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HEALTHCARE EXECUTIVE ALLIANCE SPECIAL EDITION ON E-LEARNING

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Costs, Costs, Costs!

Who Pays in Healthcare?

The nuances of the English language give "pay" and "cost" many meanings. When a person has no health insurance and no access to healthcare, what is the cost to their health? When the state pays for healthcare, when is "rationing" considered acceptable? Should non-smokers pay with their taxes to treat smokers' illnesses? The ethics of healthcare financing are considerable. When we contemplate healthcare finance, considerations of payment, cost, value for money, effectiveness, preventing fraud and waste are all in the mix.

One of the world's most successful investors, Warren Buffet, has compared healthcare costs to a tapeworm that is eating the American economy, and is "untenable over time" (valueinvestorsport.com 2010). The U.S. has been an outlier for many years in the percentage of GDP it spends on healthcare and yet still has millions of citizens who have no health insurance. Buffet advises tackling costs as the number one issue facing America, and observes that despite the huge expenditure, America has fewer doctors, nurses and beds per head of population than other countries that spend less on healthcare.

In developed and developing countries alike, a rapidly ageing population, advancing technology and competing demands are combining to create a 'perfect storm' of increased demand and less public funding. In the developed world, where infrastructure and services are widely available, the questions are around who pays and how to improve outcomes from spending. Are people willing to take out health insurance and increase spending from their own pocket? Will the move to more healthcare at home help the efficiency of the health service?

For the developing world, where governments are increasingly pursuing universal health coverage, out-of-pocket spending is already very high. Quality services may be unavailable or out of reach. The big questions are which models can expand access and be financially sustainable. What innovations can reduce costs and improve outcomes? What can developing countries learn from the mistakes of the developed world?

However healthcare is financed, every country is struggling to balance between increasing demand from an ageing population, increased costs and the need to optimise efficiency. The Chief Financial Officer (CFO) is a critical role in the healthcare enterprise. The introverted accountant stereotype is in the past, and the CFO needs to be a skilled communicator, able to challenge the CEO and the Board, whilst understanding clinical pathways with ease and evaluating and managing risks.

Individual health professionals and patients need to understand their responsibilities too. Is that test or imaging exam really necessary? Both patients and health professionals need to understand what is needed, and initiatives such as Choosing Wisely and appropriate use criteria are helpful here. Simple measures such as text message reminders about hospital appointments can save money overall: for example, missed first outpatient appointments cost the English National Health Service up to £225 million in 2012 to 2013 (UK Department of Health 2016). And such a measure may be preferable to overbooking appointments.

How can spending be reduced? With targets, or with nudges? The recently published results from a randomised controlled trial in the United States showed that including information on the costs of lab tests had a negligible effect on the ordering patterns of physicians (Sedrak et al. 2017). Studies on imaging have had similar results (eg Chien et al. 2017).

This issue of HealthManagement puts these critical questions under the microscope as experts from all walks of the healthcare sector world take an uncompromising look at what funding innovations are needed. With cooperation, collaboration and the courage to think outside the box, there is no reason for the future not to be bright. ■

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What Do You Think?

What are the money issues on your mind? How does cross-collaboration work in practice in your hospital? With future issues on People, Risk and Sustainability, do get in touch to share your ideas. As a leading digital and print publication on healthcare management and leadership, there are many ways to share your expertise. Contact us on edito@healthmanagement.org

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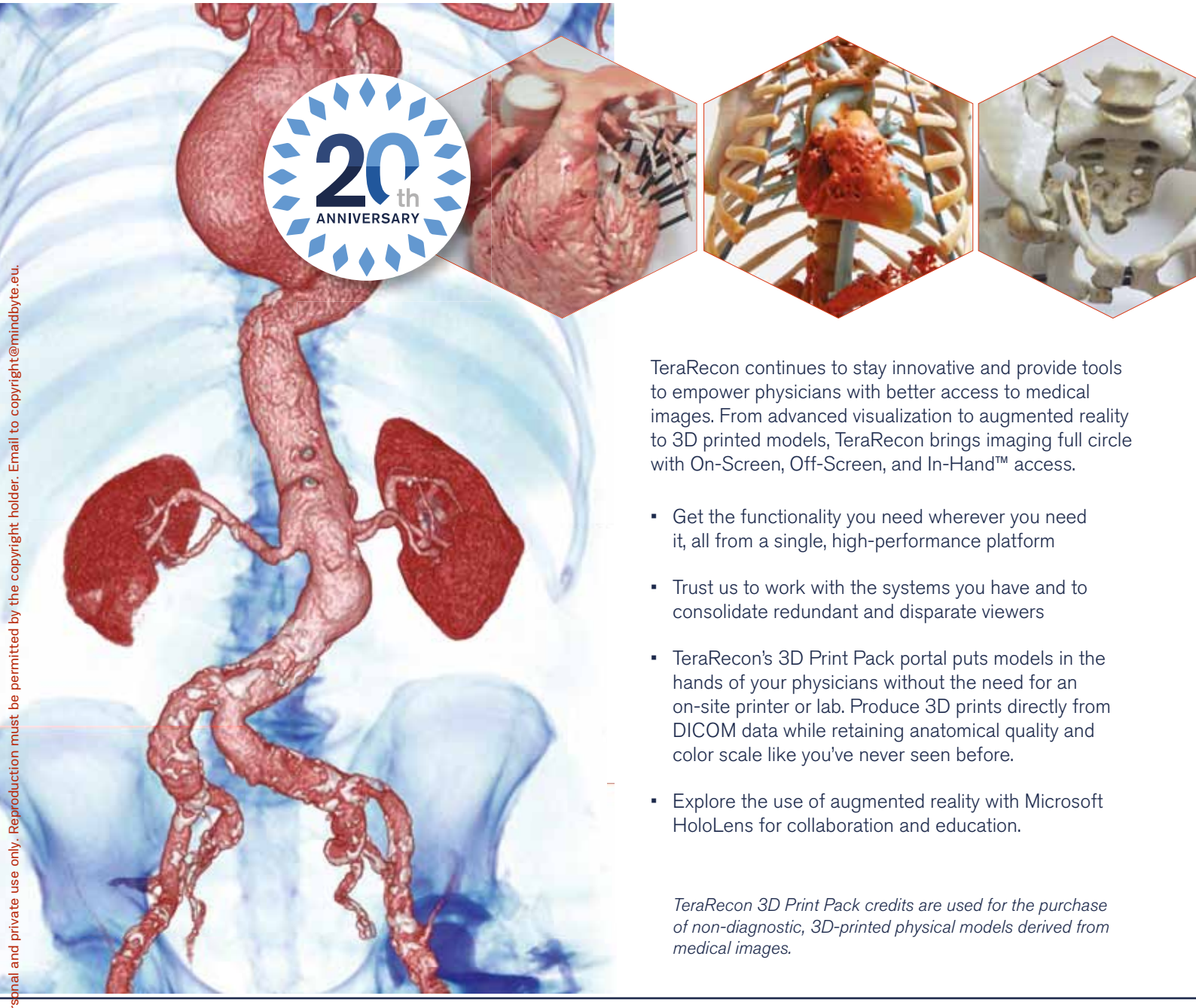

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SECTRA

Knowledge and passion

Ann Marie O'Grady: New HealthManagement.org EXEC Editor-In-Chief

Meet HealthManagement.org's new E-i-C for EXEC and find out what she hopes to bring to readers including providing a platform for healthcare executives to promote, share and learn from each other on emerging issues in the sector.

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HealthManagement.org is pleased to introduce the new Editor-in-Chief for EXEC, Ann Marie O'Grady. O'Grady is Chief Executive of Leopardstown Park Hospital, Dublin, a specialist hospital for older people encompassing services that include rehabilitation, respite care, sheltered housing, day-care services and residential care. It is a not-for-profit independent hospital providing health services under a service level agreement with the Irish National Health Service (Health Service Executive).

Following her initial qualification as a physiotherapist she continued her broad and on-going continuing professional development including post-graduate qualifications in leadership, communication and executive coaching.

She has held a number of positions, both clinical and managerial, in both the Irish and New Zealand healthcare settings since qualifying from University College Dublin. In addition she has held a number of pro bono non executive Board member positions over the years in the areas of professional regulation, professional bodies and hospitals.

She is a Council Member and Honorary Editor of the Health Management Institute of Ireland, producing the eJournal Health Manager and has been a long-standing member of the Editorial Board/Communication Working Group Board of the European Association of Hospital Managers.

How do you feel about taking over the role of EXEC E-i-C at HealthManagement.org?

It is an absolute privilege to take over the role of EXEC Editor in Chief at HealthManagement.org and I am looking forward to working with colleagues across Europe in the on-going development and delivery of this important journal for health managers.

What are your editorial aims for the publication and readers?

My first aims are to cover the key emerging issues for health managers, to learn from experiences across Europe and to provide a platform for health managers to promote, share and learn from each other in the different areas of health. I am, however, very keen to explore what health managers want from the publication, and would look to deliver on this.

What are your key areas of interest and research?

The professionalisation of the healthcare management discipline, healthcare leadership, corporate/clinical governance, and the development of high-performing teams.

What are the major challenges in your field?

Ensuring that healthcare managers are equipped, enabled and empowered to carry out their roles in an ever-changing, highly accountable and high profile environment.

What is your top management tip?

I can't pick only one, so if I can name two they would be:

Find your passion. Even in the toughest of times, if you are passionate about what you do, this will help to bring you through and keep you true to yourself.

Grow and develop people relentlessly. Denis Doherty, Senior Healthcare Leader, Ireland, made the following statement in 2000: "Your job as a leader is to identify people better than you and brighter than you and throw them past you". This has resonated with me ever since.

What would you single out as a career highlight?

Very hard to single out one highlight, but probably what I am most proud of is that there have been a number of occasions over the years when an individual, or team, with whom I have been working has excelled beyond what they thought was even possible. Their growth and achievements, and therefore their confidence to go even further, has always been an incredibly positive experience for me. In many ways, I would like to consider myself as a talent manager,

and uncovering hidden talent and ability has been a significant highlight over my career.

If you had not chosen this career path what do you think you would have become?

Difficult question, as I did not set out to be a health manager/CEO in the first instance. I have loved every role I have had, starting off my career on a clinical pathway and then moving into general management. A previous manager thought I had talents that would have made me a good lawyer. I do have a significant interest in people so maybe Human Resources or potentially occupational psychology. The main driver for me has always been that I am learning and constantly challenged in any role, and that I feel I am making a real difference. So far all the roles I have held have met those criteria

> “EVEN IN THE TOUGHEST OF TIMES, IF YOU ARE PASSIONATE ABOUT WHAT YOU DO, THIS WILL KEEP YOU TRUE TO YOURSELF”

What are your personal interests outside of work?

Family is a key part of who I am; I have two young children of 9 and 12 and a very supportive husband who has been the reason that I have been able to carry out the challenging role of a Health Manager. I am Chairperson of a volunteer Cardiac First Responder Group in my town, which is aligned with the Irish National Ambulance Service, to provide first response to cardiac arrest, chest pain, stroke and choking until the ambulance service arrives. Bringing local people together, many with no prior clinical experience, to deliver a high quality potentially lifesaving service to our locality is an absolute honour. I also make valiant efforts to get out running/exercising in the beautiful Irish countryside as much as possible.

Your favourite quote?

“Nothing in the world can take the place of Persistence. Talent will not; nothing is more common than unsuccessful men with talent. Genius will not; unrewarded genius is almost a proverb. Education will not; the world is full of educated derelicts. Persistence and determination alone are omnipotent. The slogan 'Press On' has solved and always will solve the problems of the human race.”

John Calvin Coolidge, Jr. - 30th President of the United States. ■

The Road Ahead

Value Based Healthcare and HIT

Hans Vandewyngaerde
President EMEA
Agfa HealthCare

It has been more than 10 years since Michael E. Porter and Elizabeth Teisberg published their seminal book *Redefining Health Care*, which laid down the foundation for the revolutionary and evolutionary concept of Value Based Healthcare (VBHC).

Both starting and ending with the patient experience, VBHC has since become a driving force in the economic, clinical, commercial and R&D facets of healthcare. Yet it has manifested in very different ways around the globe.

Health Information Technology (HIT) is critical to the continuing implementation of VBHC. HealthManagement.org spoke to Vice President EMEA Agfa HealthCare, Hans Vandewyngaerde, about the exciting possibilities HIT offers for the development of VBHC. As he explains, no-one would have imagined a decade ago the far-reaching role of HIT in "making the world a safer place".

What are the top challenges facing IT in VBHC?

While VBHC has been widely accepted around the globe, the way the "value" is measured differs markedly from one country to another. But in all cases, it requires a shift of focus from cost and return on investment (ROI), towards patient outcomes.

There is an enormous opportunity for HIT under the VBHC umbrella. Fundamentally, HIT enables the implementation of VBHC, and governments and hospitals must make significant investments.

By its very nature, VBHC is forcing integration across healthcare, requiring us to look towards a transversal rather than a silo model for information and HIT. Departments must work with other departments; hospitals must work with other hospitals and with GPs; care must be integrated.

VBHC requires integration, and integration requires HIT interoperability. Typically, each specialty or department has its own software, which isn't integrated into the hospital's overall system. As healthcare providers consolidate, this situation only gets more striking. For example, we are working with a healthcare group that uses more than 900 different software products. We are aiming to help them reduce this to 20 or 30.

It is important to keep in mind that the interoperability challenge goes beyond its technical aspects: when a physician – or anyone else for that matter – has become comfortable with a certain software, a certain interface, they will likely initially resist a change, even if it will lead to better integration. So together with our customers, Agfa HealthCare has to demonstrate and communicate to the physician how the new system will benefit patients and staff. At the Human Resources level, therefore, the emphasis will be on change management and collaboration.

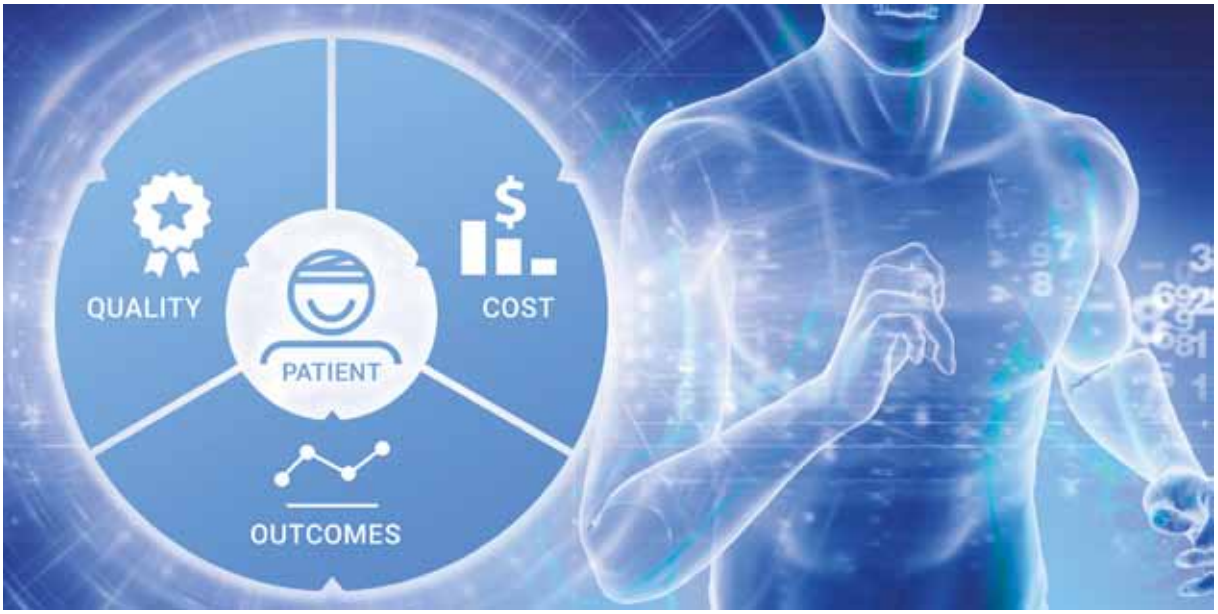
On a financial level, some GPs and hospitals worried that they will "lose control" of the patient. It will certainly have a huge impact on reimbursement models! But ultimately it will help all stakeholders, and reimbursement models will follow or should initiate the change. It isn't all clear yet, though. We have spoken to hospital CEOs who say that the transversal model will not happen, and to others who say it is only a matter of "when". Big Data presents another very significant challenge for HIT. Hospitals and healthcare groups need usable applications that capture, aggregate and integrate patient data, not only from a clinical perspective, but also for standardizing work processes and enabling hospitals to handle an anticipated workforce shortage.

> "THE HIT SYSTEMS OF TOMORROW WILL ENSURE THAT SYSTEMS TALK TO ONE ANOTHER. INTEGRATED CARE AND ARTIFICIAL INTELLIGENCE WILL STRENGTHEN AND SUPPORT ONE ANOTHER UNDER THE VBHC UMBRELLA; THE PATIENT AND THE INDUSTRY WILL BE INVOLVED IN AND BENEFIT FROM THIS PROCESS"

Can you provide examples of how the roll-out of Agfa HealthCare's HIT has contributed to developing VBHC processes?

We are contributing with platforms that address healthcare needs across three main domains.

Our Enterprise Imaging platform creates a true imaging record for every patient. It brings all of the patient's images into the Electronic Health Record (EHR), no matter where they were made, or with what device or modality. The images and linked data are instantly accessible anywhere in the hospital, or even the regional network. With this "all images anywhere, anytime" approach, Enterprise Imaging speeds up



diagnosis and enhances patient care.

Then there is our Enterprise Content Management platform (HYDMedia), which captures the patient data, manages it, and makes the patient records available where they need to be, with search, retrieval, access and sharing of all types of information. It also supports the healthcare enterprise to manage business operations workflows.

Thirdly is our Integrated Care platform, which enables healthcare enterprises to harness the power of the data existing in their systems and platforms, to support patient healthcare management and access to patient health information beyond the hospital walls.

Across all of this, we are committed to educating clinicians about HIT's role in patient care, and on offering solutions that enable doctors, patients and even governments to talk to one another in a way that ultimately leads to improving healthcare.

How will Artificial Intelligence (AI) impact the future of VBHC?

AI has a huge role to play as we move towards VBHC. It is widely thought that 2030 will mark the year when the singularity point will be reached, that is, the creation of "superhuman" intelligence that surpasses the human brain.

There is no need to be afraid of this. Human and ethical considerations must be part of the AI process and, indeed, we expect the technology to "augment" rather than "replace" in healthcare. Thus, it will never fully replace clinicians but will instead free them to spend more time with patients and complex cases.

AI will enable the capture of and access to data, the input of data into expert systems and the transformation of this data into knowledge and action. Its role will be clinical, financial and analytical. To give one example, healthcare facilities will be able to analyse where patients come from and build a strategy around this.

Is the definition of VBHC evolving and, if so, how does Agfa HealthCare monitor and keep pace in order to offer the best HIT solutions?

The definition of VBHC will not change; developments are more about how it will be implemented and monitored. It is important to note that this will differ from country to country. In some places, the emphasis will be on hospitals; in others it will be on payers.

To ensure that our solutions continue to meet real needs in this new healthcare model, we educate our R&D staff on VBHC, to keep them from focussing solely on ROI. They learn about Key Performance Indicators (KPIs) for VBHC, so that they can develop software with these in mind.

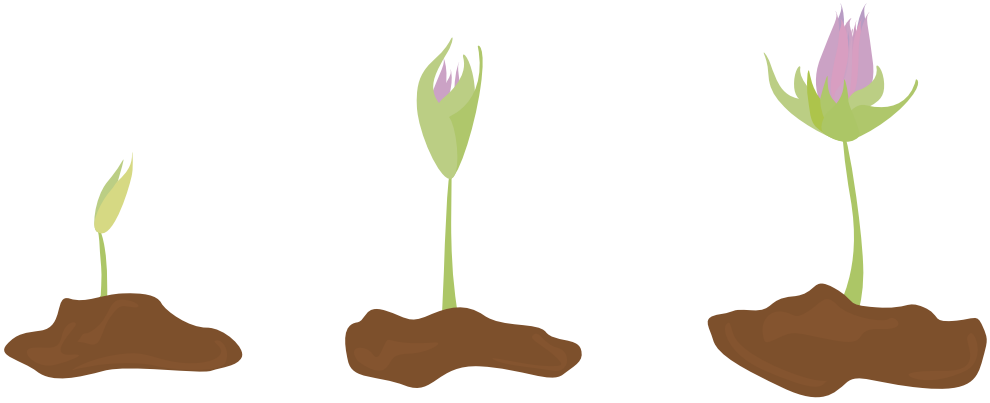
The HIT systems of tomorrow will ensure that systems talk to one another. Integrated care and Artificial Intelligence will strengthen and support one another under the VBHC umbrella; the patient and the industry will be involved in and benefit from this process.

Agfa HealthCare will continue to focus on developing and offering solutions that support healthcare to face and to leverage the digital realities of our world today and tomorrow, to make the world a safer place, and our lives healthier. ■

DISCLOSURE:
"Point of View" articles are part of the HealthManagement.org Corporate Engagement Programme

Maturity Makes Great Leaders

Five stages or thresholds can be distinguished as leaders mature.



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There is a pressing need for intelligent leaders who are able to deal effectively with today's challenges and demands—and those of the future. But intelligence alone is not sufficient. It is simply a "blunt" tool that enables leaders to get things done. Too often leaders are intelligence giants but maturity dwarfs. This has far reaching, detrimental consequences.

Leadership maturity is a leader's ability to engage consistently with him or herself, others and the world by being:

- Relevant: maturity is time, place and person dependent. It demands the ability to render wise judgments about what is appropriate in different settings
- Productive: constructive contributions are made, and something meaningful and value adding emerges.
- Uplifting: interactions are positive, fulfilling and enriching

Acquiring leadership maturity is a lifelong journey that comprises successive stages. At each stage, leaders will develop a corresponding identity. Depending on how they process life events and experiences, they may spiral upwards to greater maturity or downwards to lesser maturity. Or, they may get stuck for the rest of their life at one level.

Leadership Maturity: A Lifelong Journey

Physical and physiological maturity proceeds relatively automatically as one ages. But psychosocial-spiritual maturity is an arduous, open-ended and multifaceted journey of "ripening" holistically. It is fraught with unpredictability and ambiguity.

Five stages or thresholds can be distinguished in the process of maturation. A higher stage reframes a lower stage and successive stages may overlap. Each stage typically lasts for ten years. So, all other things being equal, leaders only reach full maturity in their late 40s or early 50s, if ever.

Migration to a new stage also depends on successfully resolving the challenges and issues unique to a stage. Unresolved challenges and issues are carried over into adult life as one ages, where they remain active as baggage because the leader has remained stuck at the stage.

Building inter alia on the views of Steinberg and Cauffman, Cook-Greuter, Du Toit, Loevinger, and Rooke and Torbet, here are the five successive maturity stages.

The Five Stages of Leadership Maturity

Stage 1: Confident Ability

In this stage a prospective leader develops a positive, healthy self-image and self-confidence, along with a firm belief in a basic "I can" competence.

He explores and discovers what his abilities are and how to apply them; how to satisfy his needs constructively; how to handle his emotions appropriately; and what is right and wrong. He also builds the courage to take risks confidently.

At the end of this stage the leader has an "identity of self-worth".

But if a person gets stuck at this stage, he will have the baggage of seeking constant approval from others because his self-worth has not been affirmed. He will lack confidence and will continuously be seeking

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security and predictability. He may also have an unclear sense of what is right and wrong.

One example of such "stuckness" is Alexander the Great, who asked on his deathbed: Did I meet with your approval, father?

Another is American automobile executive Lee Iacocca who, according to psychologist Carol Dweck, sought the ongoing approval of Henry Ford III while at Ford Motor Company in his burning desire to emulate Ford.

Stage 2: Egocentric Satisfaction

Here the prospective leader gains the insight that she is embedded in relations with others and the world. She realises that she must fend for herself, but that she needs others to satisfy her interests and needs. But she is only driven in reaching out to others to satisfy her own, immediate needs. She is in competition with others in a win-lose equation of "me first" at all times.

Because she is driving her own agenda, the prospective leader questions all rules and authority that may prevent her from achieving her ends. Though she acts manipulatively and opportunistically to get her own way, she may also ostensibly conform if this will serve her self-interests.

At the end of this stage the leader has an "identity of consumption". A leader stuck at this stage will have the baggage of always single-mindedly striving to satisfy her personal needs and interests, regardless of costs and circumstances.

Examples of "stuckness" here are the greedy Wall Street bankers who caused the 2008/09 global recession, aptly illustrated by the "Wolf of Wall Street", Jordan Belfort.

Stage 3: Personal Differentiation

Here the leader realises that, to get anywhere, he must stand out in his interactions with others and the world. He seeks to find his own voice and to distinguish himself as unique, with invaluable, rare talents and abilities.

He believes and claims that others and the world must be overjoyed that he honours them with his invaluable contribution. Everyone and everything is measured against his set of personalised standards.

At the end of this stage the leader has an "identity of uniqueness". The leader stuck at this stage will have baggage of proclaiming ad nauseam that he is the indispensable saviour of the world. Examples include Albert Dunlop, the US "chain saw" turnaround specialist, who repeatedly stated "I'm a superstar," and Kenneth Lary and Jeffrey Skilling at Enron.

Stage 4: Communality

Here the leader realises that she cannot make her unique contribution without the help of others if objectives, dreams and legacies greater than herself are to be pursued and achieved. She realises she must move from placing "me" at the centre of everything, to placing "us" centrally. This is about finding win-win ways in which everyone's abilities and contributions count equally. It is about the pursuit of a shared future for herself and others. There must be shared accountability for everything and everyone.

At the end of this stage the leader has an "identity of envisioning". The leader stuck here would carry the baggage of pushing for the parochial realisation of organisation-specific dreams, while ignoring the bigger context and dreams of other organisations, communities and greater society.

Examples in this case would be business leaders who have built massive empires with the attitude of "business is for business", like Jack Welch of General Electric, Steve Jobs of Apple, and Lou Gerstner of IBM.

Stage 5: A Higher Calling

In this stage the leader moves beyond shared but narrow, organisation-specific objectives to higher purposes and meanings. He searches for what lies behind shared objectives, dreams and legacies. It is about finding the final "why" and "whereto" to be served by the shared pursuit.

He has a growing transcendental consciousness infused by truth, beauty and righteousness. It is, for him, about the common good for all humanity. It is about timeless, multifaceted, meaningful answers instead of one-dimensional, time-restricted, pragmatic solutions.

Posing the right questions comes first, followed by finding the right answers. In his pursuit no assumptions, beliefs and values are sacred. Paradoxes and dilemmas are accepted, or integrated at higher and deeper levels of being or becoming.

At the end of this stage the leader has an "identity of meaningfulness". This is the highest form of leadership authenticity and maturity.

Examples of leaders functioning at this stage, past and present, are Bill Gates through his global humanitarian foundation, as well as political leaders Nelson Mandela, Mahatma Ghandi and Martin Luther King.

There's no doubt that humanity needs intelligent and mature leaders with the identity of meaningfulness inspired by a higher calling if we are to secure a desirable, sustainable future for all. Our continued survival is at stake. ■

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SPECIAL EDITION ON E-LEARNING / VOLUME 17 • ISSUE 2 • 2017 ISSN = 1377-7629

Special edition on e-learning from Siemens Healthineers in collaboration with HealthManagement.org

The importance of continuous education in healthcare

Offering healthcare professionals high-quality continuous education means leveraging excellence in healthcare performance.

The healthcare industry is demonstrating high growth rates in both developing and developed regions around the world. The Bureau of Labor Statistics (BLS) projects that the healthcare and social assistance sector will grow at an annual rate of 2.6% between 2012 and 2022, adding five million jobs.[1] But will the people filling these vacancies be the highly skilled and motivated staff members the healthcare sector is longing for so urgently? According to a PWC survey, healthcare CEOs see availability of skilled staff as one of their top five key risks.

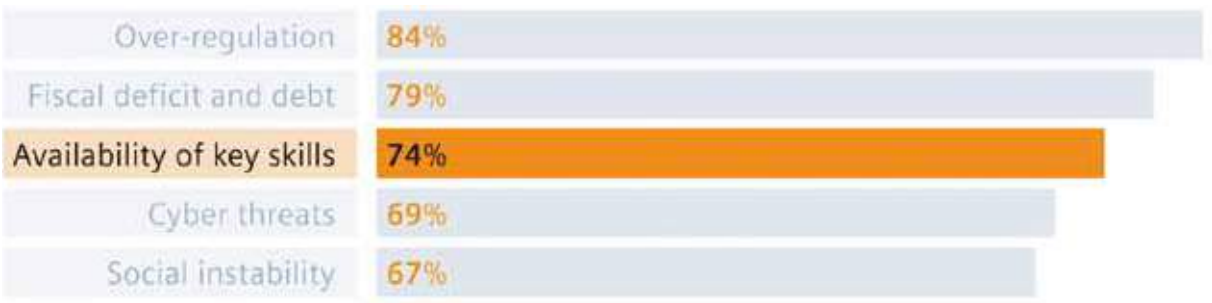
Continuous education in healthcare is key

Even though 75% of CEOs worldwide say that a skilled, educated, and adaptable workforce should be a government/business priority[2], there's a growing lack of experienced and well-trained staff in the healthcare environment in many regions around the globe. To counter this trend, there's a need to raise awareness that education doesn't come to an end once people are in the middle of their professional career. Because the healthcare industry is continuously evolving, technologies considered best practice today can change drastically in just the span of a decade. That's why care providers have to regularly keep up with new techniques and technologies and expand their knowledge and skills – which means continuous education is not a nice-to-have but an absolute necessity for any healthcare professional who wants to provide high-quality patient care.

> "WITH ACCELERATING ADVANCES IN HEALTH INFORMATION AND TECHNOLOGY, PHYSICIANS, NURSES, AND OTHER HEALTH PROFESSIONALS MUST MAINTAIN AND IMPROVE THEIR KNOWLEDGE AND SKILLS THROUGHOUT THEIR CAREERS. THAT'S THE ONLY WAY TO PROVIDE SAFE, EFFECTIVE, AND HIGH-QUALITY HEALTHCARE FOR THEIR PATIENTS."

Dr. med. Janina Beilner,
Vice President Application Services, responsible for global training and education at Siemens Healthineers Services

Top five key risks



Source: www.pwc.com/gx/en/ceo-agenda/ceosurvey/2016/healthcare.html last visited November 28, 2016

Training and retraining as a top priority in staff retention strategies

The average cost of replacing an employee amounts to fully 20% of the person's annual salary. In the healthcare industry, employee turnover is especially costly: as the rate of turnover increases, the quality of patient care significantly declines. Based on "Four Employee Retention Strategies in Healthcare," Jami Cooley https://www.ceu360.com/4-employee-retention-strategies-healthcare/ last visited November 28, 2016

Highly skilled and educated staff always pays off

The advantages of investing into continuous education are obvious: highly skilled staff, high staff retention, magnificent reputation, optimized financial performance, better patient outcomes, less medical malpractice lawsuits. The disadvantages are equally obvious: By not investing into their personnel, medical institutions risk losing their experts to other employers. And losing out on valuable knowledge gains can lead to inefficient system usage, frustrated users, and dissatisfied patients – and consequently to higher costs, wasted time, and image loss. So this raises the question: Why isn't every medical institution integrating continuous education into their everyday quality landscape? Maybe because continuous education is still mentally linked with employees being away, course fees, travelling and accommodation costs, and more.

The concept of learning is changing

The era of pure classical classroom trainings is definitely over. Based on lectures, the traditional approach involves time away and means that not every staff member has access to the same learning content. Our time is the era of flexible e-learning for continuous education. It allows the entire staff to gain the same level of knowledge directly at their workplace – and enables every member to deliver safe, effective, and high-quality patient care.

> "IT'LL ALLOW ME TO CONTINUALLY ASSESS AND GUARANTEE THAT EVERYBODY IN THE LAB, 24/7, ALL THE DIFFERENT SHIFTS AND STAFF LEVELS – WHETHER FULL, PART TIME OR PER DIEM EMPLOYEES – HAVE THE SAME LEVEL OF COMPETENCY."
>
> **Marilyn A. Leonard,**
> ASCP Supervisor, White Plains Hospital. White Plains, NY, USA

Solving time and cost issues with e-learning

We all know that the medical profession is knowledge-driven and staying up to date is crucial. But we also know that it's a very busy environment and time for education is scarce. For many hospitals and practices it's also a challenge to send employees to training centers because of budget cuts and understaffing. Sending employees to attend training courses for a few hours or even days can make work planning a challenge. And with colleagues having to stand in, it also creates overtime. E-learning helps institutions of any size solve these issues, by allowing caregivers to train more efficiently at their convenience and without having to leave work – also curbing costs.

The statements by Siemens' customers described herein are based on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist (e.g., hospital size, case mix, level of IT adoption) there can be no guarantee that other customers will achieve the same results.

Learning technologies used for 2014

Source: https://elearningindustry.com/ elearning-statistics-and-facts-for-2015 last visited March 22, 2017

E-learning fits today's learning and information needs

It's a fact that people nowadays are very mobile and spend more time online than ever before – and this lifestyle trend is growing. That's one of the reasons e-learning is a booming industry. Consequently, the e-learning market in healthcare will also continue to grow. Because when it comes to learning and information needs, medical professionals (like everyone else) will first turn to online platforms – providing the content is valuable and up to date.

E-learning is more effective than other forms of trainings

Continuous education with e-learning can help keep learners' interest and motivation up because the learning units can be enhanced with videos or interactive elements. These can be paused and

E-learning: a booming industry

Markets and Markets forecast a boom in the global smart education and learning market. North America is expected to be the largest market in terms of market size, while Europe and Asia Pacific (APAC) are expected to experience an increase in market traction during the forecast period. APAC is also expected to experience a high growth and adoption rate in this market.
Source: http://www.marketsandmarkets.com/PressReleases/smart-digital-education.asp last visited September 8, 2016

continued later on; or repeated until the participant has fully grasped its essential. Latest evidence also suggests that e-learning is more efficient in most cases because learners gain knowledge, skills, and attitudes faster than through traditional instructor-based methods – translating into improved motivation and performance.[3]

Various learning technologies for e-learning

The learning technologies used for e-learning are diverse. They include webcasts, application simulation tools, learning content management systems, performance support, mobile applications, podcasts, and more. They're all well received by the users, and employers are more and more inclined to make use of the latest technological developments. In fact, more than ever, learners and companies are turning to e-learning courses and online training events to achieve their personal and professional goals.[4]

Staying on top of chances and advancements – with e-learning

One way to always stay on top of the rapidly changing and growing healthcare market is to implement a business strategy that maximizes the synergies between life-long learning and workforce productivity. Research has shown that e-learning proves to be an excellent way to achieve quality results in a short timeframe. Learning which is delivered online, within the context of continuous education, should therefore be considered a strategic part of training and education plans for healthcare professionals. ■

In a nutshell:
Learning is a continuous process, not an episodic event.

Continuous learning is key to success

The healthcare industry is a very competitive environment, and clinical institutions have to deliver an ever higher quality of care – while staying within budget. A skilled and motivated staff that's always up-to-date with the latest developments in techniques and technologies is a huge competitive advantage. According to Deloitte's Human Capital Trends survey from 2016, senior executives see learning on the 5th place within their top 10 trends – with 84% of the responders saying learning is very important/important for them.[5]

E-learning ...

- keeps staff up-to-date regarding the latest developments
- has a positive impact on healthcare organizations by helping them be consistent with legal demands and new patient populations through highly educated staff
- reduces training budgets and costs
- makes human resources, recruiting, selection, and onboarding more manageable
- is a modern learning approach, based on the latest technologies

Download or request free copies of our white papers on continuous education and e-learning at
healthcare.siemens.com/education/pep

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[3] http://www.formatex.info/ict/book/147-153.pdf last visited September 8, 2016

[4] https://elearningindustry.com/elearning-statistics-and-facts-for-2015 last visited March 22, 2017

[5] Deloitte Global Human Capital Trends 2016: Graphic: Deloitte University Press, DUPress.com

PEPconnect, the e-learning experience

PEPconnect is an online platform from Siemens Healthineers, dedicated to the continuous education of healthcare professionals. It empowers them to engage in personalized, competency-based education that helps improve efficiency, job satisfaction, and healthcare outcomes. It can be tailored to meet varying skill levels and professional goals. Videos, webinars, interactive elements, and more turn continuing health education into a daily experience for every user.

PEPconnect simply fits

Healthcare employees are very hard-working and have lots of daily work-related stress. Under these circumstances, finding time for further education is not easy. Being accessible anytime, anywhere, and from any device, PEPconnect offers a high level of training flexibility – which is well received with users of all skill levels around the world.

The current offering

PEPconnect currently encompasses 7,000 learning modules for laboratory diagnostics and diagnostic imaging. Learning units are available in up to seven different languages – with more units and languages to come.

Find out more about PEPconnect at
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Hospital Finance

Managing in the Current Financial Climate

Alternative financing at hospital level can make a difference.

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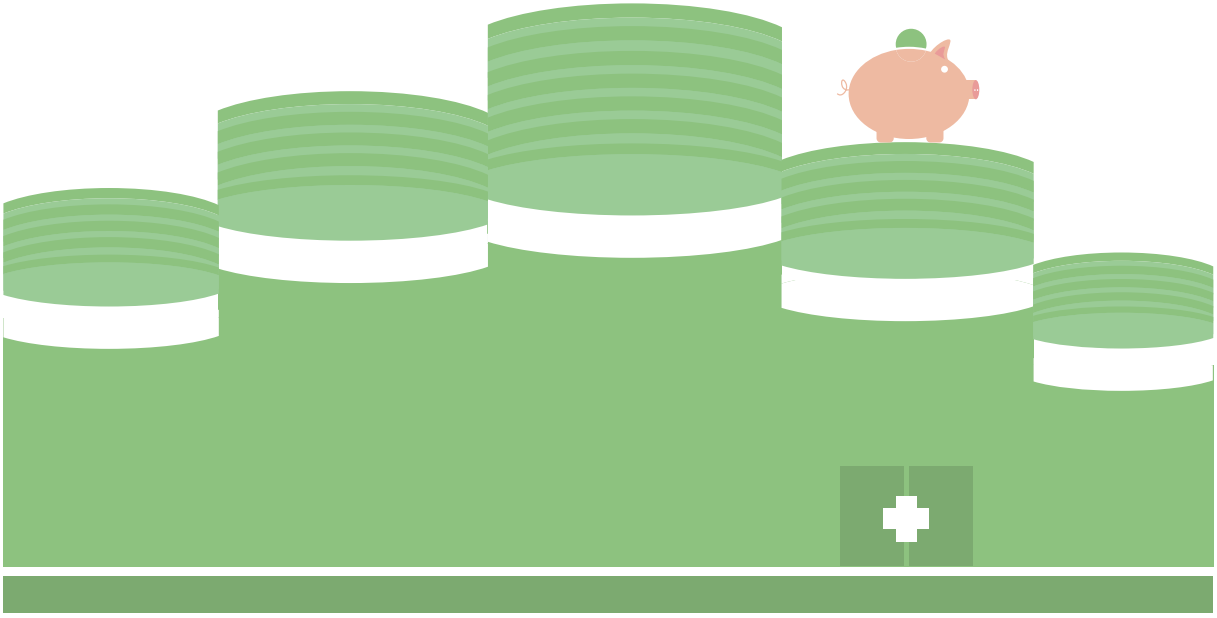

In an environment of budget cuts and increasing pressure on healthcare services how does your hospital cope?

In Belgium, and also I think globally, governments and other payers will not be able to keep up with expensive needs, such as an ageing population, personalised medicine, new anti-cancer drugs etc. There are various possible answers. You can ask for more money, but this is not our approach because there isn't any. So there are three levels where you have to intervene. The first is the macro level—the health system, and you have to play by the rules of that system, which is a national health insurance system in Belgium. Second is the meso level, the hospital level. There we can make a difference. Around six years ago, we started a programme of alternative financing. We look for money outside the typical channels of hospital funding, and it stands on three pillars. First, we started a programme in international patient care and internationalisation at large. Secondly, we began a programme to increase the valorisation of our intellectual property, such as establishing spin-off companies. We have a very powerful and sophisticated Electronic Patient Record, which we are valorising in our country now. The third pillar is professionalisation of the fundraising programme. This gives us some 'oxygen' and extra income to cope with the meso level. The micro level is the doctor-patient relationship and care in itself. We can find many more efficiencies in our healthcare delivery system. Within our hospital we allow for various managerial tactics to reach our care goal. We have some departments, which we treat as if they were small or medium enterprises. We have departments in which we allow decentralised self-steering governance. We have other departments where we have tried to materialise clinical pathways so that form follows function. Finally, we have other departments where we allow self-organisation in holacratic systems. A variety of measures, not a single answer, will solve all the financial questions. It's a multiple approach.

A few years ago we issued a financial action plan in the hospital. We invited all the medical and non-medical departments to establish an action plan to achieve 3% improvement in margin within three years. They had total liberty to work on costs or income, or preferably both. At the end of three years, we expected a 3% margin increase. In Belgium a hospital has an average margin of between 0.5 and 1%, which is

very low. Every year the government cuts away this margin, so we wanted to have some kind of reserve. This was a hospital-wide initiative with a lot of departmental freedom. There were departments that were really focused on cutting costs, whereas others were more focused on intelligent growth and revenue, and many focused on both. If you have a really concrete plan in your hands, with a business case behind it, you can make your investment decisions. Staff had to think really hard to propose things and always in the context of an increase in margin. The main drivers were "revenue before cost" and "better before cheaper".

Would population health measures, such as fighting the obesity epidemic, play a role in helping to contain healthcare expenditure?

Obesity is a public health issue on the macro level, and as a hospital, we play no active role. This is one of my criticisms of our current system: we talk about healthcare but actually we are doing 'sick care', and we are talking very little about healthcare and public health. For instance, in Belgium probably only 2% of the total budget is spent on prevention and 98% is spent on cure, which is kind of a strange business model. And 80% of what we spend, we spend during the last six months of life. I would much prefer a paradigm shift, to change to a healthcare system and not to a sick-care system, but this is politics and it's not my job!

The ageing population is already putting pressure on finances, and that will increase. What is your vision for running a hospital in a cost-efficient manner?

The major challenge for the future will be human resources, to find people. If you look at the numbers in 2045—that's a year of interest to me because then I will be 85—there will be 600,000 people aged 85+ in Belgium, compared to 120,000 or so now. There will be a huge population of very old people with probably a number of chronic diseases, and at the same time in our country a decrease in the number of active people. Nowadays there are four active people for one retired person, and that will change to 2.3 active people per retired person, and I really wonder who will take care of me. I have the impression that nobody is really working on this, at least in our country.

Patient empowerment is obviously important, and can improve patient compliance, initiative and attendance, with the potential to improve outcomes. Does it have a tangible benefit in terms of reducing costs?

I can only speculate, because I am not aware of any hard data on this. I don't look at this in terms of costs, but rather in terms of an intuitive feeling that if you increase what you call empowerment, so that the patient is a partner in the management of his or her problem—and I think that there is a demand for that at least in some parts of the patient population—then I think it's logical that this would increase outcome and speed up recovery. But you have to look at this in a very nuanced way, because from my clinical practice in oncology I also know that there is a significant part of the population that specifically does not want to be empowered.

> "WE CAN FIND MANY MORE EFFICIENCIES IN OUR HEALTHCARE DELIVERY SYSTEM"

There is also another form of patient empowerment, which I think is very much neglected. At this hospital I organise an evening every two to three months when we invite patients to have dinner with us. We close the doors and I just ask them their opinion about our hospital—what we do well and what could be better. I challenge them to tell me things I don't know and that nobody dares to tell me. I just ask them for their opinion. This is a primary source of information, which others usually don't use. I know very few hospitals that actually ask their patients what they should do to improve their experience. With very little effort you can make a world of difference for patients who have to be in a hospital, and a hospital is not the most joyful place to be. We involve patients in changing that.

Are there any other methods or tactics that you use to engage with the patient?

In Belgium there are around 100 hospitals, and if you look at the baseline of every hospital, it's always the same; the patient is central. We have to think about the unique selling point (USP) of our hospital: are we looking to be different? And if we want to be different, in what way do we want to be different? What we work hard on here is the culture of the relationship amongst ourselves and between us and the patients. A point we focus a lot on is that we really want to welcome the patient in an empathetic, warm, friendly and polite manner. This sounds very obvious and very low profile, but it really makes a difference. I've worked in 15 hospitals in my career and every hospital is different in terms of atmosphere, culture, ways of doing things or talking to each other, and in hierarchical organisation. This is reflected in the way you manage patients. You cannot

avoid that, and that is why I think this has to come from the top. You have to lead by example and show that this is very different and very important for the patient. We also try to select people on their ability and their capacity to be empathetic. For me that's perhaps the most important thing and much more important than apps or other gadgets.

Is there particular pressure in trying to maintain a world-class reputation at UZ Brussels, for example the Centre for Reproductive Medicine, in the context of budget cuts?

Not so much in the context of budget cuts, but in trying to maintain very high standards. We try to treat the Centre as if it was almost an autonomous small-medium enterprise. We allow them to manage their own business, and our role is to create the framework so that they can still use the success formula of their centre. This is focused on research and a very powerful translational mechanism where they bring their research very quickly to the bedside and have a culture of continuous improvement and innovation. We as management should not bother them with managerial issues or the '27th budget cut' of the government. We try to keep those things apart. It all depends on the people. If you are able to keep and attract the best in their field, and you try to give them liberty in the framework to do their thing, which they are very good at, I think success will follow automatically.

Marc Noppen, MD, PhD, is the Chief Executive Officer of the Brussels' University Hospital UZ Brussel. He is a pulmonologist by training, with a PhD in Health Sciences. He has authored or co-authored more than 145 scientific peer-reviewed papers and book chapters, and was visiting professor at various universities and university hospitals (Boston, Montreal, Lille, Perth). He has additional degrees in Pharmaco-economics (University Antwerp) and management (INSEAD). He is associate professor at the Vrije University Brussel, guest professor at Vlerick Business School Leuven-Gent in Strategic Hospital Management, and serves as a Director in a variety of academic and business-related Boards.

UZ Brussel is a university hospital, closely associated with the Vrije Universiteit Brussel (Free University Brussels), notably the Medicine and Pharmacy Faculties. The hospital has 700 beds, and each year admits more than 25,000 patients and treats 400,000 outpatients, both national and international. As well as patient care and clinical excellence, it has a teaching mission and conducts scientific research.

Do you feel that your strong clinical background helps you in your role as the CEO?

Absolutely, and there has been research done about this. There was a paper recently in the *Harvard Business Review* on why the best hospitals are managed by doctors (Stoller et al. 2016). My background as a doctor really helps me, because I know the business and I speak the same language as my colleague doctors. If you look at it from another angle, they can't fool me! Also, I am a doctor so I can say this: the average ego of an MD is quite big. I think it's larger than the average, and to manage a medical business without being an MD is I think a handicap in my experience and in what I see around me. Although it's not black and white; it's not a yes or no. You always have to be very careful with these statements, but I would say that, on average, it helps. More important, however, are the people in your team.

What is a problem for you in terms of managing hospital finances?

In my hospital, which is a university hospital, one of my biggest frustrations is that because of our financing system there is not enough time—this means money—to allow our doctors and scientists to perform their academic duties and interests. They are working here because they want to work in the university environment where they can do research, teaching and training. However, in the Belgian system, there is way too little financing for this. It's all about time, and hence money. It is a big frustration that I have to almost force these people into a type of medicine that they specifically did not choose. This, of course, causes tensions and a lot of debate.

As for size, it also depends on the financing system, but I think everybody will agree that a hospital with between 400 and 800 beds is an ideal-sized hospital, at least in the model of the hospital as we know it today. Maybe in 20-25 years' time the typical hospital will look completely different and will be more like a potpourri of different business units. For me, another unsolvable problem is that in a hospital there are at least seven different business processes going on, which you have to run with the same people, in the same building, at the same time. In my opinion, it's impossible to do everything right, so you have to make choices again. But that's another debate. ■

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Transforming Commissioning to Do More With Less

Making Taxpayers' Money Go Further

How can health and social care commissioners in England reinvent the tools of their trade to make funds go further?

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In England, health and social care commissioners compelled to save money often feel little choice but to reach directly for frontline services. Their various attempts to do so are charted by hostile reports of restrictions on in vitro fertilisation, rationing of hip and knee operations, and shrinking social care packages. On a grander scale, National Health Service (NHS) sustainability and transformation plans (STPs) describe intentions to reduce bed numbers and merge services. Alongside this, however, the most imaginative commissioners are also seeking long-term financial viability closer to home, through a radical transformation of the art of commissioning. Such changes throw into sharp relief how in the future people should receive the maximum amount of relevant high-quality care for each pound available.

A Long Run-Up, With Lift-Off Now Required

The four crucial elements of this story are the fusing of health and social care budgets and commissioning teams, followed by radical new approaches to contracting and market shaping. The first ingredient, which has been around for a long time, gained impetus through the Better Care Fund (BCF), and is now being extended through more ambitious local agreements, such as in Manchester and (most recently) Hackney. At the same time, many well-established joint commissioning teams cover service areas relevant to both Clinical Commissioning Groups (CCGs) and councils. These pooled budgets and integrated teams can help to control costs by making commissioners more conscious of, and able to address, system-wide spending rather than just individual provider funding. By bringing money and commissioners together, they can also combat the shunting of provision and costs between community services and social care that delays or denies the most appropriate support for some people

Yet pooled budgets and joint working, by themselves, often have little impact on the bottom line, especially as demand races ahead. This is shown by the failure of the

national BCF programme to deliver planned savings, as the National Audit Office recently reported (NAO 2017). Rather, their true potential lies as prerequisites to a more complex series of changes. This means overcoming the maze of contracts and fragmented supply chains that drive up costs as commissioners lose control of their markets. It also presents an opportunity to assert the primacy of outcomes over outputs.

From Nought to Lift-Off, in a Single Leap

This can be seen through the story of a health and care system that PA recently supported to design and kick off a major learning disabilities (LD) transformation programme, to supplement the national requirements of the national Transforming Care programme. Combined annual CCG and council costs for LD care had jumped by £11m (15%) in just two years. Without intervention, the commissioners faced adding another £14m to the bill each year by 2020. Strikingly, most of this would come from increasing costs per user rather than more people needing care.

Senior commissioners in the CCGs and council quickly embraced the logic of a pooled budget, as a technical and symbolic means of asserting shared ownership of runaway finances and uncertain value. In this they joined the quarter of areas in England that have taken this approach (Public Accounts Committee 2015). They also set about launching a joint LD commissioning team.

But they understood that these steps alone would not address the fragmented and uncontrolled market that was really driving increases in costs; likewise, they would have no impact on the disjointed supply chain hampering efforts to improve quality.

These commissioners therefore made an additional bold move, informed by the PA team's experience elsewhere and reflecting some of the most forward-looking thinking now circulating amongst their peers: to champion the appointment of a prime provider for all LD services in the county, through a capitation-funded, value-based contract. It is here that the radicalism kicks in, not just in the extreme jointness (a single commissioning voice expressed through a single budget and a single contract) but in its crisp appreciation of what, in future, commissioners should and should not try to do.

Boiled down to its fundamentals, this approach means that a single provider (or group of providers forming a new organisation) will assume financial and clinical responsibility for all LD provision. This provider will, in turn, act as a system integrator, constructing the pathways and incentives required across the rest of the market—its subcontractors—to deliver the user outcomes specified by the commissioners. A growing portion of the prime provider's contract payment will be based on the achievement of these outcomes. The prime provider also bears risk for over-spending and retains part of any savings secured through efficiencies. Over time, some functions destined for the joint commissioning team—such as assessment, review, and brokerage—will logically transfer to the prime provider, as processes more effectively executed within a provider organisation working to a fixed budget and tasked with maximising outcomes.

To what end? The purpose is to assert the power of commissioning to work most effectively at the level of the whole population group, setting outcomes and the total budget through which they must be achieved, and managing both against a single point of responsibility. At the same time, commissioners are freed from micro-management of the local market to concentrate on dealing with strategic risks and opportunities, such as the growing complexity of need, demographic and social change, and regulatory uncertainty. This work is frequently squeezed out by urgency of the operational level at which so much commissioning effort is now expended. The point is to enable the commissioners to become the masters of their market—and the outcomes it delivers—rather than, as is sometimes the case, subservient processors of its invoices.

It is also an acknowledgment of what commissioning, particularly of out-of-hospital services, is largely failing to achieve in its current form: the management of a complex and fragmented supply chain in a way that imposes cost discipline and cultivates consistent quality improvement. This work doesn't go away, which is why staff flow to a prime provider, but this model enables it to be done from within the market—driven by all the right incentives—rather than at one step removed.

It also creates the potential to drive efficiency by constructing a market with the incentives to apply its own cost restraint: up to £40m in this system over a five-year contract, against the current spend trajectory, even after sensible allowances for natural growth in costs. This is a big attraction for cash-strapped commissioners, especially in the care sector that the Local Government Association (LGA) has shown is the hardest from which to extract savings (LGA 2016).

The Even Bigger Picture

This is just one example of a gathering, but not yet general, trend for commissioners to redefine their role. It is also a partial example, focused on a single pathway, as with similar programmes for musculoskeletal services (Bedfordshire), mental health (Lambeth), and older people's services (Salford). In each of these cases, commissioners have sought to impose financial rigour and improve outcomes through a single contract with a prime provider, a prime contractor, or an alliance.

The new care models described in the *Five Year Forward View* (NHS 2014) take this much further, collecting wider service portfolios within unified contractual arrangements.

Dudley CCG, for instance, has now issued its proposed 15-year outcomes-based contract for a single entity (rather than the current 177 local providers) to be responsible for health, social care, and public health services for more than 30,000 people, valued at over £200m each year. The entity might also assume various CCG functions, including financial management, service redesign, and medicines management. In this way, the CCG will retain accountability for strategic commissioning—deciding the outcomes that providers need to focus on and the budget available—whilst the single provider entity will be responsible for operational commissioning, which means deciding, within the overall budget, who can best deliver the processes that maximise the specified outcomes.

Meanwhile, some STP footprints, such as Frimley Health, Lancashire and South Yorkshire, are moving even further to whole-population accountable care systems. These, declared Simon Stevens, CEO of NHS England, could effectively dissolve the historic purchaser/provider split by bringing together strategic and operational commissioning. Of course, providers have been key to driving these most ambitious new models; in this respect, the reinvention of commissioning they represent is as much of a provider achievement.

As ever with innovation, not all has gone smoothly. The failure of the Cambridgeshire and Peterborough older people's contract provided a salutary lesson about misunderstanding risk and excessive optimism about overnight efficiency savings. Staffordshire's ten-year, £690m cancer contract also had a difficult gestation, before being cancelled over doubts about its financial viability. However, success tends to start with failure, and the regulators' new assurance process for complex contracts (NHS England and NHS Improvement 2016) is a recognition both of the fiendish complexity of executing a relatively simple concept and the many more opportunities to work it out that are on the way.

Conclusion

The transformation of commissioning covers a continuum from half-hearted BCF implementation to well-executed pathway programmes, and now to the brave but unproven (in an NHS context) world of the new care models. As this brings a consolidation and shrinking of commissioning organisations, it is tempting to conclude that commissioning is now in retreat. But really this should be seen as an assertion of commissioners' core purpose: to commission once across whole populations or population groups, to construct markets incentivised to minimise costs and drive value, to devise contracts that promote system responsibility, and—most important—to marshal markets behind the achievement of outcomes rather than delivery of activity. When commissioners next feel the squeeze of tightened treasury purse strings, the front line is unlikely to escape unscathed. However, this will at least be after the mechanisms by which money reaches the front line have been transformed to enable and incentivise markets to deliver the maximum amount of relevant high quality care for each pound still available. ■

KEY POINTS

- ✓ All commissioners of health and social care are faced with the requirement to simultaneously deliver financial savings and improve frontline service delivery
- ✓ However, only the most innovative are transforming the art of commissioning to make sure that each pound delivers the maximum amount of relevant high-quality care
- ✓ This includes new and radical approaches to contracting and market shaping, on top of further cross-system fusing of budgets and teams
- ✓ It also involves a crisper appreciation of both the power and limitations of commissioning, as well as a creative redefinition of the purchaser/provider split
- ✓ By tackling the mechanisms by which money reaches and influences front-line care delivery, these new approaches represent an alternative—or at least a supplement—to securing financial efficiencies directly from service provision

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Making Affordable Healthcare Profitable

A win-win for the simultaneous involvement of both public and private funding in the provision of global healthcare.

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In a casual suburb of Hyderabad, India, a growing family is struggling to cope with the main breadwinners' gastrointestinal disorder. Help arrives from a new concept of day care where major endoscopic surgical procedures can be done without need for hospitalisation.

In Ho Chi Minh, a Vietnamese farmer gains access to the latest cardiovascular surgery techniques at a highly accredited hospital at a fraction of the cost previously possible.

In a little community outside Jakarta, Indonesia, a small merchant whose children have been sickened by hepatitis from a heavily polluted river is distraught. He finds help through a local company that focuses on making the world's most innovative drugs accessible, and affordable, to those who are most vulnerable.

Almost three billion people such as these form the base of the economic pyramid in Asia. This large segment of humanity not only faces significant and unmet medical needs but also lives in relative poverty. Their incomes are less than 3.00 US dollars a day and yet together they have substantial purchasing power: a 3 trillion US dollar consumer market. The businesses that serve the families above are some of the investments that we, at Quadria Capital, have made. What is clear is that our businesses are making an enormous social impact on the sustained development of these communities. What is less obvious is that these investments have the power to generate superior returns for our investors.

Demand Supply Gap

Countries in South and Southeast Asia account for approximately 31% of the world's population and almost 45% of the world's disease burden. Yet the region commands only 5% of the global healthcare expenditure.

Historical under-investment has translated into an ageing, under-developed and over-stretched healthcare system across Asia. By any measure the statistics are stark: less than 0.5 beds per 1000 against the WHO minimum recommendation of 5 and only 0.3 physicians per 1000 versus 4 in the developed world. Industry estimates suggest a funding gap of over 60 billion US dollars per year to scale healthcare solutions and finance access. But public healthcare financing is not growing fast enough to overcome the funding gap – and sometimes not growing at all. Public health infrastructure is severely underfunded, hospitals are overcrowded with long waiting times and the quality of service is low.

> "WE FIRMLY BELIEVE THAT OUR GOALS OF BOTH "DOING GOOD" AND "DOING WELL" ARE NOT JUST COMPATIBLE BUT IN FACT MUTUALLY REINFORCING"

Unlike Europe, governments in Asia have sought the active participation of the private sector to lead the way. Today, of every 10 new hospital beds built in Asia, 7 are being built by the private sector. Private capital has become essential to increase the efficiency of healthcare; meet the capital needs for new and upgraded infrastructure and to reduce the strain on public resources.

The nature of healthcare need in these markets has also evolved. With a large, growing and increasingly urbanised population base, the focus is no longer only on infectious diseases but on the same chronic diseases that impact the developed world. South Asia is now the global capital for diabetes and cardiac disease. East Asia has now a greater prevalence of colon cancer than anywhere else in the world.

To compound the difficulty of creating an effective healthcare ecosystem, the clear majority of patients in

Asia pay out of their pockets for healthcare. In South Asia, over 90% of a 1.6 billion population regularly pay cash to access healthcare services. Less than 5% enjoy private healthcare insurance and universal healthcare coverage remains nascent. The consequences of disease and the economic hardship of its financial burden have often been the most common reason for personal bankruptcy.

Innovative Business Models

These market dynamics form the catalyst of not only our own investment strategy but have spawned the emergence of innovative, cost driven healthcare business models and solutions that are transforming the delivery of effective healthcare in Asia.

New business models that substantially lower the cost of healthcare, without compromising clinical quality, have emerged to satisfy significant unmet medical need. For instance, HealthCare Global Enterprises (HCG) - India's largest network of cancer hospitals - has been able to bring cutting edge technologies like PET CT, MRI and Cyber Knife robotic radiosurgery to tier II and tier III cities, like Vadorda and Gulbarga. Companies such as the Asian Institute of Gastroenterology (AIG) have been able to substantially reduce the cost of gastric surgery to levels that make good healthcare accessible to millions. This has been achieved without compromising the quality of care. Healthcare outcomes are on par with, and in many instances superior to, some of the most prestigious medical institutions in the US.

How are some hospitals able to provide such high-quality health care at ultra-low prices? Our Investments and work with new care models have identified several common characteristics that can drive improved quality, access to care, and efficiency:

- Focused process management. This includes the standardisation of clinical and operational processes, extensive use of new technologies and analytics (for example: patient self-management or remote monitoring), and robust performance management
- Investment in people. Many healthcare systems are adopting more innovative workforce models—ensuring that highly qualified clinicians work "to the top of their license," while less-skilled tasks are taken on by new types of staff, such as health coaches. At the same time, successful organisations are continuing to provide strong leadership and implement effective people-development processes
- Emphasis on patients. This includes empowering patients to take a more active role in managing their own conditions, while enabling greater differentiation of services based on needs and desired outcomes
- Efficient asset utilisation. By focusing on an asset-light model, the emphasis is on ensuring high patient throughput in the most critical areas of a hospital (operating theatres, pathology, radiology)
- Building scale. Increasing operating scale helps healthcare providers in several ways: it supports the expansion of services, leads to improved asset and staff utilisation, and enables increased investment in IT, performance management and new ways of working

These characteristics can help healthcare systems meet the needs of their populations more effectively, and deliver significant improvement in the quality and affordability of care. The promising future for healthcare systems is that there are a multitude of models that have been proven to make a difference; the challenge now is to implement these strategies with capital and talent.

Profit with Sustainable Social Impact

In our view, Asia represents the new centre of gravity for the global healthcare industry. With powerful secular trends driving the growth of the industry – an increasing and ageing population, the prevalence of chronic diseases - the sector is set for robust growth at over 15% per annum over the coming decade. By harnessing these market forces, there is a compelling opportunity for the private sector to create superior investment returns whilst becoming a critical platform for the long-term, sustainable provision of healthcare. Connecting private capital to a market orientation can bring efficiency to healthcare provision while delivering high quality, affordable healthcare to those that need it the most.

This is not a trade-off between profits and purpose, it is a synergy. A good parallel is the transformation of the aviation industry with the advent of low-cost carriers. Such carriers have not only given access to flight for millions but have equally and, perhaps counter-intuitively, created business models that are now more profitable than their peers. A more important fact that is often overlooked, is that private investors in healthcare have not relied on profits at these hospitals to generate returns. We do not extract dividends from the businesses we invest in. All profits are, in fact, re-invested for further growth. Superior shareholder returns are driven by the value creation of larger, scaled platforms that can command high valuations in public equity and private capital markets.

We firmly believe that our goals of both "doing good" and "doing well" are not just compatible but in fact mutually reinforcing. ■

Presenting a Case

Financing IT Projects

The relationship between finance and IT can be a delicate one that varies from hospital facility to hospital facility. We have entered a time where traditional IT cycles have shortened dramatically. The situation is even made more complex by a fast-changing landscape, consolidation of the market on one side and emerging technologies and swiftly-growing startups on the other. *HealthManagement.org* spoke to top healthcare IT professionals for their advice on how best to approach C-Suite colleagues when aiming for project backing.

Mansur Hasib

Programme Chair of Cybersecurity Technology - The Graduate School of University of Maryland University College (UMUC) & Cybersecurity and Healthcare Speaker & Author

- Always tie the project to the mission of the organisation and be prepared to discuss how the project positively impacts the mission financially. Ensure that the initiative is intimately connected to an initiative that the CEO is interested in.
- Make the project a business project (instead of an IT project) with a major business partner as sponsor and champion of the project.
- Be prepared to discuss how the project will distinguish the organisation against the competition.
- Be prepared to discuss the content of your marketing plan for the initiative, which will help the organisation gain more clients and customers. These should include blogs, conference presentations, articles and news pieces written by others.

Raphael Jaffrezic

Chief Information Officer
Galway Clinic, Ireland

In my opinion and experience of our current and previous CFO at the clinic, the following points have been critical in creating a good business case:

- Stay away from the IT jargon. Use business terms to describe exactly what the business case is about in a way that is understandable by all.
- Explain the gains from a business point of view, not from an IT one. What impact will it have on specific departments, end-users and the organisation?
- Have some written support from business leaders on the request. If possible have a co-request by IT and the department(s).
- Have transparent pricing on the capex and opex impact of the proposed solution. Have a number of financial options ready, for three or five years.
- Have multiple quotes for the same solution, to show that you have done your homework.
- Do a return on investment analysis, even if it shows that there won't be any. Sometimes the project is only bringing greater quality but not an ROI; it is best to be direct about this in my experience.
- Lastly, support everything you are putting forward with data in a clear and concise manner.

Michelle Kearns

CIO, Caredoc St Dympna's Hospital
Carlow, Ireland

- Never underestimate the power of cake! If you are planning an ICT upgrade or looking for finance for a specific project, meet your CFO and explain the plan.
- In my experience, sharing your project plan is not going to be enough as it usually won't be read or make sense to those funding it. They will look at the bottom line but not the impact organisation-wide. What they need is the real personal impact it will make to your employees, clinicians and patients.
- Get input from the users to explain how the ICT is going to support them, change their work practices for the better and ultimately contribute to the work output of the company.
- Back to cake; have an informal meeting before the formal meeting. Explain to them what you are trying to achieve - not in technical fancy jargon – but in plain, simple language. Explain what makes sense for your organisation and what the impact of the new upgrade or the ICT implementation will be.
- Return on investment is a phrase that comes up a lot, along with "what's this going to save me?" IT is not there to save you money but to enhance what you do for your patients and your clinicians. You are improving your service, improving your patients experience and ultimately this will lead to efficiencies and effectiveness.

Christian Lovis,

Editor-in-Chief, IT, Health-Management.org
Head - Division of Medical Information Sciences, University Hospitals of Geneva, Switzerland
Full Professor of clinical informatics - University of Geneva

- Prepare well, in advance. So often, I have seen projects prepared in a hurry. Time is the most important value we have. However, it is way better to spend more time and resources preparing a project well than having to repeat the process several times because it failed.
- Include stakeholders in the process. This also seems obvious, but there are too many projects that are managed by isolated groups. Sometimes it is users such as finance, logistics, or users' groups, sometimes IT. There are very few IT projects that can be seen in a completely isolated way. For example, catering in hospitals is often managed separately from clinical order entry, leading to no interoperability between diet prescription and actual meals management. Another example; IT infrastructure projects are often seen as "internal IT stuff". However, they often represent large investments or decisions and are increasingly challenged by outsourcing. It is worth having good consensus between strategy and implementation, thus widening the discussions.
- Cost-Benefit, risk and added value. A careful analysis of cost and benefit is important. What is the cost of the current system or process and the cost of maintaining it, including potential risks? As far as benefits are concerned, favouring sustainability, interoperability and re-use of data software must not be forgotten. A good approach is also to try to identify the costs and benefits for all stakeholders and present them clearly. It is also important to thoroughly define the costs/risks of doing nothing.
- Thorough identification of short and mid-term added value is also an important step.
- Market review and clear arguments are key. Each good report should contain a well established list of existing solutions, a comparison table including investment and running costs and total costs at one, five and ten years if possible. Ideally, feedback from some existing implementation should also be present.
- The 'Whaaooooo' effect. Never underestimate the 'Whaaooooo' effect, but, equally, never underestimate the "deception" effect. Huge successes are often due to enthusiasm and bad failures due to the absence of buy-in of people.

National Telehealth Can Save Money and Improve Health

Since its introduction into the Danish healthcare landscape, telehealth has shown that it can lead to better outcomes and reduced costs. Hans Erik Henriksen, of Healthcare Denmark, writes about the difference telehealth has made to the senior population in recent years.

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Over recent years, Denmark has conducted a number of telehealth pilot projects, which has given them the knowledge to launch three large-scale telehealth projects. The purpose was to establish a region wide, full implementation of telehealth to support Chronic Obstructive Pulmonary Disease (COPD) patients. From the start, the large-scale telehealth projects were analysed by more than four parallel research projects to not only implement telehealth, but also build the evidence for nationwide adoption. The research projects prove not only that substantial savings are possible with telehealth, but also that telehealth can improve patients' Quality Adjusted Life Years (QUALY) and their general quality of life.

Denmark – an eHealth Society

The introduction of IT in the Danish Health sector started in the 1970s when the first Patient Administration Systems (PAS) were introduced. During the 1990s Electronic Health Records (EHR) and Electronic Medical Records (EMR) systems started to emerge and this was the basis for the organisation MedCom, established in 1994, with the single mission to create a nationwide Health Data Network.

During the next decade, different Healthcare IT-strategies drove the adoption of IT in the Danish Healthcare sector – starting out with targets for full implementation of EHR in hospitals and continuing with targets for communication and IT adoption in other parts of the Danish Healthcare Sector.

By 2002 the MedCom Health Data Network was almost complete, i.e. most prescriptions, referrals, discharge letters, laboratory results and reimbursements were handled electronically. At the same time, driven by the Health IT-strategies and by MedCom, a high level of EMR adoption at General Practitioners (GP) and specialists had been achieved, and hospitals had either implemented EHR's or they were planning implementation projects.

Interchangeable electronic healthcare data at a national level was the inspiration for establishing the National eHealth Portal (sundhed.dk), which went live in 2003.

Today, all Danish citizens can securely access their healthcare information through sundhed.dk. This includes their medical history, (dating back to 1977), all medicine and drug information, lab results, referrals and clinical notes. Protected by the security system, the same information is available to clinical professionals, when they are treating the individual patient.

> "DANISH CITIZENS ARE NOW USED TO PUBLIC ESERVICES AND EHEALTH – A PERFECT START POINT FOR THE NEXT STEPS TOWARDS NATIONWIDE TELEHEALTH"

Today, electronic sharing of Healthcare data in Denmark is handled through a national architecture, which makes it possible to pull and push data from a variety of different regional or local solutions (i.e. EMR, EHR, HIS, pharmacy) to a national repository – The National Service Platform. The National Service Platform holds the repositories and data, which patients and clinical professionals share, through sundhed.dk., but Healthcare Regions and Municipalities can also access and share data from the National Service Platform through their local systems.

For years, Denmark has been among the countries with the highest Internet penetration and, alongside

Photos Credit: TeleCare Nord/Foto AV

the eHealth journey, general strategies for digitalisation (eGovernment) have been implemented. In November 2014 public authorities in Denmark switched to electronic service and Danish citizens no longer receive paper letters from any public authority – instead all communication (and most services) are handled through the internet.

In conclusion Danish citizens are now used to public eServices and eHealth – and this is a perfect start point for the next steps towards nationwide telehealth.

Telehealth

One of the main objectives of the Danish healthcare IT-strategy 2014-2020 is to advance and up-scale the use of telehealth to empower, educate and involve chronic patients in managing their own disease.

Following a decision taken in 2012, Denmark was the first country to adopt national standards for interoperability of personal health technologies based on the Continua Health Alliance. The Danish telehealth architecture also involves using the Health Level 7 Personal

Health Monitoring Report (HL/7 PHMR) standard to further document telehealth device readings.

Danish Healthcare Regions are in the process of up-scaling the implementation of telehealth in close cooperation with Danish Municipalities.

In the North Region the project, TeleCare North, was established in 2011 and has rolled out telehealth support to approx. 1,300 COPD patients. Since then, large research programmes have monitored and analysed the effects and benefits of telehealth, in order to build the evidence for a national rollout.

The TeleCare North Project

In the TeleCare North project, The North Denmark Region, the 11 associated municipalities, Aalborg University and local doctors cooperated to enrol all patients with the lung disease, COPD, in the telehealth project.

The participants in the project received a TeleKit, which gave patients the opportunity to measure and report data about their condition by themselves. The virtual contact was supported by physical visits either at home or the hospital.

Benefits for both patients and public spending

The patients in the TeleCare North project reported a very positive experience. Six in ten experienced increased control of the disease, while more than seven in ten experienced increased comfort and mastery of their disease. Usability is key for the success of telehealth, and the patients' feedback on the TeleKit was positive. A random sample made during the TeleCare North project showed how almost ninety percent thought it was easy or very easy to use the TeleKit.

In The North Denmark Region alone, 45,000 citizens are diagnosed with COPD, and it is estimated that around ten percent of these COPD patients are characterised as severe or very severe. Figures from the Danish Lung Association estimate that around 23,000 COPD hospitalisations are made annually throughout Denmark. Hence, the economic potential is significant if telehealth leads to fewer hospitalisations.

Telehealth Evidence

The TeleCare North project proved that telehealth support provides the highest benefits for COPD patients in the GOLD 3 and GOLD 4 categories, i.e. patients with severe or very severe COPD. Patients in GOLD 3 (severe COPD) achieved the highest benefits.

For both patient categories, the researchers who followed the project documented that the patients quality of life, as telehealth patients, improved because of the increased education and insights in living with their chronic disease. Also documented was that the ability to participate and be active in controlling their own disease was an important factor in both quality of life improvements and in reducing the number of admittances to hospital.

Can Danish health authorities save money and at the same time achieve the above-mentioned effects - improving the patients quality of life and QUALY? This was the key question to be answered to enable a decision to be taken to implement telehealth on a national scale.

> "THE TELECARE NORTH PROJECT PROVED THAT TELEHEALTH SUPPORT PROVIDES THE HIGHEST BENEFITS FOR COPD PATIENTS"

The result of the financial analysis is that the payback time for investing in national implementation of telehealth in Denmark, to support all COPD patients in the GOLD 3 and 4 target groups, would be two to three years. This is based on three different scenarios, where the likely scenario indicates an annual investment/savings of 1:3 (i.e. every time one euro is invested, it generates a saving of three euros). The best-case scenario indicates a savings/investment ratio of 1:4 and the most conservative scenario a ratio of 1:2.75.

The large-scale telehealth projects for COPD patients have proved the case for telehealth as a means of reducing hospital admittances, reducing costs and improving the quality of life for patients. This has been fundamental in Denmark's decision to implement telehealth at a national level, starting out with the target of implementing national telehealth support for all Danish COPD patients before the end of 2019.

The large-scale telehealth projects also resulted in new ways of working and organising telehealth support between the regions, hospitals, municipalities and primary care services. These results and experiences are helping the regions to take the next steps towards regional implementation of telehealth support for other chronic patient categories like diabetes and heart disease patients. ■

Finance Technology Blockchain in Healthcare IT Security

Tech outfit Factom has just won a Gates Foundation grant to develop Blockchain use in healthcare security. The company speaks about its potential.

Blockchain, the Bitcoin technology, has been taking the Healthcare Information Technology (HIT) world by storm because of its capabilities to offer impregnable security and tackle the hacking threat.

As part of its ongoing humanitarian efforts, The Bill & Melinda Gates Foundation has given a grant to Austin-based Blockchain technology company, Factom, to develop the company's Blockchain projects in the developing world.

Factom co-founder & CMO Tiana Laurence spoke to HealthManagement.org about this project.

Why does Blockchain hold so much potential as a tool in Electronic Health Records (EHR) security? Which stakeholders could be positively impacted (patients, medics, insurance, etc.)?

Blockchain software could be used to track and manage documents, and the data associated with them. This would make it easier to share information between service providers while keeping track of who has had access to what information and when. It could also be used to build software to maintain a clear medical history for patients that they could monitor, update, and share.

What is the track record for the Blockchain technology providing evidence of its reliability for security?

Blockchain technology is new but incorporates a lot of older security standards like the Secure Hash Algorithm 256 (SHA), developed by the United States National Security Agency (NSA). Each Blockchain will need to go through a security-hardening period.

Factom has received a grant from the Gates Foundation to develop Blockchain technology in healthcare. Can you describe the project?

We are building a decentralised medical record management system that will help doctors, clinics, and patients manage their records in countries that do not have the EHR infrastructure.

Does Blockchain have the potential to save money for healthcare and, if so, how?

There is a lot of paper, redundant record keeping, and compliance requirements. These are all opportunities that Blockchain technology could be used to streamline.

In your opinion, what is the timeframe for rolling out the Blockchain technology in Healthcare?

Many Blockchain projects are going through testing. Gem, (**gem.co/health/**), has been doing some interesting work. We will roll out something this summer, but it may be two or more years before we see software integrations in the public domain.

Are there any obstacles to Blockchain rollout and implementation in healthcare?

New systems need to have a ten-fold benefit over an incumbent technology. Beyond building the technology, there also need to be vast improvements over what is already in place.

Cybercriminals have been making headlines by hacking into Healthcare IT systems and compromising sensitive data. Why will Blockchain succeed in securing patient and other healthcare data when other processes and technologies have failed?

Blockchains enable as near permanent data as there has ever been. System administrators can create snap shots of their systems at a simple level. There are many more complicated things that can be done through Data Access Objects (DAOs), smart contracts and chaincode.

Can you tell us about any Healthcare Blockchain case studies that you have undertaken, or are currently involved in, and what they are indicating?

We have our project with The Gates Foundation and we are also working on a project securing Internet of Things (IoT) devices for the Department of Homeland Security. IoT devices are another source of vulnerability in the healthcare market. ■

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Fraud in Healthcare

A Worldwide Concern

The Global Health Care Anti-fraud Network (GHCAN) promotes partnerships and communications between international organisations in order to reduce and eliminate healthcare fraud around the world. *HealthManagement* spoke to representatives, Simon Peck (UK), and Leigh McKenna (USA) to find out more.

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What is the range and scope of healthcare fraud?
Common healthcare fraud schemes include:

- Upcoding: billing for more expensive services or procedures than were actually provided or performed
- Charging for treatment not given
- Performing medically unnecessary services solely to generate insurance payments
- Misrepresenting non-covered treatments as medically necessary covered treatments to obtain insurance payments
- Falsifying diagnoses to justify tests, surgeries or other procedures that aren't medically necessary
- Unbundling, ie, billing each step of a procedure as if it were a separate procedure
- Accepting kickbacks for patient referrals
- Failing to provide necessary services prepaid under a health plan
- Billing a patient more than the co-pay amount for services that were prepaid or paid in full by the benefit plan under the terms of a managed care contract
- Double charging, often concealed in jargon
- Misrepresenting the type of treatment, for example doing cosmetic work and claiming it is medical treatment
- Specific types of fraud involving pharmaceuticals, for example charging for branded drugs and using simple generics, charging for more drug than was used and diversion of drugs into the black market, for example opiates or drugs of addiction
- Specific frauds involving pathology: one of the first major anti-fraud initiatives was by the Federal Bureau of Investigation (FBI) in the USA and called operation labscam, which involved many fraudulent practices by laboratories. For example the case reported here by the U.S. Department of Justice **justice.gov/archive/opa/pr/2001/January/002civ.htm**

Simon Peck (SP): There is a spectrum of behaviour, which we term fraud waste and abuse—all of which has at its heart taking money inappropriately out of the healthcare system. Fraud is a criminal offence (even though most cases are not prosecuted through the criminal system) and is the use of false statements, omission of information or abuse of a position of trust with the intention of making a gain. Waste is the deliberate consumption of resources for financial gain rather than for the benefit of patients, which includes providing unnecessary treatments or investigations. Fraud and waste can overlap. Abuse covers things like excessive and unreasonable billing.

Health fraud, waste and abuse is more often committed by healthcare providers than patients, although anyone in the system can be fraudulent. This includes patients, staff and people who are not actually working in healthcare at all, but who try to take money from the system. More serious but less common is organised criminal activity such as counterfeiting, or a recent multi-million pound scam, conducted electronically, which hit many UK-based insurers, and involved multiple bogus expatriate policies sending in fictitious bills for treatment.

Leigh McKenna (LM): While healthcare is in a state of perpetual change and evolution, fraud is seemingly a constant, complex crime that can manifest in countless ways. In the United States the sheer volume of healthcare claims and the data involved makes fraud detection a challenge. For instance, Medicare Parts A and B alone process 4.6 million claims per day. Fraud can be committed by anyone: physicians and other providers, employees with access to medical and claims records, enterprise crime organisations, and even patients. Detecting healthcare fraud often requires the knowledge and application of clinical best practices, as well as knowledge of medical terminology and specialised coding systems.

The perpetrators of some healthcare fraud schemes deliberately and callously place trusting patients at significant risk of injury or even death. There are cases where patients have been subjected to unnecessary or dangerous medical procedures simply because of greed. Patients may also unknowingly receive unapproved or experimental procedures or devices. Healthcare fraud is clearly not just a financial crime, and it is certainly

CHECKLIST

- ✓ Be aware of the risk of healthcare fraud and design it out where possible
- ✓ Where it cannot be designed out, minimise the opportunity and have robust systems of checks and audits
- ✓ Have senior management who understand and are committed to dealing with the problem

not victimless. With its complexity, the U.S. healthcare system can be susceptible to creative, nimble and aggressive perpetrators who have a knack for identifying weaknesses.

What is the scale of the problem? Is fraud becoming more sophisticated?

SP: In the UK we estimate fraud in the private sector to be about 5% of claims paid. In any environment, only a small number of people are fraudulent by nature—many more go along with the culture, and we have worked hard to raise awareness and try to send the message that such activity is unacceptable. There is no evidence that fraud has become more sophisticated in the UK. The response has, however, as we have sought to learn from our partners in the U.S. Insurers have become a lot more capable with the use of technology to highlight problems, professional investigators and other skills. We recognise that a successful response needs medical input and good legal advice as well as skilled investigators. The most important thing is to stop losses, and we always try to understand the root cause or weakness that has been exploited to prevent recurrence. The anti-cybercrime industry does this well, looking at the opportunities that were exploited when responding to a threat because closing the door to future losses may be the only thing that is possible.

The UK health insurance sector was the first industry in the UK to start comprehensive sharing of intelligence, including the names of fraudsters. This has enormously increased our capability and ended the problem where fraud in one area simply reinvents itself at a different insurer or payer.

LM: Fraud trends and schemes are constantly changing, developing, shifting, migrating and morphing, and the task for anti-fraud professionals to stay ahead of the threat is daunting. Some frauds are impressively sophisticated while others are remarkably absurd. And in many cases—such as with phantom providers—speed is the key. Someone who sets up a false storefront with the intention of filing false claims, will submit many claims, receive payment and abandon the property before investigators are able to intervene.

Some of the areas of healthcare that seem to be indicating the greatest uptick in or susceptibility to fraud include:

- Organised criminal enterprises (could invoke several types of schemes but seem to depend significantly on medical identify theft—theft of patient and provider identities)
- Infusion therapy
- Pain management (office-based opioid therapy)
- Pharmaceutical/drug diversion
- Durable medical equipment (involves significant medical identity theft)
- Behavioural health and community mental health centres
- Medical Identity Theft (Medical ID theft is often an element of a broader healthcare fraud scheme)
- Home healthcare
- Cardiology
- Ophthalmology
- Physical therapy and occupational therapy (medical necessity, spa vacations)
- Transportation (ambulatory)

> “HEALTH FRAUD WASTE AND ABUSE IS MORE OFTEN COMMITTED BY HEALTHCARE PROVIDERS THAN PATIENTS”

What do healthcare leaders and frontline clinicians need to be aware of?

SP: One of the main strands of an anti-fraud programme is creating an anti-fraud culture, which means raising awareness and mobilising the honest majority. The perception is that healthcare workers work only for the good of patients. This is undoubtedly the case for most of them, but the healthcare system also attracts fraudsters, criminals and charlatans. Awareness of the problem is the single biggest hurdle, and once this is in place, healthcare managers need to ensure that they have a robust programme to assess and minimise the risks, then put in place appropriate controls and checks, and have an enforcement regime or agency which is able to deal with the very complex issues which can arise.

Do governments and regulators have sufficient powers to combat fraud?

SP: In the UK the National Health Service (NHS) Protect Agency has extensive powers to tackle fraud and does

so using criminal prosecution. However, the regulatory system in the UK is not as effective as it should be. There are too many bodies, and they do not communicate well. Criminal prosecution is not suitable for all matters; the standard of proof is very high, it is very time-consuming and has very strict rules on evidence for example. Regulators have a very definite place in dealing with problems not suitable for the criminal courts. The UK needs an agency to oversee and coordinate the various healthcare regulators, which currently are not as effective as they should be.

LM: The laws and regulations currently in place in the United States are for the most part quite sufficient. In the 1990s there was discussion among federal and state officials, insurers and state insurance commissioners, of a federal immunity statute, for insurers sharing fraud-related information with other insurers. Unfortunately, the legislation that would have implemented these ideas was not enacted, but many states have since enacted their own state immunity statutes. NHCAA believes that we should remove unnecessary obstacles that inhibit fraud fighting efforts, and that providing protections for individuals and entities that share information and data concerning suspected healthcare fraud is reasonable and prudent.

What role does IT play in detecting potential fraud?

SP: Most payment systems are IT-based, and the most important thing is to build into the system appropriate controls, red flags and alerts to automatically identify suspicious transactions. Because most provider fraud is repeated there is an important role for IT in looking at patterns of conduct, which may be acceptable in an individual case but which if repeated are very unlikely to be genuine. IT is not the answer on its own. The basics need to be in place first, namely policies and procedures for financial controls, staff training and proper oversight.

Analytics are a useful addition to a mature entity that has the capability and understanding of the problem and is able to interpret the outputs and respond appropriately. In isolation they have very little if any value, and may actually be detrimental, as few managers want to see a problem they can neither control nor understand.

LM: IT plays an enormous role in detecting fraud. The USA's healthcare system hinges upon a staggering amount of data spread across the healthcare claim adjudication systems of numerous payers. Given the diversity of providers and payers and the complexity of the health care system—as well as the sheer volume of activity—the fraud prevention challenge is enormous.

It is more cost-effective to detect and prevent fraud before paying a fraudulent claim than to chase the lost dollars after the fact. The "pay and chase" model of combatting healthcare fraud is no longer tenable as the primary method of fighting this crime. The only way to detect emerging fraud patterns and schemes in a timely manner is to aggregate claims data as much as practicable and then to apply cutting-edge technology to the data to detect risks and emerging fraud trends. NHCAA supports efforts among its members, both public and private, to shift greater attention and resources to predictive modelling, real-time analytics and other data-intensive tools that will help detect fraud sooner and prevent it before it occurs.

However, data analytics is not a panacea. For instance, predictive analytics can generate leads for further inquiry and can help form the basis for the suspension of payments, but it has not been used as the sole basis for the suspension of payments by private health insurers without additional follow-up and corroboration.

Many of the data analysis and aggregation tools and systems being developed and brought to market are incredibly powerful and can produce potential leads at a pace that can quickly exceed what the finite investigative resources can handle. The need for "boots on the ground" is as great as ever. Technology professionals and data analysts will be in increasing demand as the use of prepayment technologies grows. And the leads and information developed by data analytics will continue to require, in many instances, skilled investigators and medical record reviewers with clinical backgrounds available to act on the information.

As we focus on the promise of technology, we mustn't overlook the vital need for smart, analytical, insightful, and committed fraud-fighting professionals. We must maintain a multi-pronged approach to fighting healthcare fraud that strikes a balance between technological resources and human resources.

What are the critical success factors for detecting fraud and recouping the money?

SP: In addition to the basics, professional investigation teams with access to clinical and legal support, clear contracts and strong management support. Key to recovering money is meticulous casework. It can be difficult for non-fraud trained management to understand the need to build a case methodically without making assumptions and collect the evidence and present it systematically. It is one thing to "know" that someone has committed a fraud, but to make a recovery this has to be proven.

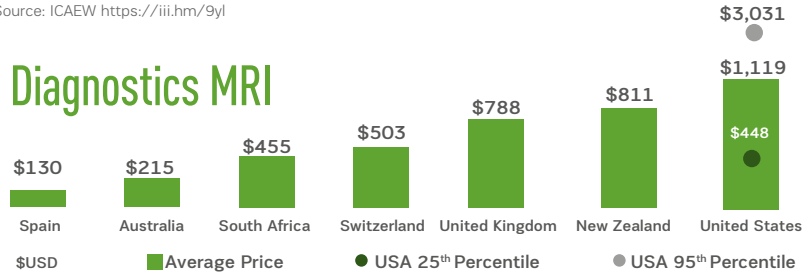
LM: Focusing on "recouping" money is no longer the sole or primary function of an insurer's anti-fraud unit. The most advantageous goal, both monetarily and for patient safety, is to prevent fraud. Detecting it before claims are paid should be the next priority. There is no single solution. The landscape we are dealing with demands multi-faceted anti-fraud efforts. ■

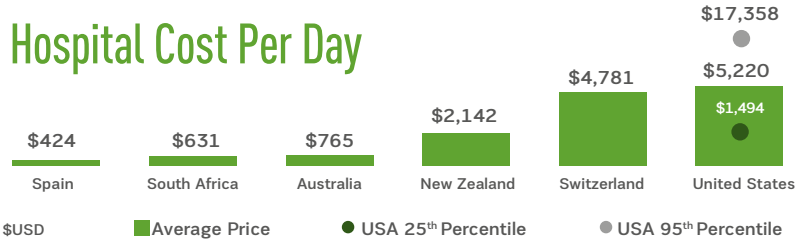
MONEY TALKS

KEY ATTRIBUTES FOR SUCCESSFUL CFOS

- Good communication and relationship skills
- Approachable
- Wider people skills, particularly the ability to lead a high calibre team
- In-depth understanding of the business
- Ability to support and challenge the CEO
- Affinity with numbers and ability to interpret them for others

Source: ICAEW https://iii.hm/9yl

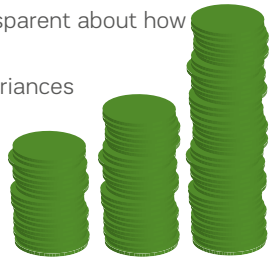




Source: International Federation of Health Plans 2015 Comparative Price Report https://iii.hm/9zo

HOSPITAL FINANCE DEPARTMENT AS A VALUED PARTNER

- Stop assuming you know what we need
- Become less siloed
- Stop withholding information
- Stop changing the operational definitions and be more transparent about how the data is derived
- Help us to understand the targets and what is driving the variances
- Eliminate your paper processes
- Standardise on a process; it's tough to manage targets and processes that continually change



Source: Health Catalyst https://iii.hm/9yi

4 REALITIES CHANGING THE ROLE OF A HEALTHCARE CFO

Historic CFO role in capital availability and cost and budget management is changing	Top line revenue risk must be actively managed and requires engaging in many cross-functional efforts such as clinical quality, revenue cycle, and population risk management	Budgetary measures as key fiscal control mechanisms no longer sufficient. Revenue risks have to be prepared for and profit & loss responsibility must be driven throughout the organisation	Post-acute care episode and population risks becoming key financial drivers for the organisation. A CFO needs to make capital allocation decisions to reflect these risks

Source: Healthcare Excellence Institute https://iii.hm/9yk

HEALTH EXPENDITURE AND FINANCING

Country	Healthcare Expenditure, % GDP
Australia	9.3%
Austria	10.4%
Belgium	10.4%
Canada	10.1%
Chile	7.7%
Czech Republic	7.5%
Denmark	10.6%
Estonia	6.3%
Finland	9.6%
France	11.0%
Germany	11.1%
Greece	8.2%
Hungary	7.0%
Iceland	8.8%
Ireland	9.4%
Israel	7.4%
Italy	9.1%
Japan	11.2%
Korea	7.2%
Latvia	5.6%
Luxembourg	7.2%
Mexico	5.8%
Netherlands	10.8%
New Zealand	9.4%
Norway	9.9%
Poland	6.3%
Portugal	8.9%
Slovak Republic	7.0%
Slovenia	8.4%
Spain	9.0%
Sweden	11.1%
Switzerland	11.5%
Turkey	5.2%
United Kingdom	9.8%
United States	16.9%

Source: OECD https://iii.hm/9zp

6 TRAITS OF A GREAT HOSPITAL CFO

- **Conviction**
- **Nimbleness and flexibility**
- **Calm demeanour**
- **Willingness to understand the clinical aspects**
- **Ability to think long term**
- **Sense of humour**

Source: Becker's Hospital Review https://iii.hm/9yj

When A Cybercrime Takes Place – Who's To Blame?

When cybersecurity is breached and sensitive data is compromised, who should be held responsible - the hacker or the victim?

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When money is deposited into a U.S. bank and someone steals it, the money remains secured and the bank must honour its obligation to return the funds. Even if the bank goes out of business or into bankruptcy, each customer is protected by the federal government (i). This set up works because the law clearly backs the consumer. Even though the company may have been the victim of a crime, the bank cannot absolve itself of the responsibility to protect depositor accounts.

In a similar case, if a person gets injured on the job due to the employer's failure to perform due diligence in providing safe working conditions, the company remains liable for damages. Once again the law sides with the non-corporate party. Even if the employer is the victim of a crime which causes the employee's physical injury, they cannot wriggle out of the liability.

Contrarily, in the case of digital harm, similar situations remain murky. Who is to blame? Major companies argue that they perhaps should not be held liable for a client's digital harm or subsequent financial harm stemming from a cybercrime. They consider themselves a victim as well.

While the laws for financial harm and physical harm appear to provide some reasonable level of protection, the laws for digital harm are almost non-existent or weak.

Who is to Blame for Cybercrime?

Clearly, compromising the security of a network is a criminal act conducted by the hacker/s involved. These actions can include gaining unauthorised access, stealing or altering data, or any other abuse of a network and its resources. The cyber-criminals are responsible for their illegal actions and, in most people's minds, should shoulder all the blame. In this area, though, the question of liability remains just that: a question. So who carries the legal liability for the cybercrime?

Can a Company be Held Liable for Having Been Compromised?

Let's consider an example. If a company is compromised and the intellectual property of a business partner gets exposed to the wild, can the holder of that IP sue for damages?

Two schools of thought are at play here. The first view believes that companies whose systems have been compromised should not be held responsible for breaches and the impact of the breaches. They consider themselves to be victims of the crime. Others suggest that if those companies did not exercise due care or due diligence with regard to the protection of their IT assets, then the victim argument does not fly. Instead corporate leadership (board members and executives) should be held responsible and accountable for the breaches. This second approach concludes that holding companies liable is the only way the industry—and the digital world as well—will truly make progress toward better security.

Should the Victimised be Liable?

Two additional questions emerge from the discussion of cybercrime liability and victimisation:

- Does being a victim absolve the person or company of all blame?
- Can holding the leadership of victimised companies accountable actually improve the security?

Can Victims be Guilty?

People generally don't like to blame victims. That action seems counterproductive and at some level just simply

Due Care?

Due care is a legal term referring to the level of judgment, care, prudence, determination, and activity that a person would reasonably be expected to demonstrate under particular circumstances. Essentially, if one demonstrates due care, often referred to as due diligence, then an injured party cannot prove negligence. The challenge, however, is that no definitive standard of due care yet exists in the arena of cybercrime (definitions.uslegal.com/d/due-care).

wrong. The reality is, however, that we often do. In several cities, when graffiti finds its way onto buildings, the government fines the owners if the graffiti isn't cleaned up quickly enough. Even though no one suggests that the building owners are guilty of vandalising their own property, they are the ones who are punished nonetheless.

Additional cases illustrate this point. If executives do not monitor the financial health of their company and it's revealed that the books have been cooked, the CEO can expect to be in trouble. The boss may make the argument that he/she didn't alter any financial statements because, or perhaps, they were focused on product development or client delivery. In those cases, the inattention to the company's financial health happened due to neglect, if not willful action. This negligence doesn't absolve the CEO of any liability; in fact it confirms it. The widely accepted view is that CEOs are responsible for the accuracy of the company's financial statements.

What Happens to Leaders Who Follow Due Care?

This last example also speaks to the value of holding leadership accountable. The logic goes that if executives are liable for the wrongdoing of their companies, they will proactively ensure their firms take security seriously. That attitude and, hopefully, resulting actions actually may bring those companies closer to being effective in protecting their networks in the first place.

This case also offers the executive leadership an out. If they follow cybersecurity best practices and standards for their industry in a demonstrable and auditable way, then leadership is not negligent and can perhaps avoid or at least reduce their liability. In such a scenario, the victim argument applies.

In our current time, the murky arena of corporate/executive responsibility persists because no definitive standard of due care exists. Fortunately, progress toward this end is underway:

- National Institute for Science and Technology (NIST) Special Publications subseries 800 (**csrc.nist.gov/publications/PubsSPs.html#SP%20800**) speaks to civilian federal agencies and is a baseline for most others (ii).
- The Health Information Trust Alliance (**hitrustalliance.net**) has produced the HITRUST Cybersecurity Framework for the Healthcare industry.
- The Payment Card Industry Data Security Standard (**pcisecuritystandards.org/pci_security/maintaining_payment_security**), managed by the Payment Card Industry Security Standards Council, established security best practices for the credit card processing industry.
- The ISO 27000 series (**iso.org/iso/iso27001**) sets security standards for commercial businesses.

There are others as well.

As we get closer to clarity and widespread acceptance on a set of cybersecurity practices that constitute due care, a set of practices that can be clearly implemented and followed, companies and their leadership may be exempt from liability in a cyber-attack. When companies cannot make such a claim, perhaps leadership should be culpable.

What about Partial Blame for Companies?

The above-mentioned situation implies that, if reasonable attempts to meet recognised security standards and best practices have been met (eg, as can be documented through an audit), then company leadership should be in the free and clear when they become victims of a cyber-attack.

It seems everyone bases guidance on cybersecurity controls and operations on the NIST SP 800 Series. If a company follows the guidance issued for their industry and is certified for having followed that guidance to a high degree by a recognised audit firm—and yet are still compromised—does this imply that some liability would accrue to either or both the standards body for creating a false sense of security, or to the auditor? Can the company and its clients, who may have suffered losses in the hack, such as the loss of their identity information, sue the auditor or NIST?

And what happens when a company can clearly demonstrate its level of effort even when no standard or widespread agreement of proposed standards yet exists (which is closer to the case today)? Or if the company simply hasn't followed existing standards, because of the unique nature of its business operations or out of a disagreement with accepted standards? If companies in such situations are hacked, should their leadership still be held liable?

Conclusion

More questions than answers currently remain in this new area of cybersecurity and digital harm. However, it is paramount that these queries be asked and that we address them publicly and legally. ■

Notes

i. The Federal Deposit Insurance Corporation protects bank accounts up to a certain bank balance.

ii. NIST has been designated by Congress as the agency to establish cybersecurity guidelines for the federal government. The NIST Special Publications (SP) 800 Series are these guidelines. They serve as the basis for many standards bodies and industry best practices in both the public and private sector.

Digital Health Hub at Your Service

If You Earn Citizen Trust

The Digital Health Hub is a joint project of Sitra, the Finnish Innovation Fund and The Ministry of Social Affairs and Health. The project goal is to facilitate the use of national data reserves and design of the one-stop shop for health and social care data.

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The mention of data exploitation may sound scary, but at its best it can mean new, more effective, targeted medicines when whole genome data sets will be available to predict the effects of medication. It can mean better diagnoses and more up-to-date information about the quality of care by different—public and private—actors.

To enable data-driven economic growth and to respond to future needs of innovative research and development, Sitra has launched a project called I*saacus – the Digital Health HUB*. From a single access point, this service organisation will provide data that can influence wellbeing and open data gathered from various registers and sources. When gathering and processing this data, special attention will be paid to privacy protection and data security so that citizen trust is maintained.

The project is being taken forward in close cooperation with the central stakeholders. The project implements the growth strategy for the health sector of the Ministry of Social Affairs and Health, the Ministry of Employment and the Economy and the Ministry of Education and Culture.

Big data and analytics are changing our mindset on how to benefit from the data. Information management practices and architecture need to be updated. The goal is to establish rules and to create agile and safe frameworks that take the interests of the individual into account in the exploitation of data and smooth the processes needed for R&D and Innovations.

What Makes Our Approach Unique?

There are similar initiatives going on around the globe, but national consensus and interagency cooperation is unique. The objective of the Ministry's draft Act on Safe Use of Health and Social Data is to ensure that it will be possible to use customer and personal data in Finland more effectively, for example when devising public policy and in the development of services. The change would ease and increase the use of information on health and social matters and open many new possibilities, not just for academic research, but also for commercial research and innovation.

Ultimately, an individual would benefit from better transparency of the use of data and new evidence-based care methods developed by swifter use of information as all permits to use the data would be granted by one permit authority. Data-secure operating environments and communication would be created for sending and handling the data.

The government bills would bring the provisions on handling personal data into conformity with the EU Data Protection Regulation, which entered into force on 25 May 2016. The reforms are due to come into force in stages, starting from 1 January 2018.

> “THE MOST IMPORTANT ISSUES THAT CONCERN FINNS ARE THE ABILITY TO SEE THEIR OWN DATA AND THE POSSIBILITY TO CORRECT OR, IF NECESSARY, EVEN TO FORBID ITS USE”

Citizen Trust on Authorities – Findings From the Survey

According to Sitra’s survey conducted by TNS Gallup in June 2016, Finns are willing to anonymously submit their social welfare, health and genetic data for the purpose of service development and scientific research. The survey examined citizen attitudes towards the secondary use of wellbeing data collected about the Finnish population. Secondary use includes, among other things, research, statistical purposes, development and innovation activities and knowledge management.

The survey results show that citizens are interested in the use of their social welfare and health data and support their use for development and research purposes. However, people also want to be informed about the use of their personal social welfare and health data. The most

important issues that concern people are the ability to see their own data and the possibility to correct, or, if necessary, even to forbid its use.

The survey confirmed that Finns have a high level of trust in the authorities. The police force is the most trusted authority and there is also a high level of trust in the public social welfare and healthcare system. The majority of the respondents also felt that it was important for an authority to oversee the use of data as well as the appropriateness of its use. Over 90 percent of the respondents felt that the following points were either important or very important:

- Being able to see their own data
- Being able to correct any errors in their own data
- Knowledge of purposes for which their data would be used and who would be using it
- Being able to forbid the use of their own data.

Finns want to control the use of their own data through express consent. Nearly 90 percent of the respondents felt that it was important or very important that an individual should be able to decide what the data collected about them was used for, especially if the data could reveal the person's identity.

Data-Driven Economy Thrives With Trust

The citizen's perspective and data protection issues must be taken strongly into consideration in the planning of operations and operational practices. The new actor must be able to work transparently. An information security audit provides a holistic picture about the current state of data processing in an organisation and an assessment about the realisation of data protection, data security and privacy protection. It is essential that the new actor will, at the very least, conduct an information security audit of its operations and ensure the data is handled in a secure manner.

However, for a data-driven economy to succeed there are also several dimensions on trust that are critical at the enterprise level as stated in a recent survey conducted by KPMG in October 2016 on data and analytics (KPMG 2016). When an enterprise plans for its strategy on analytics KPMG report recommends that they build a systematic approach that spans the lifecycle of analytics and focuses on four key anchors of trust: quality, effectiveness, integrity and resilience.

These are crucial dimensions even when planning for a national health hub. For winning the trust from the researchers and companies aiming to use the data, we need to ensure transparency and an audit trail to the data sources, and maintain good quality of data management tools and processes. Building good quality is a phased approach; in an early phase "good enough" quality might be sufficient. However, what is essential for the success in nationwide data gathering is to ensure semantic interoperability and define national metadata. This is essential not just as a one-off effort but also for best information management practices for updating the metadata with fast-changing data sources. If we cannot show audit trails all the way to the raw data it is difficult to trust analytics made from that data. What is essential in our effort is to ensure that data is going to be used in an acceptable way so Health Hub needs to be aligned with regulations and ethical principles. This is an area of uncertainty and rapid change, with enormous potential for reputational risk and perhaps even failure of the entire project. This also puts pressure on a good governance model throughout the data lifecycle. In short, for Sitra, and everyone else hoping to succeed in a data-driven economy, trust is a must. ■

Statistics	
Total population (2015)	5,504,000
Gross national income per capita (PPP international $, 2013)	38
Life expectancy at birth m/f (years, 2015)	78/84
Probability of dying between 15 and 60 years m/f (per 1 000 population, 2013)	114/51
Total expenditure on health per capita (Intl $, 2014)	3,701
Total expenditure on health as % of GDP (2014)	9.7

Source: World Health Organization who.int/countries/fin/en

KEY POINTS

- ✓ Digital Health Hub project from Sitra is a joint project of Sitra, the Finnish Innovation Fund and the Ministry of Social Affairs and Health. The project goal is to facilitate the use of national data reserves and design of the one-stop shop for health and social care data. The new authority will be up and running in 2018.
- ✓ According to a survey, Finns are willing to anonymously submit their social welfare, health and genetic data for the purposes of service development and scientific research.
- ✓ Data-driven economy is based on trust.

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Enterprise Viewers

Key Pointers

Top tips for selecting and implementing an enterprise viewer to allow clinicians to access and store medical images across the healthcare organisation.

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What are the key criteria for selecting an enterprise viewer?

1. Enables access to all images

An enterprise viewer should give access, from within the electronic medical record, to all the images an institution has for a patient, not only radiology images. Medical imaging typically starts with radiology, but images from other clinical departments also need to be viewable through an enterprise viewer. These include visible light images from endoscopy and pathology, for example, and photographic images, such as photos of a rash taken by a dermatologist.

2. Adapts to image type

A good enterprise viewer should be able to adapt to the image type. For example, if you are viewing a set of computed tomography (CT) scan images, the viewer should have the tools they need to flip through a stack of images. If you are viewing pathology slides the viewer should have the tools to enable them to flip through the images, which are of the same slide imaged at different focal points. The viewer needs to adapt to different tasks depending on what the image is, including taking measurements, and manipulating the image.

3. Allows logical organisation and easy thorough labelling

Among the fundamental differences between radiology images and other images is that radiology images are often from an ordered event. You place an order for a CT scan, a CT scan happens in a scheduled workflow and a transactional ID number is assigned to that study. If images are not scheduled, such as an x-ray taken in the operating room after an operation, or images taken in the emergency department, often they do not have an accession number or transactional ID. With a good enterprise viewer, that shouldn't matter, and it needs to be able to organise that information, certainly by date but even better by encounter. The system needs to allow labelling of those images to try to understand what they were part of and to reduce unnecessary repeat imaging. A good enterprise imaging system will allow and enable those who create the images to appropriately label them if they are not already labelled, without too much hassle. For example, if it is an ophthalmologic image of the retina, the record needs to show which eye it was, the date of the exam and the circumstances, for example if dye was put in the eye, if the pupil was being dilated and so on.

The conditions under which the image was taken are also relevant. In radiology we capture the images and the conditions in which the images are acquired, such as the reason for the exam, whether or not contrast was administered, how much radiation was used, what pulse sequences were used in the magnetic resonance imaging (MRI) scan and so on. Radiologists are used to capturing that kind of data. It's important for other disciplines that when they put images into these enterprise imaging archives they capture as much clinical and technical information about the image so it can be used to greatest effect. The simplest use case is that the patient has had a bunch of studies done, and they come into the primary care doctor's office, and the doctor wants to review their chart. There is also a lot that can be gained for research, trying to mine the medical data that we have for images that meet certain criteria, for example to see if patients with a particular disease have commonalities in images of their retinas, to find out if we can discern a trend or discover a pattern. The ability to do research on those images is severely affected by how well those images are labelled. A good enterprise image archive and viewer should be able to bring that information to the fore to allow the clinician to act on it.

4. Presents the relevant images

Sometimes less is more when you want to sift through the information effectively. In the old days, you took a picture, you looked at a picture. Today CT machines can take very thin slices of a body part, thinner than we would even like to look at. We can take those thin slices and use computer algorithms to reconstruct a 3D view of a body part, the skull, an organ etc. We store the source images from which something is rendered, but it's the thing that is rendered that is useful to look at. The original thin slices are part of the patient imaging record, however. I've had the scenario where I'm going over a CT scan with a doctor in the emergency department and they're asking me a question about slice no. 573 out of 1200. That's not useful. They need to be looking at the 100-slice view. A good enterprise viewer will not only help you get faster to the images you want, but it will also hide from you the images that you don't want. It's not concealing those, but

it will put them out of immediate view and sift them out, thus presenting the information that is relevant to the clinician, but retaining the information that we require for legal and for other technical purposes.

5. Retains key images and radiology markers

It is important for any clinical viewer to be able to convey the key images and allow the choice of showing or hiding these. If the radiology department's Picture Archiving and Communication System (PACS) system is with one vendor, and the hospital uses an enterprise viewer from another vendor, you have to make sure that the enterprise viewer preserves the marking of key images and annotations from the PACS. The radiologist may put arrows, markers, circles and measurements on images that they want the referring physician to see. An enterprise viewer also needs to be able to show or hide computer-aided detection (CAD) markers, for example circles around the areas of suspicion on a mammogram.

6. Documents are not images!

Documents do not belong in an enterprise image viewer, because they are not images. They can be turned into images, and sometimes that happens in healthcare because it's an easy option. For example, a document can be turned into a DICOM object and added to the images for a CT scan. There are zoom in and pan tools for CT scans, that don't work the same when you're dealing with a document. It's better not to have the same viewer for documents, unless the viewer is set up to work with documents, for example if it's a good PDF viewer. The typical enterprise clinical viewer is not really designed for documents.

Is it easy and intuitive for other disciplines to label their images?

Radiologists have the information automatically: the technical information is provided by the imaging equipment and for the most part the clinical information is provided by the doctor ordering the test. By contrast, when a surgeon is taking a picture either during or after surgery, they don't typically record why. It may be because they are worried about leaving something inside the patient, or worried about something anatomically wrong. They know why, they just don't write it down. I've seen situations where doctors use a regular consumer camera to acquire images and create a jpeg with information about the photograph that doesn't tell where or why it has been done, eg which eye was it or whether the patient was given an injection. In the radiology world this would automatically be known, and noted in the computer. So it is a culture shift for those other disciplines. It's not just a case of shoot the picture and store it. The more context you can give it, the more useful it will be to others, who don't know what you know when you took the image.

What are the key success factors for implementing an enterprise information strategy?

First and foremost is communication—with other departments and with referring physicians, explaining what you are planning to do. Radiology departments tend to carry most of the weight on the decision-making, because they have the bulk of the images. But that shouldn't lead them to act unilaterally, as that can cause resentment. You need to make sure you get buy in before you make any decision, so they are comfortable with the direction you are going in. Perhaps the next most important department after radiology is cardiology. Cardiology tends to use a lot of the same machines as radiology for imaging tests such as echocardiograms, cardiac CT and so on. Their needs are very similar to radiology. A good example of something they want is the ability to display cardiology data in tandem with radiology data, such as ECGs alongside the echocardiogram. You need to make sure you have buy in from the chief information officer of your institution and from all the other departments.

What are the technical requirements for running an enterprise viewer?

Today most of the companies that provide the better PACS systems also have a very strong and robust enterprise viewer. An enterprise viewer should run on Windows, Mac, IoS and Android operating systems. Viewers may run as a web solution or as a native app. Some vendors provide an HTML solution, so that the viewer is really a web page that can work across the four platforms. Others use a native application, but then they need to develop one for each platform. There are arguments to say that native apps tend to be better and more customised. However, an HTML solution gives more versatility.

Are most hospitals using enterprise viewers these days?

All hospitals have some kind of enterprise viewing solution. The solutions may be weak or old—some hospitals in the New York area are using a viewer that only runs on Internet Explorer. When hospitals started to adopt PACS in the late 1990s and early 2000s, they mostly looked at medical imaging as something they had to deal with internally. It wasn't seen as an imperative to get the images on the web. Now it is an imperative and is beginning to become mandatory. You have to put the information in the hands of the referring doctor and also the patient. It is a major paradigm shift, to get images on mobile devices. The outside world marches on, and if you want to accommodate them, you cannot use 5-year old technology, it won't work. It's as bad as using no technology. You can't drag your feet any more. That's a big change to institutions, to recognise that they need the competitive advantage. It's not an option, they have to change. ■

Cloud-Based IT Platform for Clinical Trials in Oncology

Computerisation of data collection in a multicentre clinical trial allows fast and easy conduct of the study. Cloud computing is a viable solution for storing patient data in virtual archives accessible by different hospitals. The adoption of an IT platform for centralised review of images and clinical reports in trials saves resources and time.

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Multicentre clinical trials allow rapid collection of data involving great numbers of patients, and let researchers gain specialist advice from international experts. In multicentre clinical trials it is common practice to have clinical auditors at a central radiology centre who perform secondary reading of patient data produced by various radiological centres. CDs or DVDs of radiological images and paper documents with tumour size measurements, according to the Response Evaluation Criteria in Solid Tumours (RECIST) Image Transmittal Form (ITF) (Eisenhauer et al. 2009), are both sent by courier to the central radiology centre for secondary reading. This process is time- and resource-intensive, as it requires individual documents to be physically sent. As the number of patients needing review grows, the burden and delay increases

In order to improve the process, the research team at the radiology department in the University of Pisa hospital has developed an IT platform built on a cloud-based virtual server for a more rapid secondary review of images from multi-centre locations.

Cloud Computing

In oncological trials periodic follow-ups by means of CT or MRI are performed. These imaging modalities require substantial digital storage. Although the number of patients in the clinical trial is defined, it is not possible to determine in advance the total number of follow-up procedures that each patient may undergo; consequently the overall storage requirement cannot be predicted. In this context, the adoption of cloud technology has the benefit of being able to adapt dynamically to the needs of the trial in terms of storage.

Traditionally, a local server was employed for the management of centralised reading. This method has several preliminary requirements:

1. Establish the extent of storage resources
2. Acquire computing resources (CPU, RAM) suitable for replying to requests within a reasonable time
3. Provide backup and recovery mechanisms in the event of failure
4. Dedicated human resources for management of the system at low-level (hardware, operating system, networking, backup), intermediate level (applications and archives management, interactions between autonomous systems, security) and high level (use of applications and production tools for interpretation and processing of information)

As opposed to the traditional approach, the proposed cloud technology allows, depending on requirements, for more adaptive storage resources, and it does not require the use of dedicated human resources for the management of the physical system, as the cloud service provider undertakes this task.

> "ADOPTION OF CLOUD TECHNOLOGY FOR MANAGEMENT OF CENTRALISED READING IN A CANCER CLINICAL TRIAL HAS SHOWN CRUCIAL ADVANTAGE"

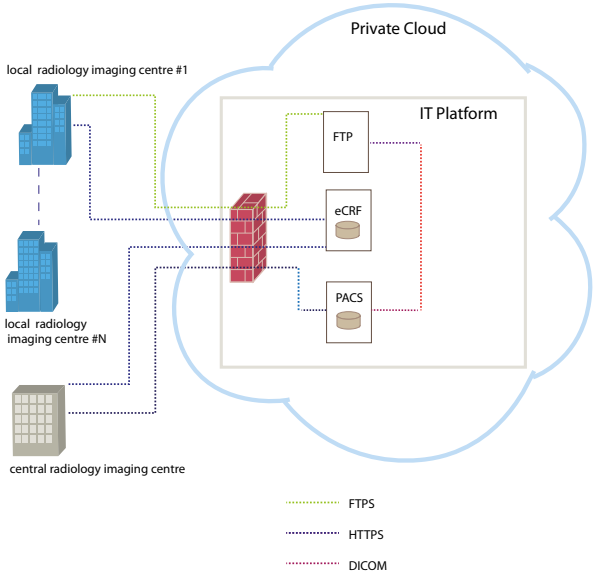

Figure 1

Figure 2

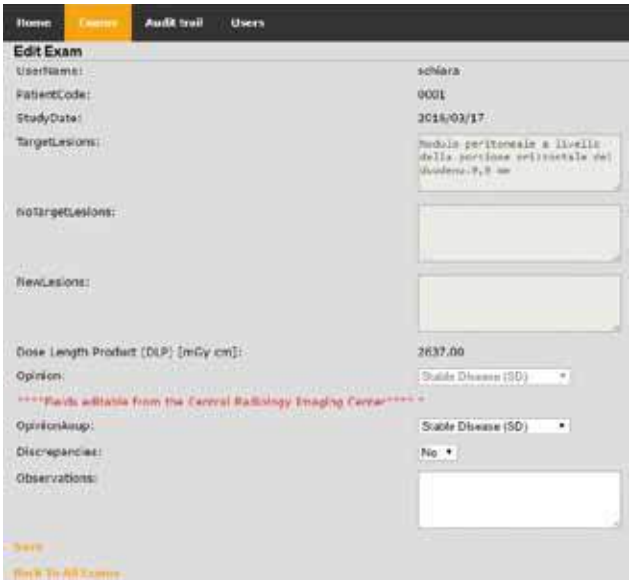

Figure 3

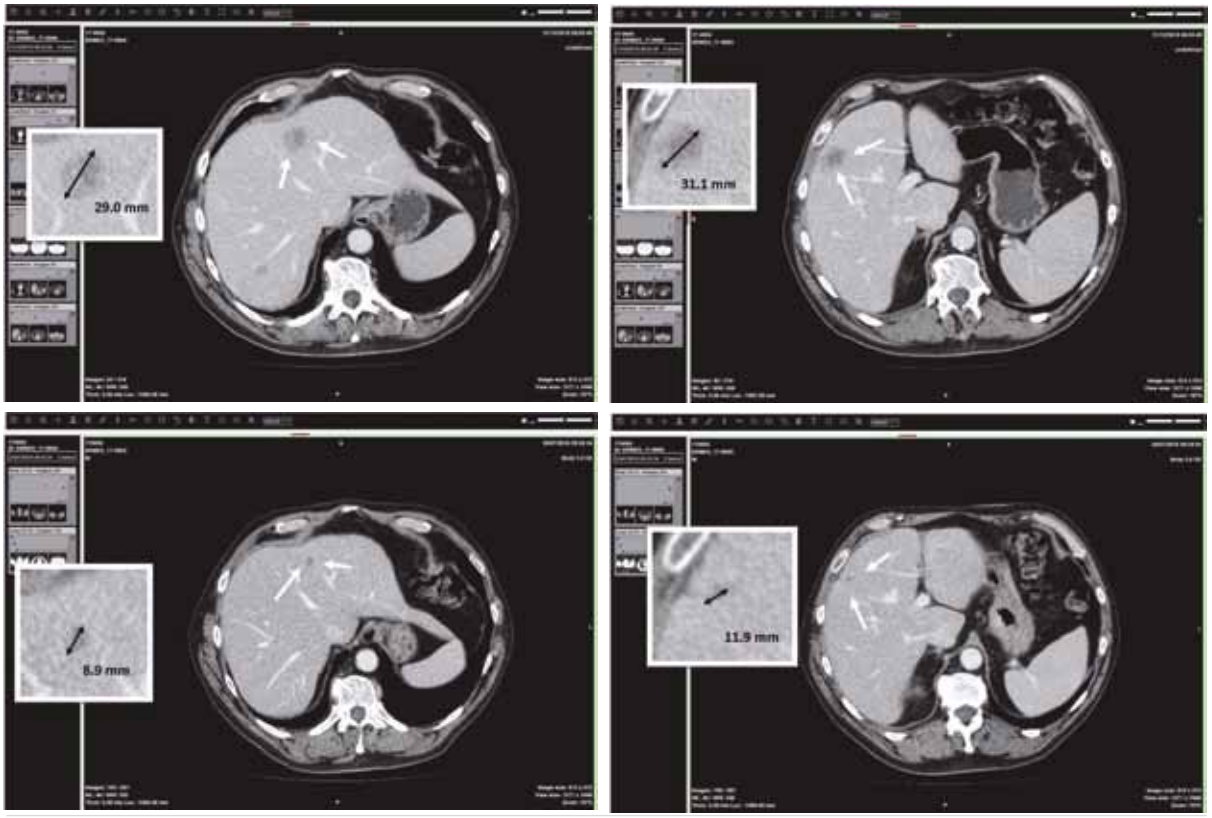

Figure 4

IT Platform

The main issues that need to be considered in designing a platform for a fully electronic central review system are:

1. The choice of a communication protocol for uploading images on the platform. The most frequently used protocols are File Transfer Protocol (FTP) and Hypertext Transfer Protocol (HTTP)
2. The choice of a Picture Archiving and Communication System (PACS) for images storage
3. Choice of a Digital Imaging and Communications in Medicine (DICOM) viewer
4. Implementation of an electronic ITF
5. Implementation of security measures to ensure compliance with U.S. Food and Drug Association (FDA) 21 Code of Federal

Case Study:
Erbitux Metastatic Colorectal Cancer Strategy

The cloud-based IT platform has been used for the management of the radiological images and their centralised reading in the clinical trial ERbitux MEtastatic colorectal cancer Strategy (ERMES), which was sponsored by Policlinico Agostino Gemelli (clinicaltrials.gov/ct2/show/NCT02484833). The University of Pisa Hospital plays a dual role, being both a local radiology imaging centre and the central radiology imaging centre.

The clinical trial ERMES is a multicentric, non-inferiority phase III randomised study in patients with RAS and BRAF WT metastatic colorectal cancer. They are randomised to receive first line FOLFIRI + Cetuximab until disease progression (or unacceptable toxicity), or FOLFIRI + Cetuximab for 8 cycles followed by Cetuximab alone until disease progression (or unacceptable toxicity). Planned accrual time is 50 months, initially planned to be 24 months. In total 600 patients will be randomised, 300 for each arm. The end of the trial will be the date of the last visit of the last participant in the protocol. Final analysis of the data and report writing will occur after formal declaration of the end of the trial. As a participating centre, the University of Pisa has enrolled and randomised 3 patients; only one of them is still on treatment. The others have reached progression and thus are continuing with a second-line therapy. Among the 3 patients from Pisa, the patient who best represents the typical disease progression is patient number 17-0002 who was randomised on 21/01/2016, underwent first dose of therapy on 22/01/2016 and exited the trial on 23/12/2016. Disease assessment according to RECIST 1.1 shows two target lesions and a single non-target lesion in hepatic subsegments IV, V, VII, respectively. **Figure 4** shows that the patient achieved a 65% decrease in tumour burden after 7 months of therapy, which according to RECIST 1.1 is considered a partial response.

Regulations (CFR) Part 11 on electronic records.

Figure 1 shows the IT platform and its main components. The platform has been installed on a virtual server within a private infrastructure-as-a-service (IaaS) cloud provided by the IT centre of the University of Pisa. The cloud-based virtual server runs the Ubuntu 14.04 operating system and is equipped with 8 CPU, 16 GB of RAM and a total of 500 GB of storage.

Communication protocol for images upload

Images are uploaded to the IT platform using File Transfer Protocol (FTP) protocol, then sent to the Picture Archive and Communication System (PACS) through DICOM C-STORE transactions. Prior to uploading, each radiology imaging centre must perform anonymisation, de-identification and assignment of a patient identifier according to how it is specified in the trial protocol. De-identification and anonymisation are common strategies that are used to remove patient identifiers in electronic health record data. The use of these strategies in multicentre research studies is of paramount importance, given the need to share electronic health record data across multiple environments and institutions while safeguarding patient privacy.

> “THE PLATFORM ALLOWS PROMPT DATA AVAILABILITY, EASY IMAGE COMPARISON...”

PACS and DICOM viewer

The Dcm4chee open source PACS, backed by a MySQL database, is used for image archiving, and the web DICOM viewer, ‘Oviyam’ is used for image viewing. All communications between the viewer and PACS are done through the Web Access to Dicom Objects (WADO) service.

Electronic ITF

The ITF is a web application that allows electronic management of all clinical information needed for centralised reading. The server side of the application is implemented in Java Enterprise Edition (EE), which leverages the GlassFish application server and can be used on any operating system with Java. The database server used by the application for data storage is the MySQL database engine, which provides different privilege levels to users based on their roles in the clinical trial. Local radiology imaging centres can upload and store measurements according to RECIST criteria for each examination uploaded on the platform. The

central radiology imaging centre can view the RECIST measurements provided by local centres and submit the results of the review. The clinical trial sponsor can view all data stored on ITF, but cannot make any database changes. A system administrator creates users and provides them with appropriate privileges. In order to ensure compliance with FDA rule 21 CFR Part 11 on electronic records, the application provides an audit trail by recording every change to the database, not only the user who made the change, but also the time and date of modification.

Figure 2 shows the form that local radiology imaging centres fill out to submit an imaging study for centralised reading. It includes information about the patient's identifier, study date, measurements of lesions (target, non-target lesions and new), Dose Length Product (DLP) and global assessment of disease according to RECIST criteria; Complete response, Partial response, Stable disease and Progressive disease.

Figure 3 shows the form used by the central radiology imaging centre to report the results of the review. It is in two parts. The first part is not editable and contains information provided by the local radiology imaging centre that has submitted the exam to centralised reading. The second part is used to archive the results of the review, including the global assessment of the disease discrepancies with the assessment provided by the local radiology imaging centre, and other comments.

Security

Security is ensured through the use of user names and passwords to uniquely authenticate users and provide different privilege levels to access the ITF. A local radiology imaging centre can only create, view and edit their own data and not those of other centres. The central radiology imaging centre can display all data and insert results of the review. The sponsor can display all data, but cannot make changes to the database.

Data exchange on the internet takes place over Secure Sockets Layer (SSL) encrypted channel. This happens for all FTP and HTTP connections. Firewall access to the DICOM viewer and PACS is only permitted to users of the central radiology imaging centre.

Conclusion

Adoption of cloud technology for management of centralised reading in a cancer clinical trial has shown crucial advantages. Since the management of infrastructure is provided by the cloud service provider, it has allowed radiology department technical staff to exclusively devote their time to implementation of the IT platform. We have used the platform in clinical practice and verified its simplicity of use, both from the point of view of the local radiology imaging centre as uploaders of data, as well as that of the central radiology imaging centre as reviewers. Overall we have found that the platform allows prompt data availability, easy image comparison, fewer human errors and time and cost reduction, thus ensuring a more rapid secondary review. ■

KEY POINTS

- ✓ Computerisation of data collection in a multi-centre clinical trial allows fast and easy conduct of the study
- ✓ Cloud computing is a viable solution for storing patient data in virtual archives that are accessible by different hospitals
- ✓ The adoption of an IT platform for the centralised review of images and clinical reports in cancer clinical trials results in an overall reduction of resources and time

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RAD-AID International and Global Health Radiology

RAD-AID is a non-governmental organisation with a mission to promote radiology in global health with emphasis on sustainability through education.

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According to the World Health Organization (WHO), approximately 3-4 billion people are at risk for widespread loss and death that could be treated or avoided if radiology was available. Additionally, 6.3 million children under five died in 2013, succumbing to preventable or curable pneumonia, malaria, injuries, non-communicable diseases and congenital abnormalities (World Health Organization 2015). Most medical decisions and public health programmes in high-income countries (as defined by the World Bank) are now influenced by medical imaging and radiology tests. The lag and absolute lack of imaging in lower income countries leaves most of the world behind. Radiology is a focal point for addressing health disparities.

RAD-AID International began in 2008 to answer the need for more radiology and imaging technology in resource-limited regions and communities of the world.

RAD-AID is a nongovernmental organisation with a mission to promote radiology in global health with emphasis on sustainability through education.

RAD-AID's mission is to increase and improve radiology resources in low-income countries and areas of access disparity around the world. Radiology is a part of nearly every segment of healthcare, including paediatrics, obstetrics, medicine and surgery; this highlights the absence of radiology as critical when considering global health disparities.

From its beginnings as a small group of interested individuals at Johns Hopkins University in Maryland, RAD-AID has grown to include more than 5700 volunteers from 100 countries, 45,000 web visitors per year, 53 university-based chapter organisations, onsite programmes in over 20 countries and an annual conference on global health radiology. The composition of RAD-AID's volunteer pool is 50% physician (including trainees), 35% technologists (radiographers and sonographers), and the remaining 15% include nurses, physicists, business professionals and public health specialists.

RAD-AID is a nongovernmental, nonprofit organisation in official relations with the World Health Organization (WHO). The aims of cooperation with nongovernmental organisations (NGOs) "in official relations" (ie officially affiliated) with WHO are to advocate integrative global health policy, technical standards and consistency in health services coverage and delivery; to ensure work towards coordinated technical and resource inputs to countries; to mobilise specific constituencies to ensure global resources for health services delivery; to maintain and develop strategic relationships with technical and research partners; and to foster relationships with relevant advocacy and civil society groups (WHO 2016). Radiology can and should play important roles in solutions and plans to address the Sustainable Development Goals (SDGs) set by the United Nations. Beyond the obvious contributions to SDG #3 "Ensure healthy lives and promote well-being for all at all ages," there are opportunities, nearly too numerous to count, across the remaining sixteen Goals. Nowhere is there greater opportunity for the traditionally resource-rich discipline of radiology than in SDG #17 "Strengthen the means of implementation and revitalise the global partnership for sustainable development." As the UN writes: "Achieving the ambitious targets of the 2030 Agenda requires a revitalised and enhanced global partnership that brings together governments, civil society, the private sector, the United Nations system and other actors and mobilises all available resources. Enhancing support to developing countries, in particular the least developed countries and the small island developing States, is fundamental to equitable progress for all" (Sustainable Development Knowledge Platform).

According to Dr. Mollura, Founder and CEO of RAD-AID International: "Radiology is an important contributor to the achievement of the UN SDGs, including:

(i) good health and wellbeing
(ii) quality education
(iii) decent work and economic growth
(iv) industry innovation and infrastructure and
(v) partnerships for the goals

because radiology is an essential technology and service for healthcare, reinforces medical workforce education, contributes strongly to economic growth and investment, underpins vital health care infrastructure and information services, and stirs cross-disciplinary

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RAD-AID in Asia

RAD-AID in Haiti

RAD-AID in Latin America

partnerships, respectively" (Sustainable Development Goals 2016).

Important recognition of RAD-AID's work includes the 2013 Community Service Award from the American Medical Association and the 2015 Global Humanitarian Award from the American College of Radiology.

What is Radiology-Readiness?

A cornerstone of RAD-AID's strategy is the Radiology-Readiness tool, which RAD-AID developed and trademarked in 2009, endorsed by the WHO in 2011. Radiology-Readiness is a systematic data collection tool for assessing how advanced healthcare imaging technology can be planned and implemented to best match the medical needs and infrastructure/personnel resources of a community. This approach of advanced assessment leads to effective planning and implementation so that RAD-AID programmes have long-term sustainability and measurable outcomes.

> "RAD-AID IS A NONGOVERNMENTAL ORGANISATION WITH A MISSION TO PROMOTE RADIOLOGY IN GLOBAL HEALTH WITH EMPHASIS ON SUSTAINABILITY THROUGH EDUCATION"

Radiology-Readiness collects information on all facets of radiology as well as the healthcare environment in which radiology will be utilised, to assure aligned needs and opportunities for improvement. Does it make sense to donate a CT scanner when the community does not have the appropriate electrical power grid? Does it make sense to screen for paediatric pneumonias with x-ray radiography when there are no antibiotics available to treat? Is it effective to implement mammography for breast cancer

screening when there are neither surgeons to biopsy nor oncologists to treat a diagnosed cancer? Radiology-Readiness analyses these and numerous other factors involved in or related to imaging to assure resources are not wasted and the radiology strategies best fit within resource constraints and clinical context of a hospital or community.

If a community needs versatile low-cost technology with many prenatal patients, an ultrasound solution may be recommended. If a community lacks women's health engagement with large marginalised slum populations, a mobile health truck may be recommended. If extensive hardware is present, but the training is insufficient, an educational strategy is implemented. If ancillary resources are needed to make the available radiology more effective, RAD-AID works to assure those resources are available to include treatment referral networks, medications and lab tests.

RAD-AID programmes then implement solutions that are multidisciplinary, including economic development (business planning for facilities using radiology equipment and personnel), clinical innovation, technology development, educational training of health workers and public health strategies (deploying radiology to address worldwide health issues).

Perspective of RAD-AID Members

What drives the volunteers themselves? Dr. Munir Ghesani, assistant professor of radiology at the NYU School of Medicine explains: "Even though I had more than 10 years of global health experience before joining RAD-AID, I have benefited considerably by adopting its strategies, with proven track record, and by making several productive connections in this expansive

RAD-AID Radiation Therapy

RAD-AID India

network." Dr. Ghesani has been passionate about global health work in Tanzania for many years and now serves as the director of the RAD-AID Tanzania programme. Through partnership with local hospitals and providers, this project is helping to train staff and implement new services in Arusha, Tanzania, with the vision of empowering local providers and building up lacking infrastructure. Dr. Ghesani encourages those interested in global health to get involved: "Whether you are just embarking on a global radiology journey or you are an established veteran of the field, RAD-AID has so much to offer you!"

According to RAD-AID Founder and CEO, Dr. Daniel Mollura: "RAD-AID provides basic structure and resources for volunteers to express their vision and desire to help others, and the projects have flourished." In creating the organisation in 2008, Dr. Mollura wanted to leverage his background as a Goldman Sachs Financial Analyst and prior success in founding start-up companies to improve the global health radiology landscape. This has led to a necessary focus on sustainability and problem-solving within the severely resource-limited settings often seen in the developing world. As he describes it: "RAD-AID's work is not just about helping other countries and the poor, but RAD-AID also aims to cultivate a new generation of health leaders who can think outside the box in charitable and innovative ways."

These opinions seem to resonate with many in the greater radiology community. "Volunteering with RAD-AID is a two-way street," affirms Bart Pierce, director of the RAD-AID Ethiopia project. As a magnetic resonance (MR) technologist and MR safety officer, Mr. Pierce has a passion for MR education that has led him professionally to an adjunct faculty position teaching MRI physics, as well as presenting seminars at the local, state and national level. In extending that same passion abroad, he has directed several projects, including the implementation and training for the first MRI machine at Black Lion Hospital in Addis Ababa, Ethiopia. "It has allowed me to give back, by sharing my skills, to improve the level of patient care around the world. In addition, becoming involved with those of differing cultures and beliefs has changed how I view the world." In this way, the RAD-AID partnership in Ethiopia has embraced a two-way exchange of ideas and professional development for radiology residents, physicians, technologists, nurses and more.

According to Dr. Berndt Schmit, RAD-AID Manager of Equipment Implementation: "Radiology is a gateway specialty for many health information technologies in the developing world. Hospitals often first adopt digital imaging such as computed radiography because they can realise the immediate benefits of improved clinical capability as well as the cost savings on consumables. Later, hospitals adopt other digital platforms such as electronic medical records (EMR) and health information systems (HIS). Part of RAD-AID's international efforts to advance radiology is donating and implementing Picture Archiving and Communications Systems (PACS) with the related IT training and infrastructure. The crucial clinical benefit of PACS is the ready availability of prior imaging studies for comparison, which enables the monitoring of disease and the earlier detection of disease. By deploying PACS, RAD-AID is helping to usher in the digital global health era for low and middle income countries."

Finally, the truly global need for the kind of work being done by RAD-AID projects has led many volunteers to create something new when necessary. As a diagnostic radiology resident at Temple University Hospital with a strong background in public health, Dr. Farouk Dako had already begun to serve the indigenous population of Nigeria. In volunteering as programme manager for RAD-AID Nigeria, he has been able to channel his experience of founding and working with in-country NGOs to get the new Nigeria project running. Dr. Dako has led two trips to Nigeria to assess the country's radiology resources and infrastructure and begin building local partnerships. For him: "RAD-AID is an organisation that is creating a connection among radiologists around the world. It is allowing us to reignite that shared passion for humanitarian work that drove all us to pursue a career in medicine."

Get Involved

RAD-AID leads programmes with emphasis on all areas of subspecialty diagnostic and interventional radiology, including strong informatics and PACS integration around the world. If you are interested in learning more or volunteering, then please visit **rad-aid.org** ■

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Radiology Education Goes Mobile

What's Changed?

Mobile devices are used by most students, residents and radiologists in everyday life. They allow fast and convenient access to all internet resources and to data stored on the devices. Entire bookshelves of information can be transported easily and are at the device user's fingertips. The interactivity of mobile devices allows new techniques of knowledge presentation to be introduced. During the past years, an increasing number of learning and reference apps that draw on this capability have been introduced. Different classes of e-learning apps can be identified. Their quality in terms of content, usability, and clarity is very disparate, as is assurance of their continued availability. There is a need for radiology e-learning apps to undergo quality control and review. In addition to mobile devices, social media will also play an increasing role in radiology e-learning.

Although mobile devices (personal digital assistants like the PalmPilot® and Windows PocketPC®) were introduced in the late 1990s and early 2000s, it was the introduction of the iPhone ten years ago that started the success story of mobile devices. Today, mobile devices are ubiquitous, and in the pocket of almost every student, resident or radiologist. Most smart functionality of mobile devices is provided by mobile applications that can be purchased on the device from so called App stores.

Advantages of Mobile Devices

Mobile devices have a number of advantages. They provide portability, flexibility, access to multimedia, and the ability to look up information quickly (Wallace et al. 2012). Mobile devices have enough memory to store huge amounts of data, enabling the user to store the equivalent of an entire library of radiology books and journal articles. In addition to the weight advantage when compared to printed media, mobile devices now have excellent screens and powerful processors, allowing dynamic and enhanced display of radiologic images or other documents. While paper is able to display only static images, mobile devices allow entire stacks of radiology examinations to be rendered, including 3D rendering of data enhanced with overlays of comments and highlights that can be turned on and off for learning purposes. Compared to conventional desktop computers or laptops, the advantage of mobile devices is their portability. This is of special interest in the learning context, since it is much more convenient to read an ebook or use a teaching app on your mobile phone than a laptop when travelling on a train or plane.

Categories and Examples of Apps

Depending on the way content is generated and used on mobile devices, different categories of mobile apps may be distinguished. Some editors propose using a combination of different categories.

Classic Media Content Transferred to Mobile Devices

Most print media are available in digital format, usually Adobe PDF®. Different reader applications allow these texts to be read on mobile devices. The digital format allows searching and the ability to use hyperlinks within the same or between different texts. Some applications also allow the reader to make personal annotations in digital documents. However, many readers still feel more comfortable reading books, because they believe it is faster to browse through these than through an ebook. Lectures can be easily recorded on electronic media and distributed through the internet. Channels of distribution include YouTube and Podcasts among other platforms. A great collection of radiology-only lectures has been collected by the European Society of Radiology (ESR) and can be found on European Congress of Radiology (ECR) Online (**ecronline.myesr.org**). ESR also offers a large collection of teaching cases with EURORAD (**eurorad.org**) and radiological posters with EPOS (**myesr.org/congress/epos**). All of these are readily available on mobile devices that have access to the internet (**myesr.org/education/online-services**).

Literature Managers

There are several powerful tools that can be accessed on mobile devices, which enable the user to organise

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figure1	figure1.com
IMAIOS	imaios.com
iCat Solutions	icatsoftware.co.uk/radiology.html
iMedicalApps	imedicalapps.com
LearningRadiology	learningradiology.com
MedShr	en.medshr.net
mri education	mrieducation.com
iCat Solutions	icatsoftware.co.uk/radiology.html
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Literature Managers	
Docphin	docphin.com
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collections of articles and book chapters. These apps allow the user to access and download articles from electronic scientific journals, and index articles or other documents from other channels. They also integrate powerful tools, which enable the user to organise a personal library. Keywords can be attributed to articles, citations can be extracted, and notes to articles can be documented. Examples of literature managers are ReadCube (**readcube.com**), Mendeley (**mendeley.com**) and Docphin (**docphin.com**).

Wikis

"A wiki is a website that provides collaborative modification of its content and structure directly from the web browser" (**en.wikipedia.org/wiki/Wiki**). Wikis are powerful and flexible knowledge management systems. The best-known public radiology wiki is Radiopaedia (**radiopaedia.org**), which provides more than 10,000 articles and 25,000 cases at the time of writing. In contrast to Wikipedia, where quality is supposed to be controlled by "crowd intelligence", the accuracy of articles in Radiopaedia is assured by a board of editors. While access to the web version is free (financed by advertising), the content for the mobile app has to be paid for.

Dedicated Radiology Learning Apps

Specialised radiology learning apps constitute a new category of media. In the best cases, they have excellent content written by an expert author, are overseen by an editor, and make good use of the multimedia capabilities of mobile devices, thus offering an enhanced learning experience. Dynamic display of images, multidimensional display, interactivity and audio are examples of new possibilities that facilitate understanding and retention of sometimes complex content. Excellent examples are the series of apps published by doRadiology® (**doradiology.com**). Technically less innovative, but with proven content, mri education has released a series of apps combining lectures to watch combined with notes on the basic physical principles of MRI (**mrieducation.com**). Radiology Assistant (**radiologyassistant.nl**) is a source of radiological knowledge both as a website and an app, with continuously extended peer-reviewed content for several subspecialties. Another app with a broad range of radiological content (in German), including books, journals, and other educational and reference material in one app, is the eRef App (**eref.thieme.de**) from Thieme Editors.

Anatomy Apps

This is a special class of apps, which together with their desktop counterpart, have rapidly replaced classic anatomy books. The major advantage for the radiologist is the ability to interactively scroll through the body in different planes, and the possibility to display

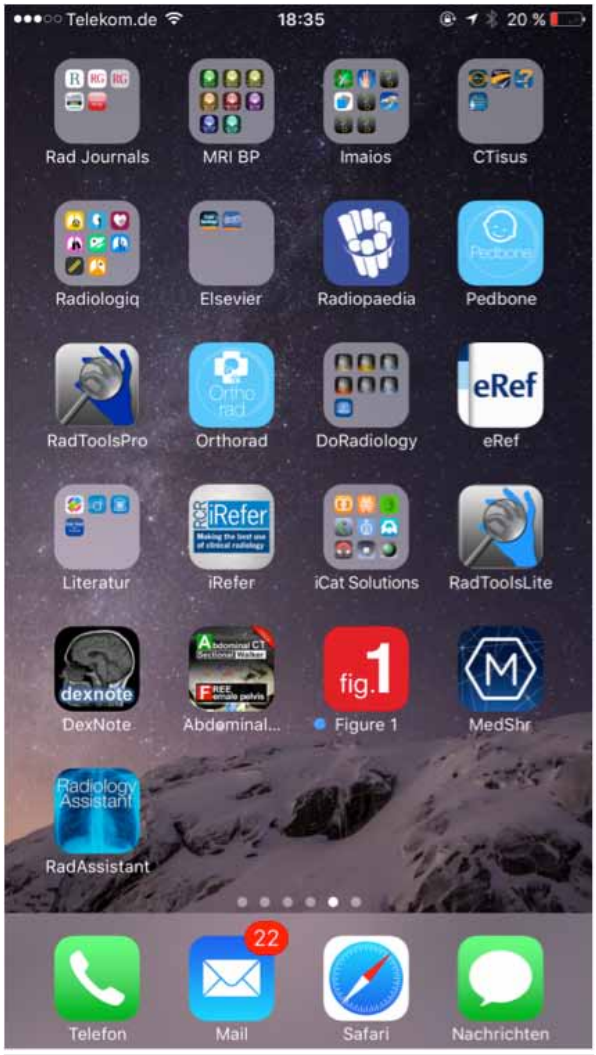

Figure 1. There is a large choice of radiology e-learning and reference Apps

schematic and MR or CT anatomy side by side. For the student or resident, the biggest advantage is the possibility to turn anatomy marks on and off. Whilst a wide variety of anatomy apps exist, it is certainly worth having a look at the innovative e-anatomy app from Imaios (**imaios.com**).

Simulation Apps

Simulation apps engage the user either to actively set up parameters in the app interface, to control a virtual device or to respond to a virtual diagnostic situation (patient simulation). Good examples are apps that simulate the control of different MRI sequences and present the corresponding images as a result of the interaction, such as MRI Sim from iCat Solutions (**icatsoftware.co.uk/radiology.html**).

Limitations of Apps and Mobile Devices

Quality and Persistence Issues with Apps

While apps on mobile devices offer many new possibilities, the radiology app market is far from mature. When searching the app stores, the sheer number of radiology apps (Rodrigues et al. 2013) makes choosing one difficult (Aungst et al. 2014). Many radiology apps have been written by one person. In these cases, an update of the app or of its content is often not guaranteed. Some older apps no longer even run on newer mobile operating systems, and this is not always evident when downloading the app. For most apps, it is also unknown whether content undergoes peer review and editorial control. For these reasons, a self-certification system for medical apps has been proposed by Lewis (2013). There are a few websites trying to help with reviews of medical apps, such as **iMedicalApps.com**. Only a few reviews of radiology apps are available in the literature. Shelmerdine and Lynch reviewed smartphone applications in paediatric radiology (Shelmerdine and Lynch 2015) and the *Journal of Digital* Imaging started in 2015 to conduct reviews of radiological apps (Shih 2015). Usability of radiology apps needs to be improved in many cases (Kim et al. 2016).

Mobile Devices are Not Integrated into Radiologists' Workflow

Radiologists in their daily routine are less mobile than other medical doctors. Since they are sitting most of the time in front of a diagnostic workstation, the use of a mobile device could be less attractive than for other specialists, especially when considering clinical decision systems, which we expect in the future to be seamlessly integrated into radiologists' workflow.

Where Are My Personal Notes?

A major inconvenience of apps, as with web content, is their very limited capability to hold personal notes made by the user. This is a real drawback when compared with classic books or journals. For many people, enriching text or other content with personal comments or highlights is an important support for memorisation, and helps them to quickly recall facts when coming back to the same text. While one can still keep a personally annotated older copy of a book, this is impossible with apps or websites. The notes are simply lost when you get an upgrade of the app or when the website is rewritten.

Future Trends

Microlearning, Integration of Clinical Decision Systems and E-Learning

The rapid increase and turnover of medical and radiological knowledge makes it difficult to learn all radiology knowledge through books and other printed media as in the past. It is almost impossible to keep up to date with

	Print Book	Print Journal	Wiki	Web	App	SoMe
Review process	++	++	+			
Continous update			+++	+++	++	++++
Persistence of content	++++	+++	++		++	
Interactivity			+		++	++++
Personal notes	++++	++				
Searchability			+++	++	++	+++

Figure 2. Characteristics of Different Learning Media
SoMe Social Media

new classifications or clinical pathways. The role of clinical decision systems will increase in the future, not only for ordering radiology examinations, but also for coming to conclusions or making recommendations based on radiology examinations. If well conceived, these clinical decision systems could lead to something Charles Kahn called "just-in-time learning" (Kahn 2006), ie microlearning during the radiology reading process. New or updated information would be presented on demand by the system during the reading of radiology examinations. It is reasonable to expect mobile devices in the future to be linked to desktop applications, thus bridging the gap between mobile e-learning and clinical decision systems.

Social Media and E-Learning

"Social media use web-based technologies, desktop computers and mobile technologies (eg, smartphones and tablet computers) to create highly interactive platforms through which individuals, communities and organisations can share, co-create, discuss, and modify user-generated content or pre-made content posted online" (**en.wikipedia.org/wiki/Social_media**). Social media are ubiquitous in the daily life of the general population and radiologists (Ranschaert et al. 2016). While general social media, such as Twitter, Facebook or Instagram, can be used to enhance e-learning (ie, to tweet about new content from sites such as LearningRadiology (**learningradiology.com**)), social media specialised in medical e-learning are appearing on the market. New relevant content is actively being pushed to the user. Information is presented in small pieces—something that appears to be an important feature for digital natives, who can have shorter attention spans than previous generations. Small pieces of information are also very convenient for presentation on mobile devices and on the go. The pioneer in this field is figure1 (**figure1.com**). Another example is Medshr (**en.medshr.net**), which is intended for discussion of medical cases in a professional social network. Social media are expected to play an increasing role in e-learning. For example, FOAMrad is a community of radiologists that shares and discusses free open access radiology education material (**twitter.com/foamrad**).

Conclusion

While print media today still have some advantages, it is foreseeable that for future generations of students, residents and radiologists—the digital natives—print media will be replaced with digital content (Duszak 2011), and digital content will, for a large part, reside on personal mobile devices. Some of today's inconveniences of digital content (including lack of editorial control, quality issues and usability) will be resolved by organisational changes, such as the expansion of small companies, or large commercial editors stepping into the mobile market. Interactivity and social media will play an increasing role in learning radiology, since these are tools that upcoming generations have grown up with and use in their everyday life. ■

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Contrast-Enhanced MRI

30 Years On

HealthManagement.org is pleased to bring you a flavour of Dr. Heywang-Köbrunner's keynote lecture to the EUSOBI 2016 annual scientific meeting, to celebrate the 30th anniversary of contrast-enhanced breast MRI.

Sylvia Heywang-Köbrunner

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In 1984, with colleagues I first began to investigate magnetic resonance imaging (MRI) of the breast without contrast to discriminate between benign and malignant lesions using different pulse sequences, calculated T1 values, T2 values and proton density values (Heywang et al. 1987). We found that in some lesions (which consisted of different tissue components) a characteristic internal structure was visible on MR imaging, reflecting their histopathologic structure. For most lesions with irregular contours a discrimination based on signal intensities or calculated T1- and T2-values did not seem possible, however.

Based on this experience I suggested studying the potential of MRI using contrast agents. The radiologists I spoke to, including the head of our department, were sceptical, and thought that MR contrast was too expensive and too invasive for breast examinations. After many discussions the first supporters who recognised the potential of this idea were researchers and managers in the industry. These people, including Dr. H.P. Niendorf, Prof. Dr. U. Speck, Dr. W. Clauss and Dr. Hans-Joachim Weinmann from the German pharmaceutical company Schering AG, carried out safety studies on gadolinium-DTPA (eg Niendorf et al. 1991). Only based on their support did our very first studies become possible.

Contrast-Enhanced MRI: The Pioneer Patients

The very first study on contrast-enhanced MRI (CE MRI) only included 10 patients, who were examined in 1985. One of these patients was a 25-year-old mother with a 3cm breast cancer on the right side. The left breast appeared normal with palpation, ultrasound and mammography. The MRI showed an ipsilateral 3 cm fast-growing cancer, and by chance a second contralateral small scirrhous cancer was detected. Even though this young mother was very brave and confident in the potential of medicine, the patient did not survive. But because of her findings continuation of our research became possible and further examinations and studies followed. Today probably many other women are alive because of her.

First Steps...

During the first studies already we noted the value of CE MRI for distinguishing dense fibrous tissue and scar tissue from carcinoma. The first publications on CE MRI also included a first case of an enhancing ductal carcinoma in situ (DCIS) (Heywang et al. 1986). The fact that DCIS enhanced with the contrast agent indicating an increased perfusion was astonishing, since DCIS is just a precursor of breast cancer, which in up to fifty percent of cases develops to become breast cancer, and it was not expected to be well perfused. Formerly it was expected that only invasive breast cancers could be associated with increased vascularity and perfusion..

In 1987/88 new pulse sequences became available, which allowed measurement of the uptake of the contrast agent Gd-DTPA at several time points after injection. This allowed evaluation of the speed of uptake, to observe the wash-in and wash-out of contrast agent with time and thus measurement of so-called dynamic enhancement curves for different tissues (Heywang et al. 1988). We found that in some cases a better differentiation seemed possible early after contrast medium than on the later scans. At that time Dr. W.A. Kaiser also began investigations into this method (Kaiser and Zeitler 1989).

Both groups of researchers showed that a variety of enhancement curves could be observed in different tissues. Some benign and malignant lesions could often (but not always!) be better distinguished by including this added information.

Overall contrast enhancement (uptake) gives functional information about the pathophysiology of the underlying tissue. Increased and early uptake, as observed in about 90% of invasive breast cancers and in up to 50% of DCIS is caused by increased vascularity, vascular permeability and increased interstitial space. Studies have shown that growth of invasive tumours beyond a size of 2-3 mm requires such increased and changed vascularity. Growth of such tumour vessels is caused by so-called growth factors, which are produced by the tumours. Approximately half of the malignant tumours also demonstrate an early washout. If present, this may be an important indicator of malignancy. Until

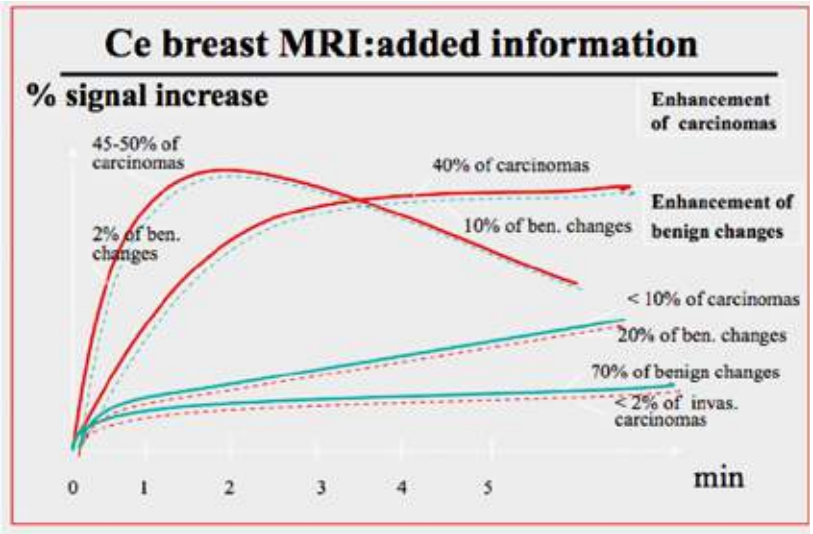

Figure 1. CE Breast MRI: Added Information

> "LATER THAN 12 MONTHS AFTER RADIATION THERAPY CE MRI CONTRIBUTED SIGNIFICANT ADDITIONAL INFORMATION"

today the above-mentioned observations constitute the basic information, which can be gained from contrast-enhanced breast MRI.

Research Continued

The late 1980s and onwards saw more publications, looking both at the benefits and the pitfalls (Heywang et al. 1988; Heywang-Köbrunner 1990; Heywang-Köbrunner and Beck 1996; Kaiser 1993; 2008).

When comparing the information that can be obtained by mammography and ultrasound we found that MR imaging provides different complementary information and thus proved "beneficial as a supplement in selected, diagnostically difficult cases". These results were published in a study of 150 patients with 167 biopsy-proved lesions examined by MRI with and without contrast and by the other imaging modalities (Heywang et al. 1989).

In 1996 we highlighted that certain pulse sequences (so-called opposed-phase sequences) cannot be used for contrast-enhanced MRI of the breast. The reason is that the signals of surrounding fat and enhancing glandular tissue may cancel each other with this technique. This observation, which predominantly concerns small lesions such as DCIS or small invasive cancers, was quite important, since otherwise these early malignancies might go undetected (Heywang-Köbrunner et al. 1996).

One major topic of our studies concerned investigation of the value of contrast-enhanced MRI for various diagnostic questions and indications:

In a 1990 study we looked at 60 patients with post-operative scarring, with (30) and without (30) silicone implants, including 28 patients with obvious normal or abnormal findings and 32 diagnostically difficult patients, who were referred to MR because of uncertain mammographic and/or clinical findings (Heywang et al. 1990). In the diagnostically difficult cases, CE-MRI proved helpful in 23/32 cases. While scarring early after surgery often enhanced and thus showed confusing results, scarring older than 6 months usually did not enhance. As most invasive carcinomas larger than the slice thickness enhance significantly, CE MR allowed excellent discrimination between scarring older than 6 months and malignancy.

We further investigated the technique for women with breast silicone implants, and found that 4/13 recurrences were detected by MRI only. In addition, MRI correctly diagnosed scar tissue in all cases with indeterminate findings. We therefore recommended contrast-enhanced MRI in patients with diagnostic problems or high risk of recurrence after silicone implants (Heinig et al. 1997). This has today become an indication for MRI, which is accepted by insurance organisations in most industrialised countries.

In a 1993 study of patients after tumourectomy and radiation therapy we investigated the enhancement of tissue during variable time intervals after therapy with CE MRI (Heywang-Köbrunner et al 1993). Up to nine months after therapy, differentiation between post-therapeutic changes and recurrence was often difficult, because both the tumour and scar tissue enhanced with contrast agent. We therefore recommended that CE MRI not be used before nine months after radiation therapy; however, after 18 months it regularly proved to be a valuable additional tool. This was confirmed by another follow-up study of our group in 1998 (Viehweg et al.). In this larger study of 207 patients who had undergone lumpectomy we concluded that in the first year after therapy, CE MRI is only indicated in selected cases. Later than 12 months after radiation therapy CE MRI contributed significant additional information. It allowed much better distinction of post-therapeutic fibrosis from recurrent cancer, and detected recurrent disease with more sensitivity and at an earlier stage. This, too, has now become a widely accepted indication for breast MRI.

In 2002 we published a study that showed that short-term anti-oestrogen medication could suppress part of the unspecific enhancement seen on breast

(Heinig et al. 2002). We had hoped that this information might be used diagnostically in the future. However, until today anti-oestrogen medication is only applied therapeutically.

Parallel to the above studies reported by our group other research groups started to investigate CE MRI of the breast and contributed various publications. Most early publications stem from 1993 and 2003. In 1996-1999 the first international multicentre study took place in 11 sites in the Netherlands, Belgium, Germany, the USA, Sweden and France. It was published in 2001 (Heywang-Köbrunner 2001). This showed that it is possible to use a widely available standardised MR technique and define statistically founded interpretation rules. The sensitivity achieved with a low specificity ranged around 97% or around 91% with high specificity level.

The above multicentre study was soon followed by a second multicentre study conducted between 1998 and 2001 in Germany and the USA, published in JAMA in 2004. It analysed MRI use as a potential replacement for biopsy (Bluemke et al. 2004). The researchers concluded that breast MRI has high sensitivity but only moderate specificity independent of breast density, tumour type, and menopausal status. However, they did not recommend using MRI alone instead of tissue sampling, a result which is widely accepted, even today.

Even though MRI is the most sensitive method for detecting invasive breast cancer, no imaging method is perfect. Thus in cases with suspicious findings, percutaneous breast biopsy, which meanwhile has been developed as a minimal invasive, very reliable and widely accepted method, is the gold standard for further assessment of imaging-detected lesions.

Breast MRI Takes Off

Following the two multicentre studies described above, the "take-off" of breast MRI can be dated to the new millenium. Before 2000 there are fewer than 500 hits for MRI of the breast in PubMed. After that date there are more than 10,000 hits.

Peters and colleagues conducted a meta-analysis of 44 studies of MRI to diagnose breast lesions (Peters et al. 2008) and found overall sensitivity of 90% and specificity of 72%. Systematic reviews of randomised controlled trials of preoperative MRI found approximately 20% additional detection of lesions in some studies (Plana 2012; Turnbull 2010; Peters 2011; Houssami 2014; Fancellu 2015; DiLeo 2015). However, the studies also found that MRI is also associated with a high number of false positive calls and with possible overdetection and potential overtreatment.

Based on the initial work described above and the existing possibility for further assessment of MR-detected lesions, MRI has been used and investigated for an increasing number of indications. CE MRI has proven most valuable for part of the indications; many indications, however, can still be solved without MRI. Indications for which MRI is not recommended include screening of women at low risk (which can mostly be solved by mammography) or work-up of suspicious lesions, for which minimal invasive biopsy methods are considered methods of choice

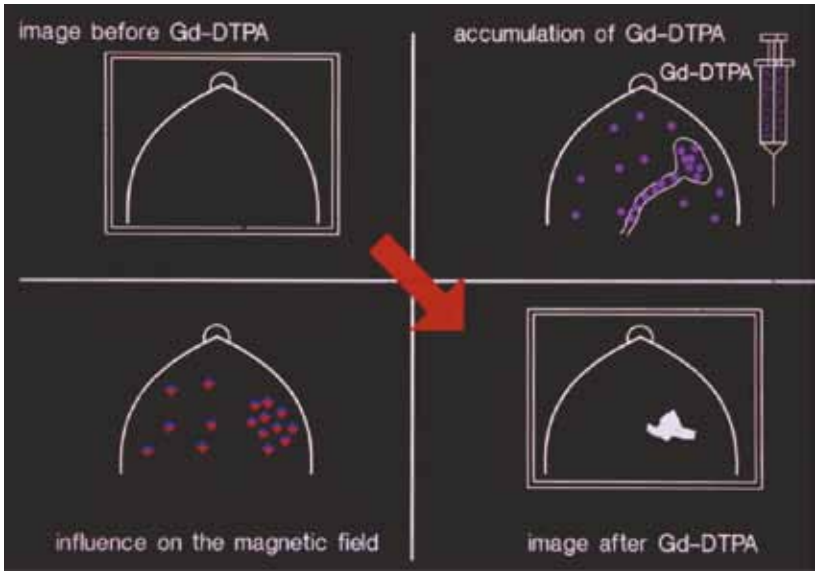

Figure 2. Overall contrast enhancement (uptake) gives functional information about the pathophysiology of the underlying tissue. Increased and early uptake, as observed in 95% of invasive breast cancers and in 50-60 % of DCIS is caused by increased vascularity, vascular permeability and increased interstitial space. Other studies have shown that growth of invasive tumours beyond a size of 2-3 mm requires such increased and changed vascularity. Growth of such tumour vessels is caused by so-called growth factors, which are produced by the tumours. Approximately half of the malignant tumours also demonstrate an early washout. If present, this may be an important indicator of malignancy. Until today the above-mentioned observations constitute the basic information, which can be gained from contrast-enhanced breast MRI.

Indications for Contrast-Enhanced MRI

So, after 30 years of contrast-enhanced MRI, how should this technique be used today?

MRI Screening of High-Risk Women

After MRI became more and more accepted as a very sensitive method for women with a high risk of breast cancer, CE MRI has become the most important imaging modality. The work is based on important research from several international groups. The most important early publications and their results are shown in **Table 1**.

In many women who are at high risk breast cancer grows earlier than in the usual population. During younger age the breast tissue is denser and mammography is less sensitive. Also, certain tumour types occur in these women, which are not reliably detected

Author	year	number of pts	cancers detected	Sens MRI	Spec MR	Sens. Mx	Spec Mx	Sens. US	Spec US
Hagen AI	2007	491	25	86%	NA	50%	NI	NI	NI
Hoogerbrugge	2008	196	17	60%	90%	41%	93%	NI	NI
Kriege M	2004 2006	1909	45	71%	90%	40%	95%	NI	NI
Kuhl (JCO)	2005	529	43	91%	97.5%	33%	97%	40%	88%
Kuhl (JCO)	2010	687	27	92.5%	98%	33%	99%	37%	98%
Leach M	2005	649	35	77%	81%	40%	93%	NI	NI
Lehmann	2005	367	4	100%	NA	25%	NI	NI	NI
Lehmann contralat ca	2007	969	30	91%	88%	NA	NI	NI	NI
Morris E	2003	367	14	100%	NI	NI	NI	NI	NI
Sardanelli	2007	278	18	94%	NI	59%	NI	65%	NI
Stoutjesdijk MJ	2001	179	13	100%	93%	42%	96%	NI	NI
Warner E	2004	236	22	77%	95%	36%	99.8%	33%	96%
added numbers		6857	293	71-90%	81-97%	36%-50%	93-99%	33%-65%	88%-96%

Table 1. Breast MRI Sensitivity and Specificity

> “MRI SCREENING, MOSTLY COMBINED WITH MAMMOGRAPHY, IS RECOMMENDED TO THOSE WOMEN AT HIGH RISK, WHO DO NOT OPT FOR SURGICAL REMOVAL OF THE BREAST TISSUE”

by mammography or ultrasound. This explains why MRI is superior to ultrasound and mammography in sensitivity in these women (**Table 1**).

Two systematic reviews confirm the high sensitivity of MRI performed with mammography in these women (Lord et al. 2007; Warner et al. 2008).

A third meta-analysis has meanwhile been published by Phi and colleagues. They assessed MRI screening in BRCA mutation carriers over 50 years of age using individual patient data meta-analysis, and found that in women over 50 years sensitivity was significantly increased, as with the under 50 years age group (Phi et al. 2015).

To date evidence is clear that MRI is by far the most sensitive method in these women. And this is accepted, even though specificity of MRI is lower than that of mammography and even though long-term data concerning survival or mortality reduction are not (yet) available.

The evidence for long-term outcomes is still being collected. One study that looked at 10-year survival of 496 women at high risk of breast cancer, who were screened with MRI, found that the cancers identified were at an early stage, and the annual breast cancer mortality rate in the study was very low (Passaperuma et al. 2012). Evans et al. (2014) found no difference in 10-year survival between women screened with MRI and mammography and mammography-only groups. However, survival was significantly higher in the MRI-screened group (95.3%) compared to no intensive screening.

Based on present knowledge, MRI screening, mostly combined with mammography, is recommended to those women at high risk, who do not opt for surgical removal of the breast tissue. Fortunately, familial high risk only makes up about ten percent of all breast cancers, and most breast cancers to date can be detected early using mammography screening, sometimes supplemented by other methods.

Women at Intermediate Risk of Breast Cancer

The group of women at intermediate risk is much larger than the groups of women at high risk. It includes women with some increased risk of breast cancer in the contralateral breast, as a small proportion of women diagnosed with unilateral breast cancer go on to develop cancer in the other breast. Researchers have shown that MRI can detect contralateral breast cancer soon after diagnosis in the other breast when it was missed by mammography and clinical examination, but the technique may also lead to a high number of false positive calls (Lehman et al. 2007; Brennan et al. 2009). A single-centre study by Kim and colleagues (2013) showed a single MR imaging screening examination of the contralateral breast in women with unilateral breast cancer increased synchronous cancer detection and was associated

with decreased diagnosis of contralateral cancer within 45 months, the "grey zone".

Also in this "grey zone", where the evidence is not yet clear, are MRI screening for women with a history of lobular carcinoma in situ (LCIS) or atypical ductal hyperplasia (ADH): the IARC working group that met in 2014 found "limited evidence" (IARC 2016). For women at intermediate family risk of breast cancer insufficient data exist on the usefulness of MR screening for breast cancer.

MRI Imaging and Neoadjuvant Chemotherapy

Several studies have evaluated MRI imaging for assessing residual tumour following neoadjuvant chemotherapy, and its concordance with pathology (Marinovich et al. 2013a). In preoperative assessment of women who receive neoadjuvant chemotherapy (NAC) MRI has been shown to be more effective than mammography in assessing residual tumours (Marinovich et al. 2013b). When evaluating early response to neoadjuvant chemotherapy (NAC) PET has been shown to be slightly more effective than MRI, but MRI had better results for imaging after completion of NAC (Sheikbahael et al. 2016). The addition of diffusion-weighted imaging (DWI) to CE-MRI gives comparable results (Wu et al. 2013)

Detection of Recurrent Breast Cancer

MRI to assess recurrence after breast-conserving therapy is more useful according to one meta-analysis comparing PET with other imaging modalities (Pan et al. 2010). MRI is most accurate in detecting breast cancer recurrence and contralateral breast cancer, although the evidence is limited (Robertson et al. 2011).

MRI for Diagnosis and Problem Solving

The aim of all breast screening is to minimise false positives. MRI has been evaluated for its role in assessing suspicious breast lesions. Medeiros et al.'s meta-analysis of literature up to 2010 showed MR as a useful preoperative test to predict the diagnosis of breast lesions (2011). Bennani-Baiti et al. (2016), in their meta-analysis, found excellent results from MRI in diagnosing non-calcified uncertain breast findings found via conventional imaging.

MRI Tomorrow?

Several recent and ongoing trials address the addition of MRI in screening women with a familial risk of breast cancer and dense breasts (Saadatmand et al. 2012; DENSE trial - clinicaltrials.gov/ct2/show/NCT01315015; Emaus et al. 2015). So investigation of MRI for risk-adapted screening will become an important future topic. Also, the use of MRI to monitor less aggressive treatment options might gain importance.

Conclusion

In the future, we need to optimise existing technologies and test new technological possibilities, including DWI, diffusion tensor imaging and diffusion weighted whole body imaging (DWIBS) and more to come...

Will CE MRI endure? It has contributed significant progress to breast imaging. However, there is potential for further improvement. We always need to weigh the advantages and disadvantages. Whatever we use, the ultimate goal is the care of our patients. ■

Prof. Dr. Sylvia Heywang-Köbrunner is recognised internationally for her expertise and innovation in the field of breast diagnostics and mammographic screening. She pioneered contrast-enhanced MRI for breast imaging, and has registered several patents for biopsy techniques. Dr. Heywang-Köbrunner directs the Munich Breast Diagnostic Clinic and runs the Mammography Reference Centre in Munich, one of the five centres that, together with the Mammography Collaboration Community, are responsible for the introduction, quality assurance, advanced training and accompanying research in German mammographic screening. In this capacity, she also manages the Screening Unit Munich South. Dr. Heywang-Köbrunner was awarded the Gold Medal of the European Society of Breast Imaging at its annual scientific meeting in Paris in October 2016 in recognition of her scientific achievements in the field of breast imaging.

REFERENCES

For full references, please email edito@healthmanagement.org or visit the website

Radioprotection in Chest CT

An Approach with Bismuth Breast Shield

The main goal of this study was to assess the viability of the bismuth breast shield in chest computed tomography (CT) examinations. Dose measurements on a phantom (Cardinal Health 76 415) with an ionisation chamber were performed with and without bismuth breast protection in different configurations using the routine chest CT protocol. Image quality control was performed using a phantom (Gammex 464). In all measurements with bismuth protection (no sponges), we observed a dose decrease of 22.6%. Dose decreased by 19.9% with protection (one sponge), 17.6% with protection (two sponges) and 28.2% with the protection coupled to the gantry. It is therefore appropriate to implement the protection configuration coupled to the gantry as a protective measure for patients undergoing chest CT scans.

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The indiscriminate use of ionising radiation for diagnosis and therapy purposes has increased significantly due to the fast development and easy access of CT equipment, and, in several cases, to weak justification of these examinations.

Since 1993 the number of CT exams in the United States has tripled to 70 million exams per year. Approximately 29,000 of the US population are at high risk of developing cancer as seen by the CT scans conducted (Berrington de González et al. 2007). In Europe, a survey about European population doses from medical imaging took place in 2015 (European Commission 2015). The participating 36 countries reported the average frequencies per 1000 of the population, for the top 20 groups, compared with similar data from the 10 European countries in the Dose Datamed 1 project and United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) Health Care Level 1 (HCL1) countries.

In all CT groups, average frequencies have significantly increased, and in some cases have more than doubled (for CT trunk, the increase was approximately threefold). These CT examinations represent a total of 55% of relative contributions of the four main groups (plain radiography, fluoroscopy, CT and interventional radiology) to overall collective effective dose.

A CT scan subjects the human body to between 150 and 1,100 times the radiation of a general x-ray, or around a year's worth of exposure to radiation from both natural and artificial sources in the environment (Storrs 2013). Therefore, there is a need to create measures and procedures to protect the patient from the biological effects of ionising radiation, which varies according to the cells' radiosensitivity and the absorbed radiation dose. At the same time, it should be noted that the tissue weighting factor (W_T) value has changed in the publications of the International Commission on Radiological Protection (ICRP) from 0.05 to 0.12 (Wrixon 2008).

The development of biological effects occurs in two ways: 1) the deterministic effects, caused by high doses of radiation in a short period of time (eg radiodermatitis) and 2) the stochastic effects caused by doses received over a long period of time (eg cancer). Thus the main objective of radiation protection is to avoid the occurrence of deterministic effects and guarantee that stochastic effects are kept to an acceptable level (Canevaro 2009; Lima 2009).

> "NEED TO CREATE MEASURES AND PROCEDURES TO PROTECT THE PATIENT FROM THE BIOLOGICAL EFFECTS OF IONISING RADIATION"

The use of bismuth protection presents some controversies regarding its practical application (Tappouni and Mathers 2013; Zhang and Oates 2012). In 2012 McCollough, Wang and Gould published a Point/Counterpoint, which consisted of a debate with favourable and unfavourable views relative to bismuth protection (McCollough et al. 2012). Gould advocated the use of bismuth protection in CT scans, since no evidence of diagnostic error due to the use of bismuth protection was published. In addition, the radiographers training to use this protection found the image interpretation relatively simple. However, McCollough refutes the application of bismuth protection when using Automatic Exposure Control (AEC). The author argues that the protection of bismuth in the breast during CT examinations decreases the image quality, verified through the increase of Hounsfield Units (HU) and noise.

Given the above, the aim of this study was to determine the percentage of dose reduction obtained by the phantom using a bismuth breast shield in different configurations. It was also to assess their viability in

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Figure 1. Phantom Cardinal Health 76-415 with bismuth shield coupled to the gantry, next to the detectors window

Figure 2. Bismuth Breast Shield

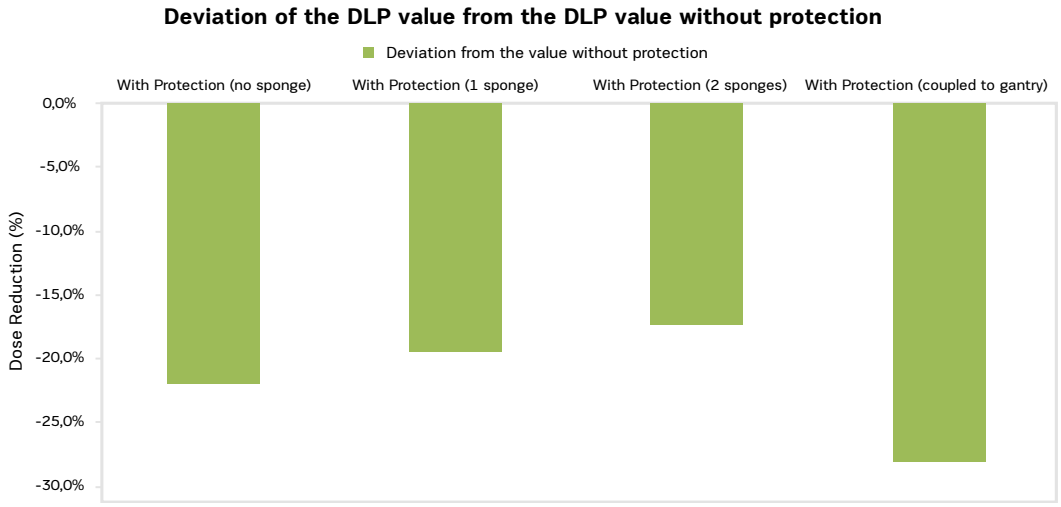

Figure 3. Distribution of the percentage reduction of DLP value with bismuth breast shield in different configurations in relation to the DLP value without protection

chest CT examinations through the evaluation of image quality, taking into consideration a broad range of scanner parameters (HU value or CT number accuracy; low and high contrast resolution, noise and artifacts).

Materials and Methods

135 measurements were made using a 16-slice CT scanner with and without bismuth breast shields in different configurations (**Figures 1 and 2**):

- Configuration 1: without bismuth breast shield
- Configuration 2: with bismuth breast shield, without sponge (directly on the phantom)
- Configuration 3: with bismuth breast shield, with one sponge (1cm of thickness)
- Configuration 4: with bismuth breast shield, with two sponges (2cm of thickness)
- Configuration 5: with bismuth breast shield, attached/coupled to the detectors window at the gantry

Dose measurements were performed on a phantom (Cardinal Health 76-415) with an ionisation chamber, taking into consideration the configurations indicated above using the routine chest CT protocol (130 kVp, 70 mAs; collimation of 4x1.2mm, rotation time of 0.6 sec. and Pitch=1). This phantom is 32cm in diameter and 15cm in length. The placement of the bismuth breast shield was only made after acquisition of the topogram, due to the automatic exposure control (AEC).

- To determine and evaluate the dose, $CTDI_w$, $CTDI_{vol}$ and DLP values were calculated:.
- $CTDI_W$ value was calculated using the weighted mean of CTDI values obtained at the centre of the phantom and at the four peripheral points (equation 1):
  $CTDIW=13\times CTDI_c+23\times CTDI_p$
- The $CTDI_{Vol}$ value was calculated taking into account the pitch value used in the acquisition (equation 2):
  $CTDI_{Vol}=CTDIW_{pitch}$:
  $CTDI_{Vol}=CTDIW pitch CTDI_{Vol}=CTDIW_{pitch}$
  Finally, the DLP value was obtained considering the range length (L) (equation 3): $DLP=CTDI_{Vol}\times L$:

Image quality control tests were performed using the phantom (Gammex 464) for the same configurations, using the chest and abdomen routine protocol. This phantom consists of solid water (0 ± 5HU) with a length of 16cm and diameter of 20cm, and is divided into four modules (Supertech 2013):

- Module 1: To evaluate the positioning and alignment, CT number accuracy (HU values in cylinder material equivalent to bone, polyethylene, water, acrylic and air) and slice thickness. The measurement was made using the window WW=400 and WL=0, and a region of interest (ROI) of 200mm^2 was placed on each material in different configurations. The analysis of HU was calculated by the means obtained for each material and its compliance was determined from the tolerance interval values presented by the American College of Radiology (ACR) CT accreditation phantom instructions (2013).
- Module 2: Low contrast resolution. This features a series of cylinders with different diameters (2, 3, 4, 5, 6 and 25mm), all at 0.6 % (6HU) difference from the background material. Using a window of WW=100 and WL=100, it was possible to visualise the cylinder with the largest diameter (25mm) and place the ROI of 100 mm^2 on that cylinder (A) and place another ROI on the left (B) of the cylinder. The contrast in the image was obtained through the contrast-noise ratio (CNR) of both ROIs where

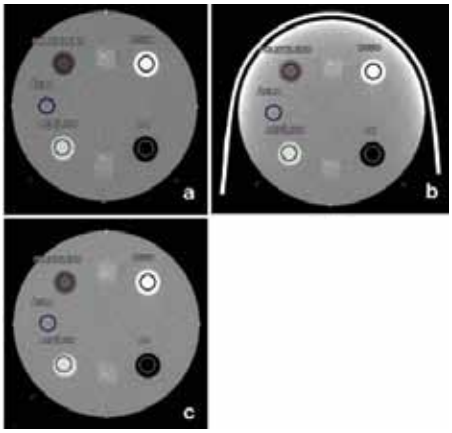

Figure 4. Regions of interest for each material on module 1 in different configurations: (a) without protection (b) with protection and one sponge (c) the protection attached to the gantry

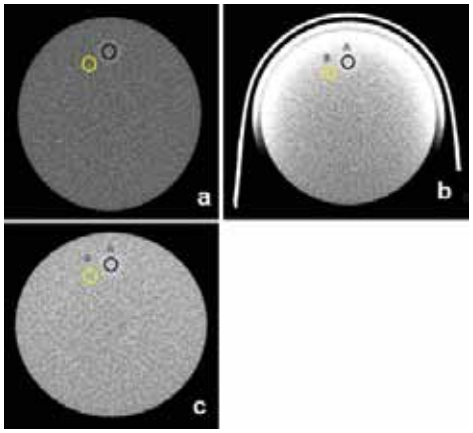

Figure 5. Regions of interest for each material related to module 2 in the different configurations: (a) without protection (b) with protection and one sponge (c) with protection coupled to the gantry

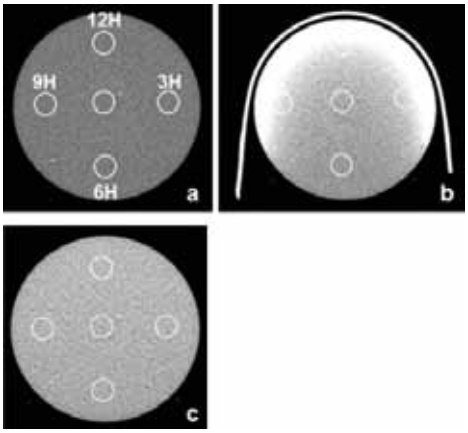

Figure 6. Regions of interest for each material related to module 3 in the different configurations: (a) without protection (b) with protection and one sponge (c) with protection coupled to the gantry

SD is the standard deviation of ROI B (equation 4). As it was not intended to evaluate the CT equipment quality, the CNR values were compared with bismuth shield against the CNR value obtained without protection in the phantom:

- CNR=|A-B|*SD*:
- Module 3: CT number uniformity assessment. This includes two small targets for testing plane distance measurement accuracy. With a window of WW=100 and WL=0, five 400mm^2 ROIs were positioned as follows in the phantom: 12H, 9H, 6H, 3H and in the centre. Values were assessed by comparing the periphery ROI values with the central ROI, where the ROI value should be between -7 HU and 7 HU. Peripheral ROIs must be within ± 5 HU in relation to the average obtained in the central ROI.
- Module 4: High contrast (spatial) resolution. This contains eight high contrast solution patterns of 4, 5, 6, 7, 8, 9, 10, and 12 line pairs per cm (pl/mm). With a window of WW=100 and WL=1110, with reduced room illumination to facilitate analysis, we observed the maximum amount of pl/mm in the image of the phantom with and without the bismuth shield in the different configurations. According to the ACR phantom testing instructions (American College of Radiology 2017), more than 6 pl/mm should be visualised for the chest protocol, and at least 5 pl/mm should be visualised for the abdomen protocol.

Results

Dose Assessment

In this study, we evaluated the dose rates for the routine chest protocol by taking into consideration the dose received by the phantom with and without the bismuth breast shield in the different configurations. The values of $CTDI_{Vol}$, DLP are presented in **Table 1**.

The DLP values in the configurations present different variations, such as: configuration 1 (5.04 mGy.cm), configuration 2 (3.90 mGy.cm), configuration 3 (4.04 mGy.cm), configuration 4 (4.15 mGy.cm) and configuration 5 (3.62 mGy.cm). The percentage of deviation from the DLP to the value without protection was, as shown in **Figure 3**, 22.6 percent with protection but without sponge; 19.9 % with protection and with one sponge; 17.6 % with protection and with two sponges, and 28.2 % with protection coupled to the gantry.

It was found that the percentage of dose reduction was higher when sponges were not used, compared to when they were used. When coupled to the gantry, the bismuth shield reduced the dose in the phantom by 28.2 %.

Configuration	$CTDI_{vol}$ (mGy)	Standard Deviation to the value without protection	DLP (mGy.cm)	Standard Deviation to the value without protection
1. Without protection	2.52	0.0%	5.04	0.0%
2. With bismuth breast shield (no sponge)	1.95	-22.6%	3.90	-22.6%
3. With bismuth breast shield (1 sponge)	2.02	-19.9%	4.04	-19.9%
4. With bismuth breast shield (2 sponges)	2.08	-17.6%	4.15	-17.6%
5. With bismuth breast shield coupled to the gantry	1.81	-28.2%	3.62	-28.2%

Table 1. $CTDI_{vol}$ and DLP values in different configurations, and a comparison with the value without protection for the chest CT protocol

Image Quality Control

The evaluation of image quality control in this study was performed by comparing the images obtained with the phantom when no protection was used with when the bismuth shield was used in the different configurations.

In module 1 it was found that with the bismuth shield, HU values for polyethylene, acrylic, air and water are not within the tolerance range for both chest and abdomen protocols. Bone was the only material within that range (**Figure 4**). In module 2 (**Figure 5**), the CNR values without the protection were 0.8 and 1.5 for the chest and abdomen protocol, respectively. Small changes in CNR values were observed with protection in the different configurations and both protocols: configuration 2 (1.2 and 2.0); configuration 3 (1.1 and 1.6), configuration 4 (0.9 and 1.4) and configuration 5 (0.7 and 1.1). As the protection of the phantom shifts away, CNR value tends to approach the CNR value without protection.

In module 3 (**Figure 6**), it was observed that without protection on the phantom, all the ROIs (12H, 9H, 6H, 3H and centre) were within the tolerance range. When the bismuth shield was placed on the phantom without and with a sponge, there was no uniformity of the periphery ROIs in relation to the central one. With the bismuth shield coupled to the gantry, it was found that periphery ROI values were within the tolerance range, except the central ROI.

In module 4, for both protocols, it was possible to identify 7 pl/mm in all configurations using a B41s kernel (soft tissue) and 9 pl/mm for a B50s kernel (lung parenchyma).

Overall results indicate that the dose values obtained with one sponge and two sponges did not reduce the dose as expected, which was influenced in some way by the interaction of radiation with the bismuth shield. The backscattering effect is what best explains this phenomenon, in which the photons when exiting the x-ray tube interact with a surface and produce secondary/scattered radiation. This, when produced in all directions, can be limited by the use of protection. Due to the presence of the sponges, a propagation medium was created, resulting in an absorption of some radiation dispersed by the phantom, and leading to a dose reduction of only 19.9% and 17.6%.

Another possible reason comes from the fact that in these two configurations, the 360° x-ray tube rotation, when emitting the primary beam in the posterior region of the phantom, allowed the secondary radiation released in the anterior region to collide with the bismuth protection and resume being absorbed by the phantom.

Once the protection was placed near the detector window, the above-mentioned effects were found to be lessened, contributing to a greater percentage reduction of 28.2% of the dose.

Conclusion

In this study, the reliability of the bismuth protection in the different configurations was verified, percentage of dose reduction was determined, diagnostic image quality was checked and the influence of bismuth breast shield coupled to the gantry in the normal functioning of CT scans was tested.

In the configuration with bismuth shield but without sponge, a dose reduction percentage of 22.6% was observed. However, the image quality was adversely affected with respect to the uniformity and presence of streak artifact. Although the configurations with one or two sponges are slightly better than the previous configuration in terms of image quality, the benefit in terms of dose reduction percentage is low.

The configuration with protection coupled to the gantry was the most acceptable in this study, proving that the low contrast resolution, noise and the spatial resolution were in agreement, without negatively affecting the image quality. It was also found that streak artifacts were lessened in this configuration.

In conclusion, and having obtained acceptable results in image quality with a decrease in radiation dose in the phantom, it would be pertinent to implement this protective measure in CT examinations as a routine procedure, especially considering that it allows a reduction in breast irradiation. ■

KEY POINTS

- ✓ A theoretical framework on the use of bismuth shield presents some controversies regarding its practical application (Zhang & Oates 2012)
- ✓ The results of this study suggest that radiographers should use a bismuth breast shield coupled to the gantry during chest CT examinations as a radioprotection measure
- ✓ Radiation dose decreased between 17,6% and 28.2% in several configurations of bismuth breast shield using the routine chest CT protocol
- ✓ Image quality with acceptable results for diagnostic purposes was obtained using a bismuth breast shield coupled to the gantry

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New Ultrasound Device Uses 3D Printing Technology

Sharper medical images using a new US device combined with 3D printed lenses promise to make focused US treatment more accurate.

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A new ultrasound device has been developed by scientists at Nanyang Technological University (NTU) that can generate sharper medical images with the use of 3D printed lenses. The precise images can help doctors and surgeons have greater control and precision during noninvasive diagnostic and surgical procedures.

Medical procedures that require the use of ultrasound to kill tumours, loosen blood clots and pass drugs into targeted cells will be a lot more accurate thanks to this new device.

HealthManagement.org spoke to NTU Associate Professor Claus-Dieter Ohl about this new device, its key findings and the advantages it brings to ultrasound treatment.

Please briefly summarise your research and the key findings.

We are working on acoustic devices. The purpose is to develop a better meter of acoustic waves that are used a lot in medical devices either for diagnostics or for therapy.

Diagnostics is commonly associated with medical ultrasound. Therapeutic uses are becoming more and more popular. One very common use is for the destruction of kidney stones called extracorporeal shock wave lithotripsy (ESWL). We are looking to have a device that can put a very narrow focus on acoustic waves. The premise of this is to deposit this acoustic energy on very small spots. Then we also want to have control on the acoustic waves. Both are non-trivial processes. Focusing on small spots means you need very high frequencies and having the control on the wave would need a complex apparatus to shake the waves from electric signals to acoustic signals.

So why have we done this? This device can help with the destruction of unwanted tissue or delivery of drugs. All is done noninvasively because we can sufficiently focus on the acoustic waves.

We came up with a device (**Figure 1**) using photoacoustic effects, which is a pretty simple phenomenon—whenever you heat something up, it expands. We heat up the surface very quickly and it expands very quickly. It then generates high frequencies. The faster it expands, the higher the frequencies. This is called a photo-acoustic effect, which involves converting the photons into acoustic waves. Using a laser, we hit the surface, the surface absorbs the light, it heats up and then sends the waves—it's as simple as that. If the wave is very short that means it was implemented for a short duration and the acoustic waves will be there for that short time.

Now, we have two pieces. One is that the surface can be shaped—meaning, the waves that we start with can be shaped accordingly. The other one is that these all work as a very simple protocol, like paint. So we have a surface which we can shape into arbitrary shapes and arbitrary waves and then we have an absorber which is put on this surface and then generates strong enough waves.

What advantages does the 3D printing used in this new device bring to focused ultrasound treatment?

We are not the first to use photo-acoustics for focused ultrasound waves. Although it is recent in research areas, a few groups have already been working on it. We not only want to focus on waves, but also have control of them and then shape the surface. Current research efforts use glass as a substrate. This has very good acoustic properties and you can control the absorber on the surface, but it is very difficult to shape glass. Glass lenses are commonly used as a surface material and the result is a single focus. These lenses only have a single focus and you have no control on it. The idea now is to use three dependent surfaces where you can design the surface with the desired wave form. There are very interesting wave forms that are already being used in medical experiments. I think they were first done on animals. There are also human trials happening where multiple shock waves are used. Not a single shock wave, but multiple shock waves. This technique is called histotripsy. Histo means tissue, and tripsy means destruction or fragmentation and it is a way to destroy benign tumours or maybe even malicious tumours. The idea is to design a device based on

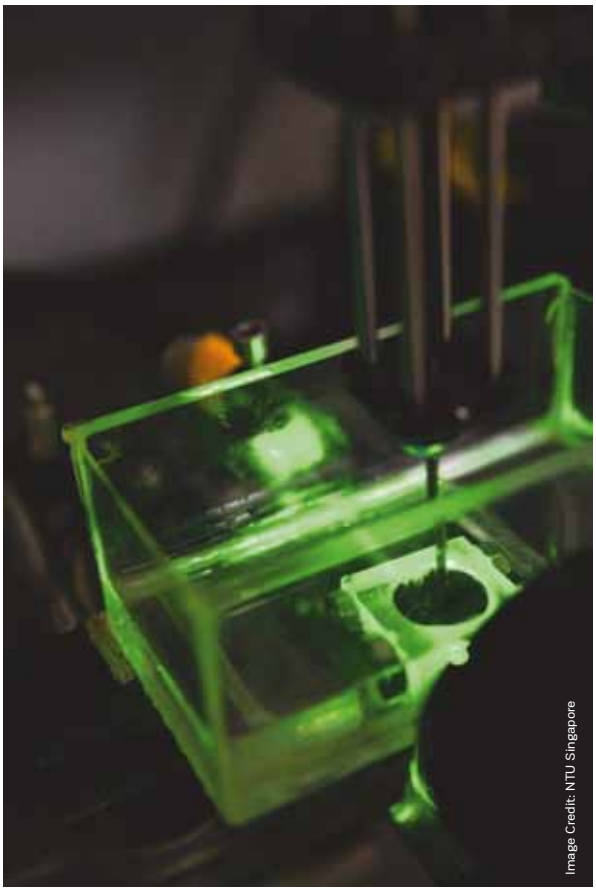

Figure 1. NTU's New Ultrasound Device

photo-acoustics and have the control that would not be possible with a glass surface. It is a pretty simple idea. The tricky part is not the 3D printing part. There must be a surface which is compatible with the plastic used and it has to have sufficient absorption to get strong acoustic waves.

What other benefits does this device bring?

This comment is not as general as it was stated. Now we have a device which can be personalised for the patient. As I mentioned before, we have a surface to adapt to the shape of the eye, specific to a patient. The focus can be set precisely. The device will make a scan of the eye and make a 3D print, much like how dental surgeons use 3D printers for braces. For ultrasound, such treatments are not yet in application. So, the comment is not as bold as it was stated, it is more like a new opportunity in medical devices.

What are the next steps to bring this into development and eventually into clinical use?

The acoustic waves need to have a certain pressure and/or tension that can press but also pull on a tissue to destroy it. This is currently underway and it is looking pretty good. So the aptitude of the pressure waves has to be strong enough and then we have to perform a first trial with tissue phantoms before we go to animals. Our idea is to use it for eye surgery. In this case, we need to have very small incisions, especially if we want to do multiple eye surgeries on a patient. For example, glaucoma and cataracts is becoming common in Asian societies. The glaucoma procedure is mainly done once. If the lenses become opaque afterwards, it is very difficult to make another incision and remove that lens. So Asian society is depending on that first cataract surgery. People may have suffered from impaired vision over ten or fifteen years after the first operation.

> "WE ARE LOOKING TO HAVE A DEVICE THAT CAN PUT A VERY NARROW FOCUS ON ACOUSTIC WAVES"

For glaucoma, the standard procedure is done while inserting small tubes into the eyes to release the pressure. This structure is typically done only once and the channels get blocked. This can be a very drastic operation, which might actually lead to blindness. Here is where we hope to release temporary pressure from the eye by making small holes.

This would be an area where this technology could be used to make very small but controlled holes on surfaces. The advantage here is that we have a surface to adapt to the shape of the eye so that it can be measured first and then printed. The high frequencies and multiple shockwaves can presumably make these very small holes. But this is still work in progress so it is not something that can be used directly just yet. ■

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3D Printed Kidney Phantoms Will Optimise Radiation Dose

How can affordable cost 3D printed kidney phantoms assist nuclear medicine treatment planning and radiation dose optimisation?

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Please briefly describe your research on 3D kidney phantoms. Why did you set up this study and what were the main findings?

Nuclear medicine is a medical specialty that uses radiopharmaceuticals for diagnosis and treatment of disease. In the last years, driven by major advances in the biological understanding of metabolic processes, new radioactive compounds, particularly for cancer treatment, have been developed and applied preclinically and clinically. In many therapies involving peptides or small molecules (e.g. ^{177}Lu-DOTATE, ^{177}Lu-PSMA, ^{177}Lu-Pentixather), the kidneys receive high absorbed doses and are considered the main organ at risk. Therefore, it is of special interest to perform accurate pre- and peritherapeutic kidney dosimetry, for which quantitative imaging forms the basis. Due to the lack or high cost of commercially available anthropomorphic phantoms, the aim of this research was to fabricate such phantoms using commercially available low-budget 3D printing hardware. For this purpose, a set of one-compartment kidney phantoms (newborn, 1-year-old, 5-year-old, adult) was developed. With this set of kidneys, an isotope-specific calibration for a commercial SPECT-CT gamma camera was performed. Although the presented one-compartment kidney models are perceived as an important step in the right direction, they show no significant calibration improvements over the typically used spherical phantoms, suggesting the necessity of more sophisticated, multi-compartment kidney models for achieving considerable improvements.

What did you find to be the main advantages of 3D printed kidney phantoms compared to conventionally produced phantoms?

All currently available imaging modalities for quantitative molecular imaging (PET-CT, SPECT-CT) suffer from a spatial resolution in the range of a few millimetres (PET) to centimetres (SPECT), which in comparison to other not inherently molecular imaging methods such as CT or MRI, leads to enhanced blurring of imaged anatomical structures, in turn impeding any quantification. By calibrating these imaging systems based on the activity distribution in 3D printed models, this insufficient resolution could be effectively recovered: the more realistic the model, the more accurate the process.

What are the next steps based on these results? Are you planning to develop more complex kidney phantoms or phantoms for other organs?

The aim of this study was to initially show the feasibility of low-budget 3D printing methods for the design and fabrication of anthropomorphic phantoms. Due to the simplification of the complex kidney anatomy to only one fillable compartment, however, only negligibly small differences to spherical phantoms—the standard in quantitative molecular imaging—were observed. Therefore, our next step will be the design and fabrication of multi-compartment kidneys, eg, consisting of an inner compartment resembling the renal medulla and pelvis as well as an outer compartment resembling the renal cortex, both of which can be filled separately.

> “THE AIM OF THIS RESEARCH WAS TO FABRICATE PHANTOMS USING COMMERCIALLY AVAILABLE LOW-BUDGET 3D PRINTING HARDWARE”

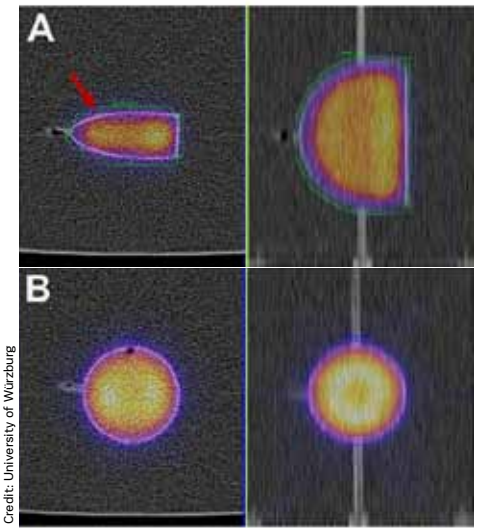
What is needed to make this technique widely available so that other nuclear medicine departments can create individualised phantoms?

At this stage, the dimensions of the kidney designs are based on a Medical Internal Radiation Dose committee (MIRD) recommendation—an organ model widely accepted in the field of nuclear medicine. In addition to this model, interested departments would need software for generating STereoLithography (STL) files of the desired model as well as 3D printing hardware to produce the phantoms. Alternatively, the 3D printing could be outsourced to a commercial service.

Credit: University of Würzburg

Manufactured set of kidney phantoms. From smallest to largest: newborn, 1-y-old, 5-y-old, and adult

To standardise calibration of SPECT-CT systems, we are currently working on a set of multi-compartment kidney models which could be made available to interested institutions. Additionally, we are working on a standardised calibration scheme that, in combination with the set of phantoms, could pave the way to more standardised quantitative molecular imaging for dosimetry in molecular radiotherapies. ■



Credit: University of Würzburg

Figure 2. SPECT/CT reconstructions and VOIs used for determination of calibration factors for the adult kidney filled with ^{177}Lu (A) and the corresponding sphere filled with ^{131}I (B).

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Preclinical Imaging in the Era of Personalised Medicine

Identification of the genetic basis of the therapeutic response obtained in mice models is important for patient stratification in clinical trials. Technological advances in molecular imaging will have a large impact on personalised medicine, and make animal reduction and refinement possible during experimentation.

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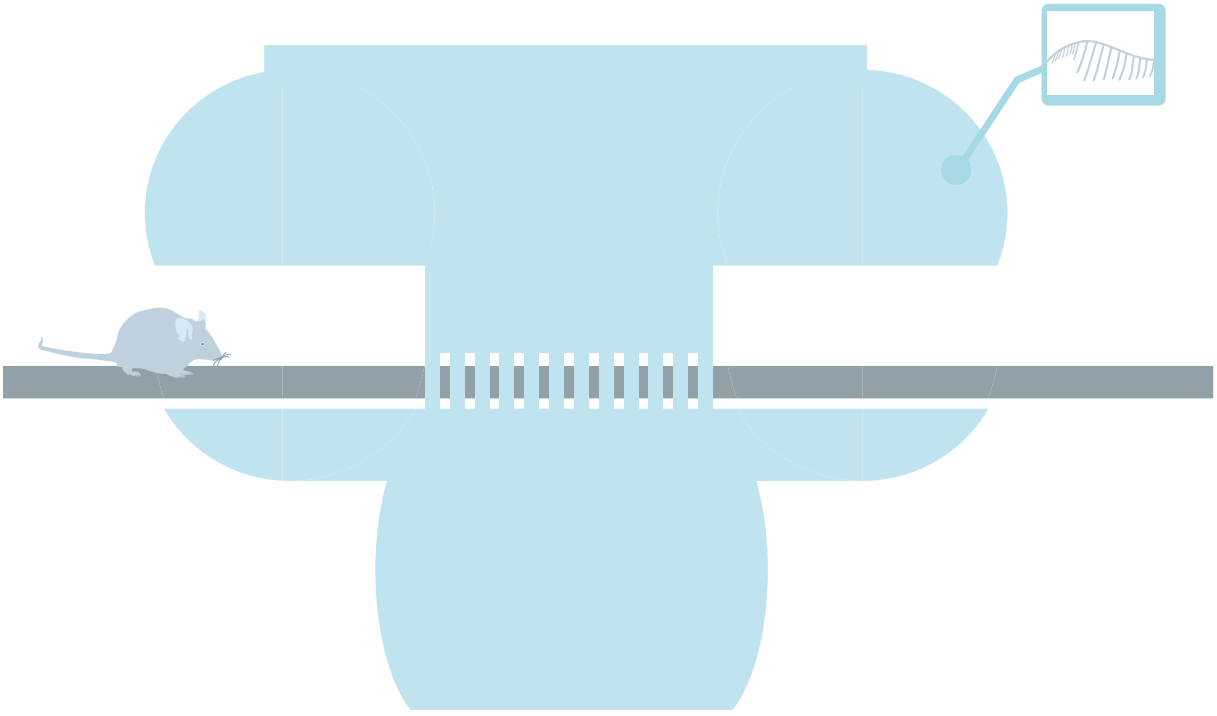

In recent years, many advances have been made in cancer knowledge. In particular, it has been seen that many patients having the same type of cancer display many different molecular patterns. This has introduced the concept of personalised therapy. In this context, mice models of human disease and advanced techniques of preclinical imaging are also undergoing a significant development.

Mice models represent the link between in vitro studies and clinical trials with patients. The mice genome is well characterised and very similar to the human one, sharing approximately eighty-five percent of genes. Furthermore, mice are easy to reproduce, maintain and relatively inexpensive to breed. However, in some cases, mouse models have failed to be predictive (Uhl et al. 2015). For example, mice and other rodent models correctly predicted human toxicity in only forty-three percent of cases in a large comparative study of concordance in the toxicity of pharmaceuticals between humans and animals (Olson et al. 2000). The maximum tolerated dose (MTD) of drugs in mice is higher than in humans, so when evaluating efficiency of a drug using doses comparable to those administered to human patients, toxicity might go undetected. Moreover, despite successful preclinical testing, only fifteen percent of early clinical trials succeed, and very few drugs are approved for clinical study by the U.S. Food and Drug Administration (FDA) (Uhl et al. 2015). On the other hand, the possibility of translating a model efficiently could be achieved through the use of emerging translational approaches like advanced preclinical molecular techniques.

Mice Models for Personalised Cancer Treatment

Having advanced knowledge of the human genome allows the characterisation of a single patient's genetic defect and hence the classification of subgroups within

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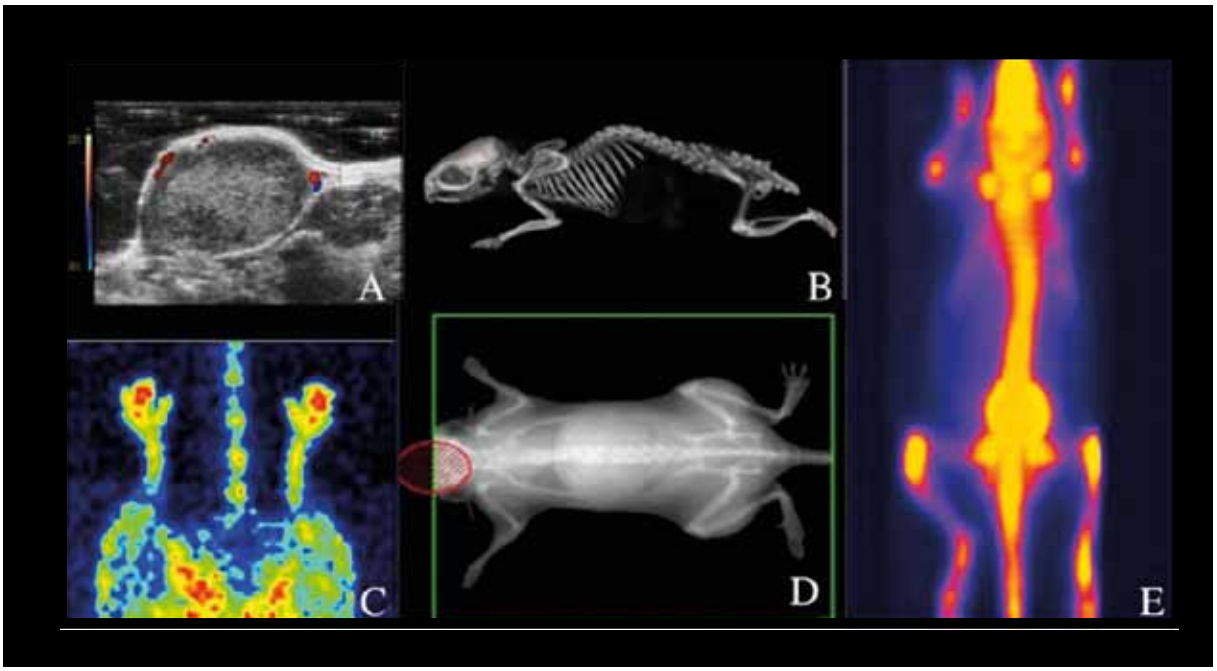

Figure 1. Preclinical Imaging Techniques in Mice

A) High frequency ultrasound of a xenograft model of lymphoma, Doppler image of the tumour with peripherical vascularisation; B) Micro-TC in a normal animal, 3D MIP reconstruction of the skeleton; C) Laser Doppler imaging of normal hind-limb perfusion; D) Dual energy x-ray absorptiometry of the total body in a normal animal; E) Total body SPECT imaging with ^{99m}Tc in a normal animal.

the same tumour histotypes, improving the chance of survival and a better prognosis. According to that, patients can be divided between those that respond better to certain therapy rather than others. As it is not always easy to perform clinical trials on patients and to have enough patients to recruit, the co-clinical trial performed at the same time in patients and in murine models of the same disease is taking hold as a new reality. Currently, there are two personalised mouse models of oncologic pathology: the genetically engineered mouse models (GEMM) and the patient derived tumour xenograft models (PDX). These models are now used in most hospitals for the co-clinical trial to guide therapy during an ongoing clinical trial. The GEMM models are used as part of the phase I/II trials in humans for drug development (Nardella et al. 2011; Malanay et al. 2014).

The identification of the genetic basis of therapeutic response obtained in mouse models is important for patient stratification in the clinical trial. In GEMM cancer models, the genetic profile is modified by mutating, deleting or over-expressing one or more genes involved in the transformation process or malignancy. This allows us to study the effect of these genetic alterations over time and to assess the therapeutic response of these tumours for the demonstration of the genetic basis of the disease. One of the advantages of GEMM is that the immune system is intact. Many therapies in cancer patients today are based on the stimulation of the immune system in an effort to make it capable of eradicating the tumour (Huijbers et al. 2015).

> “PRECLINICAL IMAGING ALLOWS MAPPING OF DISEASE MARKERS IN VIVO AND, IN SOME CASES, TO PERFORM TARGETED THERAPY AS WELL”

An accurate GEMM model mimics human cancer much better both histologically and biologically compared with xenograft models. The structural differences between GEMM and xenografts affect the results of and the response to drug therapy (Gopinathan et al. 2008). In these models, it is possible to study a single stage during the disease progression and to test different drugs at different stages of tumour growth. Mouse models can often be reproduced in more subjects, in whom it is possible to test different pharmaceutical compounds. GEMM models also have several disadvantages: it is usually difficult to drive the extensive genetic alterations as they occur in human

cancer. Often GEMM models show heterogeneity in the same cancer type. These facts do not help target therapies. Often, researchers can cure mice tumours, but there is not yet a direct correlation with the response in the human tumour. Furthermore, the development of GEMM models often requires long time periods, and not all mice develop pathological features of the human tumour. The PDX models, also known as mice "avatars" have been recently used as part of several co-clinical trials. They could be very useful when patients are not in a state of health good enough to be enrolled in a clinical trial, or there is no ongoing clinical trial for that pathology. The concept is based on the fact that implanting a patient's tumour, obtained from a biopsy or from an excised mass, in a mouse, we can study as a specific drug response and develop a personalised therapy. In addition, in GEMM models it is possible to study tumour growth with the correct cell line and in the correct tumour microenvironment interaction. It is possible in this way to predict toxic effects of the drug in the patient or an eventual lack of efficacy. The PDX models are also useful in testing the potential resistance pathways. It is possible to generate different avatar systems from the tumour of a single patient to test different therapeutic approaches at the same time. Most cancers present a large number of mutations, and there is often more than one potential therapeutic approach for each single patient. The PDX models are useful not only for the identification of drug targets, but also to define prognostic biomarkers of disease or of resistance. After engrafting a tumour in a mouse, the model is propagated through several generations (F0 to F3). Therapeutic agents are usually tested in F3. During the passage though several generations, mouse stromal components could become dominant, so that the loss of the human elements may create limitations in testing therapy.

Preclinical Molecular Imaging

Preclinical imaging is an emerging field in biomedical research. Noninvasive in vivo imaging offers numerous advantages, such as the possibility to study the same subject over time and the potential application of image-guided therapy. Molecular imaging technologies use molecular probes to visualise biological processes and molecule-receptors interactions in vivo (**Figure 1**). Due to different sizes of humans and rodents, the performance of clinical imaging devices is not adequate for a reliably precise evaluation in mice and rats. Therefore, dedicated small-animal systems with a higher sensitivity and spatial resolution are required. Many of the traditional clinical medical imaging technologies have been modified for imaging small laboratory animals. Multimodal molecular imaging, ie the combination of different molecular imaging modalities, can radically increase the functional and structural information obtained by each single imaging technique.

The clinical benefits of molecular imaging are immense. There is the possibility of early disease detection and the prediction of treatment response, which will lead to the optimisation of individual patients' therapies. Molecular imaging is already having a substantial impact on therapeutic decisions made by clinicians. This will be even more obvious as soon as individualised treatment becomes the standard of clinical practice. Another important contribution is in drug development, which typically requires expensive and prolonged preclinical and clinical trials in order to have a new drug approved for human use. Molecular imaging has the ability to noninvasively monitor the pharmacokinetic and pharmacodynamic properties of a candidate drug in a living organism. This can substantially shorten the development phase of drug production for the pharmaceutical industry, by assessing drug effects considerably earlier than by using anatomical and physiologic criteria (Jung et al. 2015). Finally, contrast agents for molecular imaging are also used as tools for drug delivery, especially in the oncologic field, to overcome problems related to therapies, eg chemotherapy and radiotherapy, such as systemic side effects (Greco et al. 2017).

> "MOLECULAR IMAGING IS ALREADY HAVING A SUBSTANTIAL IMPACT ON THERAPEUTIC DECISIONS MADE BY CLINICIANS"

Positron emission tomography (PET) and single photon emission computed tomography (SPECT) have been used in the last decades, exploiting the specificity of various probes to acquire functional information both in clinical and preclinical studies. The low spatial resolution of such techniques has logically led to their use in combination with imaging modalities offering better anatomic detail, such as computed tomography (CT) and magnetic resonance (MR). Recently MR imaging has gained much more importance due to its greater soft tissue contrast compared to CT, even if some technical drawbacks have decelerated this research field due to the incompatibility between the conventional PET photomultiplier tubes (PMTs) and MR detectors (Auletta et al 2017). The need for sophisticated methods to obtain satisfactory spatial co-registration presents a significant limitation.

Other imaging modalities that do not require the use of radioactive tracers to study physio-pathological

events, eg, fluorescence, bioluminescence and photoacoustic (PA), have been combined with morphological techniques, such as CT, MR and ultrasonography (US). The US approach is probably one of the most used in preclinical imaging. The strengths of the diagnostic and therapeutic US system are numerous:

- Cost-effective
- Can be performed rapidly and at the bedside
- Widely available and noninvasive
- High spatial resolution (50-500 µm); and
- Does not rely on ionising radiation.

US contrast agents are evolving from pure blood pool contrast agents to molecular imaging agents designed to target specific receptor sites on the vascular compartment. Molecular imaging with targeted contrast agents can theoretically be useful in early diagnosis. Finally, acoustic destruction of molecular-loaded contrast agents can be used to deliver drugs or to augment gene transfection, and it may have future applications in site-specific cancer therapy (Greco et al. 2012).

At the same time, MRI contrast agents are useful to target molecular markers of disease (such as cell surface receptors, enzymes or signalling molecules), but also cells (like stem cells or blood cells). MRI could be useful for early detection of disease, but also this technique has been recently used for target therapies. Nanoparticles for MRI can be designed to perform dual imaging; for example, it is possible to label a fluorescent probe on a magnetic contrast agent nanoparticle, to target a molecular marker of disease and to have enhanced morpho-functional imaging. At the same time the dual targeting can be used for a doubled purpose such as early molecular detection and a therapy against the same molecular marker.

Conclusion

Molecular imaging enables dynamic and quantitative visualisation of specific markers in living organisms. Mice models are important instruments for the study of cancer in human beings. In some cases, eg in toxicological studies, cell-based systems may supplement and perhaps eventually anticipate the use of animals. In many cases, the substitution of whole-animal studies cannot be afforded due to the involvement of multiple tissue and organ systems in both physiological and pathological conditions. Molecular imaging allows animal reduction and refinement during experimentation according to the 3R (Replacement, Reduction and Refinement) principles enunciated by Russell and Burch (1959). The reduction is achievable since preclinical imaging permits longitudinal studies, hence a smaller cohort of animals is needed. Refinement is obtained because imaging is performed under general anaesthesia, and all procedures are noninvasive, allowing fast recovery of mice. In recent years, this new technology has allowed progresses in early diagnosis, monitoring of curative effect and drug development. Molecular imaging has emerged as a powerful novel discipline. Today, one of the most developed research fields operates on the validation of new imaging biomarkers. Preclinical imaging will help clinicians to improve diagnosis, choose the best treatment option and predict patient outcome. Preclinical imaging may be considered a valid and unique tool for the new era of personalised medicine. ■

KEY POINTS

- ✓ Identification of the genetic basis of the therapeutic response obtained in mouse models is important for patient stratification in clinical trials
- ✓ Technological advances in molecular imaging methods will have a large impact on personalised medicine
- ✓ Molecular imaging makes animal reduction and refinement possible during experimentation, according to the 3R principles

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Induced Pluripotent Stem Cells in Cardiovascular Precision Medicine

Induced pluripotent stem cells (iPSCs) are derived from somatic cells obtained from human subjects. iPSCs can be used for disease modelling, drug screening, and regenerative therapy. iPSCs have the potential to revolutionise patient care as part of precision medicine tailored to the individual.

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Derived from terminally differentiated cells, iPSCs avoid the ethical problems of embryonic stem cells (ESCs). With patient consent, somatic cells can be obtained from a blood sample drawn from a vein to isolate peripheral blood mononuclear cells (PBMCs) or a skin sample that is used to isolate fibroblasts. Using a genetically engineered virus that overexpresses the transcription factors octamer-binding protein 3/4 (OCT 3/4; also known as POU5F1), SRY (sex determining region Y)-box 2 (SOX2), Myc proto-oncogene protein (c MYC), and Krüppel-like factor 4 (KLF4), the somatic cells are reprogrammed to become iPSCs (Takahashi et al. 2007). The iPSCs can then be differentiated into any tissue cell type using recombinant protein factors (Zhang et al. 2009). With this approach, iPSCs can be used to generate cardiovascular tissue to study complex disease states (Burridge et al. 2014; Orlova et al. 2014). iPSC disease modelling will vastly improve our ability to diagnose, prognosticate and treat cardiovascular disease.

Disease Modelling

iPSCs have advanced our understanding of the molecular mechanisms of diseases such as dilated cardiomyopathy, hypertrophic cardiomyopathy, long QT syndrome, and arrhythmogenic right ventricular cardiomyopathy (Kim et al. 2013; Lan et al. 2013; Moretti et al. 2010; Sun et al. 2012; Wu et al. 2015). The traditional method of studying human diseases uses animal models or patient-derived tissue samples. Animal models, however, are problematic due to inherent differences in physiology, reproducibility, ethical concerns and poor correlation with human clinical trial data. Patient-derived tissue samples are an excellent model for studying disease, but are limited in abundance and availability. In contrast, iPSCs can be differentiated into any tissue types, including cardiac muscle cells and endothelial cells lining the inside of all blood vessels. In contrast, iPSCs be used to identify genes responsible for a disease. Subsequently, powerful new gene editing tools can be used to study molecular mechanisms of disease (Hsu et al. 2014).

Uncovering disease mechanisms can lead to the identification of new disease-specific biomarkers as well as targets for new drug therapies (Mercola et al. 2013). Disease-specific biomarkers can expedite the diagnosis of diseases and effectively predict their responses to therapies, allowing for personalised treatment of each patient. Furthermore, when mechanistic studies identify novel drug targets, patient-derived iPSCs can be used to screen for beneficial versus toxic drug effects specific to the genetic makeup of each patient. By contrast, it is not possible to predict these effects accurately with prior approaches that use traditional animal models.

> “IPSC DISEASE MODELLING WILL VASTLY IMPROVE OUR ABILITY TO DIAGNOSE, PROGNOSTICATE AND TREAT CARDIOVASCULAR DISEASE”

Drug Screening

iPSC-derived tissues are unique to each individual. Not only can they be used to study individual susceptibilities to diseases, but they can also lead to tailored therapy, or personalised medicine. Patient-specific iPSC-derived tissue can be tested with conventional drug therapies to reveal the optimal treatment for each patient, avoiding a costly and inefficient trial-and-error approach that is prone to adverse reactions (Liang et al. 2013; Mathur et al. 2015). For example, the medical management of atrial fibrillation is complex. A doctor and patient discuss issues such as the risks and benefits of anticoagulation and, depending on symptoms, either a rate control or rhythm control strategy. Finding the optimal therapeutic regiment for a patient with atrial fibrillation, however, is challenging, time-consuming and can result in frequent emergency room visits, not to mention adverse side effects which are potentially life-threatening. By contrast, in the future, iPSCs from a patient with atrial fibrillation may be used to generate cardiomyocytes that could be safely tested with different rate and rhythm control agents. Using various in vitro assays, the optimal drug and dose could be determined empirically in a dish, thus avoiding drug titration and undesirable side effects.

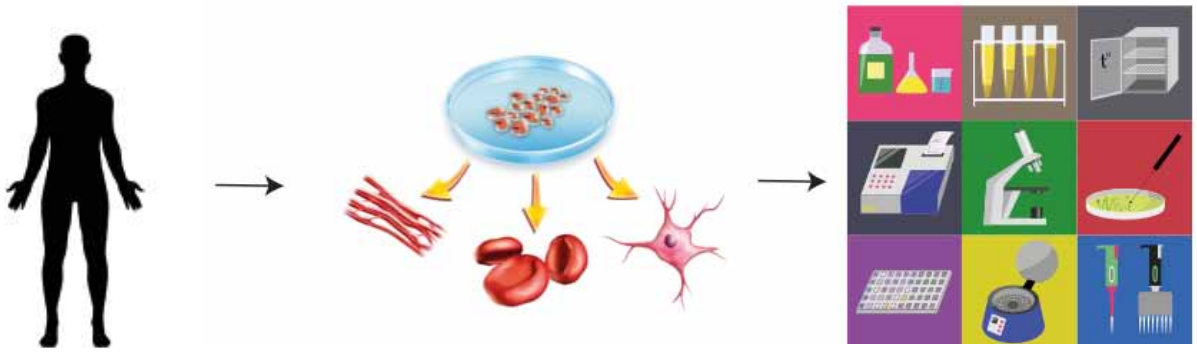

Figure 1. iPSC Precision Medicine in Cardiovascular Research

A blood sample from a patient is used to make induced pluripotent stem cells (iPSCs). The iPSCs can be differentiated into any cell type using growth factors. The iPSC-derived tissue can subsequently be used for disease modelling, drug screening or regenerative medicine.

The iPSC-derived tissues may also enhance clinical trials. For example, a medication may not have an overall effect on a large population of patients despite selection for patients with optimal demographics and risk factors. Although a subpopulation may respond to a treatment, the effect is masked by non-response in the larger heterogeneous population. To address this problem, population-based studies using patient-derived iPSCs could preselect patients with an optimal risk-to-benefit ratio prior to starting the clinical trial. A rhythm control medication for atrial fibrillation, for instance, could be tested in iPSC-cardiomyocytes from atrial fibrillation patients to predict who would respond to a drug and also to test for adverse side effects such as drug-induced arrhythmias. Patients identified to have safe and efficacious responses in the iPSC screening would be subsequently enrolled into the trial. This enriched sample population would have a larger chance of beneficial effect, which would improve power and possibly reduce cohort size. If the drug were approved for clinical use, an iPSC-cardiomyocyte screen could be used to predict which patients in a general population would enjoy the greatest benefit for the new drug in comparison to other antiarrhythmic agents.

Regenerative Medicine

Regenerative medicine is the holy grail of stem cell research. iPSCs represent a limitless source of tissue that could repair or replace organs (Lu et al. 2013). Because they are autologous, the use of iPSCs could avoid immunosuppression that complicates standard organ transplants. Moreover, if the genetic cause of a patient's disease is known, the mutation could be corrected with genome editing and a replacement organ could be synthesised in vitro and implanted. For example, patients with Marfan syndrome have a mutation in the fibrillin gene that causes valvulopathy and a dilated aorta. Over time, the valve and the aorta may need to be replaced with a prosthetic valve and aortic graft. With regenerative therapy using iPSCs, the genetic mutation could be corrected with gene editing and a new aortic valve and aorta synthesised from iPSCs. However, there are several obstacles to translating regenerative therapies from the bench to clinical practice. From primary tissue collection to generating terminally differentiated iPSC-derived tissue, regenerative medicine requires an enormous amount of time and financial cost. Even under ideal conditions, the iPSC-derived tissues are notorious for batch to batch variability and immaturity. If regenerative therapy could overcome these hurdles, U.S. Food and Drug Administration approval would require that the iPSC-derived tissue be delivered in a targeted manner with no immunogenicity, tumorigenicity or toxicity (Neofytou et al. 2015). In addition, the transition to complex tissue and organ structure is challenging, since the three-dimensional structural organisation of tissues is lost in a petri dish. Nevertheless, advances in biomechanical engineering and emerging 3D printing technologies could make it possible to emulate the environmental configuration that facilitates the transformation of a complex cellular structure into an organ.

Conclusion

In summary, iPSCs are a powerful new modality in clinical medicine. They will not only enhance our understanding of diseases and lead to the discovery of new drug therapies, but will also advance personalised medicine and expedite clinical trials by enriching patient populations. The regenerative powers of iPSCs have yet to be fully realised, but may one day lead to definitive treatments of end-organ dysfunction. ■

KEY POINTS

- ✓ Induced pluripotent stem cells (iPSCs) are derived from somatic cells obtained from human subjects
- ✓ iPSCs can be used for disease modelling, drug screening, and regenerative therapy
- ✓ iPSCs have the potential to revolutionise patient care as part of precision medicine tailored to the individual

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American College of Cardiology 2017 Meeting

Cholesterol Lowering (R)evolution, TAVI and More...

The latest cardiology research was presented at the American College of Cardiology meeting: transcatheter valve implants emerge as an alternative in less than high risk severe aortic stenosis patients; can iFR define whether your coronary artery requires a stent? Extremely low LDL-cholesterol levels at a price point – but does it translate into better outcomes? Could implantable sensors revolutionise the way we manage heart failure in the 21st century?

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Washington hosted this year's annual scientific meeting of the American College of Cardiology (ACC), featuring a broad variety of hot topics. The SURTAVI trial (Reardon et al. 2017) demonstrated that a transcatheter aortic valve implant (TAVI) is noninferior to surgical replacement in patients at intermediate surgical risk (similar rates of death and disabling strokes in both groups). This paves the way for a further push towards using percutaneous valve replacements in patients who could conventionally only undergo a surgical procedure. However, this is not without caveats: TAVI incurred an almost four-fold higher risk of requiring pacemaker implantation, and the need for re-intervention 12 and 24 months later was significantly higher in the TAVI group. The long-term durability of the implants is still in question and hence it is unlikely that TAVI will become the preferred modality for the treatment of severe aortic stenosis in younger patients.

> "TAVI IS CLEARLY DEVELOPING INTO A COMPETITIVE TECHNOLOGY THAT MIGHT GIVE CARDIAC SURGEONS A GOOD RUN FOR THEIR MONEY"

Two trials demonstrated noninferiority of instantaneous wave-free ratio (iFR) compared to fractional flow reserve (FFR) at preventing adverse cardiac events when used in the assessment of coronary artery lesions that appear angiographically of intermediate severity: DEFINE-FLAIR (Davies et al. 2017) and iFR SWEDEHEART (Götberg et al. 2017). Both observed a similar rate of major adverse cardiac events at 1 year regardless of whether the patient was investigated with iFR or FFR. Procedure length was on average 4 minutes (8%) shorter and associated with fewer symptoms in the iFR group, as this does not require the administration of vasodilating medication. Given the relatively widespread use of FFR (3-10% of all coronary angiograms performed in interventional centres, depending on the respective healthcare environment), only time will tell whether a different technology achieving similar outcomes will take hold.

Prevention rather than treatment is key—at least when correlating the amount of data presented at the ACC meeting investigating both (LDL-) cholesterol-lowering and (HDL-) cholesterol-increasing medication. Two major trials—FOURIER (Sabatine et al. 2017) and EBBINGHAUS (technically a substudy of FOURIER)—investigated safety and efficacy of evolocumab, an injectable proprotein convertase subtilisin/kexin type (PCSK) 9 inhibitor aimed at reducing LDL-cholesterol levels. Participants with established cardiovascular risk on statin therapy and LDL-C ≥ 70 mg/dl (equivalent to 1.8 mmol/l) were eligible for enrolment. EBBINGHAUS focused on whether the drug would cause cognitive impairment (it did not, at 19 months follow-up), while FOURIER demonstrated effective LDL-C reduction by 59%. Further, the primary endpoint (incidence of cardiovascular death, myocardial infarction, stroke hospitalisation for unstable angina or coronary revascularisation) was met, and evolocumab performed statistically significantly better than placebo (9.8% vs 11.3%, respectively). Overall, the drug was well tolerated and showed only a slight increase of injection site reactions (2.1 vs 1.6%). Interestingly, the benefit at three-year follow-up is predominantly derived from a lower rate of myocardial infarction (3.4 vs 4.6%), coronary revascularisation (5.5 vs 7.0%) and stroke (1.5 vs 1.9%). Cardiovascular as well as death from any cause were similar in both groups and did not seem to benefit from

aggressive LDL-cholesterol lowering medication. One might argue that, intuitively, even extremely low LDL-C levels of median 0.78 mmol/l cannot reduce cardiovascular death rates after only three years. However, this is certainly worth considering when assessing the costs of treatment. In the UK, the National Institute for Health and Care Excellence (NICE) has evaluated Evolocumab in a technology appraisal published in June 2016: it is thus recommended as an 'option for treating primary hypercholesterolaemia or mixed dyslipidaemia' (NICE 2016). The guideline endorsement only applies to patients without cardiovascular disease (CVD) in the context of hereditary forms of high LDL-C concentrations (>5.0 mmol/l; 3.5 mmol/l if high CVD risk), or patients with a primary (non-familial) form of hypercholesterolaemia at high CVD risk (starting at LDL-C >3.5 mmol/l, depending on risk factor profile). The annual cost has been quoted between GBP 4,400 and 6,100 (EUR 5,100-7100; excl. VAT). According to NICE, a discount in the context of a patient access scheme has been agreed between the Department of Health and the manufacturer Amgen, but the level of discount has not been publicised. One is thus left in a grey area when it comes to healthcare economic considerations. Would the average patient accept a two-weekly injection, given it does not prevent death but slightly modifies cardiovascular risk?

Quite exciting possibilities were presented with an implantable device (CardioMEMS HF) measuring pulmonary artery pressures (PAP) in patients with heart failure; the CHAMPION trial (Desai et al. 2017) examined whether readmissions to hospital could be averted by ambulatory monitoring of haemodynamic data. More than 1,000 patients had received the device and the percentage of patients admitted for heart failure reduced from 59% to 22% in the 6 months following implant. For the individual, this translates into a markedly reduced frequency of admissions: 0.92 vs 0.37 admissions per 6 months. This was achieved through early adjustment of the medical therapy, with intensified therapy if measured PAP increased (indicating impending clinical deterioration). Medical and quality-of-life implications aside, this makes further economic sense: An average cost of USD 23,000 (EUR 21,500) is quoted by Medicare for device implant in the US, and the average cost reduction equates to USD 13,000 (EUR 12,100) per patient per year (by reducing the number of hospital admissions), hence reaching a break-even point at roughly two years. Maybe the associated savings could then fund the rather costly PCSK9 inhibitors?

Conclusion

The field of cardiology is clearly making progress on all fronts. The field of preventive therapy sees exciting new opportunities through aggressive cholesterol reduction; the physiological assessment of coronary artery disease in the catheter laboratory could become simpler, and TAVI is clearly developing into a competitive technology that might give cardiac surgeons a good run for their money. The validation of the PAP sensor devices exhibits truly disruptive potential: remote-control adjustment of medical therapy could revolutionise the way physicians manage heart failure, leading to better quality of life and fewer hospital admissions for a large patient cohort. ■

KEY POINTS

- ✓ Transcatheter valve implants emerge as an alternative in less than high risk severe aortic stenosis patients
- ✓ Physiological assessment of coronary artery disease in the catheter laboratory simplified: can iFR define whether your coronary artery requires a stent?
- ✓ Extremely low LDL-cholesterol levels at a price point – but does it translate into better outcomes?
- ✓ How implantable sensors could revolutionise the way we manage heart failure in the 21st century

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Trump on Drugs

Part 1

A hundred days into the Trump administration, don't expect the vaunted changes to drug prices after the corporate execs get to Trump.

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After being caught up during the campaign by the media fetish over shameful drug price hikes, President Trump promised to lower drug prices. Given deep public outrage directed at high drug prices, this price lowering would be quite popular with his base, as well as all other Americans. Yet, such a task—similar to the "replacement" of Obamacare—is, in Trump's word, "complicated."

Taking on the Drug Industry

The nonspecifics in policy making that lingered from the campaign into the first months of the Trump administration came to an abrupt end with Trump's proposed Budget and House Speaker Paul Ryan's American Health Care Act (AHCA). Both proposals unleashed torrents of criticism, and revealed that neither Trump's voter base, nor the public at large, were considered much in current Republican policy-making. The content of "replacement" in the AHCA, its subsequent turbulent political process and its final defeat by the Republicans themselves, all became an embarrassing blow to both Trump and Ryan (Stanage, 2017a; Cassidy, 2017).

Given the deficit hawks Freedom Caucus stand against "tax credit entitlements," Trump now may have to shift to his next bipartisan approach to replace the Affordable Care Act (ACA). His "Art of the Deal" superpowers had failed miserably in this first legislative attempt. His final epitaph was "let Obamacare explode," which may now be the province of Health and Human Services Secretary Price (Davidson 2017; Weber 2017).

Commenting on Trump's claim that Obama "wiretapped' Trump Tower, which he heard on *Fox News* that he watches daily, Comedian Bill Maher rattled off a list of psychoactive drugs in direct-to-consumer (DTC) drug ads regularly shown on the Fox morning show, and quipped: "Don pick one!"

Pharmaceutical Industry: Complex and Powerful

The soaring use of very expensive specialty pharmaceuticals has dearly cost patients and families, along with the federal and state governments, and employers more and more each year. The number of outrageous price hikes trumpeted in the mass media brought the issue to the forefront of public debate, and in the Presidential campaign. While most pharma industry developments have received little analysis in the medical literature, corporate drug news (excepting recent notable price climbs and the $5.4+ billion spent on direct-to-consumer (DTC) drug ads [Bulik 2016]) remains the province almost exclusively inside industry corridors and a few select think tanks.

Beyond threats for drug price regulation, rolling back government regulations caused anxiety among pharmaceutical executives (Garde 2017), who feared that a less robust Food and Drug Administration (FDA) would lead to possible loss of insurance coverage for pricey drugs. In particular, there have been tensions with Pharmacy Benefit Managers (PBMs) and insurance companies, who seek added profits for their bottom lines on top of the manufacturers' discounts. By the time drugs reach consumers, the system baffles nearly everyone: "Who knew it was so complicated?"

> "INFLATION IN U.S. DRUG EXPENDITURES HAS FAR OUTPACED OTHER MEDICAL COSTS FOR YEARS"

Robust review processes are critical to both convince and encourage physicians and insurers of the value of these extremely high-cost new medicines (Beasby 2017). Outgoing FDA chief under Obama, Dr. Robert Califf, maintains that faster drug approval does not necessarily mean less expensive drugs: "There's not a direct relationship between the cost of development and the price of drugs or devices" (Califf quoted in Lupkin and Tribble 2017).

Trump seeks to radically change how the FDA vets new drugs by speeding up the "slow and burdensome" process (Kaplan 2017). Changing review standards may not be appreciated by FDA staffers and could rattle the biopharmaceutical industry, as well as their stocks. The Public Citizen's Health Research Group, among other health advocates and scientists, believes the FDA already concedes too much to industry parties (Carmone 2017).

Should Trump and his FDA designee, Dr. Scott Gottlieb, focus on speeding through new innovative medical products from the top biopharma research firms, they need to enforce strengthened post-marketing surveillance. When a drug reaches the larger patient population who experience many clinical conditions and simultaneously take multiple drug entities, mishaps become more common and problematic beyond the two company-chosen clinical trials reviewed by the FDA. Under the "gold standard," the new drug is passed based upon being better than placebo—not head-to-head against any existing competitor on the market.

Trump has made other promises for sweeping deregulation amidst the price pressures (Keshavan, 2017). With "value-added reimbursement" being introduced and surveilled, clinicians might tend to side with their patients to support Trump's Medicare Part D price controls. Doctors spend more time with patients explaining drug therapies and side effects to patients, and must deal with DTC ad explanations, PBM tiers, prior authorisations, and co-payment issues. Spending on pharmaceuticals has far outpaced that on physicians, hospitals, and other parts of the medical care expenditure pie. Aggressive pricing by drug firms produced a $324.6 billion dollars yield in 2015, up 9% from 2014; 2015 saw an additional 11.7% increase in drug outlays (Schumock 2016).

"Getting Away With Murder"

Trump picked up on the broad public resentment against drug price increases from the campaign and as President has made trenchant attacks on the drug industry. At his first news conference as President-elect Trump accused drug makers of "getting away with murder" and pledged to "save billions of dollars" for U.S. purchases in Medicare, Medicaid, the Defense Department and Veterans Administration. His comment sent drug stock prices down dramatically, but there was no follow-through with drug prices going down (Walker 2017).

After a meeting at the White House with pharmaceutical CEOs, the rhetoric on price controls eased. Pharma executives still have many concerns with a President who demonstrates little knowledge of their industry and has given few specifics. Lax regulations, along with Trump's mentioning "compassionate use of experimental drugs," are issues about which Pharma retains strong opinions. Compassionate drug use refers to drug companies expanding access to investigational drugs that are still in clinical trials. Such a patient demand should be cautiously examined for provider and payer acceptance, as well as clear safety issues. Multiple FDA-approved drugs have been removed from the market when they cause severe mishaps in the larger patient population. Wikipedia lists 178 "significant withdrawals from the market" since Thalidomide in 1961 (2017). After the FDA approved Tarceva, a $94,000 a year lung cancer entity made by Genentech, it was later found to be wasted and ineffective on about 90% or more of the patients using it. Only patients with a certain gene mutation benefited from Tarceva.

> *The story of Tarceva shows the danger of approving experimental medicines before reliable scientific data show they are effective -- which regulators are now doing more frequently. Pressure by powerful pharmaceutical company lobbyists and often dramatic testimony by patient groups looking for hope, Congress has repeatedly loosened regulations to speed medicines to sale (Petersen, 2017, p.1).*

While Pharma remains small capital compared to other industries in the American economy, it has historically wielded disproportionate political power. Multinational brand manufacturers (housed in only seven advanced nations) discover new expensive novel therapies. A key industry segment is the global generics market that chiefly supplies pharmacy benefit managers in the U.S. and many developing nations with much lower cost drugs, including APIs (approved pharmaceutical ingredients from mainly India and China) that get poured into brand entities made in the U.S. A mass of over-the-counter (OTC) products (including analgesics, digestive agents, dietary substances, vitamins, minerals and herbals) are readily consumed by the patient out-of-pocket.

Inflation in U.S. drug expenditures has far outpaced other medical costs for years despite quality efforts by managed care pharmacists to keep cost contained (CVS Health 2017; Joszt 2106). Popularly used brand drugs for the elderly, as well as most generic drugs, have seen regular double-digit price climbs (Silverman 2016).

The First Hundred Days of the Administration

Dramatic changes are usually expected to happen during the first hundred days of any new administration (Adams, 2017), starting anew with fresh desired directives and demonstrating technical expertise in full understanding of the Washington, DC, and national landscape, which is a perquisite to passing policy. The public usually allow for some novice miscalculations, but expect a give and take that is devoid of unilateral decisions.

In the case of the Trump administration, it has been much different (Stanage 2017). Trump showed he was a "man of action", fulfilling promises to his base with a long series of Executive Orders. There was much fanfare on his repeal of the ACA. This has been so badly botched where Republicans did not consider

a "replacement", let alone think it out in legislative language. The secret charade of "Hide the Bill" in a basement Capitol room for select review of the so-called "replacement" indicates deep splits within the Republican ranks. The jubilance of the Republican election sweep has seen meagre gains on their bold legislative to-do list (Steinhauer, 2017). Trump has yet to demonstrate understanding of either the healthcare system, or the pharmaceutical industry.

Ryan's American Health Care Act bill turned out as a huge tax break for the rich, while throwing 24 million Americans out of coverage. Medicaid covering some 70 million Americans was to be more than decimated through block grants to ease federal payments to the states over time. The proposed $334 billion federal cut was intended to cover forthcoming corporate and personal tax cuts under the next round of tax reform.

Contemporary pharmaceutical developments and their adverse impact across the world are evident on several fronts: global access to essential medicines, particularly for the most vulnerable; drug safety problems; controversial marketing issues; promotion expenses exceeding R&D outlays; patent protection losses; biosimilars coming to market, and the outsourcing of manufacturing and conduct of clinical trials abroad, among many others. The megamerger and acquisition fervour continues to rapidly reshape the players; this trend is predicted to heighten under the Trump administration to further consolidate their economic, and political power both nationally and internationally.

Business leaders depend upon government in crucial ways and prefer predictability for both near and longer-term planning. Outright disruption in healthcare is the best way to describe what faces, not just most Americans in health care these days, but also the pharmaceutical industry, given the commentary on sweeping deregulation, price controls for Medicare Part D, and other appeals that Trump has made to his supporter base.

Pharmaceutical executives have identified a number of precarious issues that may be forthcoming from a Trump administration, including:

- Corporate Tax reform clearly will affect the drug industry with his proposed export/import levy; reform will definitely create winners and losers among multinational drug manufacturers with international investments.
- Orphan drugs have proven to be very profitable for rare diseases; they are publicly subsidised when the numbers of patients are small, so any new policies might alter this.
- Solving the opioid epidemic involves steps to bring drug companies and practising physicians more into the spotlight of Governor Chris Christie's new Commission.
- Trump's views on vaccines causing autism, along with the potential of unleashing Robert Kennedy, Jr. on a Commission to investigate vaccine use is frightening to this industry segment that has blossomed wildly over the last eight years.
- Examining false claims for various complementary and alternative medicines that may also extend to direct-to-consumer (DTC) advertising of major brands.

> "TRUMP HAS YET TO DEMONSTRATE UNDERSTANDING OF EITHER THE HEALTHCARE SYSTEM, OR THE PHARMACEUTICAL INDUSTRY"

- Super "bugs", antibiotic resistance, and new social epidemics where firms have lagged.
- Medical devices have evidenced a number of problems in their functioning, necessitating new regulations.
- The recently passed 21st Century Cures Act with bipartisan support that favoured cancer pharmaceutical firms could be redirected in uncertain ways.
- Clinicians' and scientists' reactions to the Trump budget and its $40 billion cut to the National Institutes of Health. Many now are wary of Trump's administration's support for science in general.
- Other problematic tax issues may affect the many tax breaks firms get for R&D, plant and equipment, and a host of other areas.
- In developing the AHCA proposal, industry sources were not consulted; hearings were not held where they could offer their voice; and it appeared from newsletters, that none of the parties who had vested interests established under the ACA were givien consideration.
- Industry R&D expenditures have lagged behind promotion expenditures for many companies; future incentives for innovative drugs could be more closely examined in terms of what truly affects the public's health.
- The generic industry has blossomed with its own set of price increases. While these lower-cost entities are preferred by pharmacy benefit managers, brand manufacturers have concerns over the number of brand entities going off patent. A Trump administration attempting to keep expenditures low, which employers would

favour, might stimulate the FDA for more generic approvals, a record of more than 800 last year, with many "first-time generic drugs."
- Issues of biosimilars (complex biological entities) being imported from manufacturers abroad, or U.S. generic firms, threaten the huge profit streams of major manufacturers, which have sought delaying regulations.
- Tax policy may affect the tremendous amount of outsourcing that major manufacturers do in their drug production; these much cheaper-paying jobs are again what the Trump administration expects to tackle and bring home.
- Trump's immigration ban and visa programme affects biomedical manufacturers as well as medical student recruitment, residency placements and scientific exchanges; pharma leaders have spoken out about it.

The Trump administration has not shown great interest in using the common political process for formulating legislation. When Cabinet appointees finally get their staffing to work, will specifics in policy ideas receive full input from the corporate sector—a worry of business interests.

Trump campaigned on "huge tax cuts," but the prospects for quick tax reform according to Fortune Magazine are not looking good. It will likely be a contentious process to appease Congress where Pharma money now goes to both political parties.

Part 2 of this article will address the increasing role of specialty pharmaceuticals in the cost explosion and will detail several specific drug entities and their outrageous price increases that have been heralded in the popular press. More of what Trump and Congress may have in mind for healthcare reform may emerge over the next month. ■

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KEY POINTS

- ✓ The Trump administration is enduring multiple serious problems in its first 100 days
- ✓ Republicans face a bleak future to overcome their promise to "repeal and replace" the Affordable Care Act under Obama
- ✓ Taking on the pharmaceutical industry proves to be a most difficult endeavour for Trump
- ✓ The climbing cost of pharmaceuticals will likely continue to cause a burden to patients, employers, and government

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"The buck stops here"

THANH TRAN

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Management Tip

Treat people with respect, build trust, demonstrate caring, exude integrity, display dependability and character.

Read Thanh Tran's blog on Can A Health Collaboration Ecosystem Lead To Patient Homeostasis? at **https://iii.hm/9pk**

"If about us, not without us"

PETER KAPITEIN

PATIENT ADVOCATE, INSPIRE2LIVE, AMSTERDAM, THE NETHERLANDS

Healthcare exists because we patients exist and therefore we should not only be asked about what we want, we should also decide about all matters in healthcare. Simply for the sake of the patients and their loved ones and for the sake of lower costs in healthcare. I'm convinced and have done research on this; putting patient advocates in the right position will greatly lower the cost of healthcare.

Read Peter Kapitein's blog on Why Don't We Introduce Patients Into Healthcare Management? at **https://iii.hm/9pi**

"Data is here so search for its insights. Don't focus on the problem, look for the solution. To do this we need to have a hackers' spirit and the pride to overcome challenges"

IGNACIO MARTINEZ SORIANO

DATA SCIENTIST, HOSPITAL UNIVERSITARIO RAFAEL MÉNDEZ, LORCA, SPAIN

Career Highlight

When I went from Management Chief of IT to being a data scientist and discovered the power of the data and machine learning.

Read Ignacio Martinez Soriano's blog on How is Machine Learning Improving Patient Lives? at **https://iii.hm/9pj**

"Medical improv is an exciting teaching tool that can be used to promote emotional intelligence, communication, teamwork, and leadership skills in healthcare professionals"

BETH BOYNTON

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Management Tip

If you want to build assertiveness in staff, ask them what they need to accomplish a goal or contribute to an organisational initiative. Then listen and validate!

Read Beth Boynton's blog on What is Medical Improv and How Can it Help Us in Healthcare? at **https://iii.hm/9ph**

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