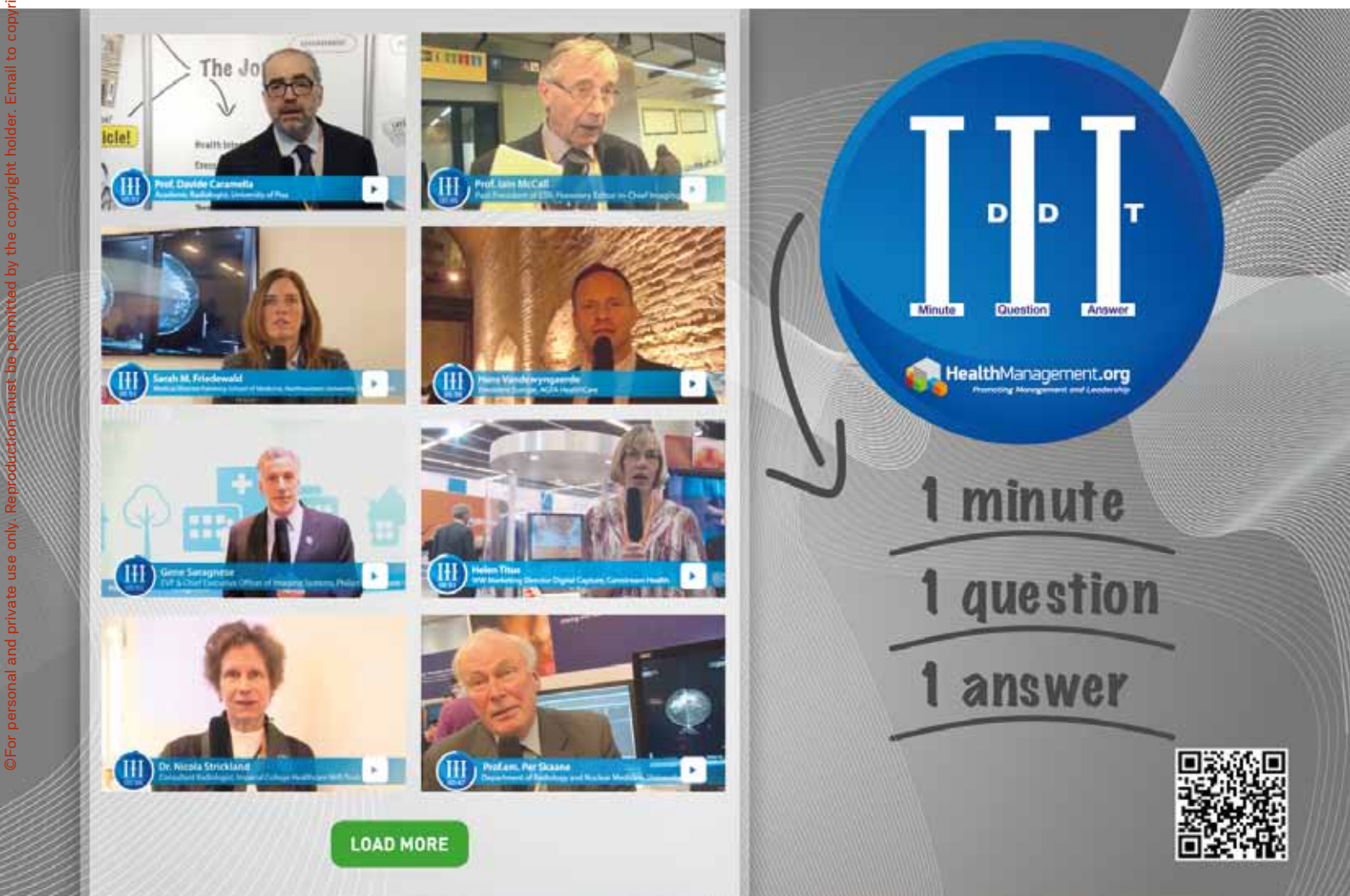
The future is in molecular and personalised medicine, information and communication technologies and mobility.

Patient safety is one of the key issues today. What do you perceive to be the biggest challenges with respect to patient safety and outcomes that laboratories face?

The use of a more automated and controlled process as well as the accreditation of laboratories through ISO standards contribute to patient safety. The balance should be found as these measures are not free of charge.

***HealthManagement* promotes management and leadership in healthcare. Is there anything you would like to add about the field of laboratory management?**

The use of technology plays a key part in management as there is a need to manage laboratory logistic and services flows and operation in a consolidated manner. Networking amongst stakeholders is of core importance. ■



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LIQUID BIOPSY: CIRCULATING TUMOUR CELLS AND CIRCULATING TUMOUR DNA

MARKERS FOR THERAPEUTIC PROGRESS IN CANCER

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Liquid biopsy in the oncology field is an emerging noninvasive diagnostic technique, which enables tracking of the course of the disease at various points in time. This diagnostic test refers to the genetic analysis of either circulating tumour cells (CTCs) or circulating tumour DNA (ctDNA) in order to predict drug response and monitor therapy. Although still in the validation stage, liquid biopsy for cancer diagnostics potentially has advantages over the genetic analysis of excisional biopsies from primary tumours.

Blood-borne dissemination of tumour cells to sites that are distant from the primary lesion (such as bone marrow, bone, brain, lung or liver) is a major determinant of patient prognosis. Liquid biopsy of CTCs captures metastatic cells released from the primary tumour into the circulation (van de Stolpe et al. 2011; Pantel & Alix-Panabières 2013).

In metastatic disease, it has been established that cancerous cells in primary tumours differ greatly in their genomic characteristics from cancerous cells in distant metastatic sites (Eccles & Welch 2007; Pantel & Alix-Panabières 2013). This is because cancerous cells become de-differentiated, enabling them to mutate rapidly. Following this they lose the ability to respond to growth control checkpoints, and they gain survival advantages through alterations in adhesion and invasion properties unique to the metastatic niche. They also resist apoptosis as well as anoikis or the inability to survive outside the normal anatomic location. Each metastatic niche has its own microenvironment, and cancer cells respond to cues in the microenvironment by mutating (Eccles & Welch 2007). Therefore genetic analysis of biopsies alone from the resected primary tumour may not yield sufficient information for the decision on effective cancer treatment.

Targeting metastatic disease will therefore require understanding of the genomes of potential initiator cells as well as metastatic cells. Outgrowth of these cells into overt metastases would need to be treated with therapies directed specifically toward the corresponding genetic subsets of these initiator cells. Liquid biopsy of CTCs, which reflects the total of CTCs from primary as well as different metastatic sites, can be used to evaluate minimal residual disease, yields genetic information on acquired mutations and is therefore, a most promising technique for enabling decisions on therapeutic regimens. Additionally, this technique yields new information on the pathobiology of metastases and guides the development of novel therapeutics, all of which will inevitably improve clinical management of metastatic disease (Murtaza et al. 2013).

Since CTCs in the peripheral blood are both rare and genetically heterogeneous, great efforts are underway to improve and standardise isolation and characterisation techniques (van de Stolpe et al. 2011; Alix-Panabières et al. 2012). CTCs are isolated based on physical properties, including size, deformity and electric charge as well as biological properties, including positive selection for the cell surface marker, EpCAM (epithelial cell adhesion molecule) and negative selection for CD45 to exclude leukocytes using conjugated magnetic beads isolation techniques. As discussed in van de Stolpe et al. 2011 and Alix-Panabieres et al. 2012, CTCs do not always "obey" the current definition of CTCs, and other markers of CTCs are also under investigation, including stem cell markers and markers of epithelial-mesenchymal transition (EMT). Assays that target specific cancer mRNAs are also being

"LIQUID BIOPSY IS A MOST PROMISING TECHNIQUE FOR ENABLING DECISIONS ON THERAPEUTIC REGIMENS AS WELL AS FOR YIELDING NEW INFORMATION ON THE PATHOBIOLOGY OF METASTASES"

evaluated for isolation of CTCs for downstream molecular and genetic analysis.

Even in the absence of disseminated disease (metastases) decisions regarding tumour therapy are greatly complicated by marked genetic heterogeneity of tumour tissues. Genotyping of individual tumour biopsies, therefore, often does not allow for a general decision on effective clinical treatment. Furthermore, surgically-obtained biopsies are invasive, often pose anatomical limitations, and repetitive biopsies for monitoring response to therapy are unfeasible. Dynamic genetic changes also occur during tumour progression and the development of drug resistance.

The development of liquid biopsy of blood samples for ctDNA has been greatly aided by improvements in DNA sequencing, PCR-based digital approaches and genomics techniques. All apoptotic and necrotic cells release cell-free DNA into the bloodstream, but since cancerous cells have higher cellular turnover than most normal cell types, circulating cell-free DNA is increased in cancer.

As described by Diaz and Bardelli (2014), current efforts in the development of ctDNA liquid biopsy are towards improving the ability to discriminate ctDNA from normal cell-free DNA. Mutations are present in ctDNA and not in the DNA of normal cells, and liquid biopsy of ctDNA is being designed to specifically detect point mutations in multiple genes of interest. This technique would allow for better characterisation of mutations that arise in cancer cells in response to treatment during development of metastases and development of drug resistance (Murtaza et al. 2013; Dawson et al. 2013). Additional genetic alterations that can be determined in ctDNA are epigenetic alterations, microRNAs and loss of heterozygosity (Schwarzenbach et al., 2013). As with liquid biopsy of CTCs, liquid biopsy of ctDNA reflects the ctDNA from the primary tumour site as well as all metastatic niches. Since the half-life of ctDNA is two hours or less, liquid biopsy of ctDNA can provide rapid, real-time and repetitive assessment of the effectiveness of treatment.

The development of drug resistance is currently inevitable with single-targeted therapy. In a recent study, Diaz et al. used ctDNA liquid biopsy to monitor the emergence of drug-resistant clones during the course of treatment with panitumumab, an anti-EGRF therapy for colorectal cancer (Diaz et al. 2012). Colorectal tumours initially lacking KRAS mutations (wild type for KRAS) initially responded to targeted therapy with EGRF blockade, but resistance to the treatment developed in parallel with the appearance of KRAS mutations in the sera detected using ctDNA liquid biopsy. Using mathematical modelling approaches, the researchers came to the conclusion that mutation-harbouring clones were present at low levels prior to initiation of treatment. During treatment, wild type cells were killed allowing the expansion of mutation-bearing cells. This study using serial ctDNA liquid biopsies provided a profound insight into molecular and genetic evolution of the development of drug resistance: "The time to recurrence is simply the interval required for the subclone to repopulate the lesion". Combination therapy targeting multiple mutations will allow the remission period to last longer.

A study by Murtaza et al. also used liquid biopsy of ctDNA to study acquired resistance to cancer therapy (Murtaza et al. 2013). They used exome sequencing of serial plasma samples from patients with advanced breast, ovarian and lung cancers to track, over the period of two years, the evolution of genetic changes in metastatic cancers in response to therapy, findings that validate the liquid biopsy ctDNA technique.

It is likely that a combination liquid biopsy using analyses of CTCs as well as ctDNA will emerge in clinical practice. This is discussed in a recent review (Pantel & Alix-Panabières 2013). Liquid biopsy of CTCs and ctDNA will undoubtedly be developed to further define the wider range of mutations occurring in breast cancer compared to cancers such as colorectal and pancreatic cancers, which seem to have mutations in a more limited number of genes. Greater liquid biopsy development is needed for cancers existing behind the blood brain barrier, which shed little to no ctDNA into the bloodstream (reviewed in Siravegna and Bardelli). Unfortunately, these are the types of cancers from which surgical biopsies are difficult to obtain. Another point to consider is cancers in which metastases occur not through the blood-borne route but through lymphatics or across body cavities (as in ovarian carcinomas), between the endothelium and along neurons (as in pancreatic carcinomas) (Eccles & Welch, 2007). In these cases, liquid biopsy of ctDNA rather than CTCs may be more useful, because ctDNA is released into the bloodstream from all cells.

Conclusion

Despite the enormous potential in the field of oncology for the use of liquid biopsy of circulating tumour cells (CTCs) and circulating tumour DNA (ctDNA). and despite the rapid development and use of tools for comprehensive tumour genome analysis, liquid biopsy cannot yet replace gold standard diagnostic techniques in clinical application. Harmonisation of procedures will be needed to create clinical standards validating liquid biopsy as a clinically relevant biomarker in cancer therapy. This calls for a decent multicentre approach in clinical trials of liquid biopsy. ■

Key Points

- Cancer cells are released into the circulation.
- Cancer cells release DNA into the circulation.
- Circulating cancer cells and DNA reflect specific tumour genomes.
- Liquid biopsy allows noninvasive, genome-specific therapeutic decisions.
- Clinical validation of liquid biopsy in oncology calls for additional multicentre trials.

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EMERGING MARKETS MEAN FINANCIAL REWARDS FOR THE LIFE SCIENCES INDUSTRY

NEW CHALLENGES FOR REGULATORY COMPLIANCE

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With healthcare spending on home soil drying up, and the UK National Health Service (NHS) set to achieve unprecedented efficiency savings of £50bn by 2020 (NHS England 2013), savvy UK life sciences firms are looking to emerging markets for growth. Unlike the UK, emerging markets are becoming increasingly appealing, due to a growing middle class that expects a better standard of living and enjoys higher life expectancy rates than ever before. All this is driving the demand for new medical products.

Specifically, whilst the global pharmaceutical market is expected to grow 4.5 percent a year on average to 2016, emerging markets are expected to grow at three times that pace (Grunwald 2014; Ward and Waldermeir 2014). The most bullish emerging market of all, China, aims to have total healthcare coverage of its 1.35 billion population by the year 2020, equivalent to an over $180 billion growth in the market over four years (IMS Institute for Healthcare Informatics 2013). IMS additionally suggests that pharmaceutical sales alone will exceed $1 trillion by 2017, making it a rich market for life sciences firms. The increased spending on medicines in emerging markets and new drugs for cancer and orphan diseases are identified as the main drivers for this growth, and given the figures, markets such as China, Brazil, India and Russia are a bountiful source of future revenue.

Changing demographics clearly play a big part in the opportunity presented by emerging markets. For example, in China, the number of people aged 65 and over is expected to nearly treble from 123m to 330m by 2050. This increase, along with chronic diseases rising by 20-30 percent, 300m people being added to the urban population by 2025, and the Chinese economy expected to reach the number one spot at $73.5 trillion by 2020, has resulted in healthcare spending growing by 7 percent (Sagentia 2011). Indeed some companies have already begun to reap the rewards of entering emerging markets. France's biggest drug-maker has increased its revenues by 20 percent since 2010 (Ward 2014) by entering emerging markets, despite revenues stalling in the developed world.

"GOOD LABORATORY PRACTICES (GLP) AND GOVERNMENT POLICIES MEAN THAT ALL NEW DRUGS MUST BE CAREFULLY PLANNED TO ENSURE THEY MEET THE VARYING REGULATIONS IN ALL MARKETS"

In December 2011 the UK government launched a ten-year Strategy for UK Life Sciences, setting out the long-term vision to support the growth of small and medium-sized British life sciences enterprises. The aim of this strategy is to help bring further investment into the UK life science industry, helping allay fears about the economy and funding gaps whilst supporting innovation in the sector. Furthermore, to encourage innovation in the UK, Patent Box tax legislation has been introduced to provide UK businesses with an incentive to perform R&D. However, latest research commissioned by Maetrics, a full-service life sciences consulting company, confirms that 43 percent of UK life sciences businesses say that reduced healthcare spending will be one of the main challenges they face this year. Additionally, a quarter (26 percent) say they are concerned about the stability of the UK economy, and that the predicted £30bn funding gap set to hit the NHS by 2020 (Illman 2013) is therefore a major concern.

Research and development (R&D) in the pharmaceutical area reportedly accounts for approximately £11.5 million spent every day, according to the Association of the British Pharmaceutical Industry (ABPI). The majority of this expenditure is funded from within the industry, highlighting the integral importance of the sector to the nation's growth and economy, but also how self-reliant it is. In 2013, 22 percent of the entire R&D activity in the UK was in the pharmaceutical sector alone, and UK companies funded 66 percent of their R&D while 23 percent of investment came from abroad (ABPI n.d.). But with cost pressures continuing to increase, the recent downturn has left many life sciences companies fundamentally reassessing their business model, increasing their efforts on factors

such as safety, personalised and targeted medicines, and network-based collaborations (Capgemini 2009).

So with businesses expanding abroad, away from the UK, it is important for them to be aware that with potential comes risk, as they then face the challenge of navigating varying complex national regulatory systems. The Maetrics research highlights the concerns respondents have when facing regulatory compliance, with 50 percent revealing this as their biggest challenge.

Regulatory compliance is of the utmost importance, as fines can not only cripple smaller businesses, but can also expose any sized business to reputational damage, patient safety issues, and criminal sanctions, not to mention the negative impact on investor confidence.

This is particularly significant, as the Maetrics study revealed that another key challenge for 2015 is new product launches, with 46 percent citing it as a top obstacle. With increased global competition, price pressures and the growing demands of ageing populations, there is a significant burden on firms to meet consumer needs all over the world. In addition drug safety, counterfeiting, good laboratory practices (GLP) and government policies mean that all new drugs must be carefully planned to ensure they meet the varying regulations in all markets in which they will be sold. Regulatory diversity in these areas means there is no 'one-size-fits-all' solution.

To emphasise the importance of GLP, the World Health Organization (WHO) outlines five points that companies must take note of in their Good Laboratory Practice report: resources (organisation, personnel, facilities and equipment); characterisation (test items and test systems); rules (study plans, or protocols, and written procedures); results (raw data, final report and archives); and quality assurance (World Health Organization 2001).

UK life sciences businesses also report that they face an industry skills shortage, with 43 percent of respondents agreeing that finding specialised staff will be difficult this year. This specialised staff shortage was initially highlighted by the Association of the British Pharmaceutical Industry in 2008, but since then the issue has worsened, and in 2012 the industry topped PWC's talent challenge poll (PWC 2012). Indeed one core aim for the Strategy for UK Life Sciences is to attract, develop and reward talent in the industry (HM Government 2012).

A more recent report by recruitment firm Hays highlighted the ongoing challenges still faced by employers recruiting in the life sciences industry, with 55 percent of their respondents saying they expect to encounter a shortage of experienced applicants in the next 12 months (Hays 2014). With businesses entering new emerging markets, it is important that their staff have the necessary skills, knowledge and experience to successfully navigate compliance issues abroad.

Finally, one in five respondents in the Maetrics study reported that merger and acquisition (M&A) activity will pose a challenge in 2015. It is widely accepted that M&A transactions almost doubled in 2014 compared to 2013, and this trend shows no sign of abating with activity still buoyant in early 2015. In particular, larger pharmaceutical companies are continuing to focus on building capability in specific diagnostic areas in order to maintain a strong pipeline. The hunt for so-called blockbuster drugs is keeping interest in smaller, specialised outfits and laboratories very much alive.

Whilst concerns remain for the life sciences industry in regard to emerging market expansion, the opportunity for growth is unprecedented. Key to successfully entering these markets is a strong quality and compliance team, whether internally or externally through a consulting partner. It's clear that to take full advantage of the opportunities the emerging markets present, confidence in understanding, interpreting and implementing regulations will play a critical role. ■

Key Points

- UK life science businesses are continuing to focus on emerging markets and therefore face the challenge of navigating a variety of complex national regulations.
- Five points that companies must take note of in their Good Laboratory Practice report: resources (organisation, personnel, facilities and equipment); characterisation (test items and test systems); rules (study plans, or protocols, and written procedures); results (raw data, final report and archives); and quality assurance.
- The hunt for so-called blockbuster drugs is keeping interest in smaller, specialised outfits and laboratories very much alive.
- There is a need for skilled and experienced staff, yet respondents also highlight a skills shortage in the life sciences industry.

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THE FUTURE OF LABORATORY MEDICINE

Introduction

There have been various predictions about the future of laboratory medicine and its subspecialties, both general and specific. The article "Future of Laboratory Medicine" by Larry J. Kricka, Tracey G. Polsky, Jason Y. Park and Paolo Fortina presents an overview of previous predictions that have already become a reality and some future predictions that are expected to play a critical role in this specialty.

Back in 1969, Tom Whitehead, the first Chair of Clinical Chemistry at the University of Birmingham identified five eras of clinical chemistry in his lecture "A view from a bridge". These include:

- the complicated era from 1920 to 1940;
- the simplified era from 1940 to the early 1950s;
- the crisis era in the late 1950s;
- the sophisticated era in the late 1960s; and
- the profile era in the 1970s.

For the future, each of these predictions has merit, and many have already become a reality. More recently pharmacogenetics has been revolving around the slogan "right patient, right drug, right time" and the future of laboratory medicine is characterised by buzzwords like nanotechnology, biosensors, genomics, proteomics and microchips.

Laboratory Organisation and Staffing

Futurists predict a world that will be dominated by large supra-regional tertiary centres or laboratory networks that will be formed as a result of laboratory consolidation. The number of laboratories will reduce, driven by outsourcing of laboratory services, competition between laboratories for hospital work and the commoditisation of laboratory tests. Greater emphasis will be placed on refocusing laboratory services toward specific population segments such as the elderly. Haematology, transfusion medicine, biochemistry and immunology will be unified as "blood sciences."

Laboratory staff will be expected to deal with demand management, and will be responsible for providing additional consultative services related to laboratory testing. The future role of laboratories will be more geared toward quality control, reducing laboratory errors, eliminating unnecessary testing and focusing on the challenges of global harmonisation. Two simultaneous trends seem to be emerging in this field. One is the consolidation of traditional laboratory testing and second is the expanding new market for near-patient testing.

Cost-containment and cost-effective operation of laboratories will be an important issue for laboratories in the future. Already there is a trend to unify independent hospitals into health systems and to consolidate specialty laboratories into a core laboratory model as evident by the establishment of the Calgary Laboratory Services (CLS) in Alberta, Canada. "Blood science" laboratories are also being developed, for example the Blood Science Laboratory at the University Hospital Birmingham NHS Foundation Trust in the UK.

Laboratory staffing shortages will continue to be a source of concern. Measures that could be used to deal with such shortages may include reducing staffing needs through consolidation and automation. While these strategies seem feasible, consolidation of services such as radiology and pathology still seems a remote possibility. Experts propose the possibility of outsourcing clinical laboratory services to countries with equally sophisticated services but lower costs. There are quality programs in place such as the ISO (The International Standards Organization), CAP (College of American Pathologists) accreditation and CLIA (Clinical Laboratory Improvement Amendments) certification to ensure global standards are met.

"THE FUTURE ... IS CHARACTERISED BY BUZZWORDS LIKE NANOTECHNOLOGY, BIOSENSORS, GENOMICS, PROTEOMICS AND MICROCHIPS"

There has also been an increased migration of testing to the point-of-care, and in future this could result in reducing the reliance on hospital laboratories as well as help in reducing test volumes in hospital and regional laboratories. Home tests can also play a role in decreasing test volumes in laboratories. Patients today are much more informed due to the availability of disease and diagnosis information. Resources such as Lab Tests Online now provide extensive information to patients about specific laboratory tests. It is believed that better informed patients will eventually drive down the cost of laboratory testing.

Automation and Robotics

This is one of the most popular predictions. The use of transport models to deliver specimens and the use of humanoid technology seems to be a fascinating concept in laboratory medicine, but has yet to become a reality. For now the capabilities of humanoid robots remain limited, and the process of automation and robotics has been quite slow in laboratory specific areas such as microbiology, molecular pathology and anatomic pathology. Automation has developed, but through the use of software that allows more effective communication between analysers, information systems and electronic medical records.

It is believed that the demand for automation and robotics will continue to rise, because of the need to have more cost-efficient laboratories. The ageing population and an already existing shortage in this field also highlight the need for alternate solutions. Thus, while robotics may still have a long way to go, it is not entirely unreasonable to hope that in future, machines may play an important role in laboratories.

Point-of-Care Testing

Many experts strongly believe that the future of laboratory medicine will be inclined towards more testing at point-of-care (or near to the patient). It would also involve the integration of point-of-care testing into patient management strategies and pathways of care and more testing at home. Point-of-care testing offers several benefits, including low cost, portability, simplicity, flexibility and built-in quality control. Predictions suggest that point to hand-held devices could be used for monitoring the top eight infectious pathogens.

The introduction of wearable devices is already a step in this direction. Phones can be used to perform analyses at point-of-care using plug-in modules. Although smartphones are still not being used as extensively as initially predicted, there are still many uses for them, including taking pictures of slides and tissues, performing colorimetric tests, providing onboard data analysis and so on. Mobile technology should play an important role in laboratory medicine in future, especially in low resource and remote regions.

Telepathology

Telepathology is already in use in some clinical laboratories, and its use for manual interpretation of differential blood counts is now routine. However, telepathology is not used routinely in surgical pathology, and digital slide scanning systems for primary diagnosis of surgical pathology have not gained approval in the U.S. It is predicted that smartphones, tablets and other mobile devices can become the hub of medicine in future and telehealth will be an important component as more telehealth applications develop.

The FDA has created the path for the implementation of digital pathology and medical software by providing regulatory guidance, and thus it is safe to say that imaging systems will facilitate slide interpretations in future and will also incorporate surgical pathology testing and interpretation.

Genomics

Genomics is expected to be very visible in future for both pharmaceutical companies and private laboratory services. There will be widespread use of DNA probes, neonatal genetic screening, viral load monitoring, high-density SNP diagnostic assays, electrochemical detection of infectious agents, gene mutation analysis, and gene and protein profiling. New diagnostic tests are also expected to be developed with the completion of the human genome project.

Expression profiling has had limited success to date, and is not expected to replace histologic diagnosis and traditional cancer classification systems, but it is considered an ancillary test. DNA testing should become readily available in the future, and large clinical studies such as the UK 100,000 genome project and the Beijing Institute for Genomics (BGI) Million genome project are anticipated to provide greater insight into the link between DNA sequence and disease.

Proteomics

Proteomics is believed to be the basis for future diagnostic tests. It is expected that analytical systems will be developed that will be capable of testing hundreds and thousands of different proteins. There are between 250,000 and 1,000,000 proteins in human cells. Many of these remain unstudied but in future, they could form the basis of a new diagnostic test.

Conclusion

Most of the predictions about laboratory medicine are optimistic, and are geared towards the development of more effective treatments, eradication of disease and longer lives. Telemedicine is predicted to play an important role for the period 2032-2062. It is important to remember though that making predictions is not an exact science and there are many previous predictions that have not materialised yet. However, an examination of the future helps in the planning process, and enables management teams to develop skills and acquire resources that could potentially lead them to making these predictions a reality. ■

Key Points

- Predictions about the future of laboratory medicine continue to be a source of interest for healthcare professionals.
- Two simultaneous trends seem to be emerging in this field. One is the consolidation of traditional laboratory testing and second is the expanding new market for near-patient testing.
- It is believed that in future better informed patients will eventually drive down the cost of laboratory testing.
- Major genome projects are anticipated to provide greater insight into the link between DNA sequence and disease.
- Most of the predictions are optimistic and are geared towards the development of more effective treatments, eradication of disease and longer lives.

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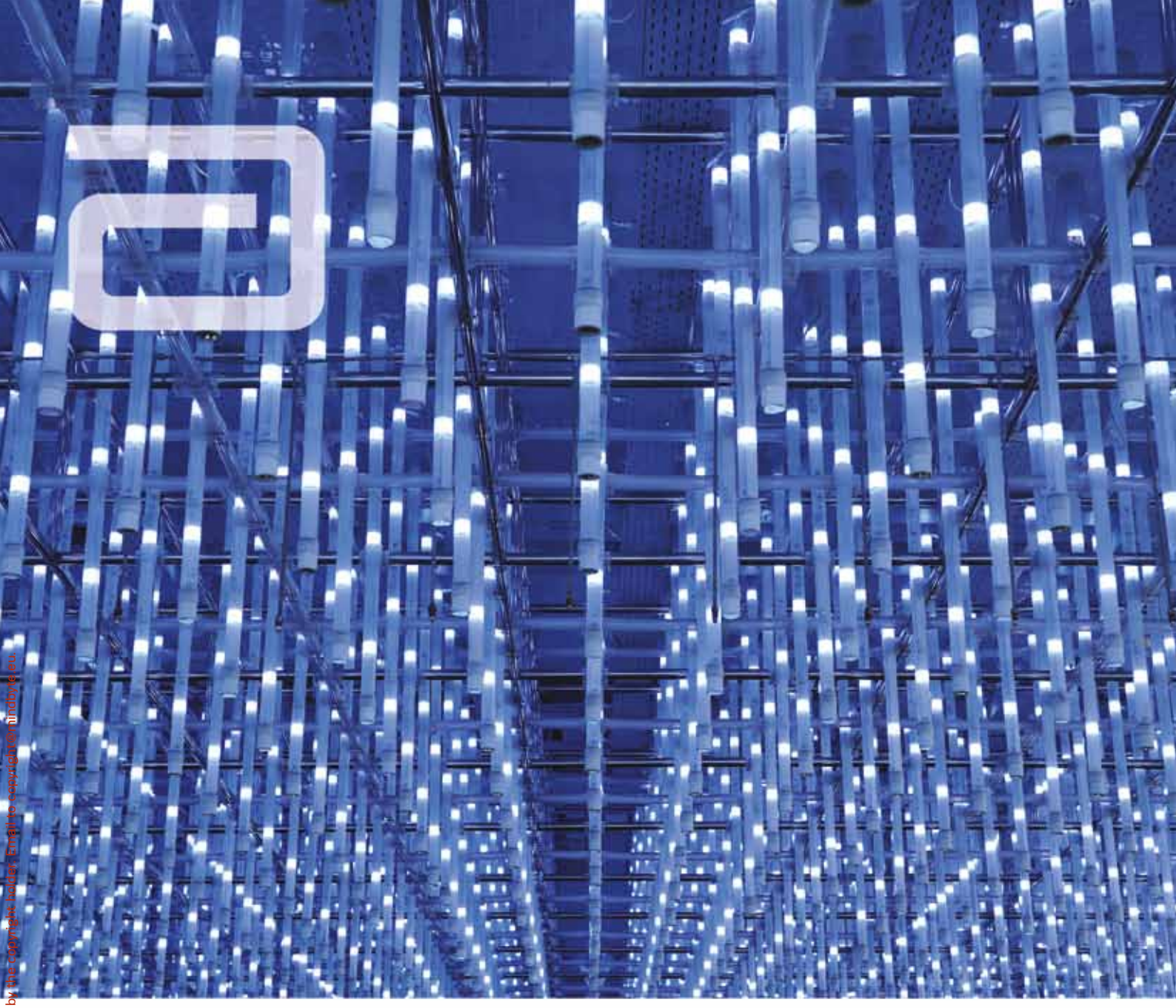

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