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1. Data on file and from public sources, 2017. 2. Results from Friedewald, SM, et al. "Breast cancer screening using tomosynthesis in combination with digital mammography." JAMA 311.24 (2014): 2499-2507; a multi-site (13), non-randomized, historical control study of 454,000 screening mammograms investigating the initial impact of the introduction of the Hologic Selenia® Dimensions® on screening outcomes. Individual results may vary. The study found an average 41% increase and that 1.2 (95% CI: 0.8-1.6) additional invasive breast cancers per 1000 screening exams were found in women receiving combined 2D FFDM and 3D™ mammograms acquired with the Hologic 3D™ Mammography System versus women receiving 2D FFDM mammograms only. 3. In an internal study comparing Hologic's standard compression technology to the SmartCurve™ system (18 x 24cm).

Risk & Danger

Without risk there is no progress or development. But risk, as with any professional action, needs to be identified and managed if its potential is to be harnessed optimally. A strong position on risk management is essential in today's rapidly-changing healthcare world to avoid danger; danger in cyber security, danger in staff care and, critically, danger in patient outcomes.

In this issue of Healthmanagement.org, these questions are put under the microscope alongside questions on how risk impacts on treatment, the risk of exposing unethical healthcare practices and improving risk literacy to mitigate risk in management and performance in the sector. In addition, a number of the latest risks, guidelines and recommendations within imaging and cardiology are outlined.

The issue opens with Professor Paul Sidhu detailing his plans as he takes the helm at the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB), while Professor Gábor Forrai of European Society of Breast Imaging (EUSOBI) gives important details about the latest recommendations for women in mammography.

Risk Management Advocate, Alexandra Freeman of the Winton Centre for Risk & Evidence Communication, asks how clinicians can fine tune their knowledge of effects of particular medical treatments – reducing risk in patient outcomes. Harding Center for Risk Literacy Research Scientist, Mirjam Jenny, explains how the organisation helps healthcare clinicians and managers make more informed decisions for care, while details of how healthcare can face up to effective risk management is described in an exciting new venture by Patrick Keady of the Institute of Risk Management.

Privacy and security legal experts, Sharon Klein and Joseph Guagliardo, examine how Blockchain technology, while touted as a protector of patient data, could face challenges from regulatory bodies presenting a risk to its implementation.

Sharmila Chowdhury writes about her experience as a whistleblower in radiology consultancy, a decision that cost her job but gave her the impetus, as a campaigner, to expose detrimental risk in the field. ECRI Institute gives details on how to protect systems from ransomware attacks and the steps to take should such an attack take place.

Colin Wright, Framework Development Manager at Skills for Health, provides guidance and key points for best practice when implementing person-centred Core Skills. Director of Continuous Improvement Daphne Leger speaks about how human-centred design improves patient experience.

Finally, a recent report issued by the Point of Care Foundation outlines some of the pressures that British healthcare workers endure and what must be done to overcome these. In addition to risk and its management, we share the latest innovations and news in healthcare across the spectrum of Imaging, Health Information Technology, Cardiology and Management in Winning Practices.

As always, we hope you enjoy this issue of HealthManagement.org. ■

Prof. Lluís Donoso Bach

Editor-in-Chief IMAGING

HealthManagement.org - The Journal

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Future of imaging

What does radiologist Prof. Paul Sidhu have planned for his tenure as Presidency of the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) and what are his thoughts on future trends in imaging?

Paul Sidhu

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Congratulations on being elected to the Presidency of the European Federation of Societies for Ultrasound in Medicine and Biology. What are the main priorities for your tenure as President?

My tenure of two years will commence in October at the EUROSON congress in Ljubljana, Slovenia. During my tenure, I intend to continue welcoming and embracing all of the European societies, to try and increase membership and to welcome all subspecialties involved in ultrasound into the society.

I'd also like to facilitate members to participate in the EUROSON meetings, particularly the annual general meeting and various workshops. I will also try and encourage younger medical practitioners to get on board and attend the meetings, since they are our future.

I'd also like to further improve our website, which is already a comprehensive website used across the globe particularly in areas where medical users are getting on board with ultrasound. We will use the website to provide educational credits, which can be entirely obtained online to demonstrate the acquisition of knowledge. This is already in motion but we will speed it up.

In addition, I plan to further develop our European Journal of Ultrasound to maintain it as a high impact publication as well as to get more researchers in Europe to choose this journal as their vehicle for publication.

Lastly, we want to encourage cross-border cooperation in scientific matters, in particular by encouraging researchers to submit results to website-based databases. One such database is already set up with about 1, 000 cases listed online and, hopefully, other projects will also follow which will ultimately encourage participation.

Gillman and Kirkpatrick wrote about portable ultrasound in 2012 and argued that a portable US device could one day usurp the stethoscope. First of all, do you foresee a time when portable US will take over from the ubiquitous stethoscope and everyone involved in healthcare will have one in their pocket? If so, what do you believe are the barriers to the universal rollout of portable US to all healthcare workers?

The use of ultrasound as a stethoscope is inevitable. Technology has allowed these machines to be used as hand-held devices. In fact, technology has even allowed the use of mobile telephones to be used as hand-held devices. It's therefore inescapable that people will use this to make a more accurate diagnosis. It's still in its infancy but the way forward is to teach it early, especially within medical school which is already happening in both EU and the US.

The barriers are the cost of the appliance - but the cost has dropped considerably since these appliances first came on to the market, so it can only continue to improve and be made readily available to everyone and, ultimately, become an invaluable tool in diagnosis.

Research is always an important facet of any healthcare system and the management of and access to the data produced is being seen by some as critical. Are there any plans within EFSUMB to enable remote access to big data via digital systems for consultants and practitioners?

> "THE USE OF ULTRASOUND AS A STETHOSCOPE IS IN ITS INFANCY BUT THE WAY FORWARD IS TO TEACH IT EARLY"

We have a vast library of case studies on the website, an EFSUMB book as well as freely available guidelines.

The databases are a different matter however. We have set up the paediatric registry, which is an anonymous database. There are a lot of legal and regulatory processes to go through. Setting up the paediatric database involved 18 months of ethics approval from the UK, for a Pan-European Database.

In future, you have to be very careful of what you upload onto a database. To get regulatory approval, much care must be taken to remain anonymous - regulations are so tight. It's a difficult process and you have to take care, but we will certainly move forward to select the important topics to establish this.

In a recent EFSUMB newsletter, Vito Cantisani wrote that, "Teachers specialised in medical education and US practitioners in different

clinical specialties currently are insufficient to teach US in an easy way, to explain artefacts and how to avoid them and to explain the limits of the procedure". Given the wide variety of US training available, as well as all the courses endorsed by EFSUMB, is this an issue that is widely recognised, and if so, how, in your opinion, can this best be addressed?

EFSUMB has always encouraged people to teach centrally so that it allows the expertise to be concentrated and be best used. We also make an effort to invite people to attend these courses, reflected in the very popular EFSUMB schools and EFSUMBS-endorsed courses. We also have centres of excellence set up across Europe, where interested persons can attend for a period of time and benefit from the local expertise. These are all vetted and verified by EFSUMB as centres of excellence.

We also work in partnership with the World Federation of Ultrasound in Medicine and Biology (WFUMB) which have set up similar centres of excellence around the world. Hopefully this is one way we can overcome the shortage of expertise to teach the younger generation. If you teach the teachers, you're moving forward as well. We hope this won't be a long-term problem and we'll see more and more people embracing the ultrasound.■

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The latest in breast imaging

Prof. Gabor Forrai speaks with HealthManagement about the future of the European Society of Breast Imaging (EUSOBI) and the latest guidelines and recommendations for women in mammography.

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EUSOBI recently updated its recommendations on information for women on mammography. What are the main updates? Also, why is it important to involve consumers, the Europa Donna organisation, in developing the recommendations?

We mainly updated the information about new mammographic technologies, which includes tomosynthesis and contrast-enhanced spectral mammography (CESM) methods. The tomosynthesis and contrast-enhanced spectral mammography are two new key methods, so that's why it's important to include detailed information especially as they become more popular with the public.

EUSOBI has issued suggested guidelines about MRI, mammography and screening. These papers appear in scientific journals, but the intention is to reach both women and non-radiology doctors with this information, because of how specialised the information is (which methods to use/which is obligatory etc). To directly target patients with information is obviously quite unusual for a scientific society.

We have a group of national societies, so we have made direct contacts in the last 2/3 years with the European breast imaging societies. We generally ask them to translate their findings in the papers dedicated to these issues into their own language, otherwise it will be too difficult to comprehend. This will also appear on EUSOBI's updated website (eusobi.org), which includes a partnership with 30 other countries.

Could you give an insight into the latest mammographic technologies and how they have developed?

Contrast-enhanced spectral mammography (CESM) and tomosynthesis are the latest technologies.

CESM is still in its experimental phase. Its place in imaging is still not 100% established, but so far we have seen promising results. It is a good technique compared to MRI because it's cheaper, it's more accessible as there are more mammography machines than MRI scanners, and there are more radiologists who report mammography than MRI. And to perform a biopsy it's also much easier to do this via mammography than an MRI. These are the direct advantages of contrast-mammo. However, there are of course still some possible disadvantages. Firstly, we have to wait for the scientific results before introducing technique to the routine care. Secondly, the method is a little invasive because we have to administer intravenous contrast; indeed, it's the same as MRI, but in comparison to tomosynthesis, for example where there is no injection involved, it makes the screening/diagnostic process a little more comfortable. Thirdly, there is x-ray.

Tomosynthesis is far more advanced. Thousands of women undergo this method, and this method is already well proven to find small invasive cancers compared to simple digital mammopgraphy, which would not necessarily be able to pick these up. This clearly outweighs conventional mammography as well, of course. It is widely agreed that this method will eventually replace the process of mammography.

Screening is used as a routine method for each patient, but we still have to wait for scientific proof that it works to use it and that it saves life and not only works during the first round of screening, but also in further rounds. Tomosynthesis seems to be a revolutionary method. However, it's still not introduced in any country's official screening programme because we are still waiting for scientific data.

"THERE IS A 35% HIGHER RISK OF DEATH FROM BREAST CANCER FOR WOMEN WHO DON'T UNDERGO SCREENING"

There is some data that states that tomosynthesis detects 30-40% of invasive cancers and that it also decreases the number of recalls. Recalls are decreased so detection of invasive cancers is increased, which is proven, but it's still not used by the whole population. This could be down to the fact that it's a new technique which means a lot of centres would also have to buy these machines. This explains why tomosynthesis is not everywhere yet but it certainly is growing.

What are the benefits of contrast-enhanced spectral mammography versus MRI?

Contrast mammography is at least comparable to MRI, but it's still unclear if it is as sensitive and specific, and we may find that patients will profit from a contrast mammogram instead of an MRI. MRI has, in fact already proven benefit for women with

high-risk – however the same is still under investigation with CESM.

What are you looking forward to at the EUSOBI meeting?

We try to include two main types of programmes in the meeting. Firstly, we deal with routine methods that are used by everyone, as well as lectures where we speak about methods as a general update. For young radiologists, we try to ditch the fine details of the classic methods. We also provide an update for experienced radiologists, as not everyone has the time to read all the latest scientific papers.

We are also speaking about very new developments which are investigated by scientists. This will be interesting going forward as we compare how different methods have evolved over the last decade and more. The developments in breast imaging are so swift, which is great.

We will have a national societies meeting where we meet with over 30 societies to discuss the latest trends, problems and news in Europe, which gives each country the opportunity to express their point of view, which is always quite surprising since it highlights how Europe is quite unique in that we all have various approaches. The accessibility of the equipment and the number of specialists etc in each country influences views a lot, so in this way we try to help each other as much as possible. In my opinion, this reiterates that Europe is not just one country, it symbolises a collection of countries that are all part of Europe.

We also have close contacts with other countries, including Israel and many others. We have many radiologists coming from outside of Europe to undergo the European Diploma in Breast Imaging diploma (EDBI), which proves that people are striving for the highest European standards of breast imaging. More than half of the candidates taking the exam come from Arabic countries, which highlights the value of the EDBI even outside of Europe.

As we know the views on screening are largely split. How do you think this will develop over time?

The opinions about screening are uniform among doctors and radiologists who are dealing with patients, so they naturally see how useful screening is.

I've personally carried out screening for a very long time and I'm very happy to meet patients who originally came for screening when we detected small cancers, and continue to come back yearly for screening and we see that they have recovered. So we see in a lot of cases how extremely useful screening is.

I don't understand why some scientists find it challenging to try proving that screening is not good for women. Of course everything in science has to be questioned, but articles that are anti-screening are based on generally very badly conducted studies with a pre-conception to manipulate the reader into viewing screening as a negative thing. This doesn't make sense, since screening is the most proven useful method of all medical procedures, including chest x-ray or abdominal ultrasound. There is lots of data and more than 30 years of follow-ups in different parts of the world to prove this. All of these published statements that are anti-screening just make women uncomfortable and unsure, which results in a lot of deaths since there is a 35% higher risk of death from breast c ancer for women w ho don't undergo screening.

Finally, what are the plans for the future of EUSOBI?

The future plan is to continue to be the leading European breast imaging radiology society. We are publishing guidelines and organising courses and meetings. We are also working on improving our connection with clinical oncological societies, firstly in the European Union and also worldwide.

We have a strong relationship with our American counterpart, the Society of Breast Imaging. We are planning to organise meetings and workshops together. We ensure we offer regular updates about what is happening in breast imaging around the world.

We also cover new scientific ideas, and we now emphasise diffusion-weighted imaging (DWI) in the field of breast imaging. The first DWI meeting will be held during the EUSOBI meeting in Berlin. This gathers scientists who deal with DWI. We are trying to find out its place to fine tune this method to publicise to breast imagers to use this technique.

Servant leadership

A journey, not a race

Servant leadership offers a fresh approach to meeting the critical leadership challenges of contemporary healthcare organisations, while honouring the humanity of everyone they touch.

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The terms of the work world have changed. Employee expectations and organisational mandates have shifted. In order to be successful and relevant in this environment, leaders must learn new ways of leading, throwing off the old command and control styles of management and adopting models that are principled and service-driven. That requires more than a to-do list: it demands a fundamental re-imagining of corporate culture and organisational health.

Servant leadership is not a new idea, but it is being "discovered" at an exponential rate. Contemporary organisations are eagerly searching for guidance in achieving their missions and goals through engaged and invested employees - employees who become co-creators of the organisation. Healthcare and servant leadership are natural partners.

Servant leadership helps positional leaders understand their role as stewards. It appeals to C-Suite executives and physician leaders with enterprise-wide impact who seek to transform the workplace. Mid-and lower-level managers and supervisors use servant leader principles to create cohesive teams, improve the work environment and develop themselves for greater responsibility. Servant leadership is a better way of doing business; it is a nobler side of leadership (Belton 2016).

Servant leadership 101

Derived from the work of Robert K. Greenleaf, servant leadership is both a philosophy and set of practices that overarches all styles of leading. It colours how we hire and fire, plan and hold accountable, think and behave, relate and communicate. From his background in business (AT&T) and education (Harvard, MIT), Greenleaf conceptualised the servant leader as a person of integrity, who leads an organisation to success by putting the needs of customers, employees and communities first, by sharing knowledge and power, and by helping people perform to their highest capacity.

The servant leader is *servant first*, whose conscious choice brings him/her to lead. That person is sharply different from one who is *leader first,* with the perks and power that implies. The difference, Greenleaf maintains, manifests itself in the care taken by the *servant first* to make sure that other people's highest priority needs are being served. How is a servant leader recognised? Greenleaf formulated his Best Test: do those served grow as persons? Do they become wiser, freer, more autonomous, and more likely themselves to become servants? (Greenleaf 1970).

While all the traditional skills and competencies are required of the servant leader, there are some distinguishing characteristics:

- Authentic humility: a regular practice of reflection
- A focus on serving followers for their own good, not just the good of the organisation; instilling a sense of collective ownership in the organisation's success
- Concern for the wellbeing of all stakeholders—from patients, families and staff to suppliers, contractors and the community
- Emphasis on providing opportunities for growth and professional development; coaching and creating more servant leaders
- Leading by moral authority instead of relying on positional authority alone: inspiring followership

Over the decades, the literature has linked servant leadership to a broad array of positive business outcomes and organisational citizenship behaviours such as collaboration and effectiveness, service orientation, satisfaction with the supervisor, innovation, individual and team effectiveness, employee engagement and return on investment. These and other studies establish a business case, a human resource case and a customer service case for servant leadership.

Servant leadership and organisational health

Organisations are like people. They can be healthy or ailing and even moribund. An organisation's state of health affects its employees, customers, processes, reputation and bottom line. It seeps into their ethics, agility, relationships, ability to attract talent, customer loyalty and culture. Healthy organisations, like healthy individuals, don't just happen: we have to work at it.

Healthy organisations are places where employees want to work and patients want to receive care. Healthy work environments demonstrate 'organisational ecology': the equilibrium between taking care of immediate tasks and concerns, and building systems that strengthen and sustain the

organisation over time. Servant leadership is about foresight and stewardship; understanding the impacts of one's leadership and leaving the organisation in a better state.

In hierarchical organisations, the optic of power is the pyramid; power is top-down. While hierarchy is in itself a neutral system, the potential for misuse is inherent. Servant leadership inverts the pyramid; upends the hierarchy, so that the ones being served are at the apex of the pyramid and the ones serving are at the base. Servant leaders do not relinquish responsibility, but they allocate power broadly.

One way servant leaders achieve this is by honouring the tenet of *primus inter pares:* "first among equals"; a sharing or dispersion of power throughout the organisation. This is not done haphazardly: staff must be trained and capable of assuming their portion of the power. It is commensurate with their ability, and accretes as trustworthiness is verified. *Primus inter pares* is not an abdication of responsibility: the leader is always accountable. Servant leadership does not relieve the positional leader of answerability; however, the attention is less on hierarchy and formal titles, and more on empowering the team.

Servant leaders seek consensus where possible. Consensus is not 'decision-making by committee' or 'managing by vote', but it does buy trust and good faith for those times when a leader must produce a speedy, unilateral decision. Consensus-building is consistent with servant leadership.

Primus inter pares offers others a 'seat at the table'. It listens to ideas and opinions, hears disagreement, and welcomes respectful caution. It teaches the team to participate in the process and the solution: in essence, to practise servant leadership themselves. Leaders have only as much power as followers are willing to give them. Servant leaders hold that power *in trust.*

Healthcare is a team sport

In an industry where the drivers are quality, safety, compassion and a solid business model, it's surprising that servant leadership isn't practised everywhere. In our estimation, and in the experience of major providers like VHA and the Cleveland Clinic, servant leadership is an ideal platform for excellence in healthcare. It is compatible with

Healthcare and servant leadership: natural partners

Linda W. Belton writes: My tenure at the U.S. Veterans Health Administration (VHA) gave me many opportunities to champion servant leadership in a massive healthcare system. VHA is on a servant leadership journey, encountering the struggles and achievements with which many systems can identify. Like most organisations, VHA is a work in progress.

Enculturating servant leadership is a daunting prospect; even more so with a system of such magnitude, political environment and revolving-door leadership. Misperceptions abound. *"Servant Leadership isn't strong leadership." "The term 'servant' offends me." "You can't practise servant leadership in a government agency." "I can't embrace servant leadership if the people above/around me don't."*

Servant leadership is not for the fainthearted! It is not soft, laissez-faire, lenient or anaemic leadership: it requires *strength of self-mastery, strength of action and strength of relationships.* Servant leaders operate from courage, persistence, resilience, accountability and a steady internal compass. They understand the difference between *service and servitude.* While ideally culture change should be guided from the top, practically it is a top-down, bottom-up, side-to-side proposition. If you are anywhere in the leadership ranks, you can be a servant leader. Don't wait for the memo! Servant leaders combine humility with determination. They are resolute in where they're going, firm in how they'll get there, and generous in sharing the road.

Despite the obstacles, the changing context of healthcare, congruence with enterprise priorities, and alignment with VHA's values and core competencies spurred the servant leadership journey along. VHA was embarking upon transformational change. Adopting major initiatives in patient-centred care, civility and engagement, ethics and psychological safety required a supportive and integrative structure. In its versatility, values, and effectiveness, servant leadership provided that framework.

Essential steps in building a culture of servant leadership

- ✓ Generate interest. Raise awareness. Talk about servant leadership. Identify examples of it in everyday practice.
- ✓ Educate both current and developing leaders in servant leader principles; train all employees in their role in a servant organisation. Elevate the conversation and clarify the expectations. *Everyone* in the organisation is a caregiver; *everyone* is a servant leader in their niche of service.
- ✓ Leaders are the primary models and messengers of servant leader behaviour, which is then replicated throughout the organisation. Language must consistently reflect the principles. Policies, budgets, position statements, employee memos, patient correspondence, etc. All must be reviewed through the lens of servant leadership.
- ✓ Provide self-assessment opportunities. VHA developed an online 360 degree instrument (McCarren et al. 2016) based on the *Seven Pillars of Servant Leadership* (Sipe and Frick 2000) to help leaders assess their servant leader competencies and plan for growth.
- ✓ Measure organisational outcomes, but allow time for culture change to take root. VHA created a servant leader index that scores supervisory outcomes, workgroup effectiveness and external quality metrics.
- ✓ Integrate servant leadership into other corporate priorities to avoid an 'initiative of the month', and to survive leadership turnover. Build it into human resource processes, performance objectives, information and communication systems, customer service programmes, etc. Weave it into the fabric of the organisation. What you are seeking is more than individual servant leaders: it is a servant organisation.

The greenleaf center for servant leadership

Established in 1964 by Robert Greenleaf as the Center for Applied Ethics, today's Greenleaf Center attracts a community of people who believe that servant leadership can reshape institutions to create "a more just and caring society." It provides a place for scholars, practitioners and people seeking something more from leadership and the institutions that influence our world. Through its online Greenleaf Academy, on-site keynotes and workshops, promotion of Greenleaf's Best Test® Assessment with certified consultants, leadership partnerships, and its annual conference, the Greenleaf Center helps those with *A Heart for Service and A Head for Results.*

Many industry-leading organisations live the servant leadership philosophy, its principles and practices, within their organisations and with their customers, suppliers, clients and communities with whom they work. As the wellspring of the movement, the Greenleaf Center's mission is "to advance the awareness, understanding, and practice of servant leadership by individuals and organisations." When you become a member of the Greenleaf Center, you join with others who may be curious about servant leadership or find your tribe—the community of people who choose to lead "by serving others first."

The greenleaf leadership conference 2017

On November 2-4, 2017, the Greenleaf Center is hosting its premier leadership conference at the Gaylord Texan Resort in Grapevine, Texas, near Dallas/Fort Worth. This is the 25th gathering of the servant leadership community with this year's theme—"The Journey Starts Here." With dynamic speakers, curated conversations, learning sessions, and scheduled time for networking and relationship building, the conference is designed to help people *Connect – Learn – Grow – Go*, creating a better world personally and professionally. Attendees from past conferences have said: *"More informed, more self aware, and better prepared to be a servant leader and advocate for the cause"* and *"Most conferences I attend try to reach you from the neck up, while the Greenleaf event reaches you from the heart up."* Plan to attend.

Visit **greenleaf.org** to learn more about the Center, register for the upcoming conference or to become a member today—The Journey Starts Here.

Now retired, **L inda W. B elton** was a senior executive in the U.S. Veterans Health Administration, directed Wisconsin's hospital system and private sector facilities.

She served on the Board of Trustees of the Greenleaf Center for Servant Leadership. A Fellow in the American College of Healthcare Executives, she is author of *A Nobler Side of Leadership: The Art of Humanagement* (2016).

Phillip Anderson serves as the Co-Program Director for the Greenleaf Center for Servant Leadership. He develops and presents training materials, teaches classes, and helps cultivate the servant leadership community. He is the founder of the ReThink! Consulting Group, helping individuals and organisations rethink ideas and relationships, especially collaborations, to make better organisations and communities.

patient-centric, relationship-centred and value-based approaches. It enhances efforts in change management, succession planning, diversity and inclusion, and is a launching pad for high-functioning teams. It is results-oriented and thrives on systems thinking, encouraging the leader to regularly view the organisation from a 30,000 foot perspective, where patterns, connections and the 'big picture' become evident.

Healthcare has grown up. It has taken its place in the fierce worlds of business and competition, science and technology. It demands a leadership paradigm that has also grown up. Servant leadership is often countercultural. As Robert Greenleaf surmised, being servant first, addressing people's highest priority needs, offering others a seat at the table, and upending the hierarchy, contradicts what many of us learned in graduate school. Servant leadership, while preparing us for the hard realities of healthcare management, achieves success by affirming the very values and relationships that make healthcare a mission.

KEY POINTS

- ✓ Leadership is a personal decision to serve
- ✓ Servant leadership does not replace traditional management functions, but shapes how they are performed
- ✓ Servant leaders may make mistakes, but they are less likely to be derailed by unethical or unaccountable behaviours
- ✓ Servant leadership is fundamental to transformation
- ✓ There is nothing impersonal about business. Decisions must be undertaken with a gravitas that acknowledges the human impact
- ✓ Service is not a by-product of leadership: it is the whole point
- ✓ We are not a servant leader until others see us as one

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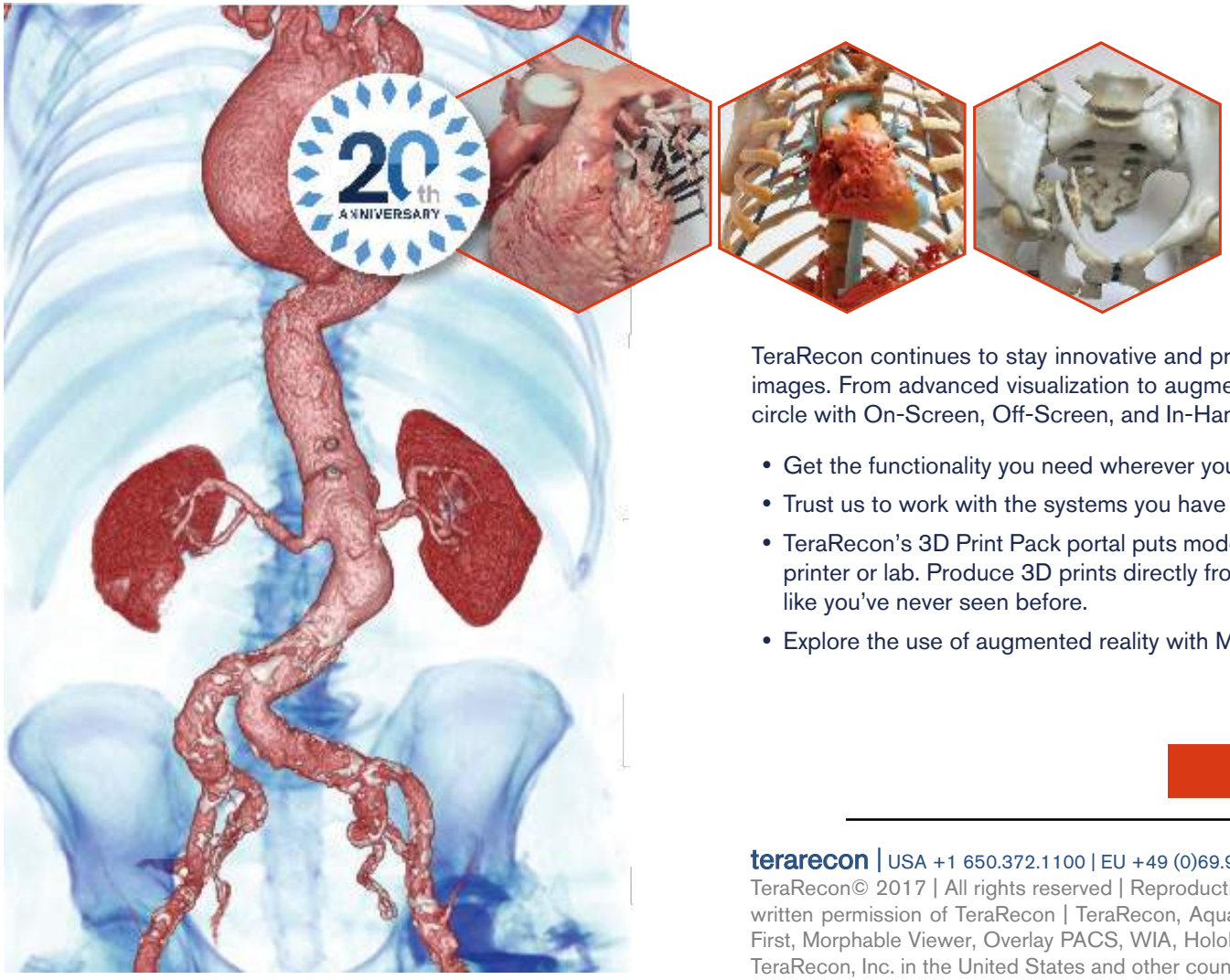

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How to energise collaborative thinking: 5 tips to trash bad habits

For better team cooperation and project success, 'collaborative thinking' could be the way to go.

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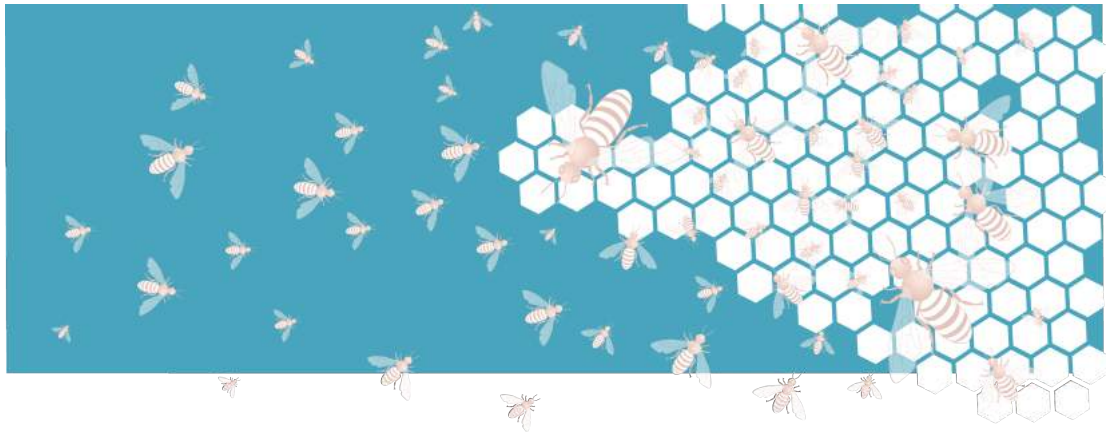

"Two heads are better than one". This couldn't be more accurate. I've always been a fan of working in a collaborative way: involving your team, sharing your thoughts and ideas with as many people as possible and getting different perspectives and inputs. Because it's all about perspectives - and the more you get, the more constructive feedback you come across, the more solid your idea or project becomes.

No one has ever achieved anything alone. If you work on your own, if you don't have a team behind you, it's likely that you won't succeed.

Unfortunately most organisations nowadays, whether it's a multinational corporation or a hospital, tend to be very hierarchical and fragmented into specific and specialised departments. Paradoxically, in a further digital, globalised and data-driven world, most medium-big sized projects demand distinct departments and several regions to work together under certain (pre)established objectives.

This is why more organisations are turning to collaboration tools and techniques - many of which are frequently used in start-ups and young companies with more flexible structures and organigrams - in order to improve their results and efficiency. Some are thought to directly increase productivity by up to 30%! This, in turn, means less risk and wastage, and consequently higher Return on Investment (ROI).

Wastage is a common issue across healthcare organisations. Whether it is linked to wasting paper or radiological film when the hospital could be working in a full digital environment, or simply by misdiagnosing and forcing the patient to repeat or go through further and unnecessary exams, this poor streamlining of operations is a heavy management burden with serious financial and sometimes human setbacks.

Many of these outcomes could be avoided through collaborative thinking - by joining forces of representatives from several departments that are directly or indirectly concerned by the process, and together trying to reach new solutions to tackle a specific challenge. Again, in such a cross-disciplinary case, it is perspectives that matter.

Dealing with highly technical issues demands even more points of view across all fields to find simplified answers and overall consensus.

Here are a few tips to start implementing collaborative thinking into your workplace:

Create the habit

Start by gathering your team and other departments once a week or fortnight to update them on ongoing projects or announce new ones. Ask for their feedback, let them share what they are working on and be constructive. Whether it's via a conference call or in a physical meeting, as long as you don't monopolise the microphone, you'll see your team exchanging ideas and becoming motivated sooner than you'd expect.

Be human

If you are launching a new project or dealing with an existing one, and the only way you involve your team is by sending out a long e-mail and ccing everyone, then you're not doing it correctly. When emails get too long, or have too many people copied in, then it's time to pick up the phone or meet in person. Don't hide behind the screen; technology will never replace the warmth and transparency of face-to-face human relations.

"NO ONE HAS EVER ACHIEVED ANYTHING ALONE"

Get everyone involved from the start

When companies start a new project, they tend to rely on just a few people or departments to kick it off, and slowly get other people involved along the way. But experience tells me that you'll probably get resistance from these people and a huge lack of motivation to participate in a project that is already half-way drawn up. Always get everyone involved when starting a project, whether they'll play a small part in it or officially come across the project within six months of its launch. Align objectives and make them feel part of it by getting their input from the start.

Through technology or in person, just collaborate

Adopt IT. It's worth it. There are several technological tools and software that are collaboration enablers, but you can also add games, brainstorming techniques and other dynamics that promote this when meeting in person, such as the ones we use for co-creation at Torke CC. The productivity and efficiency you get out of it is invaluable, and people enjoy it and have fun. Not only are you making a huge impact on your team, you are getting results and leading change in your organisation.

Above all, give your team a voice, and listen

This is the first step for collaboration. It is an attitude, a way of working. It's all about communicating, listening and giving (and asking for) constructive feedback. If you make this a simple routine on your way of working with and amongst your team, you're in the right path to guarantee collaborative thinking as being the foundation of all processes and assuring successful results in your future projects. ■

What could possibly go wrong?

Thinking about the risks and benefits of medical treatments

How much do clinicians—and patients—really know about the likely outcomes of the decisions they make, and how can we help them know more?

Should I start taking statins? Should I go for a breast cancer or prostate cancer screening test? Or even just should I take another ibuprofen for my backache—that headline about them potentially causing an increased risk of a heart attack pops into my mind...

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Our lives are full of decisions that relate to health, whether as healthcare professionals or simply as individuals, and when we make those decisions—even small ones—we are weighing up the potential risks and benefits in our heads.

But how many of us actually know what those risks and benefits really are? A recent meta-analysis of the understandings of both patients (Hoffman and Del Mar 2015) and clinicians (Hoffman and Del Mar 2017) showed a consistent problem: even specialist clinicians tend not to be aware of the actual figures for treatments they work with regularly. Hence patients and clinicians are often making decisions without really understanding what is likely to happen as a result.

What are the chances?

This situation is clearly not ideal. Clinicians I speak to resoundingly say that they don't feel that they have access to the information they need, and they don't feel confident that they can explain it to patients either—and the evidence backs that up. A recent paper reported how less than half of patients enrolled on a large, multi-centre clinical trial understood the potential risks and benefits to them, even after receiving extensive information about it (Diemert et al. 2017). The authors, in classic understatement, described this as 'suboptimal'.

> "DEALING WITH PROBABILITIES DOES NOT COME NATURALLY TO MOST OF US"

At the new, philanthropically-funded Winton Centre for Risk & Evidence Communication at the University of Cambridge, UK, we to aim to tackle these problems: to help bring together the best evidence available and to help communicate it to both clinicians and patients.

Predict

One project we are working on is the English National Health Service Predict website **(predict.nhs.uk)** (**Figure 1**). This uses a risk prediction algorithm to calculate the likely outcomes for women who have had surgery for breast cancer depending on which adjuvant treatment path they follow. It's a site that has been publicly available for many years and currently has around 20,000 users each month from all around the world. Many oncologists use it regularly in their decision-making. From a patient's perspective, however, the site is difficult to use and

easy to misunderstand—it's not remotely designed for them and yet is publicly available.

Our job, then, is to make Predict not just suitable, but useful, for patients: ideally used in consultation with their clinician, but it should also be useful to patients who might use it themselves at home to discuss with their families.

From the perspective of a clinician, Predict is very helpful in that you can quickly input details of an individual patient's condition, along with your proposed treatment, and it will output a bar chart showing that patient's predicted outcome (in terms of survival) at 5 or 10 years. The perspective of a patient, however, is vastly different.

Firstly, there is the question of what the site does. For a clinician, this sort of calculation is an everyday occurrence. In one of our focus groups, however, a woman (who had not had breast cancer) described how she could imagine sitting down at this site called 'Predict' and being faced with something that was going to tell her her future: how entering her details and then being expected to click a button to discover her likely fate would have her shaking and probably in tears. Clearly the design, the language used and the information surrounding the tool about what it will (and won't) do is vital. It's not simply a matter of avoiding or explaining technical terms, or even of making the numbers that come out of it clearer through graphics.

What does prediction mean?

Reading online forums, it's clear that many patients do enter their details into the current version of Predict, alongside other similar risk prediction sites designed for clinicians, and are then upset and confused by the different outcomes they get from each. Some talk of having 'favourite' risk prediction tools, which give them more favourable outcome predictions—without realising that there's a reason for the difference. The sites giving apparently 'better' outcome proportions are simply giving disease-only mortality figures rather than all-cause mortality. If you are an older woman,

Figure 1. The English National Health Service PREDICT website

your base chance of mortality—regardless of disease—can be significant. No wonder it 'sounds better' on sites that don't mention that.

> "THE FUTURE OF HEALTHCARE IS A FUTURE IN WHICH INFORMATION - NOT MEDICATION - IS KING"

But these sorts of perspectives—which you can read in forums but also arise out of our focus group work to understand the needs of patients—raise a whole host of interesting issues around our work. Most of us, as patients, want reassurance in the face of scarily uncertain futures, and facing our inevitable mortality is not something we choose to do. On top of that, dealing with probabilities does not come naturally to most of us. For an individual, an outcome is usually all or nothing—either my cancer will recur or it won't: there's no '70%' about it. In focus groups and on forums we hear the sentiment: "knowing the statistics won't affect the outcome for me"—except that it does when knowing the statistics helps you choose a treatment option that gives you a better chance of the outcome that you would value the most. Helping patients to recognise this—to give them a sense of empowerment rather than fear in this unfamiliar world of probabilities is a key task that we need to tackle, and help doctors deal with too.

What matters to you?

Patients should also have more power than simply understanding which treatment gives them the best chance of surviving longest. Clinicians, by default, are obliged to maximise their patients' lifespan, but we all have different priorities—and often with life, quality can be more important than quantity. One thing that has come up often when talking to both doctors and patients is the need to be able to discuss things like side effects and the risks of decreased quality of life associated with different treatment options. Helping collate and provide the figures around the risks and benefits of treatment options in terms of mortality is hard enough—adding in the side effects, which are not so well recorded, is even harder. Listening to patients, though, it's clearly important to them and so it's something that we aim to do.

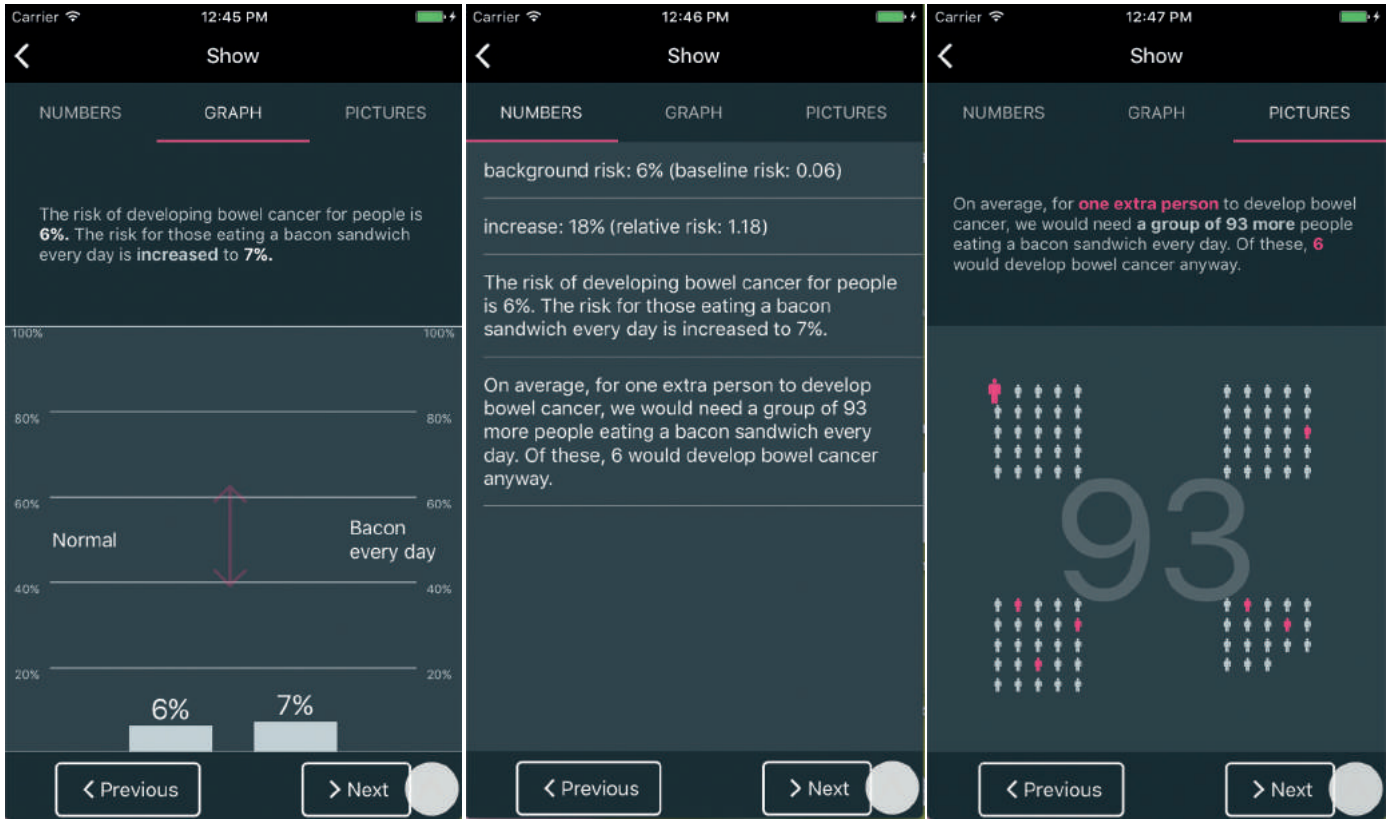

Figure 2. An app is under development

Providing clinicians and patients with risk and benefit information, tailored to the individual patient as much as possible, and in a clear and friendly format, will hopefully allow a much greater level of shared decision making. When we ask in our patient focus groups whether people would like to take an active role in deciding between treatment options, the overwhelming response is yes: of course they want guidance from a trusted clinician, but they want to feel in charge of the final decision: patients express sentiments such as "it's my body" and "I have to live with the consequences." This is reinforced by data on patient satisfaction when they have used decision aids to help them discuss the options with their doctor. These types of tool, then, should have a growing role in healthcare in the future.

Information for every decision

The NHS Predict site is designed specifically for decisions around adjuvant treatment in breast cancer, but we are planning to use it as a proof of principle for a whole range of other applications as well. Our next adaptation of it is planned to be for transplant patients, who have to make agonising decisions. With donor organs in such short supply, and increasing techniques to make use of 'imperfect' organs, transplant patients are now more than ever being put in the position of choosing between accepting a donor organ which may carry higher risk to them, or remaining on the waiting list in the hope of a 'better' organ. In this scenario, it is vital that they know the risks of each—mortality whilst on a waiting list is painfully high for some patients, something which is a difficult fact to face, and so is at the heart of a very sensitive conversation between patient and surgeon. We very much hope that a carefully designed and personalised site can help that conversation take place.

Not every health decision, though, is so sharply life and death. From popping a painkiller to taking a screening test, we all face minor decisions every day—and yet most of us make them without knowing the facts. Here too we aim to help. Many years of research have been put into developing simple tables and infographics to display the potential benefits and harms of any health decision 'at a glance'. Now, these are becoming accepted as an important addition to patient information in leaflets and on websites, and we are developing a free app that can display such information handily on mobile devices, allowing clinicians and patients to have it at their fingertips **(Figure 2).**

There is a hint that patients who are more informed might tend to choose less medical treatment (Arterburn et al. 2012)—as well as being happier in the outcome (Stacey et al. 2017)—and if that turns out to be true, it is a great incentive in a world where there is increasing pressure for medicalisation and stress on health services. If an informed patient is a happier patient, a less medicalised patient, and the patient of a doctor under less stress then truly the future of healthcare is a future in which information — not medication — is king. ■

The Winton Centre for Risk & Evidence Communication was founded at the University of Cambridge at the end of 2016. Its motto is 'to inform but not persuade' and it aims to help present and communicate quantitative evidence to decision-makers in a whole range of fields, from healthcare to the legal profession.

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Improving risk literacy

Developing risk literacy could greatly benefit healthcare.

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What research is undertaken at the Harding Center for Risk Literacy?

Our goal is to help people in their struggle to understand and assess risks and to facilitate better risk-related decisions. Our primary focus has been on healthcare where transparent risk communication can support patients to make informed decisions about their own health. More recently, we've started addressing additional areas such as consumer risks, financial risks, and digital risks. By conducting studies, experiments, and surveys, we investigate people's problems with understanding numbers and find solutions to these. We strive to raise the number of risk-literate citizens, that is, informed citizens who can critically interpret and question the risks communicated to them by experts or the media. We also offer special training for physicians and journalists, who need to know how to interpret and communicate risks to their patients, readers, and the general public.

How best can health professionals communicate risk?

One of the most important principles of risk communication is that numbers need to be made transparent. For example, changes in risk should be communicated using absolute risks and base rates instead of relative risks. Let's consider the risks associated with eating processed meat like bacon or sausages. The World Health Organization warns that processed meat is carcinogenic because it was found that eating 50 grams of processed meat a day increased the chance of developing colorectal cancer by 18%. Looking at this relative risk increase of 18%, eating processed meat seems risky. This number leaves out two important risk aspects, however: the baseline risk that one develops colorectal cancer and the absolute increase caused by eating processed meat. What does the 18% mean? A relative increase of 18% could mean an increase from 500 in 1000 people to 600 in 1000 people that get diagnosed with the cancer, for example. It could also mean an increase from five in 1000 to six in 1000. While the former risk increase would result in 100 additional diagnoses in 1000 people, the latter and correct risk increase results in one additional diagnosis in 1000 people. Stated in absolute terms, the risk increase of one in 1000 people is more transparent than the 18% relative risk increase because it provides more information. It provides the base rate, in other words, how often the cancer occurs (five in 1000 people get diagnosed with colorectal cancer) as well as the absolute risk increase attributable to processed meat (one additional diagnosis in 1000 people). There are many more non-transparent formats that are often used but that would have more transparent counterparts. Communicators need to understand why some numerical formats are more transparent than others and make more conscious efforts to choose transparent formats. Unfortunately, experts are often not aware of these differences and can themselves be misled by non-transparent formats. In addition to our work on risk perception and risk communication, we develop decision tools that help people make better decisions. These tools help, for example, emergency physicians to make good decisions quickly.

Can you tell us more about the fact boxes that the Harding Center has developed to help patients and physicians assess the benefits and harms of treatments? Do these also include risks of no treatment?

Fact boxes communicate the best available evidence about a specific topic in an easily-understandable manner. The most important benefits and harms of screenings, diagnostic and therapeutic interventions, or treatments are contrasted with each other in a tabular format thus allowing even people with no medical or statistical background to make informed decisions. Some of our own fact boxes contain graphical representations of the benefits and harms, so-called icon arrays, in addition to tables. The resulting mix of text, tables, and icon arrays make the most important numbers accessible to both patients and physicians.

The simple tabular format was originally developed to illustrate the benefits and harms of colorectal cancer screening and later adopted to improve direct-to-consumer drug advertisements. Building on that work, the Harding Center for Risk Literacy builds and disseminates fact boxes on various health topics and highlights the need for transparent risk communication in health care. Several studies show that fact boxes are effective tools for informing the general public about the harms and benefits of medical interventions.

Fact boxes are based on the best available scientific evidence on a specific topic. Ideally they are based on systematic reviews and meta-analyses. Whenever possible, we rely on the Cochrane Database of Systematic Reviews, which is currently the leading resource for systematic reviews in healthcare.

Whether a fact box includes the risk of no treatment depends on the specific question that it addresses and on the scientific evidence available to address the question. Fact boxes on topics such as general

health checks or childhood vaccinations, for example, contain information about the risk of no treatment in the sense of taking no preventive measures. Our fact box on general health checks is based on a Cochrane Systematic Review from 2012 that includes adults aged 18 or older who were followed up between four and 22 years. Amongst other things, it compares how many adults who underwent a general health check and died of cardiovascular disease to the number of people who did not undergo a general health check and died of cardiovascular disease (no treatment group). The same number of people (about 75 in 1000) died of cancer in both groups.

Other systematic reviews and meta-analyses on topics such as breast or colon cancer screening compare screening groups to groups that were not screened or received standard care. Systematic reviews addressing topics such as dietary supplements or influenza vaccinations compare intervention groups to people who received either a placebo or no intervention. In those cases we cannot disentangle the risk of no intervention from the risk of standard care or placebo and thus cannot communicate the risk of no intervention. To sum up, the information included in a fact box depends on the medical evidence that is available.

Please tell us more about your research in emergency medicine.

Emergency physicians frequently encounter patients with nonspecific complaints who report vague conditions such as feelings of weakness or fatigue. These patients are difficult to accurately triage, risk stratify, and diagnose, and their treatment is often delayed. To investigate whether key medical outcomes can be predicted in these patients, we tested an array of statistical and machine learning models in a large group of patients. Collaborating with the university hospital in Basel, Switzerland, and surrounding hospitals, we found that our models could indeed accurately predict patient outcomes. The models also predicted these outcomes more accurately than did physicians' intuitive judgments on how ill the patients looked. These results lay the groundwork for further refining triage and risk-stratification tools for patients with nonspecific complaints. Building on these findings, we are currently investigating whether we can build readily applicable clinical decision support tools such as fast-and-frugal decision trees that physicians can use for patients with nonspecific symptoms. Electronic health records could facilitate the use of such tools.

What are fast-and-frugal decision trees and how might they be applied in clinical practice?

Fast-and-frugal decision trees resemble hierarchically ordered checklists. On the basis of a few key questions to be answered with yes or no, they quickly lead to a recommendation. The yes/no questions are listed in a specific order so that the most important questions are asked first. In many cases it suffices to ask only the top few questions. In this manner, it is possible to make clear recommendations in little time on the basis of a few criteria.

In medical decision trees, each question tackles, for instance, an observed symptom. Depending on the patient's symptoms that are checked by the tree, an initial decision is made, such as whether a patient is an emergency case or not. This is helpful, for example, when doctors need to decide relatively quickly which station to allocate a patient to or which further tests are needed, or in helping patients at home decide on the basis of a small number of observed symptoms whether to consult with a doctor.

Decision trees can hence be advantageous to different groups in medicine. As mentioned, they can be used by patients to decide whether they should seek medical help, but also by medical professionals in their first consultation with a patient to rule out particular illnesses or to take the next corresponding steps.

Not all medical scenarios lend themselves to being described in this way. But in many cases, where time is limited and the most important criteria can be reduced to just a small number of questions, it is possible to make solid decisions using this method.

A couple of years ago, we developed a decision tree that detects clinically relevant depressed moods in young women. In addition to the emergency medicine setting mentioned above, we are also testing whether we can apply these methods to improve the allocation of patients after surgeries. This addresses the problem that many patients who died after surgery were never treated in the intensive care unit and were probably not monitored well enough. In summary, fast-and-frugal trees are simple and versatile decision tools. Due to their simple structure medical professionals could memorise those decision trees that they need particularly often. Due to their simple graphical structure, the trees can also be implemented in the form of posters that are put up on the walls of the emergency room, for example. Finally, due to their simple algorithmic structure, they can easily be implemented into computer software in the form of software agents and made available via mobile apps. ■

Mirjam Jenny
After receiving her PhD at the University of Basel, spent her postdoc at the Max Planck Institute for Human Development where she won the Otto Hahn Medal. Before joining the Harding Center, she spent one year at the National Association of Statutory Health Insurance Physicians as a data scientist.

Helping healthcare face up to enterprise risk management

The Institute of Risk Management is bringing together best international and cross-sector risk management practices to help improve healthcare efficiency and enhance patient outcomes.

Patrick Keady

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QualityRiskMgt

theirm.org

The Institute of Risk Management (IRM) has formed a new Health and Care Special Interest Group to help the healthcare sector deal more effectively with risk and opportunities. The Institute is doing this through professional qualifications, specialised training, publications and symposiums. Chaired by Patrick Keady, a risk veteran who has worked in healthcare risk management for 26 years in director and risk consultant roles, the group has held two specialist risk management events for members since its launch. The next event focuses on NHS Board Assurance Frameworks and a series of other sessions are planned in 2018. These events are available free-of-charge to all professionals working in the healthcare and care sectors. Distilling best risk practices from other sectors, the group is already making an impact on healthcare. HealthManagement.org spoke to Keady about the critical issues facing risk management in healthcare and how the IRM Health and Care Special Interest Group is helping healthcare tackle these.

What led the IRM to set up a sector interest group in health and care?

We are all going to die at some point. In the meantime, what we are all looking for, is increased quality of life, increased life expectancy, improved healthcare outcomes and healthcare that offers good value for money too.

Life expectancy in the UK stands at 81.4 years and OECD figures show that UK healthcare (public and private) costs $3,971 per person per annum. Publically-funded healthcare in the UK consumes about 19% of all the taxes collected. In total, 15% of the population opts for private healthcare and this costs about £25bn extra annually. UK life expectancy is 2.6 years higher than in the US and at the same time, UK healthcare costs only 43% per person compared to costs in the US. However, there is more to do. UK life-expectancy is considerably worse than in Japan, where life-expectancy is 2.3 years more and healthcare costs just 5% more per person. Life in the UK is good. But it could be much better.

The UK's Office of National Statistics suggests that 23% of all deaths in the UK are avoidable. In other words, of the 501,000 people that will die this year, 116,000 do not necessarily need to die. 35% of them will die from cancers and non-cancerous tumour tissue growths. The answer to preventing most of the 116,000 deaths rests with the Social Determinants of Health - other than healthcare – determinants such as early childhood development, income, education, job security, working conditions, housing, social inclusion and so on.

The IRM has been around for 30 years, and it was the first to run a professional diploma in enterprise risk management – mostly for the finance and insurance sectors. Graduates progress to become Certified Members (CMIRM) and Certified Fellows (CFIRM) of the Institute of Risk Management.

With, a workforce of about 1.3 million, the NHS employs less than a dozen are CMIRMs and CFIRMs. This is one of the reasons why the IRM is now focusing on healthcare so that the sector can start to reap the rewards from enhanced enterprise risk management, including better patient outcomes and a better reputation for healthcare organisations too.

What are you hoping to achieve with this group for the health and care sectors?

Our aim is to help health and care providers around the world deliver better care. The UK National Health Service (NHS) issues too much guidance and the NHS is often in the headlines for the wrong reasons. Staffing vacancies continue to grow, NHS doctors are migrating to Australia, temporary staff are being reduced and there seems to be no plan to replace the 65,000 EU-National staff who might be leaving the UK after Brexit kicks-in in March 2019. If the NHS is to continue losing staff, how is it going to deliver good healthcare with fewer personnel?

The NHS does not have a clear agreed vision. Instead, successive governments temporarily fill the gap with their own visions, and with mixed results. While there is no clear agreed vision, there are seven principles. Five of these are absolute, such as making a comprehensive service available to all, patients being at the heart of the NHS, working across organisational boundaries, the NHS being accountable to the public and patients, and access based on clinical need. However, the remaining two principles are not absolute – that the NHS aspires to best standards and it is committed to best value. As things stand, these two principles are seen as nice-to-do, rather than absolute requirements.

Spreading good practice: Risk management awardees at the IRM awards.

This leaves most NHS Trusts in a quandary - they do not have clear agreed visions either.

There are some success stories of course. For instance, ten years ago, Salford Royal Hospital NHS Foundation Trust had one of the worst poor patient safety records in England. From this low starting point, they adopted a new bold vision - to be the safest Trust in the NHS. They have achieved and sustained their bold vision in the intervening years. Not every NHS Trust can be the safest in England and this is why NHS Trusts need to review their strengths and weaknesses before adopting a vision that suits the populations they serve and the people they employ.

Vision is very important for staff. It is essential to give workers a concrete picture of why they should get out of bed everyday and what they are aiming to achieve at work. Many NHS Trusts have done a mediocre job on vision and this is where enterprise risk management can help.

Risk management is about preventing downside risks and maximising opportunities. For the other risks, it is about managing them effectively. The aim of the IRM Health and Care Special Interest Group is to help healthcare providers around the world deliver better care.

For example, referring to the Wannacry ransomware that hit organisations around the world in May this year, 34 NHS trusts were affected. I looked at the Strategic Risk Registers from all 34 trusts. These documents should have included information on top strategic (downside) risks, opportunities and mitigations. It turned out that only one of the 34 NHS Trusts affected by the Wannacry ransomware had identified cyber risk as a threat. There are lots of questions to be asked.

> "IT TURNS OUT THAT ONLY ONE OF THE 34 UK NHS TRUSTS AFFECTED BY THE WANNACRY ATTACK, HAD FORMALLY IDENTIFIED CYBER RISK AS A THREAT TO THEIR ORGANISATION"

Therefore the IRM has launched a review of the NHS Board Assurance Frameworks taking into account best practice in other sectors and how this can help healthcare. We have found that current guidance could do much better. We will be publishing our review later in 2017.

In which areas do you think health and care need to implement key risk management strategies?

We have picked up on different ways healthcare deals with risk. Prevention is the best way to deal with risk. The second option might sound counter-intuitive in the health and care contexts. That is not having to rely on people to do the right thing. Other controls include introducing policies and training, detecting the risk as it materialises and, finally, dealing with predictable risks. Detecting risk and dealing with predictable risks are still the two most

common approaches to managing risk in healthcare. I want to see this change.

Most healthcare organisations are reactive rather than proactive. In order to mitigate risk, the CEO and executive team need to have a grip on what the risks and opportunities are, specialists need to be up to date with patient safety, compliance and legal matters, the boardroom needs to be satisfied that there are robust processes in place to deliver timely reliable information on current residual risk. Internal audit can then be helpful in giving assurances on the reliability of risk management processes.

What sorts of interest have you been attracting and from what types of organisations? What are the main concerns?

We have had a lot of interest from the UK and Ireland, Africa, Europe, India and Australia.

While patient safety is having an impact on healthcare, we are hearing about silos and the challenges of sharing what is happening in one silo with other workers, specialties and organisations.

Cyber security is a big area to focus on and the Institute has developed a training programme aimed at managing cybersecurity risks as well as budget management. Financial cuts can be necessary but they really do need to be intelligent too. This is not always the case. Information is key to making good decisions and, right now that information is not always available to the key decision-makers.

Increased spending is one of the often repeated mantra's for dealing with risk in healthcare but in my view, throwing more money at risks is not always the answer. Instead, healthcare needs to have a clear vision about how it will help to prevent, minimise and treat ill-health. It then needs to coach its workers to deliver the vision.

I am very excited about the impact the IRM Health and Care special interest group can have on vision and enterprise risk management in healthcare. ■

Working internationally: the IRM forging an alliance with the Chartered Institute of Loan and Risk Management in Nigeria.

KEY POINTS

- ✓ Life Expectancy in the UK stands at 81.4 years. This is 2.5 years more than in the United States and 2.3 years less than in Japan.
- ✓ Public and private healthcare costs $3,971 per person per annum in the UK. This is 57% cheaper than in the US and 5% less than in Japan
- ✓ With a workforce of about 1.3 million, the NHS employs less than a dozen Certified Risk Professionals.
- ✓ Therefore The Institute of Risk Management is actively looking to help healthcare insurers and providers deliver better services. The Institute's health and care special interest group events are available free-of-charge to all professionals working in the healthcare and care sectors

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Cyber infection control

Time to take it seriously

Both infection control and cybersecurity support the whole care process, but why do we treat them so differently?

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In 1847 the father of infection control, Ignaz Semmelweis, took a position running maternity services in a Vienna hospital. During his time there he observed that women cared for by physicians were more likely to die (13-18%) from infection than women cared for by midwifes (2%). This led him to develop a theory that infection control was critical. He then implemented mandatory handwashing and saw the mortality rate from infection drop to 2%. Since then infection control has been a key part of all aspects of the care process. However, the question why physicians washed their hands less than midwives though was never really answered.

Today, health organisations face a new infection challenge, that of keeping their IT systems free of viruses and other attacks on their health, and they will need to treat this threat with the same seriousness.

IT is crucial to care in the 21st century

This starts by understanding that digital technology is now integral to healthcare. It touches all parts of the process: clinicians look at records electronically, lab tests are computerised, and ambulances are dispatched by computers. This role will continue to increase as we move to paperless, integrated and patient-centred approaches.

The risk of an attack on these systems will increase as they are accessed by and connected to others and the ownership and responsibility for their cleanliness gets blurred. For example with mobile carers, carers using Bring Your Own Devices, and patients wanting to contribute data from a fitness tracker—who is responsible for the digital cleanliness?

On 12 May 2017 the *Wannacry* computer malware provided a dramatic illustration of the risks. A significant number of global care organisations saw their work disrupted, and many more breathed a sigh of relief that they were not affected. While almost 50 services have been affected by malware and IT service failures in previous years, none have ever hit this hard or with such a global reach. *Wannacry* was the equivalent of letting two five-year olds loose in an operating theatre before beginning open heart surgery, and showed us all that our systems, our data access, our way of working does not support digital infection control.

Cybersecurity is infection control

In response, we all need to understand why these cyber issues occur, and what we can do to prevent them. This starts with getting the right governance and recognition at board level. Leaving it to junior members of staff means it won't be getting the right attention until it hits the headlines. Boards now need to scrutinise digital cleanliness in the same way as they treat the latest infection control key performance indicators. Worrying about cyber security must not, however, be used as an excuse to avoid embracing digital technology and the opportunities it provides to transform how care is delivered.

In the same way that a ward has a hygiene owner, digital security needs its own champion. The advent of the Chief Clinical Information Officer and its appearance in the Wachter report (National Advisory Group on Health Information Technology in England 2016), for example, go some way to addressing this. In all this digital cleanliness has to be more than the equivalent of a poster asking you to wash your digital hands properly, but be recognised as a critical priority across the organisation.

"CYBERSECURITY IS AN ARMS RACE"

In a connected world, cyber risks are inevitable

Connectivity in health organisations brings real value to patients. For example to support continuity of care, or support peripatetic carers with mobile devices, a connection to the worldwide web is necessary, but that web is a potential source of digital infection. Connecting to it exposes the organisation to risks, and it needs to understand those risks, manage them, be ready for them and react effectively when they inevitably strike.

To do this healthcare providers need a digital strategy and a cyber security and resilience plan, just as they have an infection control plan. That strategy should be linked to patient care and recognise that it is not just about investing in technology, but in people

and training. PA has found that people and behaviours are a factor in over 80% of high-impact cyber breaches. The kind of behaviour that puts information at risk ranges from the completely accidental (unaware), the careless or negligent, all the way to deliberately malicious. The best way to reduce these risks is through training and communication.

Regularly review your security measures and learn from others

The next step is to recognise that cybersecurity is an arms race. Threats evolve over time and so the work is never done, similarly to the increased resistance we currently face with antibiotics. There is a clear need for regular reviews of the threats and security measures, followed up by action to update systems, and update them when security flaws emerge. One organisation we worked with saw four zero-day attacks (these are cyberattacks exploiting a weakness not seen before) in three weeks. That underlines the clear risk if an organisation only updates its security every three months. While software providers have become pretty effective at issuing security patches, their efforts are pointless if the organisation does not have a process for applying those patches quickly.

The patch that protected against the *Wannacry* attack was available two months before it happened, but clearly many organisations were not aware of this and did not deploy it. This underlines that there needs to be a recognition that a cyber risk is like a dirty thumb print on a theatre-ready scalpel, and needs immediate action; cleanliness can be best achieved by providing a hospital with all the tools to reduce infection rather than each individual bringing their own soap and nail brushes to theatre.

Healthcare can also learn from other industries. Mature digital industries have realised that running data centres is not their core skill. So they have moved their IT to the cloud (offsite external providers) and taken advantage of the massive investments, $30bn in some cases, cloud providers have made to provide more efficient, more secure, higher quality services.

It is clear that fighting cyberattacks requires a number of layers of defence including an ability to isolate systems that can't be updated. One organisation we worked with had all its systems connected to a single network and that made it very vulnerable to attack. In the same way that a hospital isolates patients to limit the spread of infection, they should do the same with their digital systems.

Lastly they should remember that cybersecurity requires constant vigilance and systems have to be actively managed. This involves monitoring their status and looking for unusual activity and checking anti- virus protection, as well as ways to detect intrusion.

These activities will help organisations see that digital technology, when it is properly protected from infection, is an asset that allows them to deliver better care. ■

James Mucklow leads PA Consulting Group's Digital Healthcare work. He is passionate about delivering better systems to care and new treatments. He has been delivering complex innovative projects for over 25 years across all aspects of the lifecycle. His work primarily focuses on improving patient care and accelerating clinical research. He has been working at PA for over 20 years and prior to that worked at the National Institute for Health Research.

Richard Corbridge is a globally recognised expert in healthcare strategy and technology, with over 20 years' experience in the Health and Clinical Research Information sectors. Richard has a passion for business change and benefits management in health and very much insists on a focus on engagement and benefits being brought to technology implementation.

KEY POINTS

- ✓ IT and cybersecurity need to be regarded as key to the care process
- ✓ IT systems need to be connected, which exposes them to risk
- ✓ Cyber risks need to be managed

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Is blockchain technology the solution to healthcare's data woes?

In healthcare, blockchain is widely regarded as technology that will protect data from costly and credibility-damaging cyberhacking. But there's a risk; does it align with regulatory bodies' criteria?

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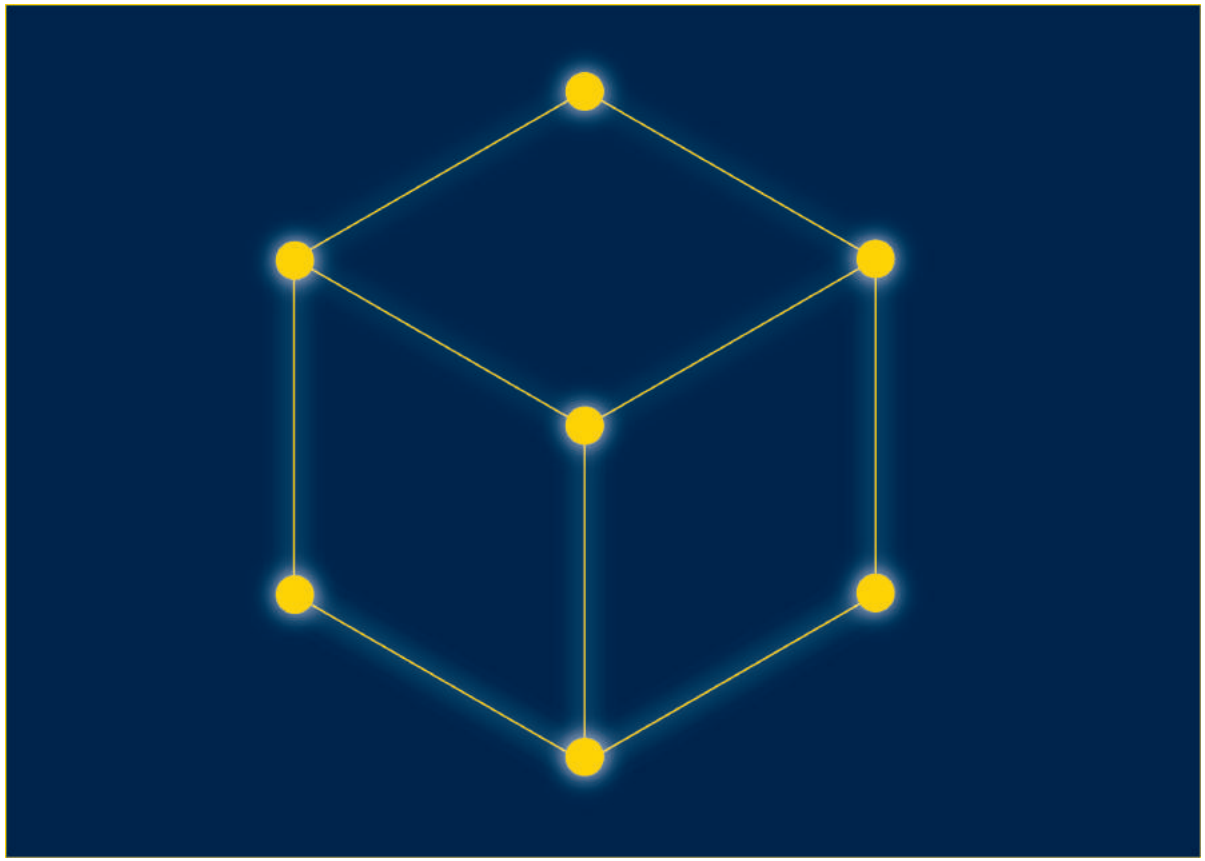

Many experts believe blockchain technology will drive innovation in health information and that it has the potential to solve critical healthcare issues, including interoperability, security, records management and data exchange. As with any new technology in a heavily regulated industry, widespread adoption of blockchain technology in healthcare is highly dependent on striking the right balance between innovation and regulation. Finding that balance requires an understanding of both the technology and the regulatory boundaries.

The fundamentals of blockchain technology

At a fundamental level, blockchain technology is distributed peer-to-peer ledger technology built around four key concepts: decentralised digital trust, consensus protocol, immutability and security. Generally, blockchain technology structures each transaction into chronologically recorded blocks of data that are encrypted on a distributed (public, semi-private or private) database (Linn and Koo 2016). Each hash in a blockchain database uses the new data to be recorded and old data from a previous block to create a unique and immutable digital signature for each new block of data (Linn and Koo 2016).

To verify that each subsequent block in a chain matches up with all previous blocks (and is otherwise a valid transaction), blockchain technology uses a form

of consensus protocol to confirm transactions before they are written to the database (Linn and Koo 2016).

Each member (or node) in a distributed blockchain network stores an identical copy of the entire database and participates in the collective verification process in real time by simultaneously running algorithms to confirm transactions (Economist 2016). Because each new block's hash is based on the hash of a previous block, any change to a past transaction is immediately apparent to everyone in the chain when the hash of a new block no longer matches up with the chain of blocks before it. At a basic level, this network consensus and transparency increases security and immutability of transactions that are written to the database and may replace a trusted intermediary (Linn and Koo 2016).

What are the challenges of implementing blockchain technology in healthcare?

One of healthcare's greatest challenges is interoperability and managing patient data across the continuum of care. Blockchain technology has the potential to solve this challenge, but experts still express some technological and regulatory concerns. Two challenges are scalability and privacy (IBM Global Business Services Public Sector Team 2016).

Blockchain technology is ideal for smaller data units, but the size of medical records would quickly make scalability problematic if applied to a traditional blockchain structure (Linn and Koo 2016). Complete medical records of each patient in a blockchain database would need to be stored at each location participating in the network, and the data-storage and bandwidth requirements needed to operate such a system would be prohibitively large (Linn and Koo 2016). Instead, a blockchain technology-based medical system would likely need to function as a control for accessing the data, noting where and when changes to medical records occur, rather than containing the entire dataset (Linn and Koo 2016). Blockchain databases can be designed so that large files, like x-rays, are "off the chain," but the links to the files are stored "on chain" (Behlendorf 2017). Blockchain technology may be useful to generate an audit trail for particularly sensitive healthcare transactions, such as the prescribing of opioids.

"IT MAKES SENSE TO EXPLORE THE OPPORTUNITIES FOR BLOCKCHAIN TECHNOLOGY IN HEALTHCARE, WHILE ALSO UNDERSTANDING THE POTENTIAL RISKS"

Given that medical information is worth 10 to 20 times more than credit card data on the dark web (Humer and Finkle 2014), privacy issues are also a concern for blockchain technology in healthcare (Cuomo 2016). Jerry Cuomo, IBM's Vice President of Blockchain Technologies, said "within healthcare, more extensive privacy protections are needed . . . One goal is to ensure that institutions and individuals can only access information they're supposed to see. A key element is 'entitled access,' which is achieved by using modern cryptography so access to private data requires presentation of encryption keys/certificates held by authorised participants" (Cuomo 2016).

Various solutions to the privacy issues posed by blockchain technology are available, however. For example, a patient's medical data must be encrypted, and permission to read or write that data could be based on an encryption key only known to the patient or his or her healthcare provider (Linn and Koo 2016). Another possible solution is a fully private blockchain database, where permission to read or write to the database is controlled by one organisation (eg a regulatory body) (Buterin 2017).

While there are workable solutions to the technological challenges of blockchain implementation in healthcare, finding solutions to the regulatory challenges will require a greater collaborative effort by the healthcare industry and will likely require action by healthcare regulators. For example, traditional blockchain implementation may not be HIPAA compliant without additional measures (LaFever 2016). Blockchain technology relies on mathematically derived pseudonyms to verify the data on a distributed ledger (LaFever 2016). HIPAA privacy rules may forbid this practice because the pseudonyms pose a risk of potential re-identification of de-identified protected health information (PHI) (LaFever 2016). If PHI is contained in and passed in a blockchain database, would hundreds of business associate agreements be required to exchange healthcare data under HIPAA?

Blockchain implementation also raises other regulatory issues, including lack of an existing legal framework for regulating blockchain technology (Tena 2017), lack of an established legal authority or data governance that makes the rules and imposes sanctions, and finding ways to incentivise the sharing of patient data and reform efforts. Despite these regulatory challenges, there is evidence that regulators are taking notice, and change may be on the horizon.

For example, federal agencies, such as the Departments of Homeland Security, Justice and Treasury have been using

blockchain services and contractors since 2015 and are now devoting increased resources towards blockchain innovation. Further, in 2016, the National Institutes of Health held a competition seeking white paper submissions on blockchain technology and its possible uses in healthcare (Linn and Koo 2016), and the FDA has partnered with IBM in the hope of developing "a secure, efficient, and scalable exchange of health data using blockchain technology" (IBM 2017).

"WHILE THERE ARE WORKABLE SOLUTIONS TO THE TECHNOLOGICAL CHALLENGES OF BLOCKCHAIN IMPLEMENTATION IN HEALTHCARE, IT WILL LIKELY REQUIRE ACTION BY HEALTHCARE REGULATORS"

The healthcare industry already has several blockchain initiatives underway, including a permissions management project for data from clinical trial patients, a patient-centric electronic health record on a permissionless blockchain database, a health identity blockchain database established by the Estonian government, and a blockchain-based healthcare claims management system (Behlendorf 2017).

Understanding risks

Adoption of blockchain technology in healthcare will require small test projects in exchanging and tracking data (Behlendorf 2017). Given the success of blockchain implementation in other regulated industries, such as the financial services industry, it makes sense to explore the opportunities for blockchain technology in healthcare, while also understanding the potential risks. ■

Sharon Klein and **Joe Guagliardo** are vice chairs of Pepper Hamilton's Technology Group, a multipractice team that advises companies where technology is the business as well as companies where technology is critical to supporting the core business. Ms. Klein is also a member of the firm's Health Sciences Department, a team of 110 attorneys who collaborate across disciplines to solve complex legal challenges confronting clients throughout the health sciences spectrum. Research assistance for this article was provided by summer associate John Melde.

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Healthcare wearables: What are the risks?

How can stakeholders harness the potential of healthcare wearables to revolutionise the care continuum while successfully navigating legislative and technical risks? HealthManagement.org spoke to Global Top 100 Digital Health Influencer, João Bocas for his insights.

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Is there a danger of health wearables developers being blinded by technology and losing sight of what a healthcare wearable is for?

Yes, absolutely. There is always a risk of becoming side tracked and not fully focusing on understanding what the real problem is that we are trying to address. I believe that understanding the process that we are trying to change is extremely important, before we can apply any technological improvement to contribute to the solution or improved outcome.

What do you think the top risks existing in the health wearables sector are right now?

I strongly believe that understanding the value of the data can be an issue - in other words, what relevant data can be used and is it reliable? If we are talking about medical interventions, we need clinically-validated data. And we are still a long way off from achieving this. Furthermore, collection of data from different entry points is extremely challenging and adding another layer of complexity will not help. The question is, how can we make sure that patients use a wearable for a sustainable period of time? Otherwise all these efforts are worthless.

How can stakeholders mitigate these risks?

By making sure that they think about all these challenges ahead and plan carefully. It's important to ensure that they have processes and procedures in place.

Is there anything legislators can do to encourage and support health wearables development? Are there any particular roadblocks that need to shift?

I believe that we need a best practice framework before we should legislate effectively. Legislators need to understand healthcare inside out before they should attempt to legislate. It's a very complex industry like no other.

"LEGISLATORS NEED TO UNDERSTAND HEALTHCARE INSIDE OUT BEFORE THEY SHOULD ATTEMPT TO LEGISLATE. IT'S A VERY COMPLEX INDUSTRY LIKE NO OTHER"

You speak extensively. What in your view are the wearables themes that are concerning the sector right now?

I really like the idea of augmented reality intersecting with health parameters. For example, imagine a wearable that enables you to receive and make calls, listen to music, gives information about the weather conditions and at the same time acts as a "Health Friend" capturing relevant health vital insights from your body functions such as heart rate, body temperature, respiration rate and even blood pressure. My audiences are amazed by what is possible right now, but, at the time, waiting to see what will happen next. The Wearable Tech world is evolving really quickly. The next two to three years will be incredibly exciting.

Do you have any advice on how incorporation and implementation of health wearables can be scaled up in healthcare facilities?

It can be very challenging to implement new solutions at first. I would recommend that healthcare organisations take time to understand the fundamentals of what's possible in practical terms and take time to analyse and evaluate existing methodologies and solutions before adding novice technologies otherwise it could be a recipe for disaster. We know that healthcare professionals have extremely limited time for training. Understanding the usage of new innovations is not always their priority due to high-stack working demands.

Lastly, I would advise healthcare organisations to validate, scrutinise and evaluate new possible solutions before entering a scaling up operation. Very often highly innovative solutions do not work best in healthcare facilities or hospital settings.

What role can cognitive technology play in improving healthcare wearables?

There is huge potential for emerging cognitive technologies to revolutionise healthcare and I think they can. If we talk about Machine Learning and

Artificial Intelligence for example, their potential is huge in diagnosing, treating, bringing cutting-edge advances from research and much more. However, there is also a concern that depersonalised and less humanistic interventions can surface.

Finally, what is exciting you most about the potential for healthcare wearables?

The potential for wearables to be used in the healthcare of the future is great. We are already witnessing great advances with practical use cases in clinical and home care settings. Innovative products are facilitating and enabling monitoring people remotely, for example, and relevant health data and changes of behaviour can be communicated and acknowledged in real time. Therefore, early interventions and a less reactive approach can be implemented when dealing with patients. I believe that we still have a long way to go in terms of having wearables that are more personalised and work around each individual's needs. ■

João will be a Keynote Speaker at Week of Health and INNovation (WHINN), 10 – 12 October, 2017, Odense, Denmark, whinn.dk and The Convention for Innovation and High-Tech in Medicine (XROMET), 21 – 23 March, 2018, Leipzig, Germany, xpomet.com.

Is radiology a vital speciality?

Reflections on medium term prospects

Comparing radiology to living at or near the ocean allows the threats to radiology to be explored via a nautical theme.

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Our specialty is heading for a period of uncertainty, disquiet, challenge and perhaps peril, one that will likely manifest itself in the medium term, five to fifteen years hence at the latest. The signs that should engender alarm are already evident, more subdued than clamorous perhaps. How can we first acknowledge them and then place them higher in our collective agenda?

Many theorists of knowledge acquisition and retention often emphasise the power of metaphor to enhance discovery by bringing to the fore compelling linkages across intellectual domains. The apt allusion often provides insight undiscovered through conventional narratives. So allow me to reference at several points in this discussion the anticipated journey of our specialty in a nautical context. I wish to compare our field of endeavour to living at or near the ocean.

Radiology over the past 45 years, since the introduction of various measures of producing sectional images, has established itself as a major contributor to healthcare. Our pictures are indeed “SEE WORTHY”. That is, the products and procedures under our stewardship and mediated by our expertise have been deemed valuable by our referrers and patients and also by economists and social opinion makers. The success of our care delivery project has enabled us to sail along, well regarded and well rewarded. In that sense, the vessel of technology that propels us has been SEAWORTHY.

> “WE ARE SEEMINGLY BECALMED IN RADIOLOGY IF WE BELIEVE THAT PROSPERITY WILL CONTINUE TO BE OUR EXPECTATION”

But like a ship on a voyage we must reckon with uncertainties—they with wind, water and weather—and we with the irresistible force of technological change. In 1814 Goethe wrote the influential poem *Calm Seas and Prosperous Voyage,* a compelling work that stimulated both Beethoven and Mendelssohn to use his words as the programmatic impetus for symphonic compositions of lasting fame. Upon first hearing, I, like most people listening today, completely missed the import of the poem by first coming to it through these musical renditions. In the era of sail (remember it was 1814) to be becalmed meant the antithesis of prosperity, not its accompaniment as by a boat propelled by a motor.

We are seemingly becalmed in radiology if we believe that prosperity will continue to be our expectation. We must adjust to the signals provided by the winds of change. For example, we have relied

on our "stock in trade", the macroscopic depiction of disease to provide value of our worthiness. But in the coming genomic age, medicine will be personalised, a tumour will have a signature, a unique identifier to be recognised. Traditional pathology, which engages in cell type delineation, ie "species" recognition of malignancy, will take a back seat, and identification of the "family" of diseases of a particular neoplasm by its radiograph delineation will become increasingly irrelevant. The identity of an individual tumour by DNA determinations through initial and recurrent inspection of peripheral blood samples will become the new means of diagnosis. In this regard we will send radiology adrift. So too will be another means by which we have prospered, the recognition of abnormality occasioned by pattern changes in the distribution of white, grey and black shadows on computed tomography (CT) and magnetic resonance (MR) images of the brain. Artificial intelligence will bear directly on the particularities of image interpretation of neural disease. This diagnostic activity, heretofore the province of radiologists, is likely to become automated for most presentations, putting neuroradiology as we know it in jeopardy.

As physicians responsible for other body systems become more adept at reviewing images, and as they set up training protocols and testing procedures incorporating demonstrations of competence, then another of our prosperous voyages may come to an end, because they too will promise to be just as "see worthy" without us as their 'pilots'. My oncology colleagues have maintained that they believe themselves to be just as capable to follow the growth or shrinkage of a lung tumour on a CT. Frankly they may be right if enough of them believe it without demonstrable contradiction. Here too our sails may not catch that wind for long.

We might now consider radiology as a heterogeneous collection of subspecialties, some more clearly defined near the West Atlantic shore than further East in Europe. Consider some of our subspecialties metaphorically as islands having coasts high enough not to be flooded by the rush of events. From my American perch I see this as clearly defined already. Paediatric radiology, a small island, is sheltered by its confinement to hospital settings where intrusions into our hegemony of imaging by clinical colleagues are unlikely. Breast radiology has become a fortress, like Malta, impregnable to invasion. It has control over all imaging of the organ, of its focus, validated by the state and acquiesced to by referrers. Interventional radiology, too, has by dint of its personal, immediate interaction with the patient and its demonstration of effectiveness become a bastion of capability and confidence and should consider itself "hurricane-proof" for the foreseeable future.

All other subspecialties in radiology are not land-based. They may be losing their moorings in the face of undercurrents they may not perceive even though there is evidence of their presence. To prepare and react they must scan the instruments of change and not rely on the past in the unchartered waters they must now navigate.

So what can be done? For one thing, "bromides" are not usually effective medicine. Saying that we must take a more inclusive role in patient care is meaningless if radical change is not introduced in the way we educate abdominal radiologists, chest radiologists and orthopaedic radiologists. Placing our hopes on expanding now conventional techniques such as CT colonoscopy as a first-line procedure will not boost our volume significantly. If we are to retain our functionality then subspecialty training must involve our dedicated, daily, on sight presence as a member of the clinical team, not as someone assigned to a distant office, who communicates only electronically. And often that communication is typically unidirectional and mechanical.

My roster of metaphorical inferences must also include a favourite flute concerto by Vivaldi entitled *La Tempesta di Mare.* The beautiful sounds of this energetic piece occasion me to ruminate further on the prospects of my specialty in this uncertain age. To be calm about it is to be becalmed, to prosper requires a change of course to pursue favourable winds and avoid becoming tossed about or even capsized by a tempest we should have seen coming. ■

KEY POINTS

- ✓ Radiology has always been "SEE WORTHY", but will it be "SEAWORTHY" in the age of personalised medicine?
- ✓ Outlines threats to radiology and suggests solutions

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Risks of contrast agent administration

Outlines the frequency of adverse effects, prevention and management, and focuses on acute reactions which may occur after intravascular injection of contrast agents, the risk of deterioration in renal function after iodine-based agents, and current anxieties about the long-term safety of gadolinium-based agents.

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Contrast agents (or contrast media) are compounds, which are given during radiological examinations to increase the diagnostic information obtained from the images. Iodine-based contrast media are widely used during x-ray and computed tomography (CT), and gadolinium-based contrast agents are widely used during magnetic resonance imaging (MRI). There are microbubble agents for ultrasonography, but these are used less often. Examinations using contrast agents are described as 'enhanced' and those without contrast agents as 'unenhanced'. This review will focus on three important areas of risk: acute reactions which may occur after intravascular injection of contrast agents, the risk of deterioration in renal function after iodine-based agents, and current anxieties about the long-term safety of gadolinium-based agents. The frequency of adverse effects, their prevention and management will be considered.

"IT IS ESSENTIAL THAT RADIOLOGY DEPARTMENTS ARE FULLY PREPARED TO DEAL WITH MANAGEMENT OF ACUTE REACTIONS"

Acute adverse reactions

Acute adverse reactions are defined as reactions occurring within one hour of injection of the contrast agent, and may occur after iodine-based, gadolinium-based and ultrasound agents. The majority are mild (eg skin redness, urticaria and itching, nausea) and do not need medical treatment. It is important to be aware that not all mild symptoms after contrast agents are caused by the contrast. This has been shown in prospective studies where patients who had unenhanced scans had similar mild adverse effects to patients who received iodine- or gadolinium-based contrast, although the adverse events were less frequent in the patients who had unenhanced scans (Azzouz et al. 2013). Moderate reactions, such as more severe urticaria, bronchospasm and vomiting are less frequent. Severe reactions, which may be anaphylaxis-like and cause hypotension, cardiac arrhythmias or cardiac arrest and respiratory arrest are rare (Clement and Webb 2014). Modern low osmolality non-ionic iodine-based agents were associated with a reaction rate of 3.13% and a risk of severe reactions of 0.04% in a large series of over 300,000 patients (Katayama et al. 1990), with the risk of death estimated to be less than 1 in 170,000 (Katayama et al. 1990). Gadolinium-based agents are associated with a lower risk of acute reactions, approximately 0.05 to 0.33%, with a risk of death in 0.1 to 2.7 per million (Thomsen and Bongartz 2014; Davenport et al. 2013; Prince et al. 2015). Acute adverse events after ultrasound microbubble agents are even rarer (Bertolotto and Oyen 2014). No differences in the incidence of acute adverse reactions have been shown either among the various low osmolality iodine-based agents or among the different gadolinium-based agents.

Some acute adverse reactions are caused by hypersensitivity or chemotoxicity and a minority appear to be true allergic reactions. Patients who have a moderate or severe reaction to contrast media should have blood tests to check for raised tryptase levels after the reaction and skin tests 1 month after the reaction to determine if there is evidence of true allergy (Clement and Webb 2014).

Patients who previously have had a moderate or severe reaction to contrast medium are at increased risk of a further reaction when they are given contrast medium again. Patients with a history of allergy also have an increased risk of reaction. When there is an increased risk of an acute reaction, it is important to consider whether an alternative examination could provide the required diagnostic information. If allergy to contrast medium has been demonstrated, then a different contrast agent to which the patient does not react on skin testing should be chosen for a subsequent administration.

The evidence for the value of premedication before administration of modern low osmolality iodine-based contrast media with steroids or antihistamines, for example, is weak. After premedication acute 'breakthrough' reactions, including anaphylactic shock, may still occur (Davenport and Cohan 2017; Freed et al. 2001; Davenport et al. 2009). The use of premedication has therefore decreased over recent years.

Since a moderate or severe acute reaction, although rare, is possible in any patient, it is

essential that radiology departments are fully prepared to deal with management of acute reactions. Patients should remain in a medical environment for 30 minutes after contrast medium injection. There should be first-line drugs and equipment available in the examination room so that there are no delays in starting treatment. Radiology department staff need to be trained in the management of acute reactions, including resuscitation, and training should be repeated regularly to keep skills up to date.

Renal adverse reactions

It has been recognised for many years that in patients with reduced renal function intravascular administration of iodine-based contrast media may be followed by further deterioration in renal function, with the risk being increased if patients are dehydrated (Fähling et al. 2017; Bartels et al. 1954). In most patients the renal function returns to baseline levels over 1 to 3 weeks, but in some it may persist or lead to end-stage renal failure requiring dialysis. This adverse effect was called contrast-induced nephropathy (CIN), and CIN has been defined as a decrease in renal function (as evidenced by an increase in serum creatinine by more than 25%), which occurs within 3 days of contrast medium administration in the absence of an alternative aetiology (Thomsen et al. 2014).

Over recent years, the use of iodine-based contrast media has increased, and over the same period there have been many publications about CIN occurring both after intra-arterial contrast medium given for angiography, including coronary angiography and intervention, and after intravenous contrast medium used for enhanced CT. It has been stated that CIN is the third most common cause of hospital–acquired renal failure, accounting for about a tenth of cases (Thomsen et al. 2014). However, most of the published studies have been retrospective, with only a few studies being prospective and using control subjects (Rao and Newhouse 2006; Prasad et al. 2016; McDonald et al. 2013). The lack of control subjects meant that all increases in serum creatinine after contrast medium were attributed to the contrast medium, even though it is known that serum creatinine is affected by many other factors, such as illness, hydration, muscle mass, diet and medication.

A recent prospective study which compared renal function after enhanced and unenhanced CT found that changes in kidney function, as measured by estimated glomerular filtration rate (eGFR), were unrelated to whether or not the patient had received contrast medium (Azzouz et al. 2014). A retrospective literature review, which included data from over 12,500 patients, and in which propensity score analysis was used to simulate randomised controlled studies, showed no difference in the risk of kidney injury between patients who had or had not received intravenous contrast medium (McDonald et al. 2014). These and similar studies indicate that the risk of kidney injury caused by intravenous iodine-based contrast media is much lower than the previous literature suggested. Estimates suggest that an eGFR of 30-45 ml/min/kg is associated with a risk of renal injury of 0-5% (Azzouz et al. 2014). (Normal eGFR is 60ml/min/kg or greater). Intra-arterial iodine-based contrast medium has been considered to be associated with a higher risk to the kidneys than intravenous contrast, because it reaches them at a higher concentration, and because large volumes of contrast are often used. However recent retrospective studies of large numbers of patients have not confirmed this (McDonald et al. 2016; Tong et al. 2016), and further data are needed to clarify the risk. No differences in the rate of renal adverse events have been shown among the various low osmolality iodine-based contrast media (Thomsen et al. 2014). The term post-contrast kidney injury (PC-AKI) has now replaced the term CIN, to remove the suggestion that the contrast medium is the cause of all renal function deterioration after contrast. Deterioration of renal function after gadolinium-based contrast agents is very rare when the agents are given in approved doses (Thomsen et al. 2014).

To reduce the likelihood of PC-AKI, it is important to identify at-risk patients either by serum creatinine measurement and eGFR calculation, or by using standardised questionnaires, which identify evidence suggesting impaired renal function. The key protective measure is to hydrate at-risk patients intravenously both before and after contrast medium. A variety of prophylactic drugs have been tried, but none has been consistently shown to be successful (Thomsen et al. 2014).

Late adverse effects of gadolinium-based contrast agents

Gadolinium ions are toxic and are therefore bound to a chelate in gadolinium contrast agents to prevent adverse effects. There are two types of chelate—linear and macrocyclic. In the macrocyclic chelates the gadolinium ions are more tightly bound than in the linear chelates, with the result that the macrocyclic chelates are more stable, with a lower risk of gadolinium being released from the molecule (Morcos 2014).

> "ONE SHOULD NEVER DENY A PATIENT A WELL INDICATED ENHANCED EXAMINATION"

As has been outlined, gadolinium-based contrast agents have a lower incidence of acute adverse reactions than iodine-based contrast media, and PC-AKI after gadolinium-based agents is very rare. However, over recent years some late adverse effects of gadolinium-based agents have been recognised. Some patients with reduced renal function who were given the less stable linear agents developed nephrogenic systemic fibrosis (NSF). The onset of NSF was typically days or even months after contrast administration, with the first signs being skin rashes and thickening. Later, patients developed fibrosis of the muscles and internal organs and in a few patients the condition was fatal. NSF has not been reported since the use of linear agents was stopped in patients with impaired renal function (Thomsen 2016a; 2016b). It has also become apparent that gadolinium may

accumulate over time in the bone, skin, liver and brain in patients who have received gadolinium-based contrast agents (Thomsen 2016c). Larger amounts accumulate after the linear chelates, and the greater the dose, the greater the accumulation. At present, the significance of this retained gadolinium is unclear, but anxiety, particularly about deposition in the brain, has led to suggestions that the use of the linear agents should be discontinued (Runge 2017).

Conclusion

This brief review of some of the more important adverse effects associated with iodine-and gadolinium-based contrast agents indicates that they are generally safe and have a low incidence of significant side effects, particularly compared to some therapeutic drugs. As with all drugs, it is important that contrast agents are only given when there is a good clinical indication, either to make a diagnosis or to direct an interventional procedure. However, the low risks associated with these agents in most clinical circumstances, and the importance of their use to many important diagnoses (eg the detection of liver metastases) mean that a well indicated enhanced examination should rarely be refused. When the patient is considered to be at increased risk of an adverse effect, it is appropriate to consider the possibility of a different diagnostic test, or perhaps an unenhanced scan. With gadolinium-based agents, at risk patients with impaired renal function should not receive linear agents (European Society of Urogenital Radiology 2017). ■

Acknowledgement

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KEY POINTS

- ✓ Contrast media are available for all radiologic modalities (x-ray and CT-scanning, magnetic resonance imaging, and ultrasonography)
- ✓ Mild, moderate or severe acute adverse reactions are seen after administration of any contrast agent; an overwhelming majority are mild. Only moderate and severe reactions require treatment; their prevalence is below 0.5%
- ✓ Reduction (mainly temporary) in renal function (post contrast–acute kidney insufficiency [PC-AKI]) is found in patients with reduced renal function after administration of iodine-based contrast media
- ✓ Gadolinium-based contrast agents have some specific very late reactions due to the toxic gadolinium eg nephrogenic systemic fibrosis, brain accumulation
- ✓ One should never deny a patient a well indicated enhanced examination

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Whistleblowing in healthcare

Although healthcare workers have a responsibility to raise concerns about patient safety and unethical or illegal conduct, if they do so they are often treated badly.

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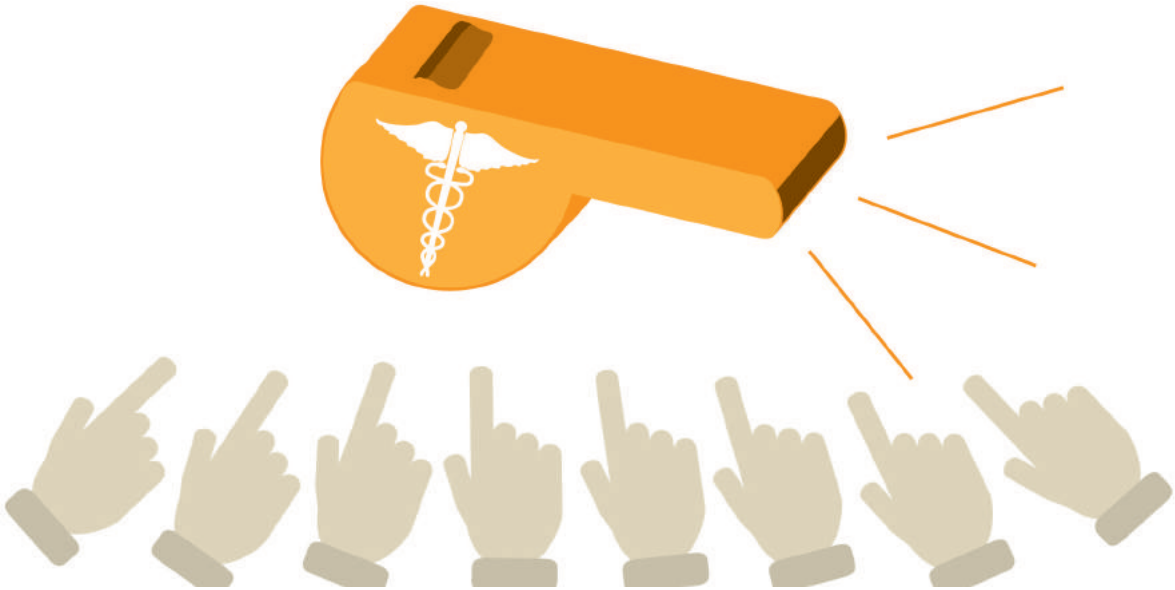

Healthcare workers have a responsibility to raise concerns about patient safety and unethical or illegal conduct. Yet those who raise serious concerns are often treated badly by senior colleagues, their employing organisations and the bodies that should protect whistleblowers. This paradox is because whistleblowers raise concerns that, if made public, would embarrass the organisation or senior and powerful individuals, who are considered less dispensable than the whistleblower. Repeatedly we hear of scandals in healthcare, where whistleblowers were ignored or lost their jobs for raising concerns, but those responsible for both the scandal and its cover-up are promoted to more senior positions in the UK National Health Service.

Risks to whistleblowers

Through membership of Patients First (**patientsfirst.org.uk**) I have met many genuine whistleblowers, who raised serious concerns about patient safety and suffered detrimental treatment and lost their jobs. Achieving a just outcome for whistleblowers in such cases is usually impossible because of inequality of arms—unemployed whistleblowers with limited financial resources fight protracted litigation against employers that spend large amounts of taxpayers' money on legal costs to conceal patient harm or to protect senior individuals.

I say "genuine whistleblowers", because I recognise that there are some individuals who claim to be whistleblowers only after allegations were raised about their own conduct. However the converse is more frequently the case: after whistleblowers raise concerns spurious reasons are found to discipline or dismiss them. If one looks hard enough one can find a mistake that can be magnified to make a case to dismiss a whistleblower and claim that their sacking was unrelated to them raising concerns. I know of cases where NHS Trusts have employed private detectives to follow a whistleblower, have secretly searched a whistleblower's office during a weekend, got the hospital IT department to give them access to the whistleblower's work computer when the whistleblower was on annual leave, and audited a whistleblower's mileage travel claim in order to allege that a minor disparity in mileage claimed amounted to an attempt to defraud the Trust.

Whistleblowers are distrusted, because someone willing to expose concerns about safety or misconduct by a colleague, cannot be trusted to remain silent when a cover-up "is required" for the sake of the organisation or out of comradeship. Other NHS organisations will not employ people who management do not consider team players, because they do not comply with the Mafia-style "code of omerta". The people who understand this

best are appointed to sit on regulatory bodies. As a result, those who raise concerns are also often treated badly by regulators, such as the UK's General Medical Council (GMC).

Treatment by regulators

The GMC instructs doctors that they must speak up if they have concerns about another doctor's competence or integrity, but also has a disparagement rule that is used to prevent doctors expressing such concerns. I chaired a national committee and the committee became concerned about the integrity of a research publication. On behalf of the committee, I alleged research misconduct by the authors. The GMC chose to investigate whether I had disparaged the doctors. After months of investigation I was exonerated, but the GMC only reluctantly investigated the allegations I raised and found them true.

"IN HEALTHCARE THOSE WHO RAISE CONCERNS ARE OFTEN TREATED FAR WORSE THAN THE DISHONEST PEOPLE THEY EXPOSE"

I have reported a number of doctors to the GMC. My complaints have resulted in some being removed from the medical register and others received lesser sanctions or "advice about future conduct". I know that the GMC makes it difficult to complain. The GMC's initial response is almost invariably that they will not consider the case. A complainant needs to know that they then need to get into a legal argument with the GMC to point out the flaws in its decision. I have gone through this process in cases when the GMC initially said that there was no case to answer, but eventually removed the doctors from the medical register. If the GMC reconsiders the case, the complainant must provide all the evidence: in one case I had to provide more than 32,000 pages of documents, which was onerous. The GMC also threatened me, the complainant, with a High Court action.

To understand the machinations and conflicts of interest that exist at the GMC, it may help to consider a case that I reported. Cardiologist Dr. Clive Handler was suspended from the Medical Register for embezzling money from a charitable research fund after I reported him to the GMC (Wilmshurst 2007). The medical director and Trust Board of the hospital where he worked agreed a settlement with him provided he left quietly. It included the Trust agreeing a payment to Handler and agreeing to conceal his fraud from both the police and the GMC. The remarkable thing was that the medical director who drew up the agreement was Professor Peter Richards, who was a senior member of the GMC. Richards was Chair of the Professional Conduct Committee—the GMC's disciplinary body. He scheduled himself to chair Handler's hearing. He had to stand down on the morning of the hearing when the GMC's own lawyers objected because of his conflict of interest. The GMC refused to act against Richards for concealing Handler's misconduct and let him return to chairing disciplinary hearing after the case. Would a judge who concealed criminal conduct be allowed to remain on the bench?

Risk of legal action

A whistleblower may also have to deal with defamation claims. They are very difficult to defend in the United Kingdom. In 1982, when I refused a bribe from Sterling-Winthrop to falsify research findings with their drug, amrinone, I was threatened with legal action (Wilmshurst 2007). I published data to show that amrinone was ineffective and unsafe. In 1984, Sterling-Winthrop told the United States Food and Drug Administration that there were so many life-threatening side effects with the drug that they had ceased to research or market it. In 1986, I discovered that Sterling-Winthrop were selling amrinone over the counter in parts of Africa and Asia, though it was considered too dangerous to have on a doctor's prescription in Europe and North America. I worked with Oxfam to get proof, which was taken to the World Health Organization. Sterling-Winthrop was finally embarrassed into withdrawing amrinone worldwide.

In 2007, when I was co-principal investigator in the MIST Trial, I expressed concern at a scientific meeting that the trial data presented was inaccurate and incomplete. The sponsor of the trial, NMT Medical, which made the medical device used in the trial, sued me for libel and slander (Wilmshurst 2012). I stuck to my claims, and they sued me three more times. The claims lasted nearly four years and my legal costs exceeded £300,000. The claims ended when NMT went into liquidation (Wilmshurst 2012). I got *Circulation* to correct a scientific paper containing false data and a new version of the paper was published (Dowson 2008). I had refused to be a co-author, but the other co-principal investigator in the MIST Trial was first author, and he was suspended from the Medical Register for dishonesty (Dyer 2015). To get that outcome took six years of effort on my part.

I have received threats of legal action from a number of doctors that I reported to the GMC, but all withdrew their threats when told what evidence I would present in court. I was threatened with legal action twice by King's College London when I exposed the cover-up of the misconduct of surgeon, A K Banerjee (Wilmshurst 2016). He was suspended from the Medical Register for a year in 2000 for research fraud after I reported him first. He got back onto the register for three weeks and I told the GMC that they had failed to deal with his financial misconduct and poor clinical skills. He was struck off the register, but he was allowed back on in 2008. He was awarded an MBE "for services to patient safety" in 2014. I raised objections with MPs and the Cabinet Office and the award was forfeited two months later. It is pertinent that when the Health Honours Committee decides to award a national honour to a doctor, they check with the GMC to see whether there is any reason why the honour should not be awarded. That did not work in the case of Banerjee.

And on it goes

The low esteem of NHS management for whistleblowers was brought home to me personally when I applied for a Gold Clinical Excellence Award at the time of renewal of my Silver Award (Clinical Excellence Awards are presented to consultants working in the NHS who perform over and above their role; the higher awards —silver and up—are decided on a national basis). I was not given a Gold, but soon afterwards received an anonymous message that my application had not been dealt with fairly. I appealed, and during the long process discovered that my regional sub-committee had been allowed to nominate four applicants for Gold Awards. My application had the third highest score, but the sub-committee nominated the doctor with the fifth highest score in my place. During the appeals process the Advisory Committee on Clinical Excellence Awards (ACCEA) disclosed documents. I discovered that ACCEA asked the medical vice-chair of the regional sub-committee to explain why I had not been nominated despite my score. She made a series of false statements about me, and said that the committee felt that exposing research fraud was not a valid contribution. The doctor with the fifth highest score, who the regional sub-committee preferred, was a consultant gynaecologist who was allowed to continue to practise after being placed on the Sex Offenders Register for accessing child pornography. The appeal panel stated that the comments of the regional vice-chair about me and my application were "completely untrue" and upheld my appeal, but ACCEA did not give me a Gold Award. The medical vice-chair whose statements about me were found to be "completely untrue" was appointed to be a medical member of the General Medical Council (GMC). From this I inferred that many senior people in the NHS prefer a convicted paedophile to a whistleblower.

Conclusion

But perhaps NHS whistleblowers should not complain. I have investigated research misconduct in other countries. In one, four whistleblowers said that they had received death threats for exposing research misconduct by a well connected doctor.

My experiences lead me to believe that in healthcare those who raise concerns are often treated far worse than the dishonest people they expose. ■

Described in Private Eye as the godfather of NHS whistleblowers, **Peter Wilmshurst** is a member of the Committee on Publication Ethics, of Patients First and of Health Watch. He was awarded the Health Watch Annual Award in 2003 "for courage in challenging misconduct in medical research", and was the first recipient of the BMJ Editor's Award in 2012 " for persistence and courage in speaking truth to power".

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Why I became a radiology whistleblower

Whistleblowers who raise concerns continue to be at risk of losing their jobs. Sharmila Chowdhury speaks the truth behind the life of a whistleblower and the severe consquences she continues to face after being dismissed by the NHS.

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I had worked in the UK National Health Service (NHS) since 1980 and qualified as a radiographer in 1983. I joined Ealing Hospital (London North West Healthcare NHS Trust) in February 2003 as Deputy Imaging Manager and was promoted to Imaging Manager in May 2008. I was in charge of 60 members of staff in the department, not including consultant radiologists. As the budget holder for the department I was responsible for signing off additional work and attendances of all staff, including the consultant radiologists.

I raised concerns that very substantial sums of money were being paid to two consultants, who were also working over several years at a private hospital. The manager at the private hospital confirmed that they had attended that hospital since April 2006 for times whilst also being paid by the Trust. The concern escalated up the management chain—all agreed this was a problem. Additionally, consultants were claiming for overtime not worked. The practice was not stopped and I was dismissed after false counter allegations were made. I was escorted out of the building in front of my staff.

While I won at the interim relief hearing and disciplinary appeal, the Trust refused to let me return as they advised my post was now 'redundant' due to technology. Although the Trust apologised, I have been unable to find work. One job offer was withdrawn when they discovered I was a whistleblower. I have had interviews cancelled and posts withdrawn. In one instance, the Care Quality Commission intervened, but without success. I am now being treated for cancer, that consultants believe may be linked to the stress of my treatment, and I have faced the ongoing threat of losing my home without income.

No action has been taken against those responsible for cheating the NHS out of large sums of money nor against those who colluded to victimise me. I have an excellent paper trail to support my claims. I contacted many organisations and politicians about my case. No one bothered to either investigate publicly my raised concerns, despite extensive evidence, nor my treatment as a whistleblower. The Department of Health (DH), the Prime Minister's Office and NHS London advised they couldn't get involved. However, from

a subsequent freedom of information request, it transpired that DH were communicating fully with the Trust about my case and settlement. They viewed my payoff as 'good value for money.'

"NO ACTION HAS BEEN TAKEN AGAINST THOSE RESPONSIBLE FOR CHEATING THE NHS OUT OF LARGE SUMS OF MONEY NOR AGAINST THOSE WHO COLLUDED TO VICTIMISE ME"

On 30 May 2014, I wrote an open letter to Jeremy Hunt, the Secretary of State for Health, asking for help. He met me and a few other whistleblowers along with Simon Stevens, Chief Executive of NHS England. Hunt commissioned a review into NHS whistleblowing led by Sir Robert Francis, QC. The published report, *Freedom to Speak Up* (Francis 2015) has raised awareness. However, this has produced ineffective change for whistleblowers. I wrote an open letter to Hunt, printed in the Health Service Journal in 2016 (Chowdhury 2016), which was the highest-read article in the HSJ for 2016. Hunt responded, but the response was unhelpful.

Campaigning for whistleblowers

I have continued to campaign for help not just for myself but for other whistleblowers, as my website (**sharmilachowdury.com**) demonstrates. Despite being featured in the media extensively no permanent solution has been found. I am currently working/helping with NHS Improvement to look into helping NHS whistleblowers back to work, supported by the Department of Health, which unfortunately still has a long way to go to remedy the current situation faced by whistleblowers.

There has been no independent inquiry into either my raised concerns or my treatment as a whistleblower. None of the managers at the Trust have been held to account for my treatment, nor have the concerns raised by me been investigated, despite £5.7bn a year being lost to fraud in the NHS as reported in my BBC interview (**https://www.youtube.com/watch?v=CgxOvsqo3E4**). The reported consultants continue to be employed by the trust. Fraud in the NHS still continues to be ignored. My case is proof that perpetrators of fraud continue to be supported by senior officers turning a blind eye.

I am currently working in the private sector, without any long-term security. I consider myself lucky in comparison to other whistleblowers. However, as my NHS pension has been ruined and I have been unable to pay off my mortgage I will have to continue to work until I die. There will be no retirement for me. ■

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RISK

CRITICAL CONSIDERATIONS IN RISK MANAGEMENT

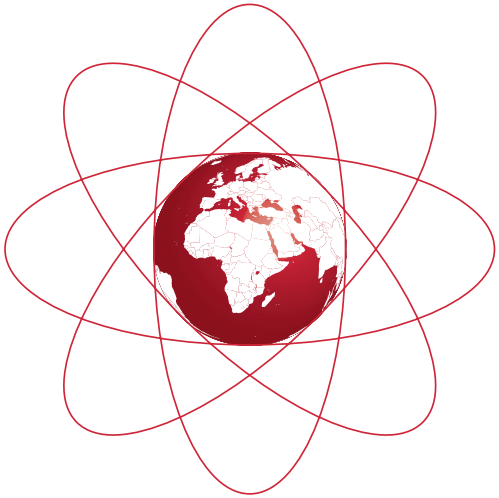
Healthcare risk management is an increasingly critical area as cybersecurity threats continue to evolve. Regardless of an organisation's size, it needs to ensure that the right policies, procedures, and tools are in place so staff members can properly protect Protected Health Information.

Source: HealthIT Security https://iii.hm/d7c

ENTERPRISE RISK MANAGEMENT

Gone are the days when one person (a risk manager, CFO, CEO) can come to grips with all the risks of a single company. Risks in supply chain, in finance, in the environment, and in reputation are global in scope. Company-killer risks exist in the ripples of events like tainted milk in China, failing banks in Iceland, residential real estate prices in the United States, and commodity price volatility from Middle East politics and the illogical acts of terrorists.

Source: IRMI https://iii.hm/d7e



HEALTHCARE RISK MANAGEMENT: HIGH STAKES

Risk management in healthcare is potentially more important than in any other industry. In most industries, an organisation develops and implements risk management strategies in order to prevent and mitigate financial losses. The same can be said for healthcare, but this is to go along with patient safety. Risk management in this industry can mean the difference between life and death, which makes the stakes significantly higher.

Source: Investopedia https://iii.hm/d7f

4 SIGNS YOU NEED BETTER RISK CONTROL

- ✓ Management ignores warnings
- ✓ Too much dependence on one supplier
- ✓ Lack of routine quality checks
- ✓ Lack of documented safety practices

Source: POMS & Associates https://iii.hm/d7h

10 PRACTICAL RISK MANAGEMENT FACTS

1	Risk management must be given greater authority.
2	Senior executives must lead risk management from the top.
3	Institutions must review the level of risk expertise in their organisation.
4	Model output with human judgment.
5	Stress testing and scenario planning can help executives respond properly to events.
6	Incentive systems must be constructed to reward long-term stability.
7	Risk factors should be consolidated across all the institution's operations.
8	Companies should ensure appropriate reliance on data from external providers.
9	A careful balance must be struck between centralisation and decentralisation of risk.
10	Risk management systems should be adaptive rather than static.

Source: RiskArticles.com https://iii.hm/d7d

Ransomware attacks: How to protect your systems

What are the steps to take when there is a ransomware attack?

Device systems: What is ransomware?

Ransomware is a form of computer malware used to make data, software, and IT assets unavailable to users. It uses encryption of data to hold systems hostage with an associated ransom demand, often in Bitcoin (a virtual currency that is difficult to trace). This encryption is used to extort money from users, with the hacker promising to give the victims access to their data if the ransom is paid.

WannaCry, a ransomware affecting Windows-based operating systems (OS), was released on May 12, 2017, and quickly spread through numerous countries, infecting thousands of computer systems. Propagating mainly through e-mail using attachments and malicious links, it has caused significant disruption to IT systems worldwide. Several hospitals in the United Kingdom and Indonesia experienced severe disruptions to hospital operations, resulting in cancellation of appointments, postponing of elective surgeries, and diversion of emergency vehicles. Unfortunately, any data that was not appropriately backed up has likely been lost in systems infected with WannaCry.

Some medical device systems may also have been affected by this attack, and a threat to patient care may exist.

While your facility's IT department is likely tackling the WannaCry threat with the currently available Microsoft security patches, some Windows-based medical device systems will remain susceptible to ransomware attacks like WannaCry because either they are based on an older version of the Windows OS (for example, Windows XP) and can't be upgraded, or they have not been validated for clinical use with the latest security patches.

Such systems are often managed separately from regular IT assets to ensure appropriate clinical functionality through adherence with manufacturer-specific setup and requirements.

In this article, we recommend protective actions you can start to take, and point to some critical differences in how attacks on medical device systems should be managed as opposed to general hospital systems.

What should my first steps be?

Common best practices should always be followed when dealing with software updates and suspicious e-mails containing links and attachments as the first line of defence against any ransomware or other malware.

"DON'T OVERREACT. EVEN WITH GOOD SOFTWARE UPDATE PRACTICES, IT'S NOT UNUSUAL TO FIND MEDICAL DEVICE SYSTEMS RUNNING OUTDATED OS SOFTWARE"

Continuing education should also be provided frequently to all levels of staff to promote awareness of and compliance with these best practices. There are also specific dos and donts to follow. These recommendations are intended for the medical device security lead, who is commonly someone from clinical engineering or IT, depending on the facility.

Dos

- Identify networked medical devices/servers/workstations that are operating on a Windows OS. Useful sources for this information may include medical device inventory (i.e., computerised maintenance management systems) change management systems, manufacturer Disclosure Statement of Medical Device Security (MDS2) forms obtained during device purchase or medical device manufacturers
- Identify whether connected medical devices/device servers have the relevant Microsoft Windows OS MS17-010 security patch. It is important to note that all unpatched Windows versions may be vulnerable to the WannaCry ransomware
- Consider running a vulnerability scan in your medical device networks to identify affected medical devices. Vulnerability scanning can be used to identify devices that may be vulnerable to malware. This method should only be used if information is not available through other sources about the existence of a Windows OS and the associated vulnerabilities on your medical devices and you already have a list of which devices and systems are compatible with vulnerability scanning. ECRI Institute is aware of

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medical device failures that occurred when systems incompatible with vulnerability scanning were scanned

- If medical devices/servers are identified that didn't receive the security patch, contact the device vendor to determine the recommended actions for dealing with the current ransomware threat. Request written documentation of those recommendations from the manufacturer
- If your device is managed by a third party or independent service organisation, request prompt installation of appropriate security patches and documentation to support risk mitigation. Identify terms in the existing service contract covering responsibilities in regard to security patch updates
- Coordinate with the facility's internal IT department to update affected medical devices in accordance with the manufacturer's recommendations as soon as practicable. Medical devices require all updates to firmware and software to be validated, which often delays the availability of patches and updates. For any medical device vendors without a validated security patch, demand expeditious validation. Many medical device updates must be installed by hand while the unit is removed from use (that is, they can't be distributed remotely), and downtime can directly impact patient care. These factors should be considered when formulating an update response
- Prioritise response on any connected Windows-OS-based medical device systems such as life-critical devices, therapeutic devices, patient monitoring devices, alarm notification systems, diagnostic imaging systems and others
- If a malware infection is identified or suspected in a medical device if clinically acceptable, disconnect the medical device from the network and work with your internal IT department and the device manufacturer to contain the infection and to restore the system. If any unencrypted patient data was involved, have risk management coordinate the hospital's response regarding the data breach, as per its obligation under HIPAA

Donts

- Don't overreact. Even with good software update practices, it's not unusual to find medical device systems running outdated OS software. Don't assume that the presence of outdated software on your systems is a threat in its own right. These systems should already be noted as exceptions in your facility's IT patch update policy, and risk mitigation measures should already be in place
- Don't install unvalidated patches. Unvalidated patches can make medical devices faulty or inoperable, and a thorough supplier validation process can take some time. Prior to installing any security updates or patches, ensure that they have been validated by the manufacturer. Ask the manufacturer for documentation of the validation
- Don't simply turn off or disconnect all networked medical devices that have Windows OS. Consider the implications of disabling network connectivity as a risk mitigation strategy on a case-by-case basis. Work with frontline clinicians to understand what the connectivity is used for and the workflow disruption that will result from disconnecting a medical device from the network. In some cases when workflow disruption is deemed acceptable, a disconnection might be an appropriate risk mitigation strategy until the security patches have been installed per the manufacturer's recommendations. ■

ECRI Institute
The Discipline of Science. The Integrity of Independence.

ECRI Institute, a nonprofit organisation, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for nearly 45 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research.

ECRI's focus is medical device technology, healthcare risk and quality management, and health technology assessment. It provides information services and technical assistance to more than 5,000 hospitals, healthcare organisations, ministries of health, government and planning agencies, voluntary sector organisations and accrediting agencies worldwide. Its databases (over 30), publications, information services and technical assistance services set the standard for the healthcare community.

More than 5,000 healthcare organisations worldwide rely on ECRI Institute's expertise in patient safety improvement, risk and quality management, healthcare processes, devices, procedures and drug technology. ECRI Institute is one of only a handful of organisations designated as both a Collaborating Centre of the World Health Organization and an evidence-based practice centre by the US Agency for healthcare research and quality in Europe. For more information, visit ecri.org.uk

Global medical device security testing labs launched

A new initiative that will improve medical device security and facilitate sharing of best practice is being rolled out internationally this year.

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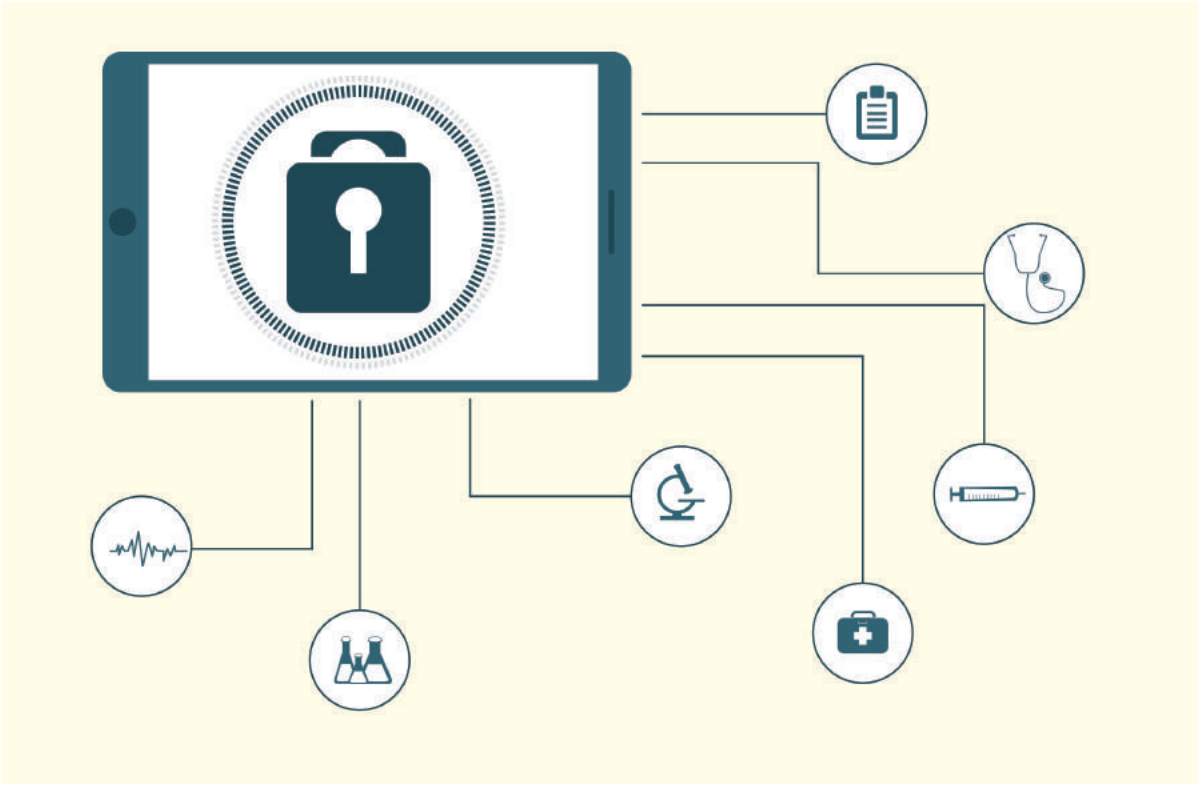

The Medical Device Innovation, Safety and Security Consortium (MDISS) has launched the first of what are planned to be more than a dozen international medical device security testing labs and cyber-ranges.

The World Health Information Security Testing Lab (WHISTL), operating under MDISS will be made up of a web of medical device security testing labs. These facilities will be independently owned and operated by MDISS-member organisations that include medical device manufacturers, healthcare delivery organisations, universities and technology firms.

"MDISS WHISTL facilities will dramatically improve access to device security know-how while protecting patient privacy and stakeholder intellectual property," said Executive Director of MDISS, Dr. Dale Nordenberg. "Solid cyber-lab governance will support an international-scale network of research and training centres of excellence, designed especially for medical device designers, hospital IT, and clinical engineering professionals."

MDISS WHISTL will vet complex multi-vendor, multi-device critical care environments including Operating Theatres, Emergency Rooms and Hospital Intensive Care Units.

"Each WHISTL facility will launch and operate under a shared set of standard operating procedures," a MDISS spokesperson said. "The goal is to help organisations work together to more effectively address the public health challenges arising from cybersecurity issues emergent in complex, multi-vendor networks of medical devices."

By the year end, MDISS WHISTL facilities will open around the U.S. in New York, Indiana, Tennessee, California and further afield in the UK, Israel, Finland and Singapore.

WHISTL is not the first initiative to tackle enterprise IT security but it is the first lab network devised around the needs of HIT personnel, healthcare clinical engineering leaders and medical device researchers.

The technology has already been rolled out to different healthcare facilities.

"Working with MDISS over the past year on WHISTL has helped us make real progress against some very complex risk scenarios, while keeping the focus on patient safety," said CBET Manager/Clinical Engineer at Eskenazi Health, Benjamin G. Esslinger.

Current 2017 Trustee and past President of the Indiana Biomedical Society, Esslinger pointed out that medical devices were still at the forefront of cybersecurity and best security device practices were still maturing.

"Our new WHISTL facility enables us to run medical devices through tougher, more realistic test regimes. Hidden vulnerabilities surface more quickly, and that helps us build more responsive standard operating procedures," he said.

"MDISS WHISTL WILL VET COMPLEX MULTI-VENDOR, MULTI-DEVICE CRITICAL CARE ENVIRONMENTS"

Facilities operating WHISTL hone in on identification and mitigation of medical device vulnerabilities and, through their network, disseminate information on best practices. Critically, they also promote device security education and awareness. As soon as new vulnerabilities are uncovered, they are reported to device manufacturers and to the NH-ISAC-MDISS Medical Device Vulnerability Program for Evaluation and Response, or 'MDVIPER'.

"WHISTL will provide much-needed insight from actual developers and users of medical devices, which will result in increased relevant and actionable information sharing and situational awareness for all stakeholders in healthcare", said president of NH-ISAC, Denise Anderson.

Under a $1.8 mln contract from the Department of Homeland Security (Science and Technology Directorate, Cyber Security Division), MDISS built the Medical Device Cyber Risk Assessment Platform, or 'MDRAP'.

The platform helps health systems, device manufacturers, and technology firms collaborate to produce and share device risk assessments. The fast-growing and standards-based MDRAP platform features moderated crowdsourcing and facilitates timely, responsible sharing of risk assessments and threat indicators, while helping automate critical device inventory, audit, oversight and vulnerability tracking tasks for hospitals.

WHISTL's device testing protocols will have their foundation in the UL Cybersecurity Assurance Program specifications especially with regards to fuzz testing, static binary analysis and structured penetration testing. ■

The Medical Device Innovation, Safety and Security Consortium (MDISS), founded in 2010, is a non-profit public/private partnership dedicated to advancing patient safety and public health and the first to focus exclusively on medical device cybersecurity. MDISS develops and delivers practical technology, operations and policy solutions for member organisations, including hospitals, health delivery organisations, doctors, epidemiologists, clinical engineers, medical device manufacturers, academics, regulators, embedded security experts and cybersecurity researchers. **mdiss.org.**

The National Health Information Sharing and Analysis Center (NH-ISAC), the official healthcare information sharing and analysis center, offers non-profit and for-profit healthcare stakeholders, such as independent hospitals, IDN "providers", health insurance "payers", pharmaceutical/biotech manufacturers, laboratory, diagnostic, medical device manufacturers, medical school and medical R&D organisations a community and forum for sharing cyber and physical threat indicators, best practices and mitigation strategies. NH-ISAC is a non-profit corporation funded and owned by its members. **nhisac.org**.

KEY POINTS

- ✓ WHISTL facilities will operate under a shared set of standard operating procedures
- ✓ The initiative is aimed at helping organisations cooperate effectively to deal with public health challenges arising from cybersecurity issues for multivendor networks of medical devices
- ✓ MDISS built medical device cyber risk assessment platform (MDRAP) with a $1.8 mln contract from the Department of Homeland Security
- ✓ The platform supports collaboration amongst health systems, device manufacturers and technology firms to produce and share device risk assessments
- ✓ WHISTL's device testing protocols will have their foundation in the UL Cybersecurity Assurance Program specifications

5 business analytics tools to improve the running of a healthcare institution

What data analysis tools can healthcare implement to streamline operations and improve efficiency?

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Data analysis is essential to run many organisations, and even has increased in importance over the last several years. With cheap computer power and storage options it has become possible to analyse vast amounts and types of data to increase business performance. The term "Big Data" was coined and overhyped, and in TV commercials everybody could see how some companies claimed their Big Data technology could improve retail performance or jet engine maintenance. The truth is that all of this is possible and is actually done in many industry verticals, but healthcare is, as usual, slow to adopt all of these potential "game changing" technologies – but change is coming. Some simple tools I use in my BI lectures could be used to improve running a healthcare institution without a big investment, while some other tools require more due diligence and good partner.

A useful distinction in Business Intelligence is "operational analytics" versus "advanced analytics". Operational analytics has been around to some extent, for example to analyse coding and look for any discrepancies that would allow re-coding and up-coding. But there are many more aspects of operational analysis that a healthcare institution should implement.

A simple improvement can be achieved by mapping referrals by a referring physician and referring zip-code. This can be easily accomplished with a free tool called Google Fusion tables, which allows geo-coding and mapping. This way, a heat map can be generated to identify if a certain disease is prevalent in a certain zip code, or if some referral regions are more active than others. While the disease heat map can be used for epidemiological research, the referral map can be used for marketing and outreach purposes.

Another common tool in operational analytics is the Dashboard. Dashboards can easily display values over time and against a goal. In a clinical environment, the goal could be to reduce hospital acquired infections. Organisations that have successfully worked in the area measured their infection rate over time and set reduction goals, so the entire team worked to keep all dials "in the green". In class, I use an old classic for Dashboards, MicroStrategy, which now offers a free desktop product. Such a MircroStrategy Dashboard could of course also be used to show complex financial data, and how each department is doing against their budget. Ideally, this is of course coupled with a strategy of activity-based cost accounting, which is the ideal foundation

for bundled payments and drill-downs into cost overruns. Another management method that can be deployed here is the balanced score card methodology, in which different goals are managed together to meet strategic objectives. Instead of focusing only on cost or only on process, financial goals, customer goals, patient outcomes, process and capacity are managed together through a system of key performance indicators (KPIs). The aforementioned dashboard can be used to measure and display actual performance against the system of goals.

In this context, it can be useful to introduce a more detailed planning process, for example in the context of quality improvement. We have seen in many studies that quality improvement and cost reduction are often directly related, meaning higher-quality processes lead to better outcomes and lower costs. If you are planning such a quality improvement strategy, it can be useful to build a model and simulate how changes in one or more variables impacts results toward your quality goals. Nowadays there are, of course, very powerful model-based simulation tools and methods available, but in class I use a very simple, yet useful tool that is also totally free to use: Plannerslab. Plannerslab makes it easy to enter the different equations and build a model, and then use intuitive goal-seek and what-if methods to find an optimal improvement path.

With the tools and methods mentioned so far it is possible to improve the efficiency of the organisation, and even to build the foundation for medical quality improvement initiatives; However, data analytics offer many more opportunities in healthcare.

The problem is that data in healthcare is often complex – it makes sense in context, but not necessarily to a machine. In the U.S. we tried to address this problem by forcing physicians to enter structured and coded data, which has caused much dissatisfaction with the data entry process. But beyond usability, structured and coded data still does not cover all the data captured. There is still a vast amount of unstructured (and un-coded) data, such as images, radiology and pathology reports, progress notes etc, etc. So in order to get access to the potential of this data, other methodologies need to be used.

"HEALTHCARE IS, AS USUAL, SLOW TO ADOPT ALL OF THESE POTENTIAL "GAME CHANGING" TECHNOLOGIES – BUT CHANGE IS COMING"

In class, we use SAS Data Miner, which also has a text analysis feature. It is ok for teaching, especially because you get an insight into all the statistics required to analyse unstructured data, but for healthcare institutions there are better options with ready-made medical ontologies.

This brings us to the part of advanced analytics, where the goal is not only to determine if you are on the right path of process improvement or cost accounting, but to find a better way to diagnose diseases and pathways, a way to identify at-risk patients before an emergency and so on. We know for a while that 3M developed a number of clinical risk groupers, which can predict the risk of a particular patient to develop a severe chronic disease or have a higher risk of complications during hospitalisation. These risk groupers are heavily based on science and decision trees, and fed with coded health data. And herein lies the problem – the algorithm needs to be fed with nicely-groomed data in order to produce useful results. The so-called "Big Data" technologies like IBM Watson, but also Google Tensorflow, rely on probabilistic matching. This means that the algorithms ingest thousands of annotated data sets to analyse similarities. Once trained, they predict a certain result. Unlike the 3M decision-trees, which are based on underlying science, the results of these machine-learning engines can change every day. The more they learn, the more data they use, the more they might change their diagnoses or the confidence level of the previous diagnosis. This changing environment is kind of difficult to digest in the context of the CE/FDA process. Nevertheless, several U.S.based hospitals already build large annotated data sets based on medical images and annotated and coded reports that can be used as training sets, and we have seen successful applications of this approach to diagnose TBC, lung cancer and other diseases. Although it is an advanced research topic, the Google TensorFlow platform and ResearchCloud are good starting points to investigate this branch of advanced analytics, and therefore the fifth analytics tool with a potential to improve running a healthcare institution today, albeit with a longer runway than Google Fusion Tables, MicroStrategy, BSC, and Plannerslab. ■

Lab automisation opens new revenue doors

How can lab automisation improve analysis services and open doors for new business opportunities?

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Laboratory testing occurs daily on inpatients and outpatients in both hospital and physician office visit settings. Do you know what happens to the vial of blood that you offer during your inpatient stay or outpatient visit? UAB Medicine recently implemented an automation line that analyses anywhere from 4000 to 5000 vials of blood daily within the main core laboratory environment. The automation line includes pre-analytical elements of equipment, a track that transports specimens to the designated analysers, and fastens storage components used for storing specimens. Additional elements include command central stations, inlets, outlets, and areas used for performing limited manual technical work, like differentials.

Automation provides robotic functions as soon as the specimens arrive from the outpatient and inpatient environments. Lab techs work diligently to manage the volume of specimens received. The bar coded specimens are placed immediately on the pre-analytical inlet where the bar coded specimen is read, sorted, routed to where it is analysed, and, finally, stored. Tests not performed online go the outlet for pickup, including reference tests, immunology, and flow cytometry specimens. The automation system performs the majority of the work. Automation provides more of a hands-free operation once lab tests arrive in the laboratory.

The automation line supports the vision of quality. The specimen tubes are resulted in a steady state fashion, improving the consistency of turnaround time testing, with minimal interruptions.

High Reliability Organisations (HRO), or an organisation that manages to avoid catastrophes in an accident-risk environment, is the vision for healthcare in the future. Laboratories that implement HRO strategies implement methods that maximise teams focusing on minimising risk, while increasing quality and standardisation of processes. Implementing the new automation system at UAB Medicine supports HRO concepts. The $7 mln plus lab debuted in 2016 and has been busily working since.

> "HIGH RELIABILITY ORGANISATIONS (HRO) IS THE VISION FOR HEALTH CARE IN THE FUTURE"

Expecting that automation would reduce labour has allowed the exploration of new industry opportunities. Being able to repurpose talented employees towards developing new businesses was an effective win-win. The already trained lab techs and technologists provided excellent clinical assets as they transitioned smoothly to the new clinical areas created.

One of the new businesses created included the Lab Medicine Customer Service area. The Customer Service area now manages all incoming calls that used to go to the automation area and surrounding Lab Medicine locations due to its success. The Customer Service personnel focus only on the customer's needs, managing the requirements effectively and without having to transfer calls multiple times. The new process frees up the limited technologists that remain in the automation area while providing a quality experience to the customer on the other end of the call. This means zero distractions with 100% quality experience delivered by talented personnel and impressive customer reviews received due to the implementation of this service.

Another industry receiving additional labour was the Diagnostic Molecular Lab department. The Diagnostic Molecular Lab is the fastest growing industry in laboratory science. Being able to add already trained labour to this environment was beneficial.

A third opportunity receiving labour was to develop a new lab, the Drug Confirmation testing laboratory. The vision includes insourcing the testing, optimising expenses and healthcare revenue, and adding value for our multiple customers and services within the healthcare system.

At the end of the automation line, small, grasping mechanical arms pick up the tubes and place them into refrigerators that can hold 10,000 tubes or into room-temperature storage for 5,000 tubes, in case further testing is needed. When clinicians order additional test(s), instead of collecting another tube of blood, automation

mechanisms sequester the original tube from the storage area and rerun the specimen through the designated analyser. Automation programming manages the needs of the specimens. The specimens are de-capped, centrifuged, re-aliquoted, analysed, and then re-capped through automation methods. All procedural steps function through the means of robotic programming.

Well-trained technologists monitor, govern, and maintain the automation process, keeping the human element in the formula for excellence. The technologists troubleshoot problems, monitor the turnaround times, and verify critical test values for immediate reporting to clinician providers.

The UAB Medicine's automation line, 32 different laboratory sites, including nine offsite satellite labs, four hospital locations, with approximately 400 laboratory employees and the Department of Pathology keep the whole process of blood analyses running smoothly. Innovation keeps us progressive and we enjoy managing the needs of patients, customers and providers to the best of our abilities. ■

KEY POINTS

- ✓ Lab automation supports a vision for quality
- ✓ High Reliability Organisations (HRO) is the vision for health care in the future
- ✓ Automation has reduced labour and allowed for exploration of new industry opportunities
- ✓ Procedural steps function through the means of robotic programming
- ✓ Several new business opportunities were enabled owing to automation including a Lab Medicine Customer Service area, Diagnostic Molecular Lab Department and a Drug Confirmation Testing Laboratory

This moving track moves tubes of blood to the automated lab (Photo Credit: UAB)

At the end of the line, small, grasping mechanical arms pick up the tubes and place them into refrigerators that can hold 10,000 tubes or into room-temperature storage for 5,000 tubes, in case further testing is needed (Photo Credit: UAB)

The automation line that analyses anywhere from 4 000 to 5 000 vials of blood daily (Photo Credit: UAB)

Responsible research innovation – heard of that before?

A reminder about who is at the centre of the complex healthcare hierarchy and industry - the patient.

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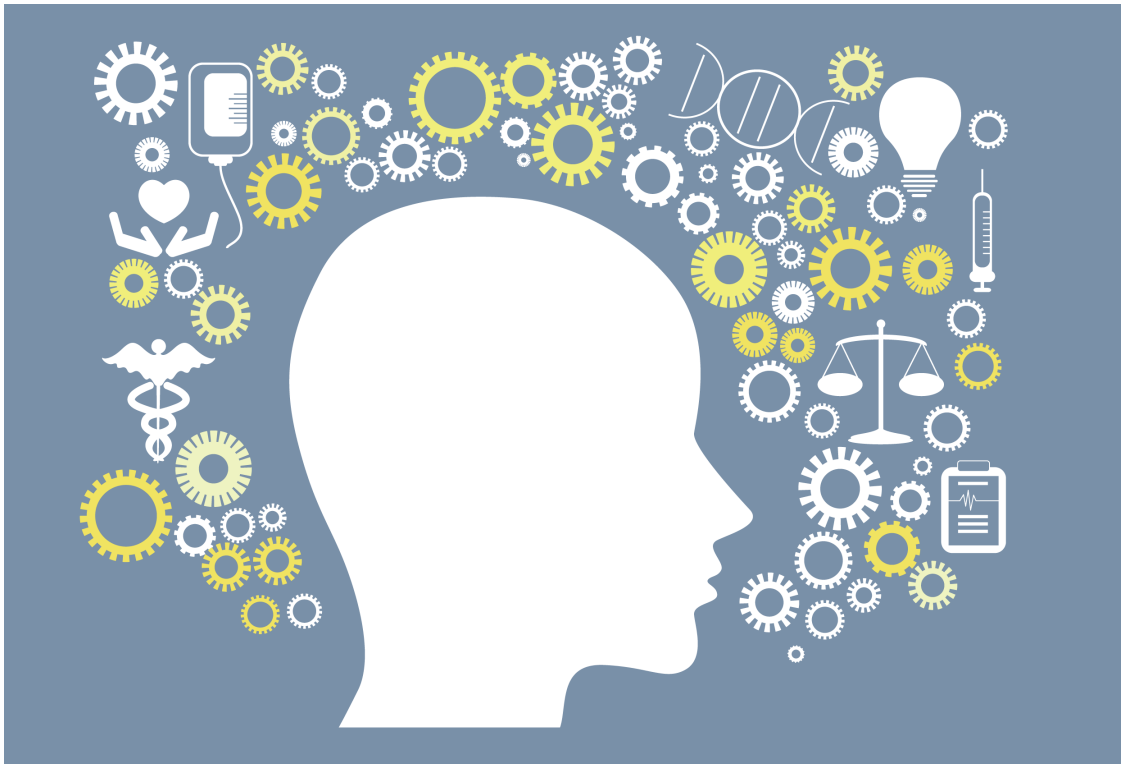

In May I was present at the excellent congress "Responsible Research and Innovation in the Health Industry", organised among others by the EU Economic and Social Committee. I had the honour of speaking about my ideas on innovation and the obstacles that are connected with it. Of course this included how these can be prevented or how we can take care that there will be solutions for the problems this new development in healthcare research is confronted with.

The chairwoman kept asking how we can do this correctly and what is needed for to go forward. It was right that she kept revisiting this: in the various presentations, namely, the word 'patient' didn't occur often. It did in the powerful and very concerned talk of Trish Grove of British Medical Journal (BMJ). I had noticed before that BMJ takes its patients seriously. There are editorial panels with patients and patient peer reviewers (in which I am allowed to participate myself). As one of the first and, as far as I know, as one of the few, BMJ has discovered that healthcare has to focus on the patient. As no other person, Trish managed to demonstrate this: "If about us, not without us" was a powerful one-liner of hers (Grove 2017). And that is how it is.

> "WHEN WILL WE BECOME HONEST AND SIMPLY SAY THAT THE PATIENT IS WORKING STOCK AND THAT THE MORE PATIENTS THERE ARE THE BETTER IT IS FOR THE HEALTHCARE BUSINESS?"

Dear stakeholders of the Medical Industrial Complex, you are here because of us, with which I say that without patients there are no revenue and profit. Please understand this in a different way than seeing us as working stock. Working stock? Yes, indeed. I had that strong feeling during the congress. We are working stock and necessary for revenue and profit. This is a very strong feeling during the talks and discussions. You also notice that nobody realises this. There is no evil intention. It is simply like that.

A short while ago there was an investigation in the Netherlands into who earns most money out of healthcare (Gupta Strategists 2017). What was the outcome? Banks earn the most out of healthcare. After that, it is the suppliers of medical equipment, then the pharmaceutical industry and then the doctors. It turned out that nurses earn the least out of healthcare. I don't think this is strange, for the further the distance from the patient, the higher the amount of money you can ask for your work. After all, behind your desk you are not confronted with the patients' suffering and needs so quickly. Bankers only see investors of the industry or hospitals and squeeze hard. There is no patient to hear complaining. This is different for nurses. They work with patients every day and they see the suffering of the patients caused by the Medical Industrial Complex and they are continually trying to alleviate this suffering.

What is the procedure with Responsible Research Innovation (RRI)? It's not much different. One of the speakers said that he has had the discussions for about 17 years now and that he in fact hasn't seen any change. Imagine 17 years and no change in the way in which research contributes to healthcare.

Meanwhile there have been hundreds or thousands of congresses about many healthcare subjects and we have concluded that much is going well, but also much is not going well. This has to be done differently and better. To my question to the panel if RRI isn't simply the same as Corporate Social Responsibility the answer was: As a matter of fact, it is. It is a little embellished and the buzzwords are somewhat different, but in fact there is not much new under the sun. However, what makes it so attractive are the hundreds of millions that are available in Europe to be divided among the same organisations that have not made the situation much better for the patient in the last 17 years. We adapt the presentations of the last few years a little, change the terminology and perhaps choose a new face within the organisations for better sales, but we are chasing the money again.

And the patient? He is not asked anything. When everything is signed and sealed, the question if the patients and/or the advisory board have been consulted is of course ticked off. Yes? Check mark. After this, submit the request for money.

How long will we say to ourselves that we are doing it for the patients? When will we become honest and simply say that the patient is working stock and that the more patients there are the better it is for our business? Be conscious of this and realise that this is how we work. Do not call this 'The System'. You cannot call the system. It is how we work. 'We'! And that brings responsibility.

Since we work like this, we can also work in a different way. We have a responsibility for the outcome of our work. Not only for the little piece we do ourselves, but also for the chain and the result. It may not be like that legally, but it certainly is morally. It was German-American political theorist Hannah Ahrendt who did a lot of work in this field and who indicated that responsibility arises in the contact with people and that we are responsible for what we do and its result (2003). If it is right, everyone is a specialist in his own field and oversees the whole. If we oversee the whole, we see that things do not go well. Then we adjust this and we ask the person for whom we are there how to handle and solve this.

Then, and only then, we can tackle the alienation (of which we are a part ourselves) that has been seen in the past decades. Alienation from the essence for which we are here. In healthcare this is always the patient. Trish Groves understood that perfectly. ■

KEY POINTS

- ✓ The patient is at the centre of healthcare
- ✓ How can healthcare research innovate for solutions?
- ✓ Banking sector profits most from healthcare
- ✓ Responsible Research Innovation needs results
- ✓ Alienation in healthcare needs to be dealt with

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Revolutionising cardiovascular medicine

The European Society of Cardiology (ESC) on eHealth and how it is disrupting the usual way patients and healthcare professionals interact.

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In recent years, the way in which one can access information in healthcare has hugely transformed, particularly for the younger generation. The European Society of Cardiology (ESC) Congress in Barcelona last month paid special attention to this theme and how the ESC has invested in its future and the ways in which healthcare professionals can benefit from the influx of innovative technologies and workshops.

eHealth opens up a new doorway in healthcare especially with the increasing demands on healthcare systems. However, the use of information and communication technologies (ICT) to treat patients, conduct research, educate healthcare professionals, track diseases and monitor public health is a concept which is not yet become normalised for some (esccardio.org 2017).

Indeed, this subject continues to draw engagement, and Professor Martin Cowie (Imperial College, London, UK) led a key session at the congress on this subject, which was attended by HealthManagement.org

Prof. Cowie explained that healthcare has become more internet-based and that patients can access expert medical advice remotely as well as by going to see a specialist. However, there are still many challenges that remain for increasing patient empowerment remotely (European Heart Journal 2017).

"The most obvious example in cardiovascular medicine would be heart failure. But it is difficult for people with a chronic condition to know exactly how to manage it, how to modify their treatment or adjust the diuretics up and down," Prof. Cowie explained. "There have been many studies in that area to try and find some system that actually improves patient outcomes."

"The ESC thinks that cardiologists should see how the world is changing. Some of these things are undoubtedly going to bring benefits; others may have issues. As cardiologists, we should be the ones raising these issues, because those creating digital health solutions haven't yet thought of them.

"If there is a new technology that works well and is a better, more convenient way of delivering the best healthcare, particularly if it saves money, we should know about it, and be enthusiastic."

He described how eHealth has been encompassing a range of technologies, from electronic medical records and electronic prescribing, to wearable technology, and remote monitoring for implantable devices. It also includes apps on smartphones; with one such app, a device is clipped onto the back of a smartphone to perform an ECG. A PDF of the reading, via the app, can then be sent to a cardiologist for review.

"There are many digital healthcare technologies that work and make a difference. The ESC aim to normalise the concept of eHealth. Anything different can seem threatening, but we need to know about it." Prof. Cowie said.

The ESC wants to play a leading role in all aspects of the eHealth agenda, helping to develop, assess and implement effective eHealth innovation to support cardiovascular health (esccardio.org 2017).

However, there are of course a few issues in eHealth that need to be addressed, including data security and validity, as well as how and whether outside information should be imported into a standard medical record.

According to Prof. Cowie, many new technologies have not been tested in trials, so eHealth can help with advice and empowering patients with the ability to access expertise anywhere in the world. A new technology needs to demonstrate that it will make a difference, and, that it is worth the money needed to produce it.

The ESC is also working with the European Commission, providing insights and representatives from the cardiology community to ensure the interests of cardiovascular healthcare professionals and their patients are well represented.

eHealth is expanding rapidly and is now the third largest industry in the European health sector, after pharmaceuticals and medical devices. So what can we expect and what are some of the hurdles that lie ahead?

The European Union has an eHealth action plan for 2012-2020. It provides a roadmap to empower patients and healthcare workers, to link up devices and technologies, and to invest in research towards the personalised medicine of the future. It has identified several barriers to widespread adoption of eHealth, including: limited awareness of, and confidence in, eHealth solutions; lack of interoperability; limited large scale evidence of cost-effectiveness; lack of legal clarity and transparency on data utilisation; lack of reimbursement; and regional variation in access (ec.europa.eu 2017).

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ESC European Society of Cardiology

New indications for coronary CT angiography

The time has come

The latest in CCTA and how the quality and timeliness of diagnosis can be improved.

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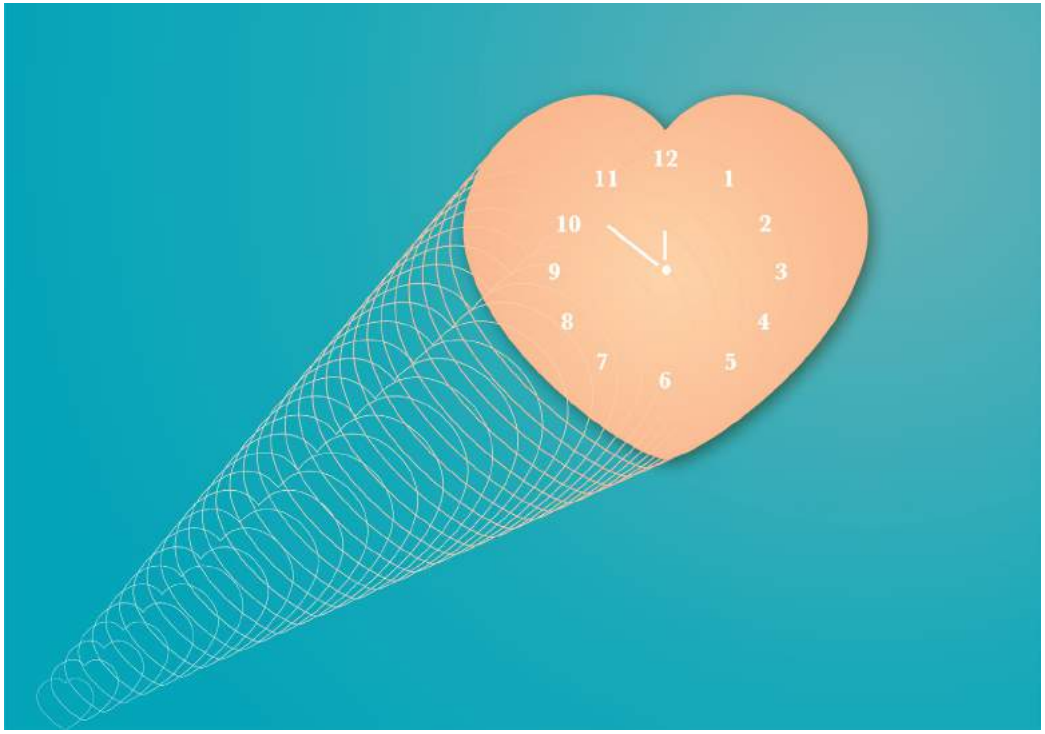

Since the beginning of the 21st century coronary computed tomography angiography (CCTA) has turned from a research tool with ill-defined indications into the recognised cardiac imaging modality with proven clinical and prognostic values. There is already a myriad of single-centre studies and over a dozen multicentre trials where the results of CCTA were compared with coronary catheterisation (as a gold standard), with very good results, favouring the use of CT for coronary imaging. CCTA has been responsible for helping us bring into practice one of the greatest physician's dreams about realisation of noninvasive visualisation of coronary arteries.

Looking into the literature one can see that the diagnostic accuracy of modern CT systems, in general, is the same as has been reported in the years 2006-2010 for the previous generation of 64-128 row scanners. But modern types of CT scanners open up the opportunity to reach significant improvements of image quality of coronary arteries and heart structures even in "difficult" patients (ie ones with arrhythmias or overweight) and to get high-quality diagnostic images with very low radiation exposure and less volume of contrast media. The decrease of tube current and voltage leads to increase of measured densities of iodine on CT images and better signal-to-noise ratios. Increase in image noise due to lower tube settings is compensated with help of iterative reconstruction and new types of detectors. The contemporary standard of CCTA is prospective-gated (variants: high-pitch or even ungated), wide-detector or dual-source acquisition with iterative image reconstruction.

"'SWISS KNIFE' TOOL FOR NONINVASIVE CARDIAC IMAGING"

Traditionally cardiologists and radiologists were mostly concerned about the detection of so-called significant coronary stenosis, causing myocardial ischaemia. In the recent past, both noninvasive CCTA and invasive cardiac catheterisation) were used for getting just anatomical information about degree and location of the coronary stenosis. However, today in cardiology we have seen an obvious shift to an increased use of functional imaging for assessment of coronary stenosis with analysis of fractional flow reserve (FFR) as a new reference standard.

Stress echocardiography, single-photon emission computed tomography (SPECT) and perfusion magnetic resonance imaging (MRI) are the cardiac

imaging modalities which traditionally are used for noninvasive detection of myocardial ischaemia, and they are recommended for this purpose in different national and international guidelines.

Modern CT scanners also allow the opportunity to study rest and stress myocardial perfusion and to combine these data with the results of noninvasive CCTA. Such an approach improves the specificity of CCTA and decreases the need for cardiac catheterisations. Perfusion myocardial CT has been well validated in several trials using both cardiac catheterisation and FFR measurements as reference standards. There are also are some other new technologies for assessment of coronary blood flow with the help of CCTA.

Probably the most interesting one is a noninvasive assessment of FFR with CT (FFR-CT) using sophisticated computer analysis. This method has been validated in several multicentre trials and attracted a lot of attention from both cardiologists and radiologists. The use of CCTA in clinical trials for detection of vulnerable plaques and stratification of patients according to the severity of coronary atherosclerotic burden has already brought very promising results concerning the assessment of patient prognosis and selection of optimal treatment plans.

There is a strong probability that CCTA turns into a 'Swiss knife' tool for noninvasive cardiac imaging. Besides coronary and perfusion imaging, it is approaching cardiac MRI (a recognised reference standard for myocardial imaging) in the assessment of different myocardial diseases. For example, many years ago it was shown that cardiac CT and cardiac MRI gave the same results about size, volume, and function of heart chambers. Now, after the development and implementation of dual-energy CT, radiologists have more interesting opportunities. Dual-energy CCTA could be used for myocardial characterisation practically for the same indications as cardiac MRI—eg for detection of post-infarction myocardial scars, myocarditis and cardiac amyloidosis. Besides this, dual-energy coronary CT helps to eliminate artefacts from calcified plaques obscuring the lumen of coronaries.

Recent changes in cardiological paradigms about approaches to diagnosis, treatment, and assessment of prognosis in patients with coronary artery disease (CAD) together with the technical development of CCTA and accumulation of scientific data proving the high diagnostic value of CCTA have resulted in very interesting perspectives concerning the use of this modality for noninvasive coronary imaging.

Current cardiological and radiological guidelines recommend the use of CCTA in patients with a low or intermediate probability of obstructive coronary artery disease or in patients with acute chest pain and low probability of acute coronary syndrome. It is a big step forward, but today these recommendations look too limited and conservative. For example, in contrary to perfusion MRI and SPECT, myocardial perfusion CT of FFR-CT so far are not included into imaging guidelines (except for National Institute for Health and Care Excellence [NICE] (UK) guidelines which recently supported use of FFR-CT and it is a good sign) (National Institute for Health and Care Excellence 2017).

But thanks to an accumulation of top-quality scientific evidence, today we are witnessing a process of steady transition from the use of CCTA as a pure 'niche' diagnostic tool dedicated to imaging of some limited categories of coronary patients to the implementation of this modality into the core of cardiovascular diagnostics. Recently several important clinical trials have demonstrated that appropriate use of CCTA improves the quality and timeliness of diagnosis and that it has a marked positive impact on the selection of the best treatment strategy, patient prognosis and healthcare costs.

It looks likely in the near future that the clinical indications for the use of CCTA will be significantly expanded and the current guidelines for the management of patients with acute and stable coronary artery diseases will be updated and revised.

In this situation cooperation between radiologists, cardiologists and nuclear medicine specialists has been gaining more and more importance. Understanding the significance of the team approach to cardiac imaging, the European Society of Radiology (ESR) has recently signed a Memorandum of Understanding with the ESC-EACVI (European Society of Cardiology, European Association of Cardiovascular Imaging), EANM (European Association of Nuclear Medicine) and ESCR (European Society of Cardiovascular Radiology). It is just a first, but important step ahead for better use of modern cardiac imaging modalities (first of all, CCTA) for the benefit of patients and public healthcare.■

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Ultrasonography in clinical practice

New roles for an old actor?

Presents a brief overview of the physics related to different sonographic techniques, indications, new improvements and possible applications in future.

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No one in the early days of the ultrasonography (US) era would believe the current clinical role of this imaging modality. As a courageous and innovative application of sonar and radar technology in biological tissues, the first US images obtained from the human body were far from perfect. Contrary to current features, early US devices consisted of huge systems in which patients were to be submerged in water, by which only rough outlines of internal body structures could hardly be obtained. However, in a relatively short time, and with the help of great achievements in acoustic, electronic and computer technology, US systems have become not only smaller, but also more sensitive and precise. In this article, a brief overview of the physics related to different sonographic techniques, indications, new improvements and possible applications in future will be presented.

Seeing by Acoustics

In daily life, we are all surrounded by an acoustic world, of which we can only hear a tiny fraction. Using the sonic components beyond our limits of perception, many creatures like dolphins or bats, can “see” to avoid obstacles and reach food. This phenomenon was first realized by Lazzaro Spallanzani from Pavia, Italy in the 18th century, triggering the achievements ending up with modern US systems. Later developments like the determination of sound speed through water by Jean-Daniel Colladon, and observation of piezoelectric effect in some materials by Pierre and Jacques Curie led to the technologic developments paving the road to medical US.

Basically, medical US systems consist of components of acoustics and processing. Sound waves are first emitted in the system, and then introduced into the human body to encounter different media. The amplitudes of reflected echoes received by the same system depend on the composition, position, size and acoustic transmitting properties of various body structures along the course of the sonic wave. Some media (eg, gas, air, bone, stone) reflect the sound wave totally, while others like low-density liquid do just the opposite. However, most body tissues produce echoes in intermediate amplitudes and attenuate the sound wave as it travels deeper.

The acquired echoes from the body carry detailed information about the physical properties of individual structures, including solidity and homogeneity. Quick and meticulous processing of these data, followed by production of representative visual information in a wide spectrum of shades of grey, constitute the basis of anatomic greyscale US imaging. Using this technique, one can easily and confidently differentiate organs from adjacent ones, delineate their components like blood vessels and biliary channels, as well as various structural changes due to solid and/or cystic tumours and parenchymal diseases including inflammation or infiltration. The modality makes it possible to evaluate the organ position, size and integrity quickly and reliably, providing valuable information about congenital or acquired abnormalities.

Contrary to stationary targets, moving media in the body produce echoes with frequencies differing from that of the initially emitted sound wave. This phenomenon (ie, the Doppler effect) and the magnitude of resulting frequency difference constitute the basis for Doppler US techniques, in which motion in the body, blood flow in most cases, can be assessed. As a noninvasive technique, Doppler US has enabled medical professionals to evaluate the patency of vessels, diagnose obstruction and analyse temporal haemodynamic changes resulting from pathologic processes.

The ability for fast structural and haemodynamic evaluation of human body parts has enabled medical professionals to use US for a wide spectrum of clinical indications. This cheap, widely available and noninvasive modality has helped diagnosis of various pathologies like cancer, stenosis in vessels or haemodynamic malfunctions. Due to its inherently radiation-free nature, US has proved to be a perfect means of follow-up, not only in diseases requiring close surveillance, but also in physiological processes like fetal growth in pregnancy, enabling noninvasive evaluation of fetus and related maternal structures, from the very first weeks of life until birth.

Thanks to the huge advances in electronic miniaturisation technology, high-resolution US devices have become available on every possible

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medical site, including ambulances, emergency rooms, intensive care units or operating rooms, where noninvasive and quick imaging of the human body is mandatory. The dimensions of high-resolution US units have been currently reduced to the scale of laptop computers, and even that of smartphones. Consequently, US devices are now exploited as the main actors in point-of-care imaging, hence called "visual stethoscope" by some authors (Gillmann and Kirkpatrick 2012).

"ONE OF THE MAIN CONTRIBUTORS TO THE TREMENDOUS PROCEDURAL IMPROVEMENT OF MEDICAL INTERVENTIONS LIKE BIOPSY, DRAINAGE OR ABLATION"

Another important and distinctive feature of medical US technology is the very high temporal resolution it inherently possesses. Due to the very short signal processing time, the operator can monitor every visceral motion nearly instantaneously as it occurs. This real-time imaging capability has made it possible to visualise and evaluate the movements of various body parts (eg, heart valves, directional and temporal changes of blood flow), but more importantly to keep an eye on the position of a needle or any other instrument we insert in the body for any medical purpose. Although one can use fluoroscopic x-ray techniques for the same purpose, US provides a radiation-free alternative. Guiding diagnostic and therapeutic procedures, US technology has become one of the main contributors to the tremendous procedural improvement of medical interventions like biopsy, drainage or ablation, which are now possible to be applied as a bedside and daytime procedure without requiring any hospitalisation or general anesthesia.

Acoustic Touching

As a relatively newer application, US technology has begun to be used in assessing the elasticity of various body parts. The inspiration for this technology was the palpation technique of physical examination, which has been used by doctors for thousands of years. Simply touching and feeling body parts has revealed valuable information about disease processes since ancient times, when diagnostic equipment consisted of only the five human senses. Implementing different US techniques, it is now possible to quantify the changes of stiffness in organs secondary to various pathologic processes, a capability to be used in diagnosis or monitoring of various body disorders. One technique relies on real-time analysis of displacement in image elements ("speckle tracking") in return for any external compression, while the other is based on measurement of sound speed, which is a derivative of stiffness of the medium. Thus it is now possible to use dedicated US devices not only to imagine, but also to assess the stiffness of body structures. One of the most significant consequences of this improvement has been the dramatic reduction of frequency rates in periodic biopsy controls to evaluate the degree of hepatic parenchymal fibrosis in patients suffering chronic liver disease (Gennisson et al. 2013).

Contrast Agents in Ultrasonography

For years, US was partially limited due to the lack of a specific contrast agent capability. However, advances in pharmaceutical research on ultrasound contrast agents (UCA) have revolutionised and expanded the clinical indications of US in recent years. The introduction of echogenic microbubble-based or nano-scaled UCA into vessels has made it possible to visualise very slow flow, thus providing information on tissue perfusion, which makes not only perfusion defects, but also small pathologic masses more apparent. Using contrast-enhanced ultrasound (CEUS) and the high temporal resolution capability of US, it is now possible to evaluate time-dependent vascularisation, perfusion and excretion patterns of individual neoplastic lesions, thus to reveal their pathologic nature in terms of malignancy or benignity. Specific uptake of some UCA by hepatic (Kupffer) cells provides a unique opportunity to reveal inconspicuous lesions as echo-poor areas on background parenchymal enhancement. These advances have made US one of the first-step modalities to detect and characterise mass lesions in visceral organs, especially those in the liver. CEUS has proven to be comparably successful in differentiating malignant tumours from benign ones in sonographically demonstrable lesions, omitting the need for more expensive, time-consuming modalities like magnetic resonance imaging (MRI) or computerised tomography (CT) (Ryu et al. 2014). Among many other applications of CEUS, those in paediatric practice, where ionising radiation is a serious concern, trump others. Using contrast-enhanced voiding urosonography, it is now possible to diagnose and monitor cases of children with vesicoureteral reflux, a potential cause of serious renal infection that may result in chronic renal failure (Papadopoulou et al. 2014). As in this example, the clinical use of CEUS not only provides a cheaper, more practical and radiation-free alternative in medical practice, but also a far more safer application of a contrast agent. In terms of contrast media reactions, it has been demonstrated that UCA have extremely low rates of adverse reactions, when compared to those used in conventional radiology, CT or MRI examinations.

Another unique and innovative implementation of UCA is targeted CEUS imaging (molecular ultrasound). In this currently developing strategy, the UCA are covered with binding ligands, which cause them to accumulate at targets related to various disease processes like cancer or atherosclerosis. This approach provides new opportunities

not only for early diagnosis, but also for applying targeted treatment and monitoring early response to it (Sutton et al. 2013). Due to the obligatory intravascular character of microbubble-based UCA, they are used in the detection of intravascular processes like angiogenesis, inflammation and thrombus formation. Likewise, some nano-based UCA targeted with antibodies or peptides and loaded with thrombolytic agents have proven to be effective in the treatment of thromboembolic processes like deep venous thrombosis, pulmonary embolism, myocardial infarction and acute ischaemic stroke. Intensive research on other nano-scaled UCA is being carried out to exploit the aforementioned diagnostic and/or therapeutic capabilities also in the extravascular space. These tiny particles, which are capable of extravasation, have been demonstrated to accumulate in sites of pathology, if targeted beforehand. Nanobubbles reaching the lesion may coalesce to form larger microbubbles to be visualised with US. If loaded with drugs, these nano-scaled UCA can even be used to deliver them right into the lesion after being activated by high-energy acoustic impulse. In comparison to nonselective systemic introduction of therapeutic agents, this targeted strategy gives the chance to reduce the total drug dose given to an individual patient, and to isolate healthy tissues (Güvener et al. 2017).

Last but not least, research and clinical trials are ongoing on sonoporation, in which pores in the cell membranes and inter-endothelial junctions are created using the mechanical effects of local destruction or excitement of micro-bubbles by US pulses. This technique allows transient and local enhancement of vessel permeability in various organs, including the brain, where temporary permeation of blood-brain barrier can be achieved. As a novel technique in progress, sonoporation has the potential to improve local delivery of drugs in many diseases like neoplastic, cardiovascular and neurodegenerative processes (Güvener et al. 2017).

Conclusion

Since the early days of US in medicine, the imaging data obtained with this radiation-free modality has permanently revolutionised clinical practice in nearly all disciplines. Throughout its history, the modality has become more portable and precise in each year. With the inclusion of new techniques, including Doppler US, sonoelastography and CEUS applications, its contribution to medical practice has become even greater and more indispensable. Becoming smaller and more sensitive, US devices are expected to be in the hands of nearly all appropriately trained clinicians in the near future. The ongoing research on novel diagnostic and therapeutic applications like targeted CEUS imaging and sonoporation foreruns the possibly expanding role of this unique modality in clinical medicine. ■

KEY POINTS

- ✓ Through continuous development ultrasonography has become the essential hand tool for every clinician
- ✓ With elastographic capability, it is now possible not only to visualise the lesions with ultrasonography, but also to “touch and feel” them
- ✓ As an old actor in medical imaging, ultrasonography renews itself to take a pivotal role in targeted molecular diagnosis and therapy

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Atrial fibrillation

Latest treatments

New techniques in ablation and imaging are broadening the options for treating patients with symptomatic and asymptomatic atrial fibrillation.

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Atrial fibrillation (AF) is the most common clinical arrhythmia seen in the daily clinic. It has an important impact on the economic health burden, as many patients are affected by this symptomatic heart rhythm disturbance.

AF increases the risk of stroke, which has the highest impact on AF-associated mortality. The most common preventive treatment is oral anticoagulation. The introduction of novel oral anticoagulants (NOACs) in 2009 increased appropriate therapy for patients for whom oral anticoagulation was withheld because of risk of bleeding (Connolly et al. 2009; Camm et al. 2017).

Another treatment for prevention of stroke in AF patients is left atrial appendage occlusion (LAA). This treatment is for AF patients who are at risk of stroke, but who cannot undergo oral anticoagulation, for example due to recurrent gastrointestinal bleeding. For this small group of patients, interventional therapy by occlusion of the left atrial appendage by the device hook is an option. After patients have successfully undergone this intervention without complications and the device is placed within the left atrial appendage of the left atrium they undergo endothelialisation and can stop the oral anti-coagulation (Holmes et al., 2014, Holmes et al. 2009; Reddy et al. 2011). If after 3-6 months everything is fine, the patients can stop taking oral anti-coagulants. They are protected both by the device and by the cessation of oral anti-coagulation. The combination of NOACs and LAA occlusion has improved stroke prevention in AF patients and is applicable to more patients. Before we had these treatments only 60% of AF patients at risk of stroke underwent adequate therapy (Camm et al. 2017).

Symptomatic atrial fibrillation: pulmonary vein isolation

Approximately 25 to 40% of AF patients are symptomatic: symptoms include palpitations, shortness of breath, dizziness, reduced exercise capability and cardiac decompensation. These patients need specific symptomatic treatment, which is interventional therapy by ablation, known as pulmonary vein isolation. The rationale is that in the pulmonary veins connected to the left atrium, in the affected muscles originate the electric impulses which initiate atrial fibrillation. Electrically isolating the pulmonary veins positively affects the initiation or maintenance of the arrhythmia. PVI is performed with a puncture in the groin, then going up the femoral vein to the right atrium to perform the trans-septal puncture to access the left atrium. The technique was introduced 20 years ago by the French cardiologist Michel Haïssaguerre, and has been evaluated in controlled trials (Morillo et al. 2014; Haissaguerre et al. 1998; Cosedis Nielsen et al. 2012). Around 70% et al. 2016a; of patients are free from any arrhythmia after one year if they undergo PVI. However, this leaves 30% of symptomatic AF patients who are non-responders (Kuck et al. 2016, Haissaguerre et al., 1998; Cosedis Nielsen et al. 2012). For patients with persistent AF this interventional therapy has a success rate of 50% (Tilz et al. 2012). Therefore there are new treatments being developed and trialled.

Mapping systems

A new development is mapping systems, which aim to get an electrical anatomical map of the atrium in respect to AF. These aim to characterise the atrial muscle, the atrial cardiomyocytes and the atrial electrical activity, in order to understand which electrical misfunction is present in the patient and is causing the atrial fibrillation, beside the role of the pulmonary vein which is already established. Rotor mapping looks for rotational activity in the atrial electrical activity similar to nature when a tornado makes a typical movement in the centre and in the core. If we ablate in the atrium building up electrical borders eliminating the rotational activity we may stop AF (Narayan et al. 2012).

> “IN THE FUTURE WE ARE LOOKING FORWARD TO BETTER UNDERSTAND THE PATHOPHYSIOLOGY OF PATIENTS THAT DON’T BENEFIT FROM CURRENT TREATMENTS”

High-density mapping systems provide the basis for high-resolution electrical anatomical mapping. While moving the catheter through the atrial chamber, touching the tissue, the system is able to provide the reconstruction of this atrium, including the information from 30-40,000 3D points and coding electrical information of the electrical

signal of this channel. High amplitudes represent a healthy myocardium. Low electrical amplitudes may display many cardiomyocytes with an impaired function or represent areas of fibrotic tissue. With this system we can create a map of diseased tissue and healthy tissue and can see how the electrical impulse information is moving around within the atrium. In addition, if we have a structured electrical activity like a circle, the re-entry tachycardia, we are able to build up this tachycardia in the 3D map and the operator is able to much better understand what pathway the arrhythmia goes along and intervene at the critical region of the pathway to stop arrhythmia and prevent recurrence. This is a huge step forward as it gives a much better resolution and a much better picture of what is really going on in the myocardium (Schaeffer et al. 2016).

Contact force ablation catheters

Contact force ablation catheters enable the operator performing the intervention to use the ablation catheter as the energy source to burn the critical region of tissue for arrhythmia. We have investigated the role of real-time compact force measurement. This technology gives an estimate of the compact catheter tissue, based on the rationale that we cannot just work with the critical region of the myocardium to get rid of the critical or cardiac cells which are important for the arrhythmia. Before we had this technique it was just an estimate, by looking at x-rays and reading at the hand when putting in the catheter. Now we have the information of real-time catheter force. This makes the procedure much more efficient in respect to procedural parameters, but it has not shown a significant effect on patient outcome yet either in my clinic or in ongoing clinical trials (Reddy et al. 2015). However, in the future we hope to better identify the patient benefiting the most from this procedure. The technique is beneficial for operators learning the technique as it's not a steep learning curve and brings them faster to the status of an experienced operator.

Imaging

Another recent innovation is gadolinium delayed enhancement magnetic resonance imaging (MRI). Prof. Marrouche's group from Utah investigated the role of late enhancement MRI of the atrial wall with the goal to visualise zones of scarring and fibrosis. The DECAAF trial showed that with intervention by ablation, you characterise late enhancement atrium and find out that the higher burden of fibrosis is associated with less good outcome after one year of ablation therapy (Marrouche et al. 2014). This information can help us stratify therapy and identify the patients in which therapy could be successful—those with low fibrosis burden, and also stratify patients who have so much fibrosis in the atrium that therapy by ablation is not likely to be successful. Therefore we would not put these patients forward for this procedure, but prescribe drugs instead. Prof. Marrouche's group is now undertaking the DECAAF-II trial (**https://clinicaltrials.gov/ct2/show/NCT02529319)** to evaluate the role of ablating or burning these disease regions, which is especially important in patients with persistent AF. To improve treatment one hypothesis is that if you could target a specific region of fibrotic tissue, which might represent diseased arrhythmogenic myocardium and thereby positively affecting the outcome of the procedure. This fibrotic area ablation is performed in addition to regular pulmonary vein isolation. So this might be one approach—imaging characterisation, identifying areas of diseased myocardium, which is probably fibrosis and then perform a pulmonary vein ablation and try to target these key areas to improve outcome. The DECAAF-II trial is ongoing and aims to enroll around 900 to 1000 patients investigating the therapeutic role of this late-enhancement MRI. This information about the atrium may give a better understanding of the underlying pathophysiology of the disease of the patient. The hypothesis is that AF is just one stage of atrial cardiomyopathy so you have a cardiomyopathy and one manifestation of this cardiomyopathy might be this rhythm disturbance. More and more we think in the order of a cardiomyopathy—if you are able to image the atrium and determine the nature of the disease assessed by fibrosis you can also identify patients at risk for AF and initiate upstream therapy such as blood pressure control and coronary heart disease checks (Goette et al. 2016). We can then look for hypercholesterolaemia and sleep apnoea syndrome in these patients.

"IN FUTURE IMAGING TECHNOLOGIES USING NUCLEAR MEDICINE TRACERS FOR THE AUTONOMIC NERVE SYSTEM WILL HELP US TO FURTHER UNDERSTAND WHAT COULD BE THE CRITICAL VARIABLES FOR THE ARRHYTHMIA IN THE INDIVIDUAL PATIENT"

Autonomic nerve system

The autonomic nerve system by sympathetic and parasympathetic activation plays an important role in the initiation of ventricular arrhythmias and are thought to play an important role in initiation of atrial arrhythmias as well (Chen et al. 2014). For example, in endurance sports such as marathon this is a risk factor for AF; the parasympathetic system and normal high activity could be one underlying contributor to initiation of the arrhythimia (Guasch et al. 2013). There are nuclear medicine imaging technologies using specific sympathetic tracers like ^{123}Iod-Metaiodbenzylguanidine (^{123}I-MIBG), which enables us to visualise sympathetic innervation in the myocardium. At the moment it is reliably feasible on the ventricular level and there are studies ongoing evaluating this technique on the atrial level. In future

imaging technologies using nuclear medicine tracers for the autonomic nerve system will help us to further understand what could be the critical variables for the arrhythmia in the individual patient.

Cryoballoon ablation

Cryoballoon ablation is an alternative to radiofrequency-guided ablation. A recently published study that compared the two found that cryoballoon ablation was non-inferior compared to the radiofrequency-guided approach in pulmonary vein ablation in AF (Kuck et al. 2016a). Cryoballoon ablation has a lot of potential benefits; it is easier to handle and easier to use for less experienced operators. It is a single shot device. The operator does not have to go around the veins with a catheter; they put a balloon in the vein, freeze and the procedure is completed. It is also less time consuming and less invasive. The second generation cryoballoon ablation device might also have the potential be superior in respect to recurrence and avoiding unnecessary repeat procedures (Kuck et al. 2016b). Trials are ongoing into the role in persistent AF, and it may turn out to be actually superior to RF ablation.

Conclusion

There are several developments in the treatment of AF to prevent stroke—therapies for symptomatic patients with rhythm disturbance and further developments for pulmonary ablation. In the future we are looking forward to better understand the pathophysiology of patients that don't benefit from current treatments, by using mapping systems, rotor mapping signal analysis and also imaging technologies to get better insight into the condition and guide therapy. Nuclear medicine will enable better analysis of the autonomic nerve system. Cryoballoon ablation is now well-established for a broad group of patients and broad group of operators. ■

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Training medical students in EHR usage

A training initiative that introduces medical students to EHR use early on to mitigate patient care risk is growing in momentum.

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Electronic health records (EHRs), or electronic medical records (EMRs) continue to be received with a mixed reception from physicians and nursing staff. While the tool, in theory, enables swift sharing of medical data, in practice, medics have voiced concerns over difficulties in navigation and in incorporating use into busy work lives.

In spite of rollout of EHRs across the healthcare sector, most of today's doctors leave medical school without any comprehensive training in their use. To counter this, the American Medical Association (AMA) and the Regenstrief Institute have collaborated on a training initiative aimed at ensuring that more medical students and trainees have access to real-world EHR use experience during their training.

"Our medical schools are very good at preparing students for the basic and clinical sciences that are essential to providing patient care," said AMA Vice President for Medical Education Susan Skochelak, M.D.. "However, many residents and young physicians are coming out of medical school with gaps in their ability to practice in the modern health system. Too often, students enter residency training without the ability to effectively and efficiently work with EHRs, even though they are one of the primary tools physicians use in everyday practice. The Regenstrief EHR Clinical Learning Platform is one major result of this collective work to ensure physicians are prepared to hit the ground running when they enter practice."

The Regenstrief EHR Clinical Learning Platform, launched earlier this year, has been developed by Indiana University School of Medicine (IU) and the Regenstrief Institute under the AMA's initiative to create the medical school of the future and is now being disseminated by both organisations to medical schools across the U.S..

The platform is a cutting-edge, educational content delivery, and critical evaluation tool designed for health professionals. Through the use of both mis- and de-identified real patient data, the first-of-its-kind platform facilitates learning in simulated, realistic clinical scenarios. It is expected to greatly improve education in clinical informatics, health system delivery science, and population health.

The first-of-its kind platform uses real, de- and mis-identified patient data from Indianapolis-based Eskenazi Health, to allow students to virtually care for 'patients' suffering from multiple, complex health conditions. Critically, they have the opportunity to do this safely within an application that is similar to EHRs used in the real work environment. It also offers a state-of-the-art, immersive teaching platform for educators. Tools for creation of customised content aligned with curriculum goals and student evaluation are some of the features for educators.

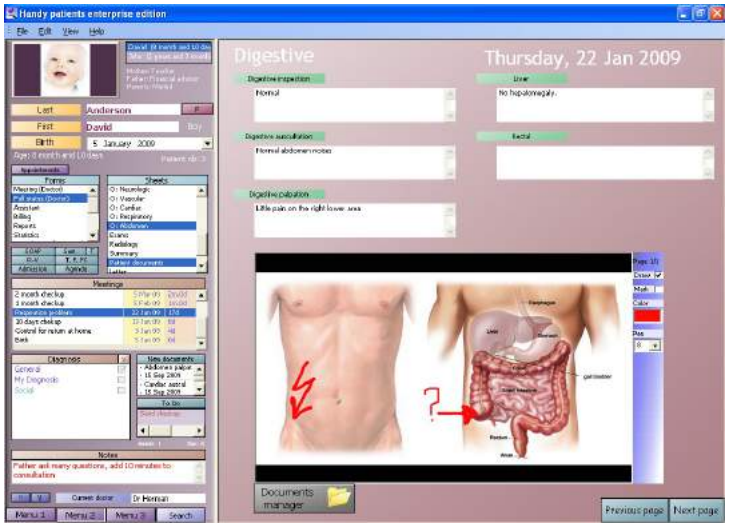
EHR training is just one of the innovations identified by the AMA's Accelerating Change in Medical Education Consortium. This 32-school strong consortium is a forum for sharing healthcare innovations. IU School of Medicine received a $1 mln AMA grant to collaborate with the Regenstrief Institute for development of a method of incorporating EHR training into its curriculum with the objective of establishing a model that could be implemented by other medical schools. Following a year of development, the platform was fine tuned for the purpose of encouraging medical educators to incorporate it into their medical schools' curricula.

"It is ironic as EHRs have proliferated in the past decade, significant medical student exposure to these systems has decreased," said Regenstrief research scientist and Assistant Professor of Clinical Medicine at IU School of Medicine, Blaine Y. Takesue, M.D. "EHRs are a tool most physicians will use every day in their practice, and data from EHRs will impact all physicians. This new collaboration between Regenstrief and the AMA reflects two realities. First, health professions schools regard EHR and informatics training as necessary for their students. Second, the Indiana University School of Medicine, the Regenstrief Institute, Eskenazi Health and the AMA believe investment in the Regenstrief Electronic Health Record Clinical Learning Platform will improve healthcare by improving the informatics 'IQ' of medical students and other healthcare profession students."

UConn School of Medicine has implemented the training into two of its courses with an interesting focus; introduction of students to patients within virtual families embedded in the EHR for clinical context to basic science, clinical medicine and social science principles. The school is also using the platform for an opportunity to mine an extensive database of mis-identified patients to learn about populations and social determinants of health and disparities.

"UConn's medical school is excited to further enhance our educational innovations by integrating the available Regenstrief EHR platform into our

Students at The University of Utah School of Medicine, member of the AMA's Accelerating Change in Medical Education Consortium



Many students leave medical school with little experience of EHR use needed to function in the modern work environment

curriculum—taking advantage of the endless possibilities that the platform offers to explore all aspects of medicine and patient care," UConn School of Medicine Senior Associate Dean for Education Suzanne Rose, M.D. said. "In our growing digital age, healthcare delivery is rapidly changing. It is critical that all medical students have exposure to integrated EHRs which will be a mandatory part of their future care of patients." ■

The AMA launched its Accelerating Change in Medical Education initiative in 2013—providing $11 mln in grants to fund major innovations at 11 of the nation's medical schools. Together, these schools formed a Consortium that shares best practices with a goal of widely disseminating the new and innovative curricula being developed. The AMA expanded its Consortium in 2015 with grants to an additional 21 schools to develop new curricula that better align undergraduate medical education with the modern healthcare system. Most recently, through its work with the 32-school Consortium, the AMA launched a new health systems science textbook that can be used by all medical schools to help future physicians navigate the changing landscape of modern healthcare, especially as the nation's healthcare system moves toward value-based care. The AMA will continue its efforts to accelerate change in medical education to ensure future physicians learn about the newest technologies, healthcare reforms and scientific discoveries that continue to alter what physicians need to know to practice in modern healthcare systems.

KEY POINTS

- ✓ Many young healthcare staff leave medical school ill-equipped to operate in the modern work environment
- ✓ The American Medical Association (AMA) and the Regenstrief Institute have devised real-world EHR use training
- ✓ Called The Regenstrief EHR Clinical Learning Platform, the EHR training is part of the AMA's initiative to create the medical school of the future
- ✓ It is now being disseminated by both organisations to medical schools across the U.S.
- ✓ EHR training is just one innovation identified by the AMA's Accelerating Change in Medical Education Consortium
- ✓ It is critical that medical students are exposed to integrated EHR use for future patient care

Person-centred approaches: a new core skills training framework

Colin Wright, Framework Development Manager at Skills for Health, provides guidance and key points for best practice when implementing and using a new Core Skills training framework.

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In the summer, Skills for Health released a brand-new Core Skills Education and Training Framework called Person-Centred Approaches. The framework aims to distil best practice and to set out core, transferable behaviours, knowledge and skills for the health and social care workforce and carers.

The new framework, commissioned by Health Education England, provides a description of behaviours, knowledge and skills needed to put a person-centred approach into practice, beginning with the underpinning of values and core communication skills.

The framework identifies that the different types of conversations crucial to a person-centred approach can be described in three steps:

- Conversations to engage with people
- Conversations to enable and support people
- Conversations with people to collaboratively manage highest complexity and significant risk.

Appropriate steps to take will depend upon the type of conversation needed in a particular situation. This is not necessarily dependent on someone's job role or level of seniority.

Implementation: Delivery of training, education and learning opportunities

The framework aims to guide the content of education and training, whilst still allowing it to be tailored to local needs.

However, achieving person-centred approaches involves more than just education; it requires a significant behaviour change for workforces. Achieving successful implementation across whole organisations requires clear and strong leadership, together with systems and processes that support this way of working.

Behaviour change

To achieve and sustain positive impact for workforces who are adapting and/or adopting new ways of working, recent research (Nesta 2016) suggests that taking a behavioural approach (including capability, opportunity and motivation) to supporting people is more successful than isolated training. Development of capability must simultaneously be supported with the right processes, systems and opportunity, together with locally relevant incentives, which build those intrinsic and extrinsic motivations.

"THERE ARE FACTORS THAT CAN IMPACT THE ABILITY OF STAFF TO LEARN AND THEIR MOTIVATION AND CONFIDENCE TO IMPLEMENT NEW SKILLS AND BEHAVIOURS"

There are factors that can impact the ability of staff to learn and their motivation and confidence to implement new skills and behaviours. These include psychological, social, economic and cultural factors within their lives and working environment.

In practice, this means the person needs to:

- Know what to do
- Know how to do it
- Think it is a good thing
- Believe that they are capable
- Believe that it is their role
- Believe that people who are important to them think it is the right thing to do.

Co-producing training

The active involvement of people and carers with experience of using services and managing health conditions is central to effective training on person-centred approaches.

Sessions should be co-designed to model person-centred approaches and to meet learning outcomes. As well as articulating the experiences and perspectives of people using services, co-production demonstrates the wider positive strengths, contributions and impact that they can make.

Individuals may contribute by sharing their story (either in person, or through a medium such as video or podcast) while others may wish to actively co-deliver theory and techniques as much as possible.

There are valid steps along the way to achieving co-production, such as engagement, involvement, participation and consultation.

When developing models for co-delivery, it is important that they include:

- Robust mechanisms for feedback
- HR process including development and support
- Remuneration
- Boundaries between dual roles of patient and educator, collaborator and service provider.

Reflective practice

To develop person-centred behaviours and approaches, it is important for individuals to take time to think about what they are doing, how they are doing things and the impact this has on other people. This draws on an individual's experiences, knowledge, values and feedback (and evidence where appropriate) to analyse and identify opportunities to change their thoughts and behaviours.

This could be achieved through:

- Keeping a diary
- Talking to peers
- Focusing on specific events
- Informal or formal mentoring
- Local role specific activities such as Schwartz rounds
- Listening and acting on feedback from people who have used services and their carers.

Continuous improvement

Continuous improvement is a principle that runs through everything we do. Embedding person-centered care will require improvements in how some services are designed, delivered and reviewed. The opportunities for improvement need to be identified, developed and evaluated in partnership with people who deliver and use those services. A continuous feedback loop is an essential component of this.

Training and development for person-centred approaches can be a component of quality improvement projects, and the principle of quality improvement should be included in training to enable staff to drive this agenda.

Value-based approaches to workforce recruitment and development

The foundation for a strong person-centred workforce begins with attracting, recruiting and developing individuals who embody the values as described at the start of the framework. It is important that the organisation commits to:

- Ongoing support to build the person-centred skills, behaviours and motivations of its workforce
- Continually seek feedback and involvement from people who use services for ongoing improvement
- Supporting staff with these approaches in the context of professional revalidation.

Organisations could achieve this through induction programmes, mandatory training, appraisals, local initiatives, campaigns, networks and opportunities for ongoing development.

Methods for delivering training

All members of the workforce need to be trained in the core relationship building and communication skills. It is important to stratify the workforce to identify those for whom the three steps are appropriate.

At each step, the mindsets of behaviour change, coproduction, continuous improvement, value-based approaches to workforce development and reflective practice, should all be considered.

All steps should be grounded in real life examples and complexity to experience the importance and impact of these conversations. ■

KEY POINTS

- ✓ The Person-Centred Approaches framework aims to distil best practice and set out core, transferable behaviours, knowledge and skills for the health and social care workforce and carers
- ✓ There are 3 conversations: to engage, to enable and support and to collaborate
- ✓ The framework guides education and training content while enable tailoring to local needs
- ✓ Key factors can impact the ability, motivation and confidence of staff to learn and implement new skills and behaviours
- ✓ For effective training, active involvement of people and carers with experience of using services and managing health conditions is central to the approach
- ✓ Reflective practice is important for consolidating knowledge and experience gained through the approach
- ✓ Continuous feedback is an essential component of The Person-Centred Approach
- ✓ All steps need to be grounded in examples from real life

To download the framework, visit:
skillsforhealth.org.uk/pcadownload

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Behind closed doors – Point of Care Foundation

A recent Point of Care Foundation report provides insights into the pressures faced by British healthcare staff and how these can be overcome.

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How employers feel at work has been the subject of debate for quite some time, particularly within the healthcare sector. It is widely agreed that staffs' happiness largely depends on the environment that they work in and thus affects their overall performance.

The UK National Health Service (NHS) has faced scrutiny over the last few years and naturally staffs' wellbeing is particularly important as the pressures they face can ultimately have consequences on patients.

A report recently issued by The Point of Care Foundation has published a new briefing - Behind Closed Doors - highlighting that NHS staff have become the "shock absorbers" of an NHS under chronic strain.

According to the report, the Point of Care Foundation highlight how critical it is that NHS employers pay attention to staff so that a positive attitude can be carried through to the patient experience.

The report recommends that staff experience should be given equal priority with patient experience at all levels of the healthcare system. Organisers should encourage frontline staff to look after themselves, to pay attention to their own and their colleagues' wellbeing, to alert their managers to pressures that can be alleviated, and to let them know when they need support, in particular allowing staff to access psychosocial support and forums for reflective practices.

"This report deserves attention. Everything in it is directly reflected in the work that the RCM has carried out with our own members – midwives and maternity support workers," Chief Executive of the Royal College of Midwives (RCM), Cathy Warwick told HealthManagement.org. "The report says that it is hard to deliver the best care in an environment in which staff themselves don't feel cared about. After seven years of pay restraint and the average midwife seeing their salary drop in value by over £6, 000 we need the government to show staff they value them by removing the public sector pay cap and making the funds available to pay NHS staff a fair pay rise. This report echoes what the RCM has been saying for years, that investment in staff is an investment in high quality, safe care."

Next year, 2018 marks the NHS' 70th birthday and perhaps within the next twelve months, the suggested recommendations from the report will indeed be taken on board so that this birthday can truly be a cause to celebrate a healthcare system which cares for both its staff and its patients.

Commenting on the report, Ed Smith, Immediate Past Chair of NHS Improvement said the report sat well with Developing People-Improving Care which was launched late last year. "It is very clear that greater attention to how people feel, what they do and how they stay primarily focused on "point of care" activity delivers better outcomes and is what our patients and public want," he said.

However, it seems the pressure is felt everywhere. The NHS is coming under an increasing amount of pressure within a financially-challenged environment. Not only are hospitals, emergency departments, ambulances services at the forefront of public attention, but also in general practice and in community and mental health services. In fact, the report suggests that a large area of interest is in leadership and cultural challenges and how both impact frontline staff and interactions with patients.

"Trying to steer the NHS from the top is like trying to turn a super-tanker. We would like to see more attention being paid to supporting bottom-up initiatives that resonate with staff and which appeal to their intrinsic motivation to care for patients", said the report.

In response to the report, Professor Neena Modi, President of the Royal College of Paediatrics and Child Heath commented on the growing demand on the NHS. "Patient expectations are rightly rising, yet investment in the healthcare workforce is failing to keep pace even though the country can and should afford to do better."

"The report highlights the pressures on NHS staff and calling for more support to protect their wellbeing. But it is only one part of the answer; there must also be long-term investment in the workforce and in UK healthcare."

The NHS is the UK's biggest employer, employing nearly 1.6 million people (Royal College of Physicians 2015). In 2016 only 31% of staff felt there were enough personnel for them to do their job properly, (NHS Staff Survey 2016).

Every year for the past four years, dating back to 2012, 15% of NHS staff have been subjected to physical violence from patients, relatives and members of the public, and near to one in five staff say they have experienced bullying, harassment, or abuse from either their line manager or other colleagues (NHS Staff Survey 2016). According to the

Behind Closed Doors report, the NHS working environment is tough in most areas, and there is convincing evidence that for black and ethnic minority staff it is even more so.

The way forward

Going forward, it is crucial to improve the working environment for staff so that the culture is more supportive and to create teams with climates that are more protective. Decisions taken at every level of the NHS affect relationships between professionals and it is vital that these decisions have the end goal of supporting staff and patients at the point of care.

In the latest NHS staff survey, the majority of staff reported that they did feel their organisation and managers were concerned for their health and wellbeing. 67% of staff reported that their manager took a positive interest in their health and wellbeing, and 90% felt the organisation was actively interested in positive action.

These results are indeed promising and hopefully a step in the right direction. In order to do so as well as to ensure that interactions between patients and frontline staff are the primary determinant of patient experience, and that staff wellbeing matters to patients, there are a few recommendations in place.

Firstly, staff are encouraged to look after themselves, pay attention to their own and their colleagues' wellbeing, alert their managers to pressures that can be alleviated, and let them know when they need support.

Staff should also actively use their voice to raise concerns about quality of care, safety and patients' experiences where necessary.

It's important to contribute ideas and insights to improve patients' and families' experience of care and also take responsibility for acting on them. Not only this, but staff need to be aware of themselves as 'on-stage' when they are within sight of patients, and remember to take the time to introduce themselves by name and make that human connection.

Finally, staff should honour the fact that patients and carers know what matters most to them, make time to listen to them and ensure that they have the opportunity to influence the way their care is delivered.

Recommendations for leaders of NHS organisations

Since the decisions that senior leaders make a large impact on staff and their relationships with patients at the point of care, the leaders of NHS organisations are also given a few important recommendations. According to the report, leaders need to recognise that healthcare staff are highly motivated by altruism and the desire to care for patients and to enable line managers to create environments that support job satisfaction.

It's also crucial that leaders make psychosocial support systemically available to staff across the organisation. As mentioned, staffs' attitude and mental state flows down through to the patients' experience so the problem needs to be addressed from the top.

Leaders also need to provide access to reflective practice for all staff, demonstrating organisational buy-in for organisation-wide interventions such as Schwartz Rounds, the international initiative that offers healthcare providers scheduled time during their fast-paced work lives to openly discuss the social and emotional issues they face in caring for patients and families, and also smaller, alternative interventions (such as team or ward-based practices) for those who struggle to attend.

Spending time with staff and observing the delivery of care and understanding fully the nature of the operational problems that prevent staff from being at their best with patients, will also help to improve the current system.

Finally, leaders are encouraged to build capacity within the organisation to use patient-focused tools and techniques to improve the quality of care, giving frontline teams the authority and responsibility for improving patients' and families' care experiences.

Recognising that, even though national bodies and regulators use data to monitor performance, it is frontline staff who collect this data, and anything that uses up time at the frontline and is not directly patient-related reduces the time staff spend with patients.

NHS England, NHS Improvement, the Care Quality Commission and local commissioners are therefore strongly recommended to:

- Continue to use their powers to simplify and reduce duplication, volume, frequency and confusion over the reports they require from providers
- Place greater emphasis on encouraging providers to examine and improve their own performance over time and rewarding them for doing so and less on comparing organisations with one another.

Perhaps with enough effort and encouragement, the NHS can become an environment where staff feel that they are valued and feel positive both in and out of work. Indeed, what's clear is that the issues no doubt start from the apex of the entire system and leaders need to be setting an example, in order for the system to run smoothly, and, ultimately look after both the staff and the patients.

As Cathy Warwick concludes, "We must act now if the public is to get the care they deserve."

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Africa healthcare federation one continent: one team

To meet the pressing need for affordable, quality and equitable healthcare, the Africa Healthcare Federation (AHF) integrates the private health sector of Africa, and presents a unified platform where the private sector can effectively engage the public sector for best health outcomes.

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The African region is experiencing steady economic growth despite many challenges, and predictions for the coming years remain favourable, with growth rates between five and six percent (well above the world average of 2.2 percent). With its increasing role and impact, the private sector is now being recognised by the international community as the engine for sustainable and inclusive economic growth.

The impact that such growth has on the healthcare sector in particular, is that a growing urban middle class is willing to pay for better treatment. This widens the door to the private sector, which is in turn starting to play a new vibrant role, often working in partnership with donors and governments to provide affordable quality healthcare services.

Built to fill the gap of the pressing need for a movement towards access to affordable, quality and equitable health care, AHF presents a unified platform where the private sector can effectively engage the public sector to improve the health business environment and promote pro-growth policies that maximise the input of both the sectors. Established in 2016, Africa Healthcare Federation (AHF) has been formed to unite the private sector, as well as to serve and facilitate collaborations among governments, development partners and international and domestic healthcare players from the private sector. It has received exceptional support and goodwill from stakeholders across the globe, including governments in Africa as well as development partners.

At the inaugural Africa Health Business Symposium (AHBS), held in October, 2016 in Nairobi, Kenya, the leaders of five regional healthcare federations of Africa (East Africa Healthcare Federation (EAHF), West African Private Healthcare Federation (WAPHF), and the key players of the upcoming Central, Southern and Northern African private healthcare federations) signed a Communiqué to pledge their commitment towards the development of AHF and to chart a roadmap for a stronger health sector in Africa. This historic launch of the AHF was graced by Ministries of Health, leading corporations within Africa and captains of the healthcare industry. AHF will unify not only the regional health federations but also the entire private health sector of Africa, across 45 countries, under a single health platform.

AHF is the voice for the private health sector of Africa with the goal of ensuring the scaling up and strengthening of health systems. Under the theme "One Continent: One Team", it also supports the five regional federations and their respective country federations to take approaches that enable Africa to deliver on the Sustainable Development Goals (SDG's) and Agenda 2063: The Africa We Want.

The main activities of AHF include:

- Advocacy
- Promoting appropriate regulatory frameworks in the regions
- Fostering public-private partnerships
- Encouraging innovations and disruptive technologies
- Facilitating pro-growth policies
- Increasing investments in health

"AHF PRESENTS A UNIFIED PLATFORM WHERE THE PRIVATE SECTOR CAN EFFECTIVELY ENGAGE THE PUBLIC SECTOR TO IMPROVE THE HEALTH BUSINESS ENVIRONMENT"

In February 2017, AHF was awarded for its "Outstanding contribution to the African Healthcare Industry" at the Africa Healthcare Summit Awards 2017 held in London. Oliver Kinross presented this award in Kensington, London, in the presence of Ministers of Health from Africa, captains of the industry, leading investors, and influential leaders in the healthcare industry. Within the first year of

AHF Team accepting the Africa Healthcare Award at the Africa Healthcare Summit in London, February, 2017

Dr. Amit N. Thakker, with AHF Directors, Dr. Anuschka Coovadia, Southern Africa Private Healthcare Federation (left), and Clare Omatseye, Healthcare Federation of Nigeria (right) at the IFC Health Event in Barcelona, May 2017.

Dr. Amit N. Thakker, Chairman of Africa Health Federation (left) engages with Dr. Awa Marie Coll Seck, Minister of Health, Senegal (right) and Dr. Ardo Boubou Bâ, President of Alliance Nationale du Secteur Privé de la Santé Senegal/ASPS, and AHF Director (centre).

its formation, AHF has been recognised at an international level.

AHF has also had incredible support from all the member countries. Most of the member countries that have a strong private sector, continue to provide assistance at the country, regional and continental level. The regional levels have been mirrored around the economic zones of Africa and incorporate member countries of the respective economic zones to carry out the AHF objectives and strengthen the partnership with the public sector.

Embarking on any pioneering path, involves breaking new ground, which is bound to involve a few obstacles. Some of the challenges we have faced have been:

- Building trust: as a newly founded organisation, building trust with the government and other entities of health can be challenging because the relationship between the public and private sector has always been weak. Historically the two entities have hardly had engagements for economic growth and prosperity.
- Inclusivity of the private sector: by nature, corporate institutions and companies have always worked with an interest of their own organisation. Bringing this fragmented private sector under a single umbrella to share a common vision has been difficult. Inclusivity is an evolving journey that many countries are still undergoing.
- Creating a robust in-country institution in every country: the in-country federations have to carry out their own activities, policy briefs, advocacy campaigns and public awareness drives. These require resources and skills that are best found in the respective country where the federation operates. As a start-up with fledgling resources, it requires innovative strategies to look for alternative sources of funding beyond membership fees so as to build operational capacity and to be sustainable.

- Impact analysis: the transformation created by the establishment of a unified federation happens over a long period of time before results can be recognised. It requires persistence, and that deters some of the stakeholders who are looking for quick results.

The passion for creating an effective healthcare sector in Africa has led us to relentlessly focus on bringing champions and like-minded people to drive the agenda of institutionalised public-private partnership which would be catalytic in creating shared value and improved outcomes. Our team has been growing, and we have received tremendous support from several development partners such as IFC/World Bank, USAID, German Association for International Health (GIZ), Japan International Cooperation Agency (JICA) and The Danish International Development Agency (DANIDA). Although AHF was formally launched in 2016, it has been about a 12 to 13-year journey overall in building our team. The new leadership in government in several of the African countries has been very receptive in adopting innovative models of public–private partnerships (PPP) in health. This has encouraged the establishment of institutions that will be sustainable in the long run through collaborations.

The wide exposure that AHF has received through international healthcare platforms, government forums, and presidential roundtables in many countries has opened up opportunities for the federation to be an international hub for investments and effective partnerships in Africa. In addition to that, through this platform, AHF also advocates to overcome the perception that health in Africa is donor dependent, by improving local resources and embedding innovation so that as a sector we are self-reliant in facing emerging challenges, and focus on preventive care rather than curative care.

The results so far have been very promising, and they have been achieved due to the contributions of the partners that we have worked with. Within the private sector, we now have a consistent platform for the sharing of best practices, thereby encouraging appropriate business models to scale up within the regional economic zones. We have seen the outcomes of this particularly in medical insurance companies (Jubilee, UAP, etc.) and in companies involved in supply chain – both local distribution companies, and multinationals setting up offices across Africa. Academic and training institutions (universities and colleges) are now also accepting students from neighbouring countries and training the students to work as health workers in their own nations. With more stability and an organised regulatory framework, there has also been an increase in investments. Local and international investors are finding it easier to put capital in this industry through the opening of clinics, hospitals, manufacturing sites, etc. We have seen in the recent past, several private equity companies coming to the market and investing in private companies. Several private equity companies are also increasingly investing in private companies in Africa.

Within the public sector, there has been an improvement in the engagement between the governments and the private sector, thus bringing greater transparency in the procurement of medicines and medical supplies. New models of engagement such as leasing and outsourcing have also emerged in the healthcare industry which has not been experienced in the past several decades. This has given the private sector greater accountability in the products and services it offers the government. Another significant achievement is the setting up of PPP units in the Ministries of Health. Several governments in Africa have now appointed senior officers to head newly formed PPP offices, which had never existed before. The focal point is now better organised within the Ministries to effectively engage with the private sector which provides over 50% of the services in most of the African countries. There have also been noticeable changes in leadership of the Ministry of Health (MOH) in many countries like Kenya that have an appointed MOH, rather than an elected MOH. Several countries have appointed leaders from the private sector to head these government offices.

This is the start of a pivotal moment that marks the beginning of a momentous change towards overcoming challenges together and achieving mutual far-reaching outcomes. As a unique organisation that embodies the entire African continent private healthcare sector, AHF is envisioned to make a significant contribution to the African healthcare industry through the ramping up and strengthening of health systems, and the development of quality and uniform standards of healthcare delivery across the continent.

We now truly embody the Old African proverb, “If you want to go quickly, go alone. If you want to go far, go together”. ■

KEY POINTS

- ✓ The private health sector in Africa now covers over 50% of medical services in many African countries
- ✓ The AHF fills the gap of the pressing need for access to affordable, quality and equitable health care
- ✓ AHF presents a platform where the private sector can engage the public sector
- ✓ The organisation promotes pro-growth policies that maximise the input of both the sectors
- ✓ The AHF structures and integrates the private health sector of Africa

AHBS
Africa Health Business Symposium

6th - 7th November 2017 King Fahd Palace Hotel Dakar, Senegal

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6 AVERAGE CHILDREN EACH WOMAN BEARS

5.5% HEALTH EXPENDITURE AS A % OF GDP

30% OF AFRICA'S POPULATION HAVE ACCESS TO PRIMARY HEALTHCARE

$29.6BN PROJECTED HEALTHCARE INVESTMENT DEMAND

$671 AVERAGE GDP PER CAPITA

500M+ MOBILE USERS

5 KEY GAMECHANGERS
UNIVERSAL HEALTH COVERAGE
HEALTH WORKFORCE
PUBLIC-PRIVATE PARTNERSHIPS
SUPPLY CHAIN MANAGEMENT
DIGITAL TECHNOLOGIES

OUT OF POCKET HEALTH EXPENDITURE HIGHEST AT 74% IN SUDAN

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Commissioner of Social Services
African Union

Hon. Dr. Awa Marie Coll Seck
Minister of Health & Social Action, Senegal

Dr. Amit N. Thakker
Africa Healthcare Federation

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Dr. Tedros Adhanom Ghebreyesus
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"We cannot solve our problems with the same thinking we used when we created them."
Albert Einstein

ABELARDO VIDAURRETA

HEAD OF INNOVATION, SALAUNO, MEXICO CITY, MEXICO

What would you single out as a career highlight?
I worked as a physician for one year and six months for Partners in Health in the mountains of Chiapas, the poorest state in Mexico, where I understood the connection between effective medicine and social inequities. I made the decision there to shift my career to healthcare management.

"Be positive."

HUGO SANER

SENIOR CONSULTANT - UNIVERSITY CLINICS OF CARDIOLOGY, SWITZERLAND

Research Associate - ARTORG Centre for Biomedical Engineering Research University of Bern Switzerland, Congress Director - European Congress on eCardiology and eHealth

What would you single out as a career highlight?
I was one of the initiators of the European Association for Cardiovascular Prevention and Rehabilitation (now the European Association of Preventive Cardiology) and I was the first president. I was co-founder and first editor in chief of the European Journal for Cardiovascular Prevention and Rehabilitation (now the European Journal of Preventive Cardiology). Another highlight was becoming official chair for acute and preventive cardiology at the First Moscow State Medical University, the largest medical university in Russia.

Thomas Watson, IBM President 1943 said: "I think there is a world market for maybe 5 computers". Never try to predict what might happen!

ANDY ROGERS

PRESIDENT (2016-2018)
- BRITISH INSTITUTE OF RADIOLOGY, UK

What is your top management tip?
Management is different from leadership! Leadership - have a vision that is shared with your team and lead from the front.

"Do not underestimate the effort, costs and time that are necessary to properly train the users of any OAI system, and have these users become committed in making the best use of the system and in contributing to its continuous improvement. In short, consider the most important human factor, which are the human actors themselves."

FEDERICO CABITZA

ASSISTANT PROFESSOR, UNIVERSITY OF MILANO-BICOCCA & IRCCS IO GALEAZZI, MILANO, ITALY

What would you single out as a career highlight?
Having a viewpoint published in JAMA. It is not just the academic achievement per se; rather it is the satisfaction as a computer engineer of having succeeded in creating a bridge between the computer scientists and the medical community, in having medical doctors understand the implications of taking AI seriously instead of heedlessly, and in contributing in making some concepts more popular It was also rewarding to see the article become one of the most discussed and shared ones on the social media.

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4th EUROPEAN HOSPITAL CONFERENCE

Chances and Challenges of E-Health

The 4th EUROPEAN HOSPITAL CONFERENCE (EHC) takes place as part of MEDICA 2017 and the 40th German Hospital Day on 16 November 2017. The EHC will address different political, medical and economic topics from across all of Europe.

Programme

Room M, CCD Congress Center Düsseldorf (CCD Ost), Messe Düsseldorf

Morning Session – European Strategy

10.00 – 10.10
Welcome
Session Chair
Gerry O'Dwyer
President EAHM

10.10 – 10.40
E-Health Action Plan 2012 – 2020 of the European Commission
Andrzej Rys
Director, Directorate General SANTE, European Commission

10.40 – 11.25
Stakeholders' Positions with respect to the Action Plan

10.40 – 10.55
Eva Weinreich-Jensen
Madam President HOPE

10.55 – 11.10 h
João de Deus, MD
President AEMH

11.10 – 11.25
Heinz Kölking
Past President EAHM

11.25 – 12.00
Discussion
Chair
Heinz Kölking
Past President EAHM

12.00 – 13.30
Break

Afternoon Session – National E-Health Strategies

13.30 – 13.35
Introduction
Session Chair
Eva Weinreich-Jensen
Madam President HOPE

13.35 – 14.55
Specifi c national E-Health Concepts

13.35 – 13.55
Tomas Lithner
Director for National Healthcare Services, Sweden (Swedish concept)

13.55 – 14.15
Adrian Schmid
Director, eHealth Suisse, Switzerland (Swiss concept)

14.15 – 14.35
Andreas Grode
Head of Innovation, Society for telematics applications, Germany (German concept)

14.35 – 14.55
Morten Elbæk Petersen
CEO, Sundhed, Denmark (Danish concept)

14.55 – 15.40
Specific examples for the implementation of the E-Health-Concept

14.55 – 15.10
Arturo Romero Gutiérrez
Deputy Direction on Information Systems and Evaluation, Ministry of Health, Social Services and Equality, Spain (HOPE)

15.10 – 15.25
Henrique Martins, MD
CEO, SPMS.EPE, Portuguese Ministry of Health, Portugal (AEMH)

15.25 – 15.40
Peter Asché
CEO, Uniklinik RWTH Aachen, Germany (EAHM)

15.40 – 16.10
Discussion
Chair
Eva Weinreich-Jensen
Madam President HOPE

16.10 – 16.30
Conclusion
Dr. Erich Theo Merholz
Vice-President AEMH

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