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The Journal

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## The whole patient

am a cancer patient. I have experience first-hand how society's view on patients deals a massive blow to your own sense of self-worth. Friends stop calling you, or they call you way too much. Healthcare professionals are too stressed out to talk to you. To top it all, you are limited to doing absolutely nothing for several months, or even years. These things combined, together with the obvious physical challenges of going through cancer, make it easy to understand why many cancer patients suffer from depression.

While I speak from a cancer patient's perspective, I have no doubt that those facing other conditions experience similar feelings of alienation. My own experience led me to establish WarOnCancer. This health tech company is on a mission to solve the mental health problem for everyone affected by cancer.

The fact is, the patient is becoming more and more central to and engaged in their own healthcare. Where I see patient engagement contributing most is to mental healthcare. Listening to patient's needs and preferences is a great first step towards making patients feel more human. I believe that self-worth, to feel like a strong human being, is a key desire for most patients and something that is overlooked in the debate on mental health todav.

One of the biggest challenges to effective patient engagement is the lack of digitalisation within the healthcare sector as well as information overload. Physicians today are stretched to their limits with regards to administration, data

processing and research development. The reality is that it is very hard for physicians to process all that extra layer of "engagement" from patients into their work routine. Hence. investment into digital infrastructure and AI to aid the physicians is essential as a first step.

We also need to take a good, hard look at patient reported outcome measures (PROMs). Research points to that collecting PROMs leads to better care delivery as well as increased mental health for the patients. To accelerate the adaption-process, we should implement a system where PROMs data is used to compare and reward hospital performance within a pay-forperformance scheme.

Will a holistic understanding of the 'whole patient' lead to better clinical outcomes and more positive patient experiences? A whole patient understanding is crucial. It is not solely about one condition; health is personal and health systems need to find a way to identify what information should be leveraged to understand a patient holistically. Such actions will lead to more efficient clinical outcomes and more positive patient experiences.

We hope the articles you find in these pages inspire you to look at patients and their contribution to better healthcare with even newer eyes and the insights from leading sector professionals offer fresh ideas on leading and managing. Happy reading! ■



### **Fabian Bolin**

Keynote speaker and co-founder of WarOnCancer

waroncancer.com





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### What Do You Think?

Will a holistic understanding of the 'whole patient' lead to better clinical outcomes and more positive patient experiences? We explore patient empowerment and engagement in our patient-themed issue. We welcome your ideas. Contact us on edito@ healthmanagement.org

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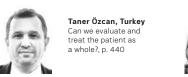
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Point-of-view articles are part of the HealthManagement.org Corporate Engagement Programme



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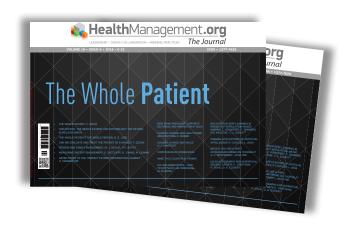
Patients are people when they leave the doctor's office. They live a life, have jobs and families. Taking a whole person approach is the only way forward to face today's and tomorrow's healthcare challenges.

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1. FDA submissions P080003, P080003/S001. 2. Results from Friedewald, SM, et al. "Breast cancer screening using tomosynthesis in combination with digital mammography." JAMA 311.24 (2014): 2499-2507; a multi-site (13), non-randomized, historical control study of 454,000 screening mammograms investigating the initial impact of the introduction of the Hologic Selenia® Dimensions® on screening outcomes. Individual results may vary. The study found an average 41% increase and that 1.2 (95% CI: 0.8-1.6) additional invasive breast cancers per 1000 screening exams were found in women receiving combined 2D FFDM and 3D® mammograms acquired with the Hologic 3D® Mammography System versus women receiving 2D FFDM mammograms only.

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Stefan Heinemann, Germany

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The potential impact of artificial intelligence in radiology is impressive; vendors and major academic centres are developing a wide array of artificial intelligence applications and neural networks to aid radiologists in clinical diagnosis and clinical decision support.

Renato Cuocolo, Lorenzo Ugga, Italy

### Would you use a dirty ultrasound probe on yourself?

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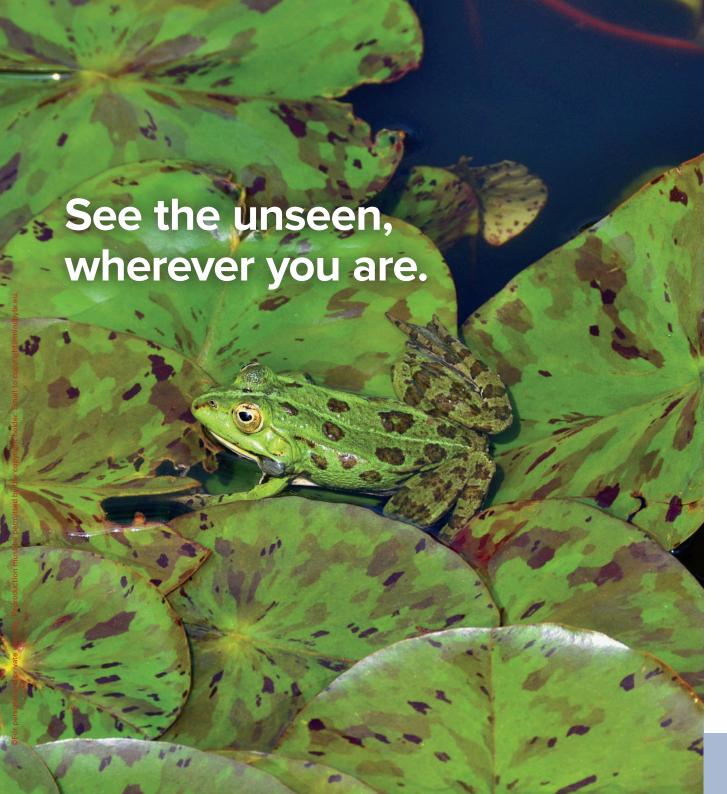
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## New EAHM President supports exchange and innovation

Looking towards a pan-European vision

The new President of the European Association of Healthcare Managers (EAHM) says healthcare needs radically new thinking for necessary solutions to new challenges



Philippe Blua

Director Hospital Centre o Troves, France

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irector of the Hospital Centre of Troyes in France, Blua was elected the new head at the 48th EAHM Ordinary General Assembly held at the congress. *HealthManagement.org* caught up with Blua to find out what his priorities are for healthcare managers across Europe.

## What are your objectives as the new President of the European Association of Healthcare Managers (EAHM)?

The objective is to increase exchange among the hospital managers of Europe because the professional landscape has changed and continues to change rapidly. We have a higher proportion of elderly, there is new information and communication technology and there are serious financial pressures. We have to work together to find a solid solution for the future because everywhere in Europe is facing the same issues.

### Do you think there's a need for more healthcare leadership C-suite training?

Yes, I do. For instance, I think it would be valuable and interesting to create an MBA for hospital mangers. We could build a new vision of the future of hospitals together with a European point of view. In terms of training, we are at a place where we need to try



new approaches and, afterwards, to select and develop what works and discard what doesn't. We are at a moment of great change. The present-day world climate of technological innovation and swift change can be compared to that of the 15th century Renaissance era.

### What is first on your agenda?

One of the first tasks I will take on is to meet with all the national associations across Europe to update on all the challenges facing hospital leaders. You have to keep ahead of the game to move with the times so getting feedback from and brainstorming with these associations is the first step. It's simple; we have to find new solutions because the old ones don't work anymore.

More than 1000 delegates from 35 countries attended the EAHM Congress. People-centred care, integration of care, innovative provision models, population health and sustainability dominated the agenda. Next year's congress is being held in Ghent, Belgium, September 12 − 14. ■

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US Manager, December 2017 http://klasresearch.com/comments/sectra-pacs/1814

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## Imaging innovation's critical role in healthcare's future

With the shift toward value-based care, healthcare providers are focused on their most pressing challenges: improving the patient and staff experience; increasing diagnostic confidence; enabling greater efficiency and productivity; and facilitating data-driven practice management. The need to connect data and technology to enable precision healthcare and expand our understanding of disease and view of traditional diagnosis and treatment has never been greater. Imaging innovation and technology advances can help us get there—raising the quality of care, accuracy of diagnosis and identification of workflow or system inefficiencies. Philips executives from the Diagnostic Imaging Business Group provide their views on some of the most talked about topics in healthcare today ranging from artificial intelligence to precision medicine to patient safety and the crucial role imaging plays in achieving healthcare's goal of seamless care.



Homer Pien, PhD Chief Scientific Officer, Diagnosis and Treatment, Philips

### How artificial intelligence can make an immediate impact in patient care

"To enable precision medicine in the future, we need to do a better job on the diagnostic side first by integrating all the relevant information on a timely basis in order to provide treatment based on the individual patient's particular characteristics, not the general category of disease."

If we shift our thinking, and focus on a particular clinical problem, we can readily see how clinical AI can go from research to implementation and make a dramatic difference in patient care today. This is how artificial intelligence becomes *Adaptive Intelligence* because it is applied in the context of patient specifications and specific disease conditions.

Radiation therapy is an example of precision medicine - highly individualised and very complicated. There are numerous parameters and constraints that you must be able to satisfy while at the same time adhere to the contour of the tumour from

all the different perspectives of the radiation beam. Al is used to optimise that very, very complex equation and it is not trivial. Frequently, it's not possible to satisfy all the constraints, so then you must calculate what is the minimum violation you can incur while delivering the proper dose to the patient. For cancer patients, delay of treatment is both impactful on the clinical outcome and the emotional strain for patients and families.

With Adaptive Intelligence, we are able to do a better job of satisfying all those constraints more quickly and with fewer iterations, reducing time to create an image-to-plan treatment from 12 days to 1-2 days. Having both the informatics that integrates all of the data, as well as the adaptive intelligence that will sort through all of that and make sense of all that data in context, is highly important. This will enable us to make an immediate impact in patient care today and facilitate personalised medicine in the future.



Kees Wesdorp Business Group Leader, Diagnostic Imaging, Philips

### Why we need to take a systems view of imaging

"Imaging should be seen from the point of view of a health system, in which technology and data connect seamlessly to empower all the stakeholders to drive the transition to valuebased care."

In order to shorten the path to a confident diagnosis and treatment, health systems must look at the needs of many stakeholders—patients, technologists, radiologists, administrators—and understand their unique concerns and challenges. A systems view of imaging is based on the idea that a deeper understanding of each stakeholder's experience can provide important insights that help patients, clinicians and administrators fulfil their respective roles more effectively and efficiently, with less stress and more confidence.

Healthcare is foremost about patients, and in order to

make the patient experience better—all the people involved in healthcare have to work better—individually and with each other. In the imaging system everyone has a unique set of requirements to do their job well. Supporting and connecting these people in a truly meaningful manner is directly related to creating value for patients and the health system at large.

Here is where a systems view of imaging is vitally important for providers as well because health data is often distributed and sequestered across many applications and departments which makes it hard to compile a comprehensive view of individual patients and populations. By merging data with clinical expertise at the modality and image processing levels, we can move the power of imaging from "behind the scenes" to "front and centre" to help streamline the path toward a confident diagnosis and enable precision medicine in the future.

### Why productivity while driving sustainability matters in imaging

"Value-based care is not just about looking for short-term gains; it's about finding long-term solutions to drive efficiency and lower cost while providing outstanding care to patients."

With imaging's central role in value-based care delivery, healthcare leaders are always looking to balance speed. comfort and confidence with productive, cost-effective and sustainable operations. To that end, healthcare providers are becoming aware of the potential operational and financial effects of helium gas usage of Magnetic Resonance Imaging (MRI) scanners.

A leading modality for healthcare organisations, MRI accounts for a significant proportion of largest uses of helium gas today in the science and healthcare field. MRI scanners are responsible for 20% of helium consumption worldwide; in the USA, the figure is as high as 31%. As a result, the technology is highly susceptible to fluctuations in supply and healthcare providers are directly affected by the consequences of helium's eventual dissipation.

Today's MRI scanners feature magnets with a non-sealed helium volume of 1500 litres. This means that hospitals need to replenish their supply of the gas and creates logistical installation challenges to comply with helium-safety protocols. Fulfiling this requirement frequently entails costly floor adaptations and extensive planning. These issues are driving a new era in MRI technology advancements that are less reliant on helium. For the C-suite, ensuring productivity while driving sustainability is an integral part of managing a healthcare organisation's total cost of ownership.



Arien Radder Business Leader, Global MRI Philips





Sham Sokka VP & Head of Radiology Solutions, Philips

## The promise of AI in radiology department operations

"Radiology professionals must have a clear idea about how the data might be translated into practice—what it could look like, and how it will impact both the way they work and patient care in the long run."

Al-driven healthcare solutions can enable radiology departments to become stronger and more productive than ever before, with more visibility into their operational status, from equipment maintenance to scheduling to postimaging follow-up. It all starts with data, which delivers actual information and insights into what is happening. Then, Al and predictive analytics offer further foresight, enabling staff to better respond to what is likely to happen.

These capabilities do not stand to replace the responsibilities of clinical or technology professionals. However,

they do provide these individuals with greater information, layered alongside their years of experience, enabling them to work more efficiently, improving operations and ultimately enhancing the patient experience. Having the right data can enable teams to predict such an occurrence and issue patches proactively, to avoid downtime, maintain workflow, and provide a better experience for the staff and their patients.

For hospitals looking to integrate Al into their radiology department, the focus should be on: accurate patient data collection, standardisation and change management. Most importantly, radiology professionals must have a clear idea about how the data might be translated into practice—what it could look like and how it will impact the way they work. Al can help radiologists perform higher-level tasks that demand human ingenuity, creativity and compassion.

## The importance of an integrated approach to quality and safety

"It's about that holistic view of enabling hospitals to deliver care in the most expeditious way but also the most caring and safest way not just for patients but staff as well."

With the shift from volume to value-based care, the role of safety and quality is becoming even more critical. It's not about how many patients you can see each day; it's how well you can provide their care.

In imaging, reliability and consistency are key tenets of ensuring quality outcomes. Healthcare providers must have processes in place to consistently monitor and measure to ensure uptime, maintain quality and service, and mitigate risk.

While these measures are ultimately designed for delivering patient care that is safe and effective, they also provide business benefits because by not having to bring people back in for re-scans, healthcare organisations can increase throughput which reduces overall cost.

A true quality mindset requires a behaviour-based approach to determining how system or workflow processes can be improved by observing how clinicians interact with patients and imaging equipment so that the potential for human error due to training, decision errors, or workflow constraints is reduced. From a business standpoint, the impact of safety and quality initiatives directly correlates to patient satisfaction, more confident diagnoses and improved operational performance.



Austin O'Connell
Head of Quality and Regulatory,
Diagnostic Imaging, Philips

For more imaging thought leadership content, please follow the Philips Imaging Showcase Page on LinkedIn via https://www.linkedin.com/showcase/philips-imaging/ and visit our web site via www.philips.com/radiology.

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<sup>1</sup> JR Campbell & Associates; USGS.

## ValueBased Prize HealthCare 2019



## Applications will be accepted as of **September 1st, 2018**



"Winning the Prize brought us recognition and new possibilities by all different stakeholdergroups."

-Dr. Henk-Jan Aanstoot (Diabeter, winner VBHC Prize 2017)-

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- Network with VBHC pioneers;
- Be at the **center** of healthcare innovation;
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## How artificial intelligence spells real change for patients

"At Affidea, the scale of our operation gives us unique capabilities in AI, including rich data sets which we can use to drive forward innovations in patient care both internally and with our partners. We want to help create a future where healthcare professionals can devote their time to doing what they do best – delivering the best possible care for patients."



Giuseppe Recchi CEO Affidea

he world's population is expected to increase by one billion people by 2025, with nearly a third expected to be aged 65 and over. It is a testament to medical science that we are all living for longer, but whilst these advances have enabled us to spend more time enjoying retirement, Europe will increasingly be left with an ageing population – and this brings with it a set of challenges for healthcare systems and the patients they look after.

Across Europe, there are a growing number of older people whose complex healthcare needs will have to be met. Cancer, in particular, presents a major concern. The data of the WHO (World Health Organization) show that in Europe, there are more than 3.7 million new cases and 1.9 million deaths from cancer each year<sup>1</sup>.

The global cancer burden is rising, with more people receiving cancer diagnoses than ever before. Getting it diagnosed early is crucial, because it provides the patient with the best chance of a good outcome. However, two thirds of people on the planet do not have access to basic radiology services, such as x-rays or ultrasounds.

### So how can we improve the situation for patients?

The advent of artificial intelligence (AI) is a promising way of solving the problem of medical capacity as well as the impact of human error on patient outcomes. New digital technologies allow not only higher automation and productivity, but enable clinicians to analyse enormous amounts of imaging data, which otherwise would not be possible with current staffing structures.

As the leading European provider of advanced diagnostic imaging, outpatient and cancer care services, Affidea is uniquely positioned to help realise the potential of Al and big data in the benefit of patients and doctors. From teleradiology to radiation therapy, we are looking into applying advances in Al to radically transform patient care and shape best practice across Europe.

We are the only healthcare operator in Europe to sit on the Imaging Advisory Boards of IBM Watson Health, and we also sit on the board of Microsoft Cloud. We are trusted with important amounts of data – 13 million scans every year in our 246 centres, located in 16 countries across Europe. These rich datasets can help analyse and benchmark, to work out what works best for patients and clinicians.

We want patients to have better access to advanced diagnostic imaging, diagnostic performed with state of the art technology and the best medical professionals. Ultimately, our goal at Affidea is to improve outcomes for patients and ensure good health for all. No small task, but we believe that Al innovation offers the greatest possibility yet of facing up to the challenges of the European health systems today.

Why is this important? Because demand for MRI and CT exams has increased across a range of countries over the past ten years, although the number of exams carried out per capita varies significantly. This disparity is reflected in the number of radiologists per 100,000 of the population, from 31 radiologists per 100,000 people in Greece, 12 radiologists per 100,000 people in Spain and Portugal and just 3 per 100,000 people in Italy.

Even when patients do have access to diagnostics, erroneous interpretations may

occur. Some studies have demonstrated differences in interpretation between radiologists reading the same scan as high as 30%. Some AI can already achieve an accuracy of around 90-95% which is very high. Add to this the fact that nearly half (48%) of radiologists report symptoms of burnout, likely caused by inadequate staffing, it's not surprising that errors may occur.

Al-powered medical imaging systems can produce scans that help radiologists identify patterns - and help them treat patients with serious conditions more quickly. The result is clear and more accurate.

I see AI as a powerful tool which can enable us to become stronger and more productive than ever before, with more visibility into operational issues, from equipment maintenance to scheduling, to reading and analysing data. Through this data we can gain information and insight into what is happening, using these learnings to design healthcare services and improve patient care. Al solutions offer further input, predicting what will happen and enabling healthcare professionals to better respond to this.

### For diagnostic imaging in particular, AI has the potential to help transform the industry.

Al will help radiologists identify patterns. A CT scan generates data about tissue density, and in human tissue about 3000 different density levels can be differentiated and converted in tones of grey; a standard monitor can display 256 tones, whereas the human eye can only detect about 30. This means that just by displaying imaging data in a format a radiologist can read, information is lost. That is why we should do everything we can to increase the capacity of the radiologist to read all the available data. That's where AI will improve things - it will read through a lot more data than is physically available to radiologists.

It will offer radiologists enhanced productivity, increased diagnostic accuracy, more personalised treatment planning, and ultimately, improved clinical outcomes, which means healthier, happier patients.

"WE WANT PATIENTS TO HAVE BETTER ACCESS TO ADVANCED DIAGNOSTIC IMAGING. DIAGNOSTIC PERFORMED WITH STATE OF THE ART TECHNOLOGY AND THE **BEST MEDICAL PROFESSIONALS"** 

It's no wonder, then, that the AI market is booming. The world market for AI and machine learning in medical imaging is set for a period of robust growth and is forecasted to top \$2 billion by 2023, while the AI healthcare market is expected to hit \$6.6 billion by 2021<sup>2</sup>.

And the benefits for patients could be enormous. Freeing up time for clinicians to be able to focus more valuable time on patients is just one. In many European countries, pressure on health services is leading to shorter consultation times with less doctor-patient interaction. In Italy for example, the average GP consultation time is only around ten minutes. Al and machine learning have the power to speed up diagnostic processes, allowing doctors to spend more time with patients.

But these advances won't replace people with machines; it's about creating a more accurate and more efficient patient pathway. Currently, physicians spend just around 30% of their office day on direct clinical face time with patients, and over 40% of their time doing paperwork<sup>3</sup>. Al has the potential to change that. At Affidea, the scale of our operation gives us unique capabilities in AI, including rich data sets which can help drive forward innovations in patient care both internally and with our partners. We want to help create a future where healthcare professionals can devote their time to doing what they do best - delivering the best possible care for patients.

### Affidea at a glance:

- Present in 16 countries across Europe, 246 centres, over 7,500 professionals, producing 13 million scans
- European healthcare provider sitting on the Imaging Advisory Boards of both IBM Watson Health and Microsoft Cloud
- 50% of the European winning centres awarded by the European Society of Radiology belong to Affidea

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<sup>3</sup>Annals of Internal Medicine: Allocation of Physician time in ambulatory practice: A time and motion study in 4 specialties

## Climate change and healthcare architecture

IFHE Vice-President hopes for more sustainability in healthcare

HealthManagement.org spoke to Daniela Pedrini, a leading light in the International Federation of Health Engineering (IFHE) on the changes she wants to see taking shape in healthcare architecture in the years ahead.



### Daniela Pedrini

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### What are your responsibilities holding top positions in the IFHE?

There are two phases, as it is stated in the Standing Orders of the (IFHE) during the 25th Congress just concluded in Brisbane, Australia. Now the Council has officialised my nomination as first Vice-President of the federation and confirmed the location in Rome, Italy of the 26th International Congress.

At the Rome Congress, programmed for May 24-27, 2020 I will be nominated President of IFHE International for the following two years.

The forthcoming period will see my engagement, supported by members of the Italian Association SIAIS, a group of IFHE Europe and IFHE International members, in organising the scientific content of next Congress, selecting the presentations and key note speakers while supervising and coordinating the complex logistic and organisational "machine".

The next Congress has a particular meaning for our federation, marking the 50th anniversary of its foundation, which took place in Rome in 1970.

Naturally, I will have also to present on that occasion, not only my programme for the following



two years, but also propose new ideas and a vision for enhancing the contribution that such an important association can and must give to the healthcare system.

"PRIORITISE THE NEED TO **EVALUATE ACCURATELY AND IN** DEPTH THE "HEALTH" OF YOUR FACILITIES' STRUCTURES AND RELATED TECHNOLOGIC SYSTEMS"

### What are the biggest challenges in healthcare architecture at present?

There are different sets of challenges for healthcare architecture. From society are coming pressing needs of care closer to the patients, not based only on hospitals (which will be more and more highly technological for acute patients) using new technologies that require the definition of new models of delivery of healthcare services. More integration between social and medical care is becoming mandatory, with a vision of an urban fabric that includes new forms of support for health and wellbeing. Additionally, from the enormous challenges presented by climate change-related problems, come the needs for safer hospitals, referred now as resilient,

in terms of physical structure and for proactive institutions in the battle against this environmental situation.

### What do you find the most exciting with healthcare architecture at present and what do you see ahead?

We are, in fact, producing buildings that are reducing energy consumption, the use of water, producing less waste and are more patient-centred with solutions before not envisaged. Not only health facilities designers, architects and engineers, but policy makers, managers and staff are requested to participate in the process of planning new facilities and post-occupancy evaluation (POE) is becoming more commune. What I hope will be ahead is a more diffuse awareness in the planners and designers part of the importance of the starting phase of conceiving a healthcare facility and the need just in such a phase of the contribution of all the so-called "stakeholders", including patients, the humility of learning from mistakes, an appropriate use of evidence-based knowledge.

### If you had a room full of healthcare facility managers in front of you, what would you tell them to prioritise?

Without any doubt. I would tell them to prioritise the need to evaluate accurately and in depth the "health" of their facilities' structures and related technologic systems especially taking into account the most important risks of the area in which their hospital is located.

### What is your top management tip?

The hospital is a complex organism and the solution to any problem has always to be seen in details, but also considering the whole system, which implies the need to understand what a partial solution could produce on the totality of the complex. Furthermore, investments have to be evaluated not only on their immediate cost and return, but in the framework of the period of their life-cycle.

### What is your favourite expression?

Prevention is better than cure, also for healthcare facilities.

Daniela Pedrini is also President of SIAIS. (Italian Society for Engineering and Architecture) The IFHE Presidency has just passed from Eng. Douwe H. Kiestra (NVTG, Nederland) to Eng. Darryl Pitcher (IHEA, Australia).

## Leading change and value

An alternative approach to leadership

Diabeter employs a leadership style which incorporates value into all its clinics. Prof. Henk-Jan Aanstoot explains how he keeps a motivated, coherent team and what his future plans are.



Henk-Jan Aanstoot

Diabeter

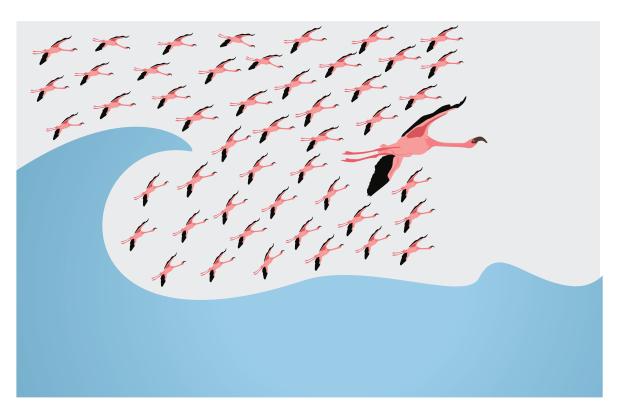
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diabeter.nl

ithin Diabeter, we have developed a valuebased healthcare (VBHC) model that transforms healthcare delivery by providing a combination of innovative technologies, patientcentric care delivery, and reimbursement on the basis of outcomes rather than volume. One of the most important aspects of the VBHC agenda (Porter and Teisberg, 2006) is to create an integrated practice unit (IPU), including a coherent team. The staff are a hugely important asset here, impacting on our care delivery, and we are aware that our new value-based system brings changes that challenge staff. This is why it is important that our staff share our values and goals, settle into this shared belief system, and that we continue to support and motivate them accordingly.

When it comes to developing a VBHC model, I think two things that are hugely important are leadership style and the possibility to adapt to new things and developments. Of course, the leadership style has to carry that philosophy across the organisation. We have been doing this now for 12 years, and that has had an important effect on leadership style. Leaders should have their feet on the ground somewhere close to where care takes place.

We also realised something else in previous years. There's a famous saying from Dutch abstract expressionist artist Willem de Kooning, "you have to change to stay the same", and I think that says it in some way. We have to adapt ourselves to new technology but we still have to be caregivers, listening



to the needs of patients. So it's an issue of high touch, high care and high tech.

That being said, the leadership in healthcare is often quite stable and not able to bring changes guickly. So, the leadership should not only lead the clinic, but should also have a very clear vision of what's happening around the clinics in the world. For us, Henk Veeze and myself, that was the main reason to leave the hospital we previously worked in; we couldn't create the IPU and transfer the knowledge that we had on how the disease would develop and what's happening in the world, thus getting what was needed done.

Moreover, we could not create a small but highly efficient loop of information from patient care through providers to leadership, and towards new decisions for change. Right now, we need rapid changes, alternative leadership and change management. In my view, leadership is absolutely important to have this flexibility. Rather than be in the board room, be on the floor. As we see how quickly traditional care changes in the next three years, enabling improvements in the outcomes of patients with diabetes, it is also our duty to 'change and stay the same'.

### "I FADERS SHOULD HAVE THEIR FEET ON THE GROUND SOMEWHERE CLOSE TO WHERE CARE TAKES PLACE"

### **Collective leadership**

In our leadership model, we are further developing the combination of medical leadership working with 'chiefs of staff'. This model comes from successful big clinics like the Mayo Clinic and the Cleveland Clinic. At the top, there are two people: one is medical, and the other is an expert in organisational aspects. I think that a leadership model is a basis for future healthcare development, so a model with strong medical vision and medical leadership combined with optimal chiefs of staff who run the show on HR. finances etc. is important. In my country of the Netherlands, a lot of hospital boards don't have a lot of medical experience, so if you look at developments in medicine, they usually start low on the ground or somewhere in the field, and when you bring it into the hospital, somewhere they get stuck.

### Support and motivate staff using outcome data

I think if you have a VBHC model where people can see that improvements take place and patients like the care, it's very motivating. You don't need to apply effort in that area. The biggest problem that we see is that sometimes things change rapidly and you need to give some time for people to adapt—that matter of change management again. In addition, the jobs will change in the next generation of healthcare: diabetes nurses will either become 'diabetes technologists' focusing on technological solutions, or become more involved in motivation and support. Similarly, education will change from a full-diabetes-curriculum to modern teaching, focusing on situation awareness and problem solving. As most people trained in healthcare come with a traditional background in care and have to switch to a 'high tech, high touch' environment, we've learned that when people come to work with us, we need to, what we call 'Diabeterise' them: no paper, lots of technologies, no electronic patient charts but a disease management system that helps and checks your work etc.

One of the things we introduced this year is to deliver outcome data not only at a clinical or patient level, but also at a healthcare provider level. As in a lot of industries, staff members now have their own data, their own results presented every month, so that they and others can learn from this. We saw, for example, that some nurses were excellent at implementing technology, but the number of patients they offered this to was limited. Conversely, we do see HCP's that prescribe technology but are behind in achieving better outcome with it. Discussing and sharing such data and experiences helps towards making improvements. By being transparent with personal outcome, group outcome, team outcome, and clinic outcome data, staff are stimulated.

At the beginning it can be frightening, with staff saying: "Oh my god, they're looking at my data." But eventually it works. The whole strategy requires good leadership—not only to implement it, but also so that you don't misuse it and cause staff to become frightened about data and outcome etc.

In a VBHC model, if you talk about outcome constantly, then you also have to talk about personal outcome and learn from it, including HCP individual outcomes. Currently, we have introduced this in 80% of our staff members and when seeing what you can do, share and improve, they look at it in a positive way. Their interest has even extended to an eagerness to get involved with its further development, such as personal dashboards on outcomes. So, it's working out, and that's a fairly new step in healthcare. At least we don't see it happening often. It's hugely stimulating and promising.

Of course, if you have very bad outcomes, you ask yourself: why is it? Did I follow the patient? Did I follow the protocol? Do I need more training? What can I do about it? You can compare with others and begin to see how better outcomes could be achieved. Learning through the system in one of our centres this year caused an enormous drop and improvement in A1C outcome. So this scheme looks very promising. We were very careful when we started it, and we are now very happy with it. Our clinic is actually the leader in our field, which is great to see. It's interesting to see that outcome discussions go that way.

### Outcome data as a training tool

We learned from our studies and publications with the Hvidoere Study Group that three aspects of chronic diabetes care are key: a) frequent contacts, b) agreed treatment goals and targets with patients and c) a clear coherent 'onevoice' view from the team of HCP's. As this last one is very important, we are changing our HCP education to e-modules, which start with teaching about our vision and VBHC model with innovative technologies and patient-centric care delivery. The history behind Diabeter, the goals that we have, the key learning that will be achieved via the outcome scheme are now part of the introduction. They re-emerge in discussions, in schedules and in evaluations, providing staff with many opportunities to learn from what we have done in the past. It also provides openings to ask for input and information about new systems and changes.

With this new HCP training, the next step is to include that in our patient education. We are moving much more towards situation awareness education. Situation awareness education can be utilised to reveal potential issues in healthcare quality and increase patient safety. Through training, HCPs can learn to be fully engaged and aware of their environment and minimise or deal with any current or potential distractions or dangers. With education, so can more and more patients. To develop this further we decided to split our team efforts and create a separate technology team that include nurses that are good with technology that can handle all the technology developments with a patient. We already use a 'closed-loop' data system with our patients (called ther@pymail), which uses patient data as a bridge between the team and the patient. The new 'cloud care' approach is required to create the next step, using new insulin pump and glucose sensor technologies, together with

automated contacts and a control room. A great new area of technology we are looking into is virtual reality. Here, the candidate would put on virtual reality goggles, see how the clinic works via a virtual world, and participate.

### Finding suitable, coherent staff

Finding the right kind of person to join your organisation is an important part of building a strong and effective team. Rather than the right qualifications, knowledge and experience, it is important to ask potential colleagues how they feel they could add to VBHC and how they can combine technology with empathy, compassion, working style and vision.

What we currently do after somebody applies for a job is we ask them in for an interview as well as to be on our clinic for half a day or a whole day. It is key that this experience fits' with their expectations, and also with ours. There is a considerable shortage in healthcare staff here in the Netherlands and in other countries, but we do see that people are motivated to work with us when they see it's all about outcome and that we can add to that. Although there are people who in the process say, "I'm not equipped for this job. I want to be in clinics where I just see people. I don't want to have email or data and things around me", there are others who have been looking for exactly this kind of model and clinic to join. Some who were averse to the idea to start with have later seen the huge value it delivers.

### KFY POINTS



- Right now, we need rapid changes, alternative leadership and change management
- Leadership is important for providing flexibility and meeting valuebased healthcare goals
- Effective leadership involves transferring knowledge on the disease and learning from outcome data
- By offering a coherent team, patients believe in and understand what we're doing



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## Compassion

The human dimension of productivity

Findings from recent studies on compassion in the workplace, the business case for compassion and some practical tips on how to create a more compassionate workplace.



Meysam Poorkavoos

Roffey Park Management Institute Horsham UK

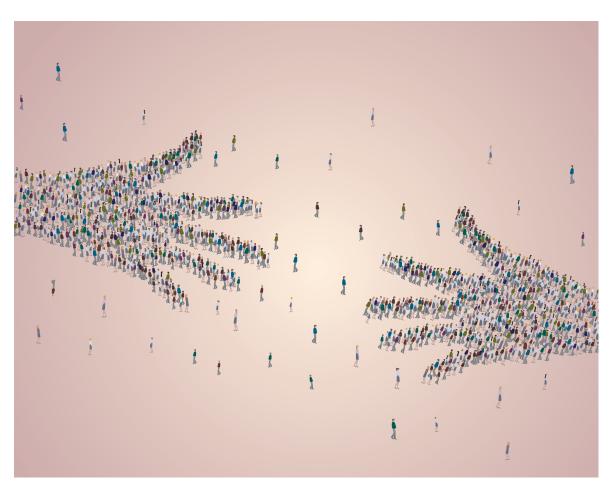
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f you work in the healthcare sector, you agree that compassion is fundamental to patient care. The majority of the people in healthcare work hard to offer compassionate care to their patients. Mid-Staffordshire Hospital in the UK is just one example where a lack of compassion led to people experiencing serious failings in basic standards of care, which led to suffering and avoidable deaths.

Think about doctors, nurses and all the other people who work directly or indirectly with patients. Do they all need compassion? Would they be able to offer the care that every patient deserves in a workplace that lacks compassion? First, let's find out more about what compassion in the workplace looks like and then look at how compassionate workplaces might impact on staff, patients and the overall organisation.

### What is compassion?

Dictionaries define compassion as feeling pity, mercy and sympathy. But being compassionate is far more than feeling sympathetic or being kind to someone. I define compassion as being moved by and feeling sorrow for another person's suffering and taking action to alleviate the pain felt by that person. Put simply, compassion is taking action to alleviate the sufferer's pain. In my opinion, taking action is the most important part of compassion and a key differentiator of a compassionate person from the rest.



Through my research I have identified five characteristics of a compassionate person in the work environment. The five characteristics are:

### Being alive to the suffering of others

Being sensitive to the wellbeing of others and noticing any change in their behaviour is one of the important attributes of a compassionate person. It enables the compassionate person to notice when others need help. Noticing someone's suffering could be difficult, particularly in workplaces where people are busy with their work and preoccupied with their deadlines. Also, depending on the work environment and the culture of the organisation, people may tend to hide their pain from others.

### "COMPASSION IN THE WORK ENVIRONMENT IMPROVES STAFF WELLBEING AND POSITIVELY IMPACTS THE BOTTOM LINE"

### Being non-judgmental

A compassionate person does not judge the sufferer and accepts and validates the person's experience. He or she recognises that the experience of a single individual is part of the larger human experience and it is not a separate event only happening to this person. Judging people in difficulty—or worse, condemning them—is one of the obstacles that prevents us from understanding their situation and thereby being able to feel their pain.

### Tolerating personal distress

Distress tolerance is the ability to bear or to hold difficult emotions. Hearing about or becoming aware of someone's difficulty may distress a compassionate person but does not overwhelm that person to the extent that it stops them from taking action. People who feel overwhelmed by another person's distress may simply turn away and may not be able to help or take the right action.

### Being empathetic

Feeling the emotional pain of the person who is suffering is another attribute of a compassionate person. Empathy involves understanding the sufferer's pain and feeling it as if it were one's own.

### Taking appropriate action

Feeling empathic towards someone encourages the observer to take action and to do something to help the sufferer. Customising actions depending on the sufferer's personal circumstances is also important. Taking the right action depends on the extent to which we have made efforts to know the sufferer.

### The business case for compassion in the workplace

Over the past few years of working on this topic, I have found substantial evidence to support the hypothesis that compassion in the work environment improves staff wellbeing and positively impacts the bottom line.

There is strong scientific evidence for the link between stress and illness. Selye (1950) was one of the pioneers in this field of study who found that stress compromises the body's immune system. Another study by McEven and Stellar (1993) shows that stress can compromise the immune system so severely that it raises blood pressure, weakens resistance to viral infections (think about this and working in a hospital), increases the risk of heart attacks and speeds up the spread of cancer.

In an interesting experiment (published in the Journal of Advancement in Medicine, 1995) researchers demonstrated

just how long the effects of stress can remain in the body. The experiment involved two groups of healthy volunteers, one of which was asked to spend five minutes thinking about an experience that made them angry; the other group were asked to think about an experience of care and compassion. Researchers then measured their IgA (a key immune system antibody which helps the body resist invading bacteria and viruses). For participants in the first group (the ones remembering a situation that made them angry or frustrated), IgA level increased briefly and then dropped substantially and stayed low for five hours. The IgA level of participants in the second group (the ones focused on caring and compassionate feelings) rose and stayed at a high level for six hours.

This study suggests that simply remembering an emotion can have a significant impact on our immune system. Now imagine experiencing those negative emotions on a daily basis and their impact on our bodies. Based on these studies, the link between compassionate workplaces and staff wellbeing is self-explanatory. A compassionate workplace in which people feel safe to share their problems and seek help will help to reduce the level of stress and consequently improve the overall level of staff wellbeing. In a recent survey conducted by Roffey Park, 83% of respondents (out of 500 respondents) said they have been managed by someone who in their view lacked compassion. I asked each of them how their manager's lack of compassion impacted on them and their colleagues. They said it increased their level of stress and anxiety, made them feel demotivated and disengaged, and made them leave the organisation. They also said it created a culture of distrust, fear, poor performance and dysfunctional teams.

Studies also show that compassion in the workplace can impact the bottom line. I have summarised some of those studies here:

 Those working in care-giving organisations that are compassionate are more likely to have the emotional resources needed for caring and are less likely to experience burnout (Figley 1995; Lilius et al. 2011)

- Compassion breeds compassion—those who experience it are more likely to demonstrate it towards others (Goetz et al. 2010)
- · Supervisors who perceive that their organisation values their wellbeing are more likely to show supportive behaviour towards the people they manage (Shanock and Eisenberger 2006)
- · Not only do people who receive compassion benefit from it, but the person demonstrating compassion also benefits, as do colleagues who witness compassionate acts. This leads to relationships which are stronger and more positive, and therefore more collaboration in the workplace. (Dunn et al. 2008). It also reduces employee turnover and increases organisational citizenship (Lilius et al. 2011; Fryer 2013)
- · Compassion can help to grow trust between individuals and creates psychological safety (Worline and Dutton 2017). This can create a willingness to discuss and learn from errors and failures, which can result in more innovation

### How do you create a compassionate organisation?

Creating a compassionate organisation is as much about focusing on individuals (both self and others) as it is about focusing on the organisation as a whole. To answer the question of how to create a compassionate organisation, I have brought together recommendations from previous studies and my own research. I have identified three steps to building a compassionate organisation:

### 1-Self-compassion

The first step is to be compassionate towards yourself. Self-compassion is about understanding your thoughts and feelings as they arise and avoiding pushing them away. It is about giving yourself time and space to recover from those feelings. Self-compassion is similar to compassion towards others; it is about understanding and acknowledging your feelings and being kind to yourself (non-judgmental). It is also about avoiding self-pity and being resilient so that you take appropriate action. Taking appropriate action could involve encouraging gentle change where needed and adjusting patterns of behaviour to avoid similar situations.

### "COMPASSION IS TAKING ACTION TO ALL EVIATE THE SUFFERER'S PAIN"

### 2-Compassion toward others

The next step is about being a compassionate colleague. Compassion is about understanding colleagues' pain and problems and taking action to lessen their suffering. Remember those five attributes I mentioned earlier in the article. You can also go to www.roffeypark.com/cwi and complete the Compassion at Work Index (CWI) questionnaire to find out your own level of compassion. The CWI provides a personalised report of how you see your own level of compassion at work across the five attributes as well as practical tips to improve or enhance your approach.

### 3-Fostering a culture of compassion

The third step is creating a culture of compassion in the organisation. In such a culture, people trust each other and feel it is acceptable to talk about their problems and seek help and support from their colleagues or the organisation.

As a leader you can foster a compassionate culture through:

- Role-modelling compassion by showing compassion towards colleagues and encouraging team members to do the same
- · Celebrating, recognising and rewarding compassionate actions
- Encouraging people to share their personal stories of compassion at work to increase empathy and share ideas on how to enhance your organisations' compassion capabilities.
- · Promoting healthy practices at work; for example, making time for individual one-to-ones
- Actively encouraging and empowering others to respond to a colleague's suffering
- Making sure that there is a strong connection between people in your team which makes them feel joined, seen, felt, known and not alone
- Creating a safe environment for your team members to share their personal problems, issues and challenges.

Activities at an organisational level that foster a compassionate culture include:

- Providing coaching support to leaders so that they model cultural values that support compassion
- · Embedding compassion into company values.
- · Raising awareness about compassion through compassion training and sharing stories of

- compassionate decisions, or lack of them, and their consequences
- Redesigning recruitment processes to emphasise compassion, high quality connection and empathy, and which fit cultural values of shared humanity at work
- Creating opportunities to bring people together regularly and enable personal connections to be made
- Designing policies and procedures to give people guidelines on what support mechanisms are available in the organisation. Any policies need to be flexible so they can be adapted depending on people's personal circumstances.

### **Concluding remarks:**

I recognise that creating compassionate workplaces is not an easy task and may require a complete cultural shift. However, I hope that the business case I have offered here will encourage you to take up this journey. The three steps I have suggested are a good starting point to introduce compassion in our workplaces and eventually build compassionate organisations.

### **KEY POINTS**



- Studies show that compassion, amongst other things. can improve staff health and wellbeing, improve retention. increase engagement, encourage innovation and ultimately improve productivity within organisations.
- The five attributes of a compassionate person in the workplace are: being alive to the suffering of others, being non-judgmental, tolerating personal resilience, being empathetic and taking appropriate action.
- Compassion can create a willingness to discuss and learn from errors and failures, helping to reduce defensiveness, achieve successful double-loop learning and improve problem solving.
- A good starting point to encourage more compassion in your workplace is to be compassionate towards yourself. Next is to be a compassionate colleague and last is to encourage a culture of compassion in the organisation.



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## Make this count

Your enthusiasm differentiates vou

Second chances are not an option. Trainer, Michael Virardi, on how commitment and preparation are of prime importance when faced with gamechanging career choices.



Michael R. Virardi Award-winning Keynote speaker and Trainer

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t's no secret to the people closest to me: I'm very ambitious. Ever since I can remember, as a young boy growing up in Cyprus and, later, working for our family business, I had a strong desire and determination to succeed: a desire to make sure that whatever I did. I did well.

This ambition was amplified by the fact that my late father, wanted to see me excel not just professionally but on a personal level too. With hindsight, I can now see that his advice always focused on how I could create added value, in particular for people at the forefront of business but also for broader society.

### The U.S. perspective

The United States is the homeland of so many great professionals and some of the most successful entrepreneurs this world has known. Business in the U.S. is no joke. Every word, every gesture, every smile matters - especially in New York. "The lights will inspire you" as the Big Apple song goes, but those very same lights can also overwhelm and distract you if you're not careful.

I was recently in New York following a training delivery invitation from the American P&I Club. As I strolled through Central Park, reflecting on how I would make the upcoming workshop I had just one thing on my mind: I need to make this count.

### Be more than prepared

I knew that it was time to raise my game if I was going to deliver a successful workshop on "How to gain a competitive advantage" to one of the world's leading shipping insurers. After all, how do you stand out in an industry where differentiation is so hard? The question was not a simple one for the company and while I didn't have all the answers. I knew that I could deliver insights and facilitate deep discussion to enable and empower those capable people to find the solutions they needed.

"I CROSS-CHECKED THE INFORMATION WITH OTHER SOURCES TO HAVE A CLEAR PICTURE IN MY MIND OF THE CHALLENGES I NEEDED TO DEAL WITH"

Make no mistake, I needed something more than 19 years of training and facilitation experience to make this intensive five-day endeavour a success.

I pulled together the pieces of the puzzle by traveling beforehand to Athens to meet with members of the American P&I management team in person. I interviewed people with much more experience of their business than I could ever have gathered in a short space of time and cross-checked the information with

other sources to have a clear picture in my mind of the challenges I needed to deal with. Ray Dalio, the founder of Bridgewater Associates, one of the world's largest hedge funds, calls the process "triangulating", I call it dedication and commitment to delivering value.

Wishing to leave nothing to chance, I went all out with more than 50 hours of intense preparation. I strived to enhance my business and life perspective through numerous phone calls to trusted friends and advisors while, at the same time, rehearsing my performance like a highly disciplined soldier. For days before the event, as well as during the event in New York City, I'd go to bed at night with the same thought in my head: "Make this count".

### Reaping rewards

A few hours after the workshop was over, the management team expressed their enormous satisfaction with the result of my efforts and not just in words but in actions: they asked me to go back once a quarter, starting next year, to help their team identify and address more business challenges. All the hard work had paid off. It usually does.

I left the U.S. feeling both exhausted and fulfilled. I also left as a much better professional and, I believe, a better person.

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## The patient, the whole patient and nothing but the patient

Clinical competence and limiting factors

In this short opinion piece, carer and consumer advisor Belinda MacLeod-Smith challenges us to consider crucial elements of whole patient care, and how they can be impacted by limiting factors.



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aring for someone with ongoing, occasionally acute, health needs means I have a high level ✓ of interest when it comes to hospital-based services and the concept of 'whole patient' care. My husband and I often reflect that as a survivor of heart failure, severe sepsis and total organ failure following heart transplant, it's technically a miracle he's still alive and thriving.

His survival is an absolute testament to the medical expertise available as part of Australia's system of universal healthcare. We're always careful to include the word 'medical', because there's a parallel. defining element of his experience in multiple wards, emergency departments and intensive care units in six hospitals across three states over nearly ten years.

That defining element is that he's often felt like, in his words, a 'meat-bag'. While this could be expected during the times he's been sedated and ventilated. his role as a passive recipient of care has sometimes been enforced even when he's been conscious, lucid and absolutely capable of participating in decisions, or at least conversations, about his care.

More often than not, our experience has been that we should expect and accept medical competence, and not much more. Of course there are sparkling

outlier moments, times of breathtaking humanity and consideration, but those moments are exceptions.

While I'm beyond grateful for the medical system that's saved his life multiple times. I believe we need to go forward with open eyes about the multiple system elements that have to change before we can achieve sustainable, agreed versions of whole patient care.

### A model for whole patient care

"A whole patient understanding is crucial. Quite simply, people don't perceive themselves as a collection of conditions. Health is personal, intertwined with people's individual perceptions and mindsets, with the environments in which they live and work and the people with whom they interact." (Dudgeon 2015)

I believe the most important thing to consider is whether we (healthcare workers, patients, families and carers) have a shared understanding of what's meant by whole patient care. An online search will throw up a multitude of terms (more than 2,400,000) in relation to 'whole patient care'. Holistic care, person-centred care, and patient-centred care are other terms I've heard. I see hospital vision and mission statements

by the dozen that reference 'putting the patient first' or 'the patient at the centre'.

In my background reading, I found one particular article really helpful. In her 'Understanding the whole patient' article, Kate Dudgeon suggests a fourlayered model for 'whole patient' care (Dudgeon 2015). Dudgeon's research with patients found the following four areas as key factors in a holistic model of care: medical, psychosocial, attitudes/beliefs and information/communication preferences.

Medical: Earlier, I used the phrase 'medical competence'. Of course medical condition or need is central to every patient. If my husband hadn't received competent clinical care for heart failure, nothing else would have mattered. What Dudgeon explains as important to note here is that if an individual has a number of health issues, they see their medical needs as whole and interconnected. My husband never saw himself split into the separate conditions of heart failure, kidney failure, or a toxic thyroid—he was all of these things together—it was the specialists and outpatient clinics that were separate.

Psychosocial: Along with our medical condition is our psychosocial state: our mental and emotional state, social systems, and functional capabilities. Does a person suffer from anxiety? Are they depressed? Do they have a functioning and positive social support network and environment? This layer is important to understand because it can either inhibit or enable a person's ability to actively take part in caring for themselves.

I've often found myself to be an informal advocate for patients and families I've met in waiting rooms, or who have contacted me through the transplant community. Like my family, they've had to travel from interstate or regional areas to receive medical care, and don't have their usual 'community' around them. This lack of a support network creates additional logistic and emotional stress that can have a massive impact on both care experience and care outcomes.

OUTPATIENT DEPARTMENT	PHYSIOTHERAPY
ONCOLOGY	LABOUR ROOM
ELDERLY CARE UNIT	INPATIENT DEPARTMENT
RENAL UNIT	NEUROLOGY
ACCIDENT & EMERGENCY	GYNAECOLOGY
CHILDREN'S WARD	UROLOGY
ANTE NATAL CARE	ORTHOPEDIC
RADIOTHERAPY	PHARMACY
PEDIATRIC	MORGUE
CARDIOLOGY	SURGERY
OPERATING ROOM	X-RAY
<b>←</b> A&E	<b>→ → →</b>

Attitudes and beliefs: Dudgeon's article suggests the next whole patient component addresses attitudes and beliefs, which she breaks into two parts. First are the beliefs or perceptions formed over time about your own health and care, often based on your own experiences or those of family and friends. The second part is the attitudinal category we fall into, which depends largely on how much involvement we have in our own health and care. My husband, prior to becoming acutely unwell, would have been categorised as a minimalist—someone who denies a health condition or does the bare minimum recommended by a healthcare provider. At the other end of the scale, I'm definitely a maximalist, someone who proactively seeks health information and is engaged in my own care planning. My husband is also a great example of how this category can change over time. This is probably best shown by his weekly ritual of prepping his thrice daily post-transplant medications, around 130 tablets every week, with 15 different scripts of varying strengths and quantities—he's got a lot of 'skin in the game' when it comes to medication adherence.

### "IF AN INDIVIDUAL HAS A NUMBER OF HEALTH ISSUES, THEY SEE THEIR MEDICAL NEEDS AS WHOLE AND INTERCONNECTED"

Information and communication: The last element of Dudgeon's model of whole patient care is information and communication preferences. Simply put, this relates to how someone learns, when they're open to learning, how they seek out information, and how they prefer to exchange information with a care team. Personally, I love a detailed brochure or pamphlet that I can take away, write notes on and absorb. My husband likes a short conversation, and would be happy in a world where everyone communicated using Twitter rules—280 characters or less.



### **Limiting factors**

When I think about the whole patient model described by Dudgeon, I'm reminded of a concept used in agricultural science—Liebig's Law of the Minimum. Liebig's law states that crop growth happens at the rate permitted by the most limiting factor. So growth isn't dictated by the total resources available, but by the scarcest resource (limiting factor).

This concept was originally applied to plant or crop growth, where it was found that increasing plentiful nutrients didn't increase plant growth. The growth of a plant or crop can only be improved by increasing the amount of the limiting nutrient (the one most scarce in relation to need). I believe this 'a chain is only as strong as its weakest link' concept is the perfect metaphor for whole patient care.

Yes, a patient can survive with the essential nutrient of medical care, but whole patient care, the kind of care where a patient thrives, can only happen if we're conscious of all the 'nutrients' needed for wellbeing.

So what's it going to take to get us there? As I think about what kind of actions 'shake things up' and act as positive disruptors in the pursuit of whole patient care, I think we could use the agricultural metaphor to consider and discover the limiting factors within a hospital system.

### "THE KIND OF CARE WHERE A PATIENT THRIVES CAN ONLY HAPPEN IF WE'RE CONSCIOUS OF ALL THE 'NUTRIENTS' NFFDFD FOR WELLBFING"

In caring for my husband and another close family member, I've seen a smattering of well-intentioned approaches that theoretically enable better whole patient care. Most recently, I experienced bedside communication whiteboards. I was so excited when I first saw them, and thought how they could be a truly powerful platform to focus attention on all the elements of whole-patient care.

Here's the thing. During a recent admission, I saw that many bedside communication boards on the ward were blank,

or had the wrong date and no pens to write with, or erasers to clean them.

As a whole patient care initiative, those boards were a complete mirage of hope. When I asked about pens, I was told there was budget to buy the boards and get them up, but not for pens. When I asked about unanswered questions and incorrect days/dates (horrid for someone experiencing delirium) I was told that staff didn't have time, that they didn't have capacity to update boards or even have conversations about them.

So what are the limiting factors at play here? If we accept the notion that whole patient care involves paying simultaneous attention to all the things that contribute to a person's wellbeing, we need to consider paying the same kind of attention to hospital systems. In the case of the whiteboards, I can only guess more attention needs to be given to culture, governance and possibly funding - some pretty critical limiting factors.

Let's get excited about the patient, the whole patient and nothing but the patient. But please, before we start rolling out well-intentioned initiatives let's make sure there's a clear understanding of any limiting factors that could result in us sitting around, staring at empty whiteboards.

### **KEY POINTS**



- The condition-specific focus of health services is at odds with the intrinsic, holistic nature of humans who do not see themselves as a collection of conditions
- We can consider four spheres of need: medical, psychosocial, attitudes/belief and information/communication
- Like healthy growth in plants, achieving optimum whole patient care is dictated by the scarcest resource or limiting factor



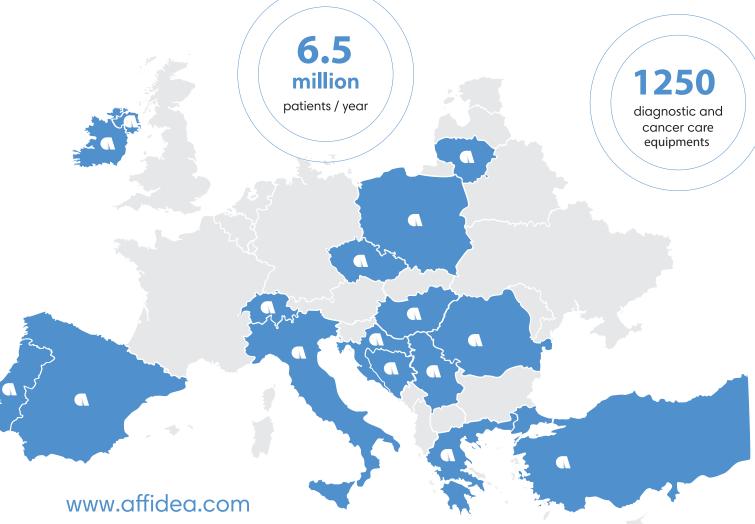
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# The whole patient? The whole person

I am myself and my circumstances (Ortega y Gasset)

Patients are people when they leave the doctor's office. They live a life, have jobs and families. Taking a whole person approach is the only way forward to face today's and tomorrow's healthcare challenges.



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hy is talking about the whole person relevant today in healthcare? Let's start by highlighting some key facts:

- It is estimated that four non-communicable diseases, namely cardiovascular diseases and stroke, cancer, diabetes and chronic respiratory diseases will account for 75% of all deaths worldwide by 2030. The number of people diagnosed with more than one chronic condition is only increasing
- Chronic diseases also cause disability, often for decades of a person's life. In fact, as much as half of the burden of disease is caused by chronic conditions
- · The direct costs of healthcare resources and non-medical goods and services consumed in the treatment of chronic diseases are enormous but also are the indirect costs associated with the disabilities and loss of quality of life associated with them
- The most important modifiable risk factors behind the top four chronic conditions are: unhealthy diet and excessive energy intake, physical inactivity and tobacco use

These are facts. Let's now take a look at what happens in real-life examples, to real people.

Too often people start a diet and quit before achieving the expected results or sustainable results. The success rate of any given diet is partly determined by the number of diets a person has unsuccessfully tried in his/her lifetime. So, how do we increase health resilience and reduce the number of "failures"? What a person diagnosed with diabetes eats today, and how this affects his/her blood glucose levels, will have an impact on the diabetes-related complications years down the line. How do we keep this person motivated to manage their health today for a better health today and in the future? Too many people miss taking their medication, miss the screening test, miss the medical appointment for early disease detection and prevention. Compliance with treatment protocols is one of the unsolved problems of chronic care. Factors such as health literacy, and the knowledge and the perception people have about their treatment and its expected outcomes determine their compliance. How do we motivate a patient to follow a treatment protocol and commit to his/her own role in it? We have all heard stories of heavy smokers that light up a cigarette as soon as they get out of the surgical theatre. We can also tell the stories of "real fighters", people that get up and fight time after time, surgery after surgery, against disease progression or metastasis, but we also know of others that "give up". What is behind some

people quitting and some others fighting? Also, some people are faced with the difficult financial decision of having to choose between having medical treatment and having a baby.

The answer to all these questions is the same: considering the person as a whole. Having a whole person approach means accounting for - or at least recognising - previous experience, expectations, education, beliefs, stress, personality, support networks, social impact and financial circumstances. All of these are inherent to the patient, are inherent to the person.

We still talk about disease management, as if each disease a person is diagnosed with characterises that person, as if each disease acts in isolation in the body and mind of the person, as if each disease doesn't impact anything else in the life of a person.

Most of today's chronic diseases have common modifiable risk factors which include unhealthy diet, lack of physical activity or tobacco use, and therefore, interventions should account for these lifestyle changes, both when it comes to prevention, but also when it comes to treatment. A whole person approach is a must when aiming at achieving long term sustainability of health-related behavioral changes.

Patients are human beings with habits, and habits are hard to change. Especially when the required changes are deeply rooted in any person's life. It is not that easy to wake up one day and start exercising, eating fruits and vegetables and quit smoking, after years of a very different lifestyle. These changes affect every aspect of our lives, from the way we shop to the way we socialise. Isn't it easier to follow a diet when you eat at home every single meal? How does this affect your social life? Would you know what dishes to choose in a restaurant to still achieve your dietary target? How do we support people in their numerous daily decisions for their health? How do we support these changes through time? The only possible answer is by taking a whole-person approach.

#### "HOW DO WE KEEP A PERSON MOTIVATED TO MANAGE THEIR HEALTH TODAY FOR A BETTER HEALTH TODAY AND IN THE FUTURE?"

It is often said that "cancer is a family disease", that is, it does not only affect the person diagnosed with it, but his/ her whole family. Chronic conditions in general, affect whole families. Covering the health expenses of one family member may have as a consequence of another family member dropping out from school to start working or quitting a job to take care of a relative. At the other end of the spectrum, patients supported by significant others and family members are less likely to be affected by stress and depression to the consequences of their health conditions. This is especially relevant as we gain a more and more active role in our own care and as self-management of our health is needed to cope with the increasing number of people affected by chronic conditions, and an increasing demand for on-going support. Patients seldom live in isolation and a wholepatient approach should account for this. An illustration of the importance of a whole family approach when supporting patients with one or multiple chronic conditions is the fact that this year's WHO movement for Global Diabetes Day is focused on the family. A whole-person approach means a whole-family approach. I would like to make a special note about WHO, because its constitution, back in 1948, already defined health as "a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity".

Financial situation often drives health decisions. I dream of the day that cost of the treatment does not drive all health decisions, that one can both have a baby and afford a treatment, that family members can afford continuing education while treatment is ongoing. Healthcare cost trends are not going down. New technologies take time to show long-term financial impact, and decisions are too often taken on a short-term outcomes basis. Cost is often a barrier to health innovation and misalignment of financial incentives also makes it difficult to embrace new business models. Person-centricity also calls for value-based healthcare, for patient-related-outcomes, for processes that are adapted to the needs of this growing segment of the population.

Considering patients as a whole is the only way forward to face today's and tomorrow's health challenges. The whole person, not just the patient. The person is his/her physical, mental and social wellbeing. The person has a social life, a job, a family. The patient is a person in and out of the doctor's office.

#### **KEY POINTS**



- Demographic and epidemiological trends require new models in healthcare
- Lifestyle changes are needed to prevent chronic diseases and minimise their consequences
- Each of us has an increasingly active role in managing our own health and ongoing support is needed to sustain our commitment to stay as healthy as possible
- Psychological factors such as motivation, anxiety, or social support are key to understanding and managing chronic conditions
- Patients are people with families, jobs, social lives and what works on paper may not work when accounting for their realities

# Can we evaluate and treat the patient as a whole?

What is the potential for a more rounded healthcare approach?

If we want to implement the WHO definition of health, we need to build people-centred care and service systems that we will evaluate the patient as a whole.



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n 1948, the World Health Organization defined the concept of health as follows: "A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO 2018). This definition suggests we evaluate the patient from a very broad perspective. However even today, it is still difficult to say we do so especially for the follow-up of chronic and complex illnesses.

Since people may not have a complete perception of their own health condition due to health literacy, as the healthcare sector and professionals, we have to think of the patient as a whole in order to provide him/ her with an integrated quality healthcare. According to my observations, doctors adopt the same approach to all diseases in the direction of their own medical knowledge and experience. This approach may not meet the patient's individual needs and values. I even know doctors who don't take enough time to listen to the patient and don't look at his/her face. This is a kind of operational blindness.

#### Isn't it still a valid definition after 70 years?

From those years until today, could we evaluate and treat the patient as a whole?

Dr. Samuel Silver (2008) writes these words about a cancer patient in his report 'Cancer care for the whole patient - a new Institute of Medicine report:

"In the rush of busy clinics, during our previous visits, I really had not paid attention to my patient's affect. If I did think about it, I would probably have passed it off to a minor, totally understandable "reactive" depression. I was not "Meeting the Psychosocial Health Needs" (the subtitle of the report) of my patient."

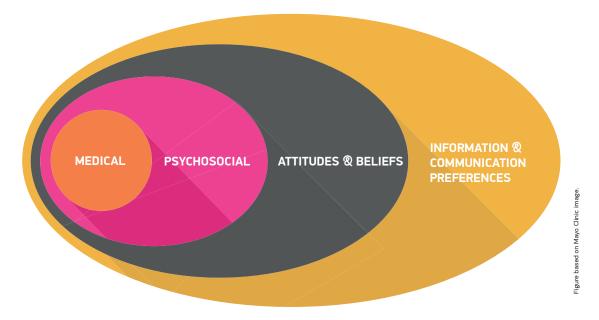
According to a recent survey by Quest Diagnostics, 95% of primary care physicians (PCPs) say they became a doctor to treat the "whole patient." Yet, 66% of PCPs say they don't have enough time and/or bandwidth to worry about non-physical, social issues of their older patients with multiple conditions. The survey also demonstrates two out of five patients (44%) want to tell their doctor about their medical conditions, but not about non-medical issues they face such as loneliness, financial, and difficulties of transportation. Many of them are afraid of falling in or outside the home and of developing other conditions, but they do not share these concerns with others for fear of being a "burden" (Dlott 2018).

Integrative medicine seeks to embrace a more comprehensive view of healing and to see and care for individuals in their completeness. More and more research demonstrates that integrative care results in improved health outcomes. Contrary to expectations, today's medical specialisations seem to focus on individual organs rather than systems.

In addition, unless the patient is aware of his/her chronic condition and gets support to deal with it, it's impossible to assess his/her health status holistically. For example, a cardiac patient with a sedentary life, inappropriate nutrition regimen, lack of health literacy and an unhappy professional life, cannot be fully evaluated. It is obvious that the healthcare model will continue to be reactive, rather than proactive, if health system isn't designed to holistically understand and support patients.

#### "TODAY, IT IS STILL DIFFICULT TO SAY WE LOOK AT THE WHOLE PATIENT FOR THE FOLLOW-UP OF CHRONIC AND COMPLEX ILLNESSES"

A person who enters the healthcare system at any stage because of health needs do not easily achieve optimal benefits when the data received by health services from various departments hasn't been integrated and evaluated by certain individuals. In this context, a holistic view of patients is significant. Basically, people do not have a perception of their own health conditions. Health is personal so that each patient should be evaluated with the environment they live in and work as well as the people who they interact with. In other words, we need to evaluate



**Figure 1:** Graphic from Patient Type Research, completed by Meredith Dezutter, Mathew Jordan, and Kate Dudgeon on behalf of Mayo Clinic's Center for Innovation.

people within their own habitat as an individual and build health systems that will ensure that we get the right data to help us evaluating the patients holistically. Otherwise, there will be a communication gap between patient and healthcare provider, which will lead to poor clinical outcomes and negative patient experience.

The providers should meet patients where they are functionally, emotionally, and socially in order to establish a quality health services centred on a patient. Additionally, in order to understand the perception of health of the

patient, providers should consider mental state, family life, and beliefs of patient.

Having created a holistic patient evaluation system, lora Health Center writes on its website:

"We are restoring humanity to healthcare. We believe in primary care that puts people first. Because when we can connect on an individual level, we can impact the entire healthcare landscape" (Dudgeon 2015).

According to Mayo Clinic's Center for Innovation, holistic understanding of a patient comprises many layers (**Figure 1**).

At the core of every patient is "Medical" condition. According to this model, an individual who has a number of health issues perceives his/her medical needs as an interconnected whole. No matter whether it is a minor or major, medical or health-related need is what defines the care request and clinical interaction (Dudgeon 2015). The patient may have several healthcare problems and be aware of them, but the specialised clinician probably focuses on a single condition. Consequently, the condition cannot be evaluated as whole.

The second is "Psychosocial" layer denoting a patient's mental and emotional state, social system, and functional capabilities, deeply affected by beliefs or perceptions he/she has formed over time regarding one's health and care. This layer is crucial to understand because it can inhibit or enable a person's ability to actively take part in caring for himself/herself. For example, many people find themselves in a deep depression upon a diagnosis, after having realising that their once-normal state no longer exists.

Another component of the whole patient is one's "Attitudes and Beliefs", which break into two parts. Beliefs often depend on the individual's own experiences or those of his/her family and friends. People often share with others an overly positive or negative experience of receiving care. Second attitudinal category depends largely on how much involved the individual is in his or her own health and care (Dudgeon 2015).

According to this model, the last layer that makes up a whole patient is "Information and Communication" preferences: how someone learns, when someone is open to learning, how someone seeks out information, and how someone prefers to exchange information with a care team. Nowadays, I see and know that most patients communicate with the physicians via email, Whatsapp or any other digital

way. They send messages to their doctor about their health problem rather than initially scheduling an appointment.

#### "HEALTH IS PERSONAL SO THAT EACH PATIENT SHOULD BE EVALUATED WITH THE ENVIRONMENT THEY LIVE IN AND WORK AS WELL AS THE PEOPLE WHO THEY INTERACT WITH"

Another study, the Institute of Medicine's report Cancer care for the whole patient: meeting psychosocial health needs makes a series of recommendations to improve cancer care. This article focuses on the recommendations for the oncologists. The report suggests that failure to address psychosocial issues "compromises the effectiveness of health care and thereby adversely affect the health of cancer patients." The IOM therefore proposes a new standard of care for integrating psychosocial care into routine care to overcome these barriers and improve care for the whole patient.

We all know the saying, "Treat the patient, not just the disease." Every disease can have a different course in every person. Diagnosis and treatment approaches may differ according to patient as individually. So, we have to build people-centred care and service systems that we will evaluate the patient as a whole. Models such as this one can be used as a tool to start. It is obvious that the physicians have the critical role within this system. And we know that the physicians want the best healthcare outcomes for their patients. So, what are we waiting for?

#### KFY POINTS



- Does healthcare look at the patient's state of complete physical, mental and social wellbeing?
- Research shows that integrative care results in improved health outcomes
- Each patient should be evaluated on an individual, personal
- Physicians have the key role within this system



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# Person and family engagement

The key to caring for the whole patient

Person and family engagement (PFE) has been called the blockbuster drug of the 21st century. How can hospitals implement engagement so that patients and families are partners in patient safety?

hat if I told you there is a new medicine that could accelerate medical error prevention, improve outcomes, reduce readmissions and increase your patient satisfaction scores? Would you be interested?

Now, what if I told you that this new medicine was also low-cost and tied to incredible success rates? Without a doubt, most hospitals—and most of your patients—would be interested.

That low-cost, low-tech method to reduce medical errors is called person & family engagement (PFE), something Health Affairs editor Susan Dentzer calls the "blockbuster drug of the 21st Century" (Dentzer 2013). PFE has been recommended by the World Health Organization (WHO) as integral to its patient safety programme since 2005 (WHO 2006). The Centers for Medicare and Medicaid Services (CMS) have embraced PFE as a transformation strategy and are now tracking implementation in every U.S. hospital (Figure 1).

Person and family engagement at its core is activating patients and their **families** as true partners in the planning, delivery and evaluation of patient care (Glover 2017). While it sounds simple, it's a paradigm shift. PFE goes beyond informed consent in legal boilerplate language that few understand to real shared decision-making between patients and their providers. It is about open and honest communication and support for patient management in ways that involve family and

community as part of the solution. It is about building a care relationship that is based on trust and inclusion of individual values and beliefs (Centers for Medicare & Medicaid Services 2017). It is also about healthcare providers continuously learning from the experiences of their patients.

#### Need for person and family engagement

Although patient safety has been seen as a healthcare priority for decades, an estimated 4.8 million people across the globe and over 200,000 people in the United States die in hospitals every year from preventable and avoidable causes (Makary and Daniel 2016). That makes medical errors the third leading cause of death in the United States and the fourteenth worldwide. Medical errors claim the lives of more people than HIV, tuberculosis and malaria, combined. For the first time 2018 research shows that more people die from poor quality healthcare worldwide than from lack of access to healthcare (Kruk et al. 2018). Everyone needs to engage to address this global crisis.

Death is not the only measure. Patient harm and the cost of care are both alarming. One in twenty outpatients experiences a diagnostic error, and an estimated 160 million medication errors occur each year in primary care each year (Singh et al. 2017). One in nine emergency room admissions is tied to medication error (AHRQ 2018).

The statistics don't end there. The U.S. Agency for Healthcare Research and Quality (AHRQ) estimates that up to 80 percent of information shared in a primary care visit is immediately forgotten by patients (Kessels 2003). A recent study found that only 12 percent of U.S. adults had proficient health literacy, the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (U.S. Department of Health and Human Services 2007). And over a third of U.S. adults, about 77 million people, have difficulty with common health tasks, such as following directions on a prescription drug label (U.S. Department of Health and Human Services 2008). Given the complexity of the healthcare system, it is not surprising that limited health literacy is associated with poor health (U.S. Department of Health and Human Services 2007). PFE involves providers partnering with families and communities to support patients and populations who face these challenges.

#### Evidence to support person and family engagement

The evidence is accumulating fast. A study posted in the North Carolina Medical Journal found that patients who are actively involved in their health and healthcare tend to have better outcomes and care experiences and, in some cases, lower costs. Implementing patient



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and family engagement strategies led to fewer healthcareassociated infections, reduced medical errors, reduced serious safety events and increased patient satisfaction scores (North Carolina Medical Journal 2015).

Another study, published in JAMA Internal Medicine, found that when patients and healthcare providers were primed for a conversation about a patient's treatment plan, the chance that a goals-of-care conversation occurred was higher (Curtis et al. 2018). The study followed 132 physicians and 537 patients between 2012 and 2016. During this time, patients specifically primed for a conversation with their healthcare provider reported a significant increase in patient-reported goals-of-care conversations during routine outpatient clinic visits. Seventy-four percent of the intervention group reported having the goals-of-care conversation compared to only 31 percent of the usual care group.

The study noted that physicians caring for patients with a serious illness experienced more effective treatment, better quality of life, and reduced intensity of care at the end of life when fostering improved patient engagement (Curtis et al. 2018). Despite this information, physicians frequently do not have conversations with their patients about their prognosis and goals of care.

#### How do you implement person & family engagement?

Person and family engagement can be implemented in different ways. According to the CMS Quality Strategy (Centers for Medicare & Medicare Services 2016), a PFE programme includes four goals:

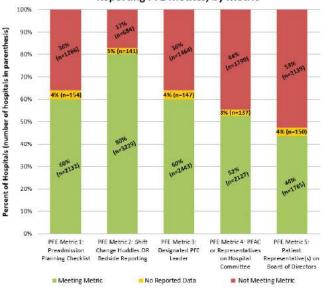
1. Actively encourage person and family engagement along the continuum of care within the broader context of health and wellbeing and in the communities in which they live. This will exceed the traditional boundaries of

- setting-specific care and will identify opportunities to bridge and forge partnerships among providers, persons and community resources.
- 2. Promote tools and strategies that reflect person and/ or family values and preferences and enable them to actively engage in directing and self-managing their care.
- 3. Create an environment where persons and their families work in partnership with their healthcare providers to develop their health and wellness goals informed by sound evidence and aligned with their values and preferences.
- 4. Improve experience and outcomes of care for persons, caregivers, and families by developing criteria for identifying person and family engagement best practices and techniques in the field from CMS programmes, measurements, models and initiatives, that are most ready for widespread scaling and integration across the country.

Under CMS' strategy, they drive five main items which formed the basis for the actionable patient safety solutions (APSS patientsafetymovement.org/actionablesolutions/actionable-patient-safety-solutions-apss) on person and family engagement. The five pillars include:

- Implementation of a discharge checklist—this ensures that all patients are getting the same level of care systemwide regardless of how busy a unit may be. Included in this checklist is information including where are you going, do you have a caregiver at home, do you have a way to get your medication, etc.
- Bedside huddles or shift changes at the bedside—where you engage the patient rather than talking about or over them.

#### Percent of Hospitals Meeting, Not Meeting, or Not Reporting PFE Metrics, by Metric



502 hospitals have no scheduled admissions (exempt) and are thus excluded from the PFE 1 denominator

Figure 1. U.S. hospitals reporting patient and family engagement metrics Source: HIINgagement Monthly Apr 2018 fha.org/files/PFE/April2018HIINgagementMonthly.pdf

- · Staff—Are there people in your organisation who coordinate PFE?
- Start a Patient Family Advisory Council— this brings in the wisdom of the patient who has experienced hospital care into improvement work.
- · Do you have someone who identifies primarily as a patient or family caregiver on your Board of Directors?

#### Implementation of CMS' strategies have proven to yield positive results.

At Parrish Medical Center (Titusville, Florida), they've utilised the Patient Safety Movement's PFE APSS and CMS' person and family engagement strategies to improve handoff communications (HOC). The hospital used the checklists in the Patient Safety Movement APSS and built a process around it. The goal of the new handoff process was twofold:

- · Zero harm in transitions from the medical-surgical unit to the emergency department
- Implement person to person handover, including the person in the bed.

The hospital also used their electronic medical record as a means to help capture transitions in care and instructions.

"We had experienced a number of patient harm events related to HOC and wanted to find a measurable way to improve. In designing this new process, we created a checklist, utilised the electronic medical record and decided that we wanted all transitions in care to be person to person. We felt it was important to include the person at the centre of this care, namely the patient, as well as the nurses," explains Parrish Medical Center's Chief Nursing Officer Edwin Loftin.

The process was implemented 6 May 2018, and in just four weeks demonstrated remarkable results

Before the change, Parrish Medical Center recorded 48 events of patient harm in 1.5 years, whether that was medication error, delay in care, etc. Since the implementation of the new handoff process, the hospital has had zero harm events in 600 transitions.

The new handoff process has had additional benefits. including a 35% decrease in time of transition, whether that is transitioning a room or implementing care as well as increased patient satisfaction.

The hospital plans to release final results of their implementation in 2018. But what about your hospital? It is time to engage patients and families as partners to improve patient safety.

#### **KEY POINTS**



- Patient and family engagement enables partnership in planning, delivery and evaluation of patient care
- PFE is low-cost and low-tech and has the potential to reduce medical errors and improve patient safety
- Parrish Medical Center has implemented a new handoff process, with positive results



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# Hyperthermia. An amplifier for radiation therapy

Hyperthermia can further enhance the therapeutic outcomes of radiation and chemotherapy, while keeping side effects at a minimum. A treatment method with many advantages



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#### What is hyperthermia?

Hyperthermia is the intentional overheating for therapeutic purposes, either throughout the body or in individual organs. The method of directly and precisely targeting individual body regions with hyperthermia systems is referred to as regional hyperthermia. The interventional aim of hyperthermia is to increase the temperature in the deep-seated areas of the relevant body region to be treated.

Celsius 42 has particular expertise in the development of regional deep hyperthermia systems. Two noninvasvie electrodes heat up a tumour region to over 40°C in order to boost and intensify the efficacy of chemotherapy or radiation.

#### When is hyperthermia primarily used?

The technology is currently used in oncology because cancer cells are more heat-sensitive than healthy cells. Hyperthermia can increase the efficacy of radiation and chemotherapy with low side effects.

The applied heat promotes the oxygenation and blood circulation in the therapeutic area. This effect makes cancer cells more sensitive to radiation. The more oxygen accumulates, the greater the efficacy of radiation in destroying or minimising cancer cells. Hyperthermia therapy enables the surrounding healthy tissue to regenerate faster. It many cases, that offers the option to individually vary a patient's radiation doses without additional side effects.

Hyperthermia also promotes the uptake of cytostatic drugs and their metabolism in the cell in chemotherapies. These effects for radiation and chemotherapy have been clinically proven in numerous studies. Moreover, hyperthermia boosts and activates the immune system, modelled after fever as a natural defence mechanism of the human body. In this way, the body and hyperthermia join forces in the fight against the disease.

#### Is hyperthermia an equal partner in the arsenal of medical treatment options?

We are well on our way. Over the past 20 years, global studies have shown that combined therapies that include hyperthermia guarantee significantly better outcomes in terms of tumour control and survival rates. However, the excellent documentation of hyperthermia's benefits is not yet reflected in day-to-day medical practice. Doctors don't yet consider hyperthermia as a natural therapy complement.

#### How can this reluctance be explained?

Paradoxical as it may sound, it may be associated with the truly simple and comprehensible plausibility of hyperthermia. When it comes to



Innovative technology. Maximum therapeutic success

cancer treatment, we are used to thinking in complex procedures with multiple side effects. In contrast, hyperthermia is natural, low in side effects, and effective. We have to relearn this combination when it comes to life-threatening illnesses such as cancer. Gentle approaches can indeed produce maximum success.

Physicians are increasingly reporting positive experiences with hyperthermia. Meanwhile, patients are stepping up the pressure by requesting concomitant hyperthermia treatment. All of this results in greater lobbying for hyperthermia—a lobby for healing and success.

#### What are the risks associated with hyperthermia?

Hyperthermia scores exceedingly high in risk-benefit analysis. The principle is based on the body's own intelligent processes and is so gentle that there are hardly any side effects.

#### "GENTLE AND EFFECTIVE. HYPERTHERMIA AS AN AMPLIFIER FOR CHEMOTHERAPY AND RADIATION"

Risks are present when hyperthermia is not applied properly. That makes training, experience reports and publicity especially important. Hyperthermia should not be used too soon after surgery and the treatment areas must be kept free of sweat to avoid burn injuries.

Limitations also exist in certain body areas such as the abdomen, where temperature is difficult to measure, or in morbidly obese patients.

#### Are there other application areas of hyperthermia in addition to oncology?

Chronic inflammation processes are an application area where hyperthermia offers promising solutions. Such processes weaken the immune system and can trigger carcinogenic processes over the course of decades. We also have first positive studies on the treatment of fatigue and acute depression as well as neuropathic pain.

#### Which developments do you expect?

In my mind, this is primarily a question of structured and publicised effectiveness control. The more study outcomes and research results demonstrate how valuable and



effective hyperthermia can be in the fight against cancer, chronic inflammation and depression, the broader its reach will become.

One decisive impulse would be the recognition of hyperthermia by all health insurance providers. The first positive steps in this regard have already been reported in countries such as Switzerland.

#### What are the future prospects for hyperthermia?

Hyperthermia must become accessible to all patients with the corresponding diagnoses. That means acceptance by hospitals and health insurance providers. Broader use will generate funds, which in turn will benefit hyperthermia research and the associated technological innovation.

Physicians and patients should be able to benefit from this gentle and effective technology. A technology that has

been proven in studies to increase the efficacy of radiation therapy by a factor of 1.2 to 5, as in radio-modification.

I am certain that hyperthermia will prove itself in clinical practice over the coming years and will become an established method – as a strong partner in the fight against cancer.



Further information: celsius42.de



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# Measuring patient engagement

Why and how we need to assess patient centricity

Focusing on the issues and opportunities in quantifying patient engagement in pharma

economy'. For close to a decade pharma has worked relentlessly – sometimes seeming to run in circles - chasing the 'perfect' infrastructure to implement a company shift to a patient-centric focus. Now, whether the system is 'C-level', grassroots or truly embedded in a multistakeholder model across an organisation, the gap between wanting and doing is closed and, like it or loathe it, every pharma and biotech company is now firmly committed to at least some sort of patient-centred initiative. As such, we are now able to demonstrate what 'good engagement' looks like - to deliver return on investment (ROI) data that substantiate and ratify that patient centricity delivers better services for patients and a more sustainable business promise for industry. We can benchmark, assess and audit the success or redundancy of the patient-centred initiatives we choose to undertake.

Having disentangled ourselves from ethical ruminations - 'should we?' 'could we?' - the momentum now underpins an attitude of 'can we?' and if so, when? The sweet spot of better outcomes for patients and more business success for pharma lies in the implementation of systematic inclusion of the patient voice at the translational level; garnering insights from patients about living with a condition as early as possible and anchored within the Medical Affairs department but permeated across the entire

t is an exciting time to be a member of the 'patient' product lifecycle. The huge challenge is bringing together expertise and knowledge within companies that are usually multi-therapeutic, made up of thousands of employees, multiple geographies and differing cultural expectations; a model not wildly dissimilar from many given patient populations. Pharma companies have built resources, strategies, approaches and even pipelines more in tune with what patients are looking for. The next step therefore is to measure, share and innovate - to keep up the momentum that took so long to build.

> "HAVING DISENTANGLED OURSELVES FROM ETHICAL PHARMA RUMINATIONS - 'SHOULD WE?' 'COULD WE?' - THE MOMENTUM NOW UNDERPINS AN ATTITUDE OF 'CAN WE?' "

#### Pharma still has some way to go

There will always be a disconnect between what patients need and what pharma is able to deliver within the highly-regulated world of drug development, where products are investigational but patients are desperate for answers, solutions and even 'cures'. Perhaps we should accept and embrace the differences as arguably they drive

collaboration and innovation. Recently published results from Ipsos/The Aurora Project show that whilst 72% of biopharmaceutical and medical device company employees agreed with the statement, 'My company communicates with care and compassion, transparent and unbiased information on diseases. treatment options, and available resources', only 32% of the patients surveyed agreed – even when considering the company that they interact with the most (Ipsos & The Aurora Project 2018). There is also divergence in expectations between doctors and patients - again this might be 'normal' as each party enters a dialogue with a different need. Patients seek efficacy first, but pharma and doctors are risk averse and seek safety as a priority. Here, therefore, is the opportunity to provide patient services that have a therapeutic affordance in their own way. It is universally accepted that people come to pharma for holistic solutions applicable to their entire lives and the very nature of the R&D and clinical trial process turns them into patients. Furthermore, language or poor health literacy continues to be a barrier that healthcare professionals must hurdle to reach a more impactful relationship with (NHS 2018). In essence, a patient wants to be seen as a person, not as a number; accordingly the increasing popularity of physician, pharma and even patient rating sites, co-collaboration platforms and research hubs continue to develop apace.



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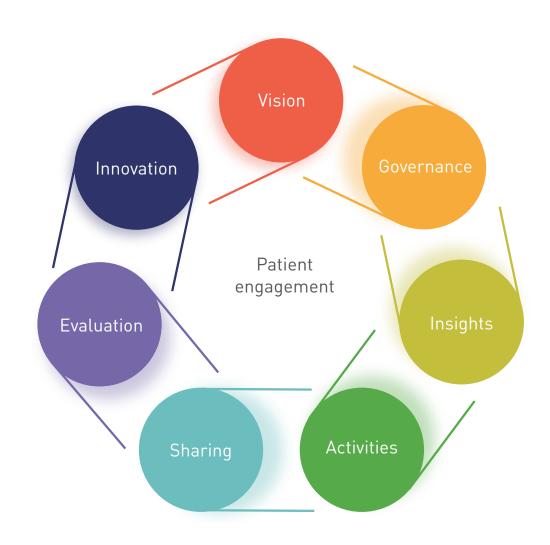
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#### Challenges in implementing and measuring the success of patient engagement strategies

There is a risk of being overwhelmed by an urgency for any patient initiative ahead of one that delivers a quantifiable benefit. Quantifying patient engagement is difficult for a number of reasons. There is a lack of shared guidelines and instruments, meaning that even identifying a baseline is near impossible. Evaluating the direct impact of engagement initiatives on patient outcomes requires time and therefore a long-term rather than short-term focus. For this reason, we primarily see patient engagement strategies run by commercial marketing sectors, and research and development (R&D) departments are often forgotten about to focus on basic science. However, it is imperative that the patient voice is heard from the very beginning of drug development, not just when it is time to market the finished product.

#### "BY PROVIDING MORE PATIENT-CENTRED CARE, WE CAN DRIVE BETTER HEALTH AND OUTCOMES AND EMPOWER PATIENTS TO BE ACTIVE IN THEIR OWN CARE"

It is also tricky to distinguish between those who hold responsibility for patient engagement and those who are accountable; setting up patient affairs departments or appointing chief patient officers may seem like a good idea, but there is an argument that doing so reduces the personal responsibility that other employees feel in being patient-centric.



#### Approaches for quantifying patient engagement

At NexGen Healthcare Communications we have developed a patient engagement audit called

'HaloGEN' that is based on our collective experience as pharma executives working with more than 100 organisations - pharma, patient advocacy groups (PAGs), non-governmental organisations (NGOs), academia and individual patient opinion leaders (POLs) that seeks to be both broad and deep in reach and impact. By taking the temperature of patient engagement across all departments to seek to consolidate 'islands of excellence', we are able to provide a given company with both a measure of work done, and a blueprint of priorities that will deliver greater return on engagement (ROE). HaloGEN comprises seven interlinking domains that are proven essentials to build a competent attitudinal and practical shift for demonstrable patient centricity. Those sections deliberately vary in depth of dissection according to the 'feel' and specific obstacles an organisation might be facing but always include the core elements: Vision, Governance, Insights, Activities, Sharing, Evaluation and Innovation.

Vision is the opening 'scene' of the audit as it sets a clear precedent both for the individual participating in the interview and a macro message that HaloGEN is intended to deliver a 'what next' set of results - to keep pharma execs rolling their sleeves up - not putting their feet up. Importantly, this also liberates participants from the expectation that they must know every aspect of patient advocacy and lobbying, which is and should remain a specialist function within a company - the HaloGEN audit is a business assessment and improvement tool. Once the Vision is set, the remaining sections are a natural segue and when an employee enters the HaloGEN dialogue, they rapidly release all that is known and desired as they work through the sections.

As experienced practitioners who have run hundreds of individual interviews, we have yet to experience a diminishing of interest as the interview progresses; more often than not, we vastly overrun the allocated time. There is impressive commitment across all departments to contribute to this and to get it right. Governance follows as how much a company can do often relies on their internal processes and the resources dedicated to it. Insights are needed for a company to understand their patients, their needs and opinions, before organising activities to involve patients directly in their business. Once the organisation has gathered knowledge and expertise, it needs to share these both internally and externally, and then evaluate the impact and success on its business, particularly as it relates to patients. Finally, the company needs to continually innovate to stay ahead and enhance patient products and services.

Companies that excel in all domains are poised for success in an environment where patients are becoming more knowledgeable and demanding more of a say in their own treatment. By providing more patient-centred care, we can drive better health and outcomes and empower patients to be active in their own care, ultimately feeding back into a more motivated and efficient workforce and an improved financial picture.

#### **KEY POINTS**



- Patient engagement is a buzzword that is thrown around a lot, but less frequently acted on with truly positive effects
- There are many challenges, both in implementing and in measuring the impact of patient engagement strategies
- Surveying the right people can reveal the success of patient engagement strategies across several key domains



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# Seven steps to the 'Perfect Patient Information Journey'

#### Leadership comes first

High-quality patient information is crucial to the success of personalised care. Leadership from the management team is critical in embedding patient information throughout patient pathways.

hy should healthcare managers make patient information a priority when there are so many other pressing items on the agenda? The answer is simple. Without access to high-quality, accessible health information the move to personalised care will fail. High-quality healthcare information, which is developed with its users, is the common foundation to the six pillars of personalised care identified by the National Health Service (NHS) England (2017):

- Shared decision-making
- Long-term conditions care and support planning
- Patient choice
- Social prescribing
- Patient activation
- Personal health budgets

#### Why healthcare information?

There is already overwhelming evidence that health information, when it's reliable, clear and provided at the right time and right place for the individual, is hugely beneficial (Patient Information Forum 2013). And what's

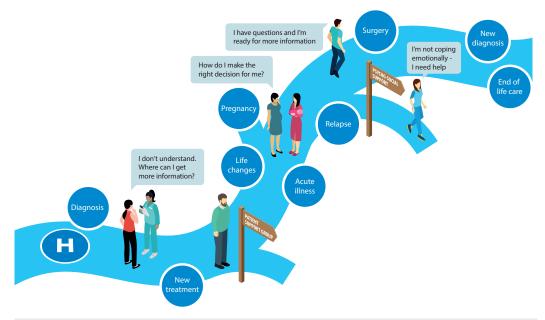


Figure 1. Patients need personalised information at the right time on their journey with a chronic condition

more, a person's right to information to inform their care is enshrined in the NHS Constitution (Department of Health and Social Care 2012).

But patients still report they are not receiving the information and support they need to make informed decisions about their health and wellbeing. In a survey by Patient Information Forum (PIF) of 1,500 people with long-term conditions (Duman et al. 2015), 36% said they did not have enough information when first diagnosed. This figure rose to 58% for 18-24 year olds. And in 2016, only 56% of hospital in-patients felt involved in decisions about their treatment (Care Quality Commission 2017).

#### Patients' responsibilities and rights

As the NHS creaks under pressure, there is a renewed push for people to take greater responsibility for elements of their own care. But if we're going to take responsibility for our health, then it's essential our rights as patients are met. Putting patients in control through access to information and support will enable people to take greater responsibility. With a growing emphasis on shared decision making (National Institute for Health and Care Excellence 2017), the first step needs to be ensuring everyone can access basic information, whatever their level of health literacy. And it's worth bearing in mind that up to 61% of working age adults lack the literacy and numeracy skills to understand health and wellbeing information as currently produced (Coulter and Collins 2011).

#### What needs to change?

The good news is that high-quality information, and the tools and resources to support shared decision-making and selfmanagement already exist and are being developed further. The problem is they are often not made widely available to patients (see Box 1 for results of the patient information survey we carried out at St Mark's Hospital). To address this issue, the Patient Information Forum worked with patients and clinicians to identify and create a pathway that embeds the provision of accessible and tailored health information into the provision of care, from diagnosis, through treatment, to longer-term management (Figure 1).

#### The perfect patient information journey

Working with patients and clinicians, supported by AbbVie, the Patient Information Forum has developed a seven-step process to support healthcare services to develop and embed patient information across their pathways (see Figure 2). By using this process, services can create a 'Perfect Patient Information Journey' and transform the information experience of patients in a matter of months. By putting patient information needs at the forefront of service planning and by thinking about the Perfect Patient Information Journey for patients, healthcare professionals can ensure that individual patients receive the right information, in the right format, at the right time.

#### Leadership is critical

Leadership is essential to make sure everyone in a service knows their role regarding patient information, to make sure it is a priority and guarantee it happens. Ensuring that the leadership team of a service understands the value of information to patients is critical in changing the culture and embedding information throughout the pathway.

In busy, complex services, having clear roles and responsibilities amongst staff for information provision is crucial. Think about:

- Who will lead the seven-step process?
- · Who can review available patient information sources from other sources and approve them?
- · Who will be responsible for embedding patient information within care pathways?
- Who will make sure all staff know what is available?



Figure 2. The Perfect Patient Information Journey process is based in a cycle of continuous improvement

Timescales can be adjusted to reflect the complexity of the information/care pathway.

#### Learning from pilots

The seven-step process was tested at two pilot sites; the inflammatory bowel disease (IBD) service at St Mark's Hospital, North West London (a recognised centre of excellence) and Hereford Hospital Trust. Both pilots demonstrated the importance of investing time in the process and in having clear leadership to drive improvements across an organisation.

The IBD pilot study revealed a wide range of information needs through the process of gaining patient and staff insights, including a lack of awareness of patient support

#### Box 1

#### St Mark's Hospital - IBD Service

The patient survey gave insight into awareness of services and resources.

For example, of the patients surveyed:

- A third were not aware of the telephone advice phone
- Over half were not aware of the email advice service
- Almost a third of patients did not feel they had enough information about their medicines
- Less than a third of patients had been given the St Mark's IBD patient book
- Three-quarters would find it useful to have more information about self-management and first steps to take during a flare of their disease

A national flare card scheme is being introduced in Scotland after a successful pilot (Squires et al. 2017) found reduced service use, reduced steroid use and reduced unscheduled care in a flare card supported cohort.

#### Box 2

In February 2018 PIF was asked to facilitate Step 1 of the sevenstep process at Hereford County Hospital, bringing key members of the hospital together who had an interest in patient information. The session highlighted the need for clearer leadership and designated roles for patient information across the organisation. Participants agreed the policy for patient information needed to be reviewed, updated and relaunched across the Trust. This was supported by patient experience feedback which showed the most common topics for complaints in the Trust were around communication and information, in particular a lack of information given at discharge.

services designed to boost efficiency (see Box 1). The Hereford pilot showed that lack of appropriate information was a source of common complaint, particularly related to discharge (see Box 2).

PIF's next step on the project is to develop and pilot a template for evaluating the impact of information interventions.

#### Ensure delivery of patient rights to information

PIF would like to see every healthcare service adopt our 'Perfect Patient Information Journey' and use the seven steps to embed and signpost high-quality, easy-to-understand and simple-to-access information for patients when they need it.

In failing to provide patients with all the information and support they need to participate in decisions about their healthcare, the health service is currently compromising all three key dimensions of quality care: patient experience, patient safety and clinical effectiveness. If patients are to take greater responsibility, we need to respect their rights and enable them to participate.

So, to the Government and others who are calling for patients to take greater responsibility for their health, we would challenge them to step up and meet their responsibilities to ensure that patient rights to information are met and delivered.

#### Conflict of interest

The Perfect Patient Information Journey project was funded by an educational grant from AbbVie.

PIF's expertise in facilitating the development of a Perfect Patient Information Journey using the 7-step process is available on a cost-effective, not-for-profit consultancy basis to NHS Trusts and other bodies. For further information contact: Sophie Randall, Project and Partnership Manager sophie.randall@pifonline.org.uk

For more information on the Patient Information Forum visit www. pifonline.org.uk

#### **KEY POINTS**



- ✓ Patient information is a management issue, it can improve outcomes and reduce service use if people are empowered to self manage.
- ✓ Patient information underpins the six pillars of personalised care
- Patients report being uninformed about their care and only 56% of hospital in-patients felt involved in decisions about treatment
- ✓ Ensuring information is health literate makes services accessible and helps tackle inequality
- ✓ PIF has developed a 7-step process to deliver a perfect patient information journey
- ✓ If the NHS wants people to take more responsibility for their health it needs to provide or signpost information they can use and act



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Coulter A, Collins A (2011) Making shared decision-making a reality: no decision about me, without me. London: The King's Fund. Available from kingsfund.org.uk/sites/default/files/Making-shareddecision-making-a-reality-paper-Angela-Coulter-Alf-Collins-July-2011\_0.pdf

For full references, please email edito@healthmanagement.org or visit https://https://iii. hm/or6



# Empowering communities to improve their health and wellbeing

WHIS connects people and communities

World Health Innovation Summit (#WHIS) connects people and communities to improve their health and wellbeing (salutogenesis approach) while creating and sharing opportunities.



#### **Gareth Presch**

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#togetherweinspire #WHIS

echnology is an enabler and now we have the means to share knowledge worldwide in an instant. We can use these means to support people's health and wellbeing while generating value.

This brings opportunities and the World Health Innovation Summit (WHIS) platform can not only improve people's health and wellbeing but also deliver new meaningful jobs.

#### Whv?

Three years ago I started a social enterprise World Health Innovation Summit in Carlisle, Cumbria the initial idea was to support local National Health Service (NHS) and social care services with recruitment and retention.

The World Health Innovation Summit is not just a conference or a meeting. It is about people coming together to support each other through a salutogenic approach to health and wellbeing, to network on a continuous basis. By supporting our communities, sharing knowledge, inspiring and innovating we as individuals and as a community benefit.

#### How?

By bringing patients, clinicians, managers, voluntary sector, education and businesses together to

exchange knowledge, inspire and innovate together we all learn and our health service will benefit.

Health touches every sector: education, transport, food and agriculture, housing, waste, energy, industry, urbanisation, water, radiation, nutrition (WHO).

In order to find solutions we need inspiration and innovation. WHIS is about each and every one of us helping to support our health services. In order to do that we need a platform for people to contribute and meet to share their knowledge. The World Health Innovation Summit (Federation) provides that platform to do this in a consolidated structured process and innovate solutions.

The World Health Organization's determinants of health are:

- the social and economic environment
- the physical environment, and
- the person's individual characteristics and behaviours

#### 5 Pillars - WHISKids, WHISatwork, WHISSeniors, WHISGreen, WHISTech

We have supporting programmes running alongside the summits such as WHISKids (Health & Wellness for the next generation) and WHISatwork (Stress management within the workplace), WHISSeniors (Elderly care to improve quality of life), WHISGreen (Energy, waste, water) and WHISTech (WHISInspire). All programmes support our communities while looking for solutions to ease pressure from our health and social care services (Prevention).

#### 5 Goals

- 1. Deliver the United Nations Sustainable Development Goals (SDGs)
- 2. Restore the balance to the environment
- 3. Create equal opportunities
- Improve people's health and wellbeing
- 5. Support the most vulnerable

#### **Outcomes**

#### **Outcomes for WHISKids activities**

- Outputs = 2000 young people + parents/staff reached so far across Cumbria
- · Key outcomes = Improved emotional wellbeing and resilience in young people
- Indicative social return on investment\*

Cautious calculation = £1: £7.50

Key outcomes from summits were decreased isolation and improved motivation amongst healthcare, social care and community-based professionals.

- 67% said "I have improved my professional network"
- 63% said "I have better access to new and innovative ideas through WHIS"
- 53% said "I have a more positive professional outlook"
- 52% said "I have improved my general professional knowledge base"
- 48% said "I feel less isolated professionally"
- Indicative Social Return on Investment\*
- Cautious calculation = £1: £36

Our prototyping is complete. We now have opportunities to scale WHIS right across the world. We're speaking to local authorities and have started to train facilitators to deliver our WHIS programmes around the world. We're generating value and sharing it so we all benefit.

#### **Opportunity knocks!**

Knowledge transfer across all sectors to improve our health and wellbeing will benefit us all:

- We can improve our population's health and wellbeing: WHISKids, Atwork, Seniors etc.
- Restore the balance to the environment: WHISGreen (energy, waste, water)
- Develop a network of communities to support solution-focused innovation for health and social care worldwide
- Bring social capital and intellectual capital together to tackle challenges we face and support solutions
- · Access to all market sectors worldwide



- Deliver new purposeful jobs that are flexible and agile in line with the future of work through the WHIS platform
- Support governments and local authorities improve our populations' health and wellbeing while creating new opportunities for meaningful and regenerative growth
- Support the delivery of the Sustainable Development Goals

The World Health Innovation Summit team is committed to collaborating so our communities benefit. Our

#### "BY SUPPORTING OUR COMMUNITIES, SHARING KNOWLEDGE, INSPIRING AND INNOVATING WE AS INDIVIDUALS AND AS A COMMUNITY BENEFIT"

business model ensures our events and activities are accessible while providing opportunities through the WHIS Federation (local community networks with central support that have independence with internal affairs (#togetherweinspire).



Founder Gareth Presch @garethpresch @HIC2016 @UN #WHIS #SDGs #GlobalGoals #UNGSII

We bring in revenue from community support, partnerships, sponsorships, digital sales, advisory services and a number of other commercial activities, which means we can return money back into our local communities. Excess funding after our costs will go to community projects.

We have held successful events in Carlisle, Manchester, Nottingham, Fylde Coast, Birmingham, Liverpool (UK) and around the world (Greece, Thailand, Philippines) to share knowledge and improve healthcare for all.

We have community ambassadors and we are delighted to be working with such inspiring individuals who work diligently within their communities.

Our motto is "Together, We Inspire" and by working together we will inspire and deliver better healthcare. Our goals and vision support the 17 sustainable development goals as set by the United Nations (un.org/sustainabledevelopment/ sustainable-development-goals).

We have partnered with the United Nations Global Index Institute to support the implementation of the Sustainable Development Goals (#SDGs #GlobalGoals #UNGSII) and Globethics (Ethics in Higher Education). ■

#### **KEY POINTS**



- ✓ Technology is an enabler and now we can use these means to support people's health and wellbeing while generating value
- ✓ By supporting our communities, sharing knowledge, inspiring and innovating we as individuals and as a community benefit
- ✓ WHIS is about each and every one of us helping to support our health services
- √ "Together, We Inspire" by working together we will inspire and deliver better healthcare

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# Dense breast reporting laws in the USA

What has been the impact?

A new study reports on the impact of breast density legislation in the USA on awareness of breast density and conversations between doctors and women about screening.

lmost 10 years after the first breast density notification law was passed in Connecticut in 2009. 36 states in the USA now have such legislation. Research commissioned by Are You Dense. Inc., and Are You Dense Advocacy, Inc. set out to measure the impact of these laws from the patient perspective. The findings of the survey are published in the Journal of the American College of Radiology (JACR).

The results show that dense breast reporting laws in the United States significantly increase breast density awareness as well as prompt conversations between women and their healthcare providers about supplemental screening. And nearly 90% of women surveyed, regardless of the state's law status, completely or mostly agree that they would prefer to know their breast tissue type than not know.

Study results also show that women from states where density reporting laws have been in place longer are more likely to know their own density type and to report that their provider talked to them about supplemental screening.

The survey, conducted in February 2018, included 1.500 women in all 50 states, between 40 and 74 years old, who had a mammogram within the past two years. Survey results were compared across five groups based on law details and between women residing in states with laws versus without laws.

HealthManagement.org spoke to lead author Nancy M. Cappello, PhD. founder of Are you Dense, Inc. and Are You Dense Advocacy, Inc. and the inspiration behind the first density reporting law in the United States and co-author Christoph Lee, MD, MS, Professor of Radiology and Health Services at the University of Washington School of Medicine to find out more.

#### What are the standout findings from this survey from your perspective?

Nancy Cappello: Regardless of a state's density reporting status, the consumers of mammography, the patients, want to know their breast density status as part of their mammography reporting results.

Density laws are associated with increased breast density awareness (those in reporting states are more likely to know if they have dense breast tissue) and are more likely to have conversations with their providers about screening beyond the mammogram.

My state of Connecticut was the first state to enact a density reporting law (it took us 5 years of relentless advocacy). These results show that women in Connecticut are more likely than women in any other US state to know their tissue type AND, if heterogeneously or extremely dense, have conversations with healthcare providers about adjunct screening.

Our survey had several strengths. We surveyed women from all 50 US states with a diverse distribution. of sociodemographic characteristics. We had a relatively large number (1.500 sample - 300 in each of the 5 groupings) and this large sample allowed for a robust 95%

confidence levels for our statistics of +5.8% or smaller for each survey question.

#### Has the discourse around breast density improved?

Nancy Cappello: Clearly patients who have been harmed by the limitations of mammography because of the impact of dense tissue on missed, delayed and advanced stage breast cancer, have led the discourse about dense breast reporting and its impact on access to an early breast cancer diagnosis. Right out of the gate, physician trade organisations were opposed to density reporting saying that we were mandating medicine through legislation.

There have been several peer-reviewed papers about the negative effects of dense tissue disclosure using overdiagnosis, patient and provider confusion and scaring women as reasons why women should not receive this information through legislation. However, through research, starting in CT after the 2009 law, the significant yield of increased invasive cancer using ultrasound on otherwise normal mammograms has informed other practices across the USA.

Immediately upon enactment of the 2009 law, breast radiologist Dr. Jean Weigert, representing the Connecticut Society of Radiologists, who had testified a year before in opposition to the density reporting bill, began acquiring data to investigate whether screening breast ultrasound improves breast cancer detection in women with dense breast tissue and a recent normal mammogram result and her third research paper covered four years of screening women with dense breasts with bilateral ultrasound (Weigert 2017). Dr. Weigert spoke of her amazement in a recent article. "I pulled out the data from my five offices for the years 1 through 4. I tallied it all up, compared it, and found—much to my surprise—we continued to find 3.2 additional cancers per thousand in this cohort of patients with breast tissue density greater than 50%" (Green 2015). Additionally, the study demonstrated significant progress in reducing the false positive rate of biopsy, often cited as a harm of routine ultrasound screening, where ultrasound now equals the acceptable biopsy rate for mammography.

#### **Nearly 10 years on from the first state breast** density legislation in Connecticut what are your reflections on the next steps?

Nancy Cappello: We need a national standard of density reporting. We are encouraged, under the leadership of U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb that density reporting, through changes in the Mammography Quality Standards Act (MQSA) is getting closer to becoming a reality across the US. On 18 October 2018, a communication was issued by the FDA concerning dense breast tissue reporting across the US. "The FDA intends to propose a new rule that will modernise mammography quality by recognising new technologies, making improvements in facility processes and updating reporting requirements. The agency is proposing updates that incorporate current science and mammography best practices, including addressing breast density reporting by mammography facilities to patients and health care providers. These updates are intended to improve the delivery of mammography services" (U.S. FDA 2018).

#### Why are some state laws time-limited?

Nancy Cappello: Even since the first density reporting law in CT in 2009, we have received huge resistance, mostly from physician trade organisations, using legislative efforts to communicate density reporting to the patient as part of the mammography reporting results. California became the first state in 2013 to use a "sunset" clause in the law where the existing law is eliminated on a certain date. The language of these laws is negotiated and for the bill to pass (the first one was vetoed by the Governor), a sunset clause date had to be part of the law or the opposition would not agree with its passage. A revised law was recently enacted which extended the sunset clause to January 1, 2025. There is a guide to the 36 state density reporting laws on our website at https:// iii.hm/oal

#### Do radiologists have effective tools for educating women about density and risk-based screening?

Christoph Lee: Radiologists are working with primary care physicians, policy makers, administrators, and patient advocates to effectively address density reporting laws. However, we have a long way to go. We need to generate better evidence regarding which women would benefit from which supplemental screening imaging examinations.

Currently, the evidence suggests that there are both potential benefits and harms associated with additional testing beyond mammography. We also need to incorporate better risk stratification in an age of multi-modality screening options, and better inform women regarding their overall short-term and long-term risks for developing breast cancer.



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#### **FURTHER INFORMATION**

Learn more about breast density and its relationship to breast cancer risk and legislative efforts across the U.S. at areyoudense.org and areyoudenseadvocacy.org. You can also visit mammographysaveslives.org and download the ACR Breast Density Brochure.

### Data power to the patients!

Patient-driven data business, not data-driven patient business

Data-driven business models make up the medical and healthcare market in large parts, a trend reinforced by further technological developments and regulation. Care must be taken to avoid a situation where only a few players benefit.



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ho lives outside the GAMFANNAT economy (Google, Apple, Microsoft, Facebook, Amazon, Netflix, Alibaba, Tencent)? An increasing market capitalisation of approximately \$5 trillion (July 2018)—a multiple of the market value of all German Stock Exchange 30 companies together—and an even deeper connection of services and products with our increasingly digitally organised and experienced life clearly show that large parts of the global consumer society today and even more tomorrow and the day after tomorrow will become data-driven spheres. It is easy to imagine a world without fossil fuel-powered automobiles, but with flying autonomous vehicles—a bit harder without cell phones, and with brain implants. A world without data in the sense of their intensive generation and usage, in all areas of life seems to be hardly tangible (unless as a conscious and fairly complete renunciation of technology).

The development of data-driven activities as a whole is increasingly ethically questioned. In Germany, the Data Ethics Commission has recently been created within the Federal Ministry of Interior, Building and Community, and in England the Data Ethics Framework of the Department for Digital, Culture, Media and Sport. Today, it is unimaginable not to use digital advances in medicine, which are certainly critical in ethical terms, yet impressive, especially data-driven ones, for positive precaution, diagnosis, healing and aftercare

opportunities for patients and healthy people. From AI in radiology to precision medicine in oncology, people want to be, become, and stay healthy. Here a peculiar tension erupts.

In the GAMFANNAT world, considerably more people are using the services offered than would be expected in view of the level of trust that users have in their data usage—apart from the fact that hardly anyone, for example, really works through, understands or can decipher privacy statements. Transparency as a condition of the opportunity for fair consent looks different. To put it clearly: The GAMFANNAT Grandpa should not be sitting next to Lehman Granny. Nor is it to be expected that, in the end, patients will not give priority to the medical benefit of their data because of concerns about a "patient credit bureau", even if the treatment contexts are hardly accessible to the individual patient. Convenience has always limited data protection requirements in real terms, and data protection should not be a luxury for the healthy. In addition, the GAMFANNAT players are already today recognisable openly or only in contours—increasingly active in the medical and healthcare market and game changers.

What data-related opportunities and risks arise for patients from a business perspective? How can patients not only be masters of their data, but use data business cases for themselves? What is the value of their medical and health-related data?

Which commercial, social or individual medical use of personal data makes sense and is as safe as it can be in the digital realm?

#### Economically, data is neither oil nor currency - but nevertheless the central future exchange unit for patients

Economically, oil is private property with exclusive ownership. My oil is my oil. Only I can use it, nobody else. When it's used up, it's gone, and I can only use one litre of oil to the extent of one litre of oil. If I mix 1,000 litres of oil, it won't become "super oil". In economic terms, data have a completely different nature. I can share my data with multiple users, so they are not rivals, and when many different pieces of data come together, they create network effects that can in part lead to significant benefit increases. In addition, data can be copied virtually unlimitedly. does not wear out, can be transferred, and can be handled through access, use, and change, and distinguished into private club goods or public data assets (eg weather data). And you can do amazing mathematics with it: statistics is the new basic subject for understanding the data economy.

My personalised medical data may only have limited economic value for me-which may be existential—but economically cannot be increased arbitrarily. However, for a company, various data such as my personalised but also impersonalised data (anonymised, pseudonymised, or purely machine-generated) can, when aggregated, lead to completely new insights and offers, and in the end even to innovative value added. In modern data medicine, such effects are currently on the agenda, and therefore, for example, for the pharmaceutical industry, of great interest.

#### "IT'S WEIRD THE PATIENT HAS TO BECOME A CUSTOMER IN ORDER TO BE A HUMAN BEING IN THE HEALTH BUSINESS"

The emancipation of correlation versus causality does not take place in strict scientific theory, but in the pragmatic world of business models—even with seriously anonymised data, cross-referencing and correspondingly smart data analysis models can often compensate for the information about the person that has been legally deleted, provided that those data are cleverly combined with other data (eg data from search engines or fitness devices). It is known that 87 percent of the US population can be re-identified by the combination of zip code, gender and date of birth (Sweeney 2002). Precisely because my data does not generally represent a significant value for me, there was—and is—a tendency to pass it quite relaxed to the companies in exchange for services and products. That's just how it is as a consumer: "If you are not paying for it, you're not the customer; you're the product being sold" (Lewis 2012).

To a large extent the enormous market value of the corresponding data-driven companies is explained. Because they do not really share the cake. With a view to patients, this trend slowly begins to gain contours in the medical and healthcare sector. Strictly speaking, the medical data of patients is not a currency for patients themselves, because they are not a constant reference value, but depend essentially on their context. However, data can replace financial transactions via their specific value—and yet, no oil, no currency, but an economic value that should be repaid.

#### Business models for the use of medical data and ideas for determining the value of data are diverse and rarely recognisable today

Which business models in the medical and healthcare industry use data and how is this money earned? This very simple-sounding question says it all. In principle, data can be traded or used directly (or as in the case of open data provided without consideration, or data sharing). The GAMFANNAT economy usually does the latter and thus comes to steadily richer and deeper user experiences and increased, individual benefit, leading to a corresponding willingness to pay and, above all, loyalty—and last but not least, to competitive advantages. The algorithms of the companies are ultimately unregulated and in large parts even for an insider a black box, which makes exact analysis of the value-added context no easier, as well as a social assessment (think of the potential for discrimination, currently the Berlin initiative d21 initiatived21.de is taking corresponding first steps with the expert group "Algorithms Monitoring"). What

is still emerging in medicine as personalised medicine, for example, is for consumers of media an everyday experience (certainly media are far less complex and consequential). Today we see no "MediFy", but Spotify.

When it comes to trading data (as practised by IQVIA, for example), transparency is less visible. Who really knows how their health insurance provider does the ultimately decisive risk assessment? Which data were used? The fact that you can no longer digitally live without advertising and this advertising is personalised on a data-driven basis, may cost some nerves and evoke countermeasures, such as paying for less advertising; others enjoy hyper-personalised content, but ultimately, it's a comparatively less critical data usage. With patient data selling you will want and have to look more. Opt-out must always be possible for the patient, but today it is not. Just say "No" if you do not want to be part of the game (as long as it is doable for the average person). Solutions such as privacy-enhancing tools, which are available for online offers, for example, are far from available for medical data and records. The data system of the medical and health industry has a breathtaking opacity.

Good providers of data services will ensure transparency and participation, legally offered to patients integrating them economically (and of course doctors, who will soon be seeing new business models in the house, new risks but also new opportunities; no Al will ever replace a good heart (until we do not see an AI as an Existence in the full ethical sense) and doctors are always the natural intelligence needed, think of the actual critical discussion of Watson (IBM). And pay attention to the data quality: statistical

modelling is only suitable for intervention in medicine, if it has at least objectivity, reliability and validity with regard to the actual data used and the corresponding analysis methods. With good data, medical systems can be trained and multiple variables can cleverly be linked to newly empirically demonstrable correlations, which in turn may suggest prevention or therapy. Unfortunately, even with data success, neither the corresponding model can be verified nor a causality be proven. Statistics make more or less meaningful predictions depending on the sample size. But that's just what makes new hypotheses possible. And with the exponentially growing flood of information in the medical sector, it's difficult to avoid big data and AI (& Co.). In this sense, in my opinion, patients in the medical and healthcare sector want to deal with their data more sensitively than in previously common consumer areas—and hopefully do it well-informed—and in the end want to use the statistically usable or even personal data-generated value.

On the other hand, what speaks in principle against patients paying in a transparent and well-structured manner, for example, to receive special medical services in a smart hospital with their data? Self-pay may also be achievable for less wealthy patients. What speaks against a patient selling or licensing their genetic data for legal and legitimate and transparent purposes? In the upcoming DNA marketplace, the DNA "donors" should get economic participation; smaller companies such as EncrypGen or Nebula Genomics look for appropriate solutions, and often key technologies such as blockchain play a crucial role. Consequently, questions about the taxation of data will also have to play a bigger role in the future. And, of course, security and economic value issues—hacker attacks from outside and criminal energy within medical institutions—are likely to increase as the incentive potentially increases.

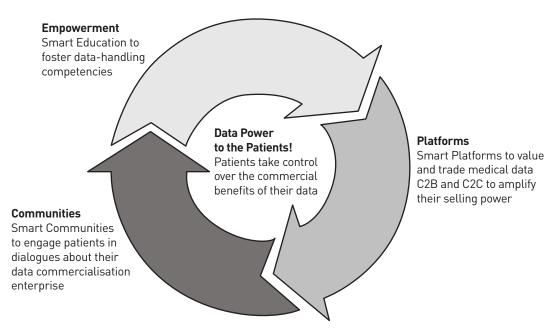


Figure 1. The centrality of the patient in the commerce of digital healthcare

Patients may not have a clear understanding of what their data is really worth, and most of them might not care about the business models at this stage without recognisable participation (in a democratic sense). Companies in the medical and healthcare industry have a decisive advantage here, not least because the value of data constantly changes with the context of (today often unclear, but tomorrow...) business models. Of course, companies are often denied the final clarity on digital business models in the smart healthcare world. In the end, it will be crucial whether patients are adequately involved in certainly-not-marginal

welfare gains. Enlightenment is likely to be necessary not only in legal but also in economic terms, otherwise consent declarations remain notoriously ineffective and economically not necessarily positive for the client or patient, because the data-collecting company determines what data it collects for what. But alternatives are also discussed, for instance, personal information management systems (PIMS). Also important are smart communities to engage patients in dialogues about their data commercialisation enterprise among themselves and with medical and other experts.

Not least so that patients not only—as usual in the data economy from the customer's point of view—look for short-term benefits such as discounts or the like, but also take long-term positive effects into focus. This decisionmaking need not necessarily lead to the decision between added value and the protection of data but can combine both elements. It will not necessarily be about life-changing business when patients use their data or parts of their data economically. But then they are in the game, sitting at the table, and they also should sit there, if, in the end, it comes not through advertising but eg via insurance model-funded data platforms. Patients themselves can increase the price and promote transparency by treating their data with the utmost care, which will be essential for an adequate position of providers (patients) towards buyers (companies). Today it is not foreseeable whether there will be minimal value added, exchangeable, or even a greater value added in the individual economic exploitation of individual, personalised or impersonalised data. A third way to do this would be to point out the current, ultimately unquestioning availability of data and self-marketing of the individual, which is likely to lead to lower prices through asymmetry.

Unlike other consumer data, medical data is absolutely necessary for factual medical care, but for the healthy some medical data are theoretically economically usable even without specific treatment, and not even prevention. The entire life as a prevention and data event is newly articulated in the quantified self. It will probably result in a holistic path connecting electronic medical record (EMR)

data, wearables, and business to consumer (B2C)-driven genetic data. A conceivable impact can be the connection between pay and data exploitation, as known and practised in the media industry. The licensing of intangible assets answers the question as to which data, where, when, for how long, to whom and for what purpose and consideration are put into use (Kerber 2016). Companies like to talk about "data ecosystems" as Terminus Technicus instead of "trade". Platforms to value and trade/license C2B and maybe even C2C could be an instrument, but always and only if patients are educated to handle their medical data, which is for example for sure one of the challenges of direct to consumer (DTC) genomic businesses (23andme etc.) because people are confronted with information (might it not be a diagnosis), which they may not be able to handle on their own without further professional advice, eg by a doctor.

In practice, such basically legal issues are not really resolved. In the case of personal data, the term "property", or at least property-like entitlements, may be used, and in the case of non-personal data, it may be called a copyright aspect. Since there are many mergers of data forms that are likely to increase in the internet of things era, even this distinction with property reference may be difficult in practice, and thus the likelihood of lower transaction costs for personal data and its markets. The lawyers will get a lot to do.

If it is ethically correct and legally required in a constitutional state to focus on the patient's benefit, and also economically attractive—albeit a little weird that the patient has to become a customer in order to be a human being with dignity in the health business—then the consistent empowerment of patients to handle their own data is essential. And this does not in the least include the benefit that these can provide—only for the individual patient medically, but also financially, or, for example, by means of data donation in research, potentially for society as a whole or in cooperative models (eg Healthbank in Switzerland). For this, a social consensus must be worked out that supports this form of economic participation. In addition, the lack of factual interoperability of existing patient records is a major obstacle and a significant costly one for convincing implementation. There are initiatives such as MyData from Finland, which generally demand a "human-centred personal data management" for data, and with the concept of the "selfsovereign identity systems" the final idea of the autonomy of users finds its way into the debate. New companies like Longenesis also build on similar approaches.

#### The GDPR potentially drives the individual data business in medicine

In my opinion, the European Union General Data Protection Regulation (GDPR) tries to manage the balancing act between data protectionism and innovation bondage in favour of a reasonable middle-of-the-range solution. It can, despite certainly not unjustified criticism in detail, become the gold standard to make personal data with privacy and data portability a valuable asset in a seller's market. Businesses, as well as other public-sector institutions, for example, who deal with impersonalised data and, most importantly, personal data of patients, are highly obliged to ensure the maximum possible security of this data from misuse. Since true impersonalised data is not easy to grant, this form of data, although not covered by the GDPR, should be considered data protectio- relevant when we talk about patient data.

It is a good initiative of the GDPR to put consent clearly in the centre. It is about protecting people, not protecting data. In the end, patients will have to learn to responsibly handle the most valuable data they have—their medical data—and to read the privacy policy. The "fine print" re-enters the consciousness, and that's a good thing. In addition, the much-cited informational self-determination is

#### "THE CONSISTENT EMPOWERMENT OF PATIENTS TO HANDLE THEIR OWN DATA IS ESSENTIAL "

no guarantee of absolute power of the individual over "their" data, because also the protection of privacy takes place in a social context. There remains the problem that the GDPR does not directly address the involvement of consumers in the economic exploitation of their data. It is easy to understand, however, that consumers want more than data protection as soon as the economic opportunities in data markets become clearer to them (Spiekermann and Korunovska 2017). It should be similar for patients, not just because of private return perspectives but also to foster their healthcare outcomes.

This might also increase their motivation eg to share their data with research organisations and become a proud data donor. Precision medicine for everyone needs so many institutional barriers to overcome—patients as smart customers can make it happen.

No sensible person can object to better medicine; however, care must be taken to ensure that there are no distorting data monopolies and non-transparent business models that in the end only really benefit a few players. If a legal, legitimate and efficient business is to emerge, it must properly engage patients as customers and data providers in the value chain. The centrality of the patient in the commerce of digital healthcare is crucial—also from my point of view for a holistic patient experience—even though it may be very complex and difficult, it is not impossible.

#### **KEY POINTS**



- Data-driven business models make up the medical and healthcare market in large parts, a trend reinforced by further technological developments and regulation. Care must be taken to ensure that, in the end, not only a few big players
- The digital data world is becoming the core of medicine and



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### Preparing your lab for the future

#### The gain from entering the digital landscape

With the clock clicking for fully entering a digital landscape that will benefit patient and provider, medical labs need to act fast. Baher Al Hakim, CEO of Medicus, an Al-based platform that converts data for effective health insights, spoke to HealthManagement.org about the whats, whys and, importantly, the hows.



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**■ ©DrBaher** 

#### What are the challenges ahead in healthcare IT?

While the centrality of the patient has been on the agenda for years, this direction has only recently been put into practice. Now, decision-makers are trying to think about what they can offer that works for the patient and it isn't because they are trying to meet an agenda; it's because it's important for their survival.

Secondly, we have seen the C-Suite has started to realise they need to evolve - to update their systems and infrastructures to be more innovation-ready but there are so many areas to tackle that they're not sure where to start. Added to the challenges is there is no one-size-fits-all strategy. For each party, digital innovation means something different.

In healthcare there are few CEOs who have prioritised digital innovation.

#### What's the medical lab situation?

Our focus is on the diagnostics industry. This is one of the most promising fields of growth due to the assets labs possess, but at the same time, the most threatened. Lab directors only have a few years to decide how to react to the impending waves of innovation incrementally disrupting their industry. The industry is under severe pressure because of rising healthcare costs, and diagnostic spend is one of the easiest to squeeze. The market is really struggling under this pressure and regulations are becoming tighter and tighter.

There are two universes in healthcare: the medical field which encompasses diagnostics, medication and treatment, and wellbeing which encompasses lifestyle and wellness apps. Even though these industries interact and touch upon the same entity our health – they are considered as separate product categories. They work differently, the reimbursement model is different and even the market treats them as different industries. Medicus believes they should not be separate and, in fact, they are fundamentally interlinked. We believe we can give labs a way to play successfully in this new reality where the wellbeing category is growing, and there is an opportunity to differentiate and grow with value-add services. For example, labs can start to offer prevention packages, specific condition coaching or female health management. We advise and support clients in that direction. Encouragingly, many of them had started this process before we stepped in.

#### How can Medicus assist towards innovation?

Each member of our team has experience in the medical, technology and consulting worlds so we have a set of tools, industry learnings and guidelines that help us along the way. We approach clients in a flexible and personalised manner. It is important to first understand their market dynamics, what their main challenges and opportunities are, and what their vision is as this influences their direction. The fact is, we can't truly know this until we have spent an adequate amount of time speaking with everyone involved. This includes not only CEOs and managers but the people interacting with the patients and the end users. This way, we can present a strategy that works across the whole organisation.

We also pay a lot of attention to something that is often overlooked: change management. If we implement a system, how will it flow and get adopted across the organisation?

#### What advice would you have for decision makers working in the diagnostic industry?

Healthcare management is used to a slow-moving industry but it's simple; forget the idea that there is a perfect strategy and just start your own process. Define an initial strategy quickly, empower the right people, deploy fast then iterate through experimentation and learning.

### Patient engagement: What do advocates think?

#### Challenges and opportunities for keeping engaged

With patient engagement there comes increasing responsibility - on the patient, their family and the provider. HealthManagement.org spoke to four leading patient advocates for their views on approaching patient engagement and the challenges that lie ahead.

"Becoming engaged in your health is exactly the same as caring for yourself in other ways. When we're young and vulnerable, good people care for us. As we grow, we learn to think and act for ourselves, which in healthcare as everywhere else, brings new risks, responsibilities, and independence."



Dave deBronkart

Patient Advocate, Speaker and Author

dave@epatientdave.com, epatientdave.com ✓ @ePatientDave

"Healthcare is about patients and therefore they need to know and decide. Together with their physician they 'built' the best treatment for their own health at this moment. This 'Precision medicine' creates value in healthcare and therefore it will be efficient as well. For patients this is an uphill battle, for many stakeholders do not see the added value of patients in the improvement of healthcare. Nevertheless, they are."



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"Patient engagement has become a buzzword in the healthcare industry, used to describe everything from engaging patients with hospital portals to tracking vitals with wearables. I've seen it co-opted by industry stakeholders, described (often interchangeably) as patient activation, involvement, participation, compliance, and centricity. But what I have yet to see is any significant progress in turning the rhetoric of patient engagement into a discernible reality in the real-world in which patients live. Patient engagement has enormous potential to transform how the industry delivers care to patients, but until patients themselves define what meaningful engagement looks like, I fear it will remain nothing more than an empty phrase."



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"The biggest opportunity (and challenge) is the removal of barriers and complexity that make it very difficult for patients to do the right thing even when they are motivated to do so. Wherever possible, and especially for those with chronic/complex/costly conditions, healthcare should offer a one-stop shopping experience where the patient does not need to have a PhD in project management in order to adhere to a care plan."

# THE WHOLE PATIENT

Health systems still struggle to identify what information should be captured to understand a patient holistically, and how best to engage a patient in a conversation that uncovers this information. This

gap leads to misalignment between the patient and care provider, which in turn leads to poor clinical outcomes and negative patient experiences.

Source: https://iii.hm/op9

#### PATIENT ACCESS TO ELECTRONIC HEALTH RECORDS:

USA, 2016-17 data

93%

84%

allow patients to nominate caregiver to access

allow submission of patient-generated health data

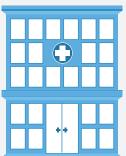


80% of patients accessing patient portal at 1 centre said it helped them take better care of themselves

of patients offered access

18% of physicians believe patients should have full access to EHR

Sources: https://iii.hm/ope, https://iii.hm/opf, https://iii.hm/opg,



hospital records (2017)

of hospitals allow online access (2013)

Sources: https://iii.hm/opa https://iii.hm/opb

#### PATIENT EMPOWERMENT

- What is my main problem?
- What do I need to do?
- 3 Why is it important for me to do this?
- 4 What are my options?
- What are the pros and cons of each option for me?
- How do I get support to help me make a decision that is right for me?

Source: https://iii.hm/opd



"Often, the 'Oh, by the way'

comments are the biggest thing"

Dr. Mary Murdoch, Southern Oregon Pediatrics

Source: https://iii.hm/opi

#### 7 GUIDING PRINCIPLES FOR SUSTAINED ENGAGEMENT

Map my path so I can make the right choices for me Place triggers in my pathway to turn effort into habit. Address the smallest action that matters most to unlock a chain reaction for success.

Communicate in my language so I know that you're invested in my

> Support my supporters to strengthen my network of care

Deliver the right information at the right time to teach me but not overwhelm me.

Build on what I am doing right to nurture good behaviour.

Source: https://iii.hm/op



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# ISO implementation: How to motivate lab personnel

Transforming the pressure of accreditation into team engagement

With the requirement that ISO 15189 imposes on medical laboratories, which approach can motivate personnel to embrace the assessment criteria?

s an internationally-recognised benchmark for quality management systems and competence standards, medical laboratories are constantly under pressure to secure ISO15189 accreditation. But increasing stringency of the latest 2012 version of the standards model and even more expected demands in the next ISO15189 version, currently under review, how can management engage staff so they will and can meet the challenges?

#### Overcoming the challenges

The most recent ISO15189 is very demanding and I'd even say it goes too far in some areas. Securing accreditation is not always easy or fun.

One of the most important challenges is how staff can be interested in both management and technical processes as required by the standard. A lot of the time, personnel don't understand why it's important for them to observe ISO criteria and, for example, to follow training with periodical evaluations again and again or to perform internal audits periodically. But the latest ISO15189 is very clear, you must be transparent and demonstrate how you fulfil the complete Plan-Do-Check-Act (PDCA) cycle in practice.

Therefore, it's important that you explain the ISO criteria well more than once to staff and explain the consequences for the team and the laboratory organisation of not meeting the criteria and fulfilling

the complete PDCA cycle. It's also important to show that all procedures provide opportunities for staff to learn new skills and processes, to demonstrate how well the team does the job and that they focus on the end result: a successful external audit that the laboratory organisation has achieved as a full team. It's a matter of focusing on the positive things rather than the negative aspects of implementing a quality management system.

"ONE OF THE MOST
IMPORTANT CHALLENGES IS HOW
STAFF CAN BE INTERESTED IN
BOTH MANAGEMENT AND
TECHNICAL PROCESSES"

#### Focus on personnel strengths

Staff aren't all interested in the same areas. Some are good at competencies, others at quality control or auditing. In order to foster staff engagement, let individual team members focus on what is of interest to them. The fact is, that it's incorrect to assume that management always knows best. It doesn't. Get solutions from the staff who are on the work floor. They often know the most efficient and effective way of dealing with a problem because they tackle it every day. This also means that team members feel

engaged and own their part in the ISO accreditation process.

It's also important to know when to step in and when to step back. There is no point in forcing people. For example, in order to engage and motivate staff we hold a lot of meetings but we start with the 5% to 20% of staff who are engaged and enthusiastic about implementing the ISO requirements to lead the way of quality improvement. There will always be sceptics, but the few who are enthusiastic will eventually inspire everyone to go on a quality improvement expedition by talking and demonstrating the benefits for their own work and suggesting the possibilities for a personal contribution. Once the sceptic notice that there are tangible results of the team efforts, they will of course end up joining the quality improvement process naturally.

Take different cultures into account. My lab is the main one in a network of satellite labs, each facilitating a different laboratory process. Each lab has also its own team culture which works well for the site. So, it would be a mistake to impose our culture - the culture of the largest organisation - onto the smaller satellites. In order to work well all together, the best approach is to harmonise the different procedures in all the laboratories while retaining its own identity. There is no point in forcing a change of culture. It only serves to make satellite staff feel devalued, alienated and invisible.



#### Clear direction

Having a crystal-clear objective with a possibility to anticipate organisation developments, is indispensable. If you are at rating 6, aim for rating 8. Don't always try to jump up to level 10. It's more realistic and more satisfying because jumping up a couple of levels is a very good achievement.

Above all, at the end of the day, it's all about the patient. That's also why we have chosen a job in healthcare and we must keep that in mind. ■

#### **KEY POINTS**



- During process, focus on individual interests of personnel to encourage engagement
- ✓ Allow enthusiastic staff to go on the accreditation expedition and lead the way for sceptics
- ✓ Explain clearly and in a timely manner why implementing a quality system is necessary so staff can understand
- Focus on the end result and aim for it as a team
- Don't impose an alien company culture on a satellite lab
- Create clear objectives
- Put the patient at first in all lab activities



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# Big data for deep learning in radiology: population-based imaging

How artificial intelligence is about to transform radiological research and clinical care

Big data and deep learning techniques are increasingly being applied to radiological problems, where they serve as powerful complements to traditional study designs.

he concept of artificial intelligence (AI) has been around for more than 50 years and has recently found its way into medicine, particularly into the field of radiology. It is currently widely discussed in both scientific and non-scientific communities as a potential game changer likely to improve diagnostic accuracy, efficiency and effectiveness along with paving the way towards personalised medicine.

Particular focuses of these discussions are machine learning and its sub-discipline deep learning, which is one of the latest developments in the constantly evolving field of Al. In deep learning models, multiple layers of artificial neural networks are linked to create complex algorithms most commonly in the form of "convolutional neural networks". The exponential increase in the amount of data required to train these systems is leading scientists and companies to seek out new sources of sufficiently large data sets and is serving as a major driver of big data.

#### Big data and the 'black box' problem

Although there is no formal definition of big data, a description proposed by the McKinsey Global Institute is widely agreed upon. It characterises big data as "data sets whose size is beyond the ability of typical

database software tools to capture, store, manage, and analyse" (Manyika et al. 2011). In the context of learning in radiology, we need to particularly aim for big data, the 5 Vs should be considered: (1) Volume, which quantifies the number of records and/or storage size; (2) Variety, which specifies the number of sources data is drawn from; (3) Velocity, which measures the frequency of new data being added; (4) Veracity, which describes the quality and accuracy of the acquired data; and (5) Value, which assesses the economic benefit of the inferred conclusions (White 2012; Kwon and Sim 2013; Fosso Wamba et al. 2015). Several of these features have the potential to introduce noise and errors in databases, including those of medical images. Although a well-adjusted algorithm has the ability to overcome such variations in the data much better than traditional prediction models, the initial training of its underlying deep neural network is highly sensitive to errors, and the algorithm may consequently be prone to misclassifications. Moreover, trained neural networks have a "black box" problem: while the prediction matrix of a traditional model may well be comprehended against its input characteristics, the computations performed by deep neural networks can be so arbitrarily complex that there is no simple link between the weights of the input characteristics and the function being approximated.

Thus, when talking about big data for deep changes affecting two Vs—yielding increased veracity and decreased variety. There are several sources of medical images, which if separated by origin, may be stratified into clinical data and research data. Clinical imaging data is abundant [it is estimated that digital healthcare data will amount to 2,314 exabytes (2.3 billion gigabytes) globally by 2020 (IDC 2014), with the vast majority coming from clinical images] and reflects real-world problems. However, it suffers from both high variety and low veracity. Promising alternative data sources are large-scale, population-based cohort studies that employ standardised protocols for medical imaging.

#### Structured population-based imaging studies

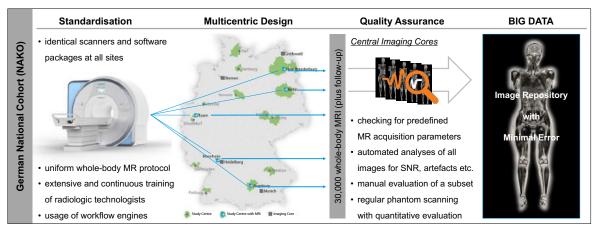
Population-based imaging in large cohort studies is increasingly being used in epidemiological studies with the aim of identifying physiologic variants and detecting subclinical disease burden. Several such studies are ongoing. Among the most prominent examples are two European projects: the UK Biobank (aiming for 100,000 whole-body MR scans among



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NAKO is a population-based cohort study including 18 sites across Germany; a subset of about 30,000 participants will undergo whole-body MR imaging at 5 different sites. After baseline, followup examinations will be conducted including repeated MR scans after 4-5 years. Large extent of standardisation and intensified quality assurance by dedicated imaging cores guarantee minimal random error in the image repository—a significant source of big data for deep learning. SNR denotes signal-to-noise ratio.

500,000 total participants) and the German National Cohort (NAKO; aiming for 30,000 whole-body MR scans among 200,000 total participants). The NAKO study is divided into 18 study sites across Germany and the MR substudy is performed at 5 of those locations, where identical 3.0 Tesla scanners have been installed (Figure 1). The uniform imaging protocol used at each site comprises a set of 12 native series covering the neurological, cardiovascular, thoracoabdominal and musculoskeletal body regions with a total scan time of approximately 1 hour (Bamberg et al. 2015). In addition to the cross-sectional baseline study that began in 2014 and is projected to end in 2018, follow-up examinations including repeated MR scans will be conducted after 4-5 years and will permit supplementary longitudinal analyses. Embedding the MR substudy into the larger main study allows for imaging data to be correlated

with a series of other assessments, including eg neurocognitive function tests, blood pressure measurements, electrocardiography, echocardiography and a range of biomaterials, such as blood samples or DNA. Drawing from the extensive data repository outlined above, these projects are, among other insights, expected to make valuable contributions to the field of radiomics by identifying and validating new imaging biomarkers with a predictive value for future clinical disease manifestation.

The structured design of such population-based imaging studies allows for a decrease in variety and an increase in veracity. With respect to the NAKO Cohort, the identical MR scanners and their unified imaging protocol help to eliminate technical variances almost entirely. Centralised staff training and certification, in conjunction with real-time, automated quality assurance

for completeness of data, conformity of scan regions and scan parameters as well as adequateness of global image features (such as signal-to-noise ratio and a mathematically defined universal image quality index) effectively warrant high veracity of the data (Figure 1). The cross-sectional study approach means forgoing real-time data and limits data volume to a predefined amount, but implicitly keeps data velocity at a controllable pace and data variety at a manageable level. Although these arrangements contradict traditional big data attributes to some extent (the above-mentioned 5 Vs), they enable consistency and will thereby facilitate research in a field where several previous big data approaches have failed, particularly due to data complexity and high level of error.

#### "THE STRUCTURED DESIGN OF SUCH POPULATION-BASED IMAGING STUDIES ALLOWS FOR A DECREASE IN VARIETY AND AN INCREASE IN VERACITY"

The application of big data techniques is a relatively novel endeavour in radiology compared to other industries and fields of research. The objective to build up large imaging biobanks and to extract previously unidentified features somewhat replicates the ventures undertaken several years ago in the distantly related areas of genomics and proteomics, but comes with a unique set of challenges. MR imaging has already emerged as the modality of choice for dedicated population-based cohort studies, yet other aspects such as the accomplishment of reliable and accurate organ segmentations remain challenging and require

further consideration (Schlett et al. 2016). Novel segmentation algorithms based on deep learning approaches are currently being developed for and on the standardised acquired MR data from population-based cohort studies. These algorithms will certainly also have a direct impact on the clinical work of radiologists, as will the comprehensive imaging data itself: with whole-body MR scans being performed in an increasing number of population-based cohort studies, we will be able to not only inspect isolated organs but also to develop novel knowledge on how diseases affect multi-organ systems and/or whether subclinical alterations of one organ are a risk marker for the impairment of others. Consequently, multi-level relationships of diseases can be studied and image-based risk stratification systems suitable for personalised medicine may be established. The insights gained will benefit research as well as clinical care. Another matter of discussion touches on the subject of evidence-based medicine, which also encompasses evidencebased radiology: we need to ask ourselves whether or not the previously mentioned black box problem is a tolerable issue for determining pathophysiological links based on correlations derived from deep learning algorithms.

## Conclusion

As with any pioneering work, there are many more topics that are still up for debate. In a larger sense, however, the application of big data and deep learning methods in radiology is holding a vast and as yet largely untapped potential for significant advancements in healthcare. Traditional study designs along with their methods of data collection and analysis remain important and we aim to promote the synergistic effects between these two scientific paradigms—capable of serving as powerful supplements to, rather than substitutes for one another. Large population-based cohort studies involving whole-body MR imaging, such as the NAKO, embrace this synergy and may function as a fruitful source of big data for deep learning in radiology.

#### Note:

The authors' institutions both take part in the NAKO study. FB and CLS serve as head of the MRI substudy.

# **KEY POINTS**



- Within the healthcare sector, radiology is taking a leading role in implementing artificial intelligence solutions into research and clinical imaging
- Big data concepts rely on the "5 Vs" as key variables: Volume, Variety, Velocity, Veracity, and Value
- The German National Cohort (NAKO) features an embedded MR substudy that was designed in accordance with big data and deep learning requirements
- Large-scale population-based imaging research can benefit heavily from big data concepts and deep learning methods



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# Imaging applications of artificial intelligence

The potential impact of artificial intelligence in radiology is impressive; vendors and major academic centres are developing a wide array of artificial intelligence applications and neural networks to aid radiologists in clinical diagnosis and clinical decision support.



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rtificial intelligence (AI) is one of the trending topics in medicine and especially radiology in recent years. Research papers are published every month investigating applications of machine learning in medical imaging, from image acquisition to image interpretation and prognostic evaluation. These can be contextualised in the developing field of radiomics, in which great volumes of quantitative data are extracted from medical images. These have quickly proven difficult to evaluate by traditional statistical means and have little direct applicability in the clinical setting. Thus, researchers have turned to development of AI and computer software that could better employ radiomic data in order to translate them to practical usefulness.

Machine learning is a subfield of AI that is centred on the development of algorithms that give the ability to computers to learn from data and subsequently perform predictions without explicit prior programming (**Figure 1**). Some of the possible tasks that can be assigned to these are:

- Classification: assignment of a given instance to two or more previously labelled classes
- Regression: classification using a continuous output rather than discrete labels

- **Clustering:** grouping of inputs without prior given classes
- Density estimation: outputs the spatial distribution of inputs
- Dimensionality reduction: maps instances to a lower-dimensional space.

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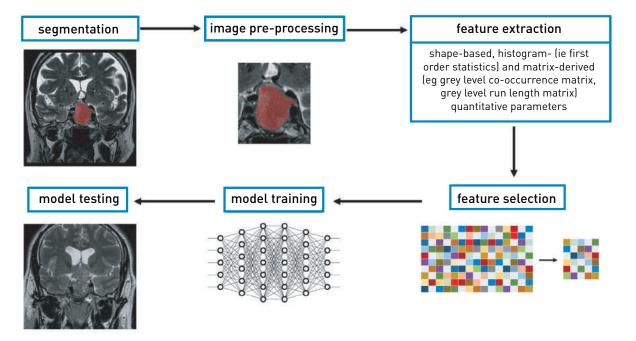
These are widely used in technological advances outside of medicine. In the context of medical imaging, classification problems are the most widely approached by using machine learning algorithms. For example, lesion differential diagnosis or patient prognosis prediction are common aims of studies.

Machine learning algorithms can be subdivided based on the type of learning. In supervised learning, more frequently used for classification in radiology, the data are labelled prior to the training process and these are also used as the reference standard

to evaluate algorithm performance in the test set. In unsupervised learning, no prior labels are given, and the software automatically clusters the given inputs. In reinforcement learning, the algorithm learns based on continuous feedback on its performance in the assigned task, in other words learning from its mistakes. Finally, all these approaches may be combined to enhance prediction performance (Figure 2).

# **Data extraction**

Most algorithms require data to be extracted from medical images prior to development of predictive models. The most commonly used techniques for data extraction fall under the umbrella of texture analysis. This evaluates inhomogeneities in images, represented by distribution of pixel or voxel values (eg Hounsfield units for computed tomography, CT, or intensity values for magnetic resonance imaging, MRI). In summary, various statistical formulae are used to extract shapebased, histogram- (ie first order statistics) and matrixderived (eg grey level co-occurrence matrix, grey level run length matrix) quantitative parameters. The main difference between first and higher order statistics is that the latter also retain information on the spatial distribution of pixel and voxel values. Furthermore, other than from the original image, features may be extracted after application of filters. The most commonly used



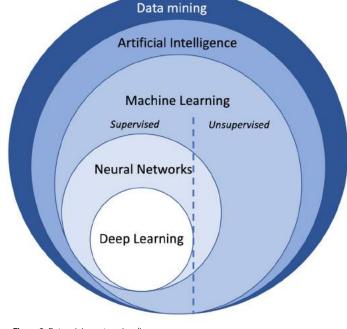


Figure 2. Data mining categories diagram

Figure 1. Example of a radiomics and machine learning workflow

are Laplacian of Gaussian filters that, based on given sigma values, influence image texture fineness or coarseness and wavelet decomposition, reducing noise and highlighting some texture features. Finally, some algorithms, such as neural networks, do not require any prior data extraction but only input labelling.

# **Neural networks**

Neural networks are a peculiar subset of machine learning inspired from how the brain is structured, with hidden layers representing interneurons. A simple model may accept image data as a vector composed of voxel intensities, with each voxel serving as an input "neuron". Next. one must determine how many layers (how deep) and how many neurons per layer (how wide) to include; this is known as the network architecture. Each neuron stores a numeric value, and each connection between neurons represents a weight. Weights connect the neurons in different layers and represent the strength of connections between the neurons. The suitable value of these weights is estimated through the training process, which is necessary to obtain a correct classification. A "fully connected" layer in which all neurons in one layer are connected to all neurons in the next can be interpreted and implemented as a matrix multiplication. The final layer encodes the desired outcomes or labelled states (Figure 3). For example, if one wishes to classify an image as "haemorrhage" or "no haemorrhage," two final

layer neurons are appropriate (Zaharchuk et al. 2018).

# **Imaging applications**

Machine learning applications are not limited to lesion detection, although this remains the focus of most studies in the literature. Al has many possible applications in other aspects of medical imaging, such as image acquisition, segmentation and interpretation, other than detection.

Using AI, it may be possible to capture less data and therefore image faster, while still preserving or even enhancing the rich information content of MR images. This could be possible by training artificial neural networks to recognise the underlying structure of the images, and what

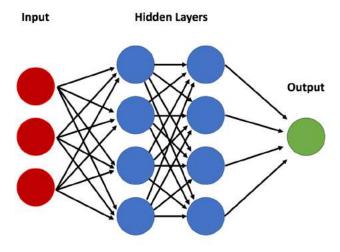


Figure 3. Artificial neural network example diagram

types of things tend to be clustered together. Facebook and New York University (NYU) have announced they are exploring how artificial intelligence can be used to make MRI scans 10x faster. NYU will provide Facebook with approximately 3 million MR images of the knee, brain and liver to help train its algorithms, including both images and raw scanner data. Furthermore, an intelligent MR imager may recognise a lesion and suggest modifications in the sequence to achieve optimal characterisation of the lesion.

Automated segmentation of medical images is an interesting application of machine learning. While manual

segmentation is still considered the gold standard, it has shown limitations in inter- and intra-reader reproducibility. Various studies have shown the potential of Al in this post-processing task, possibly with higher accuracy and

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reproducibility. One example is tied to the segmentation of the heart's left ventricle on 4D MRI exams that allows for a faster, automated assessment of cardiac function (Ngo et al. 2017). In this setting, various commercial products derived from machine learning are already available for clinical practice. Deep learning has been employed for unsupervised segmentation of breast tissue on mammographic exams, useful for reproducible scoring of breast composition, as required by current imaging guidelines (Kallenberg et al. 2016). A third interesting field to which AI has been applied for segmentation is musculoskeletal imaging, aiming to surpass previously used methods based on models and atlases (Pedoia et al. 2016). Probably the field where most advances have been made

is neuroradiology. Deep learning networks have shown great usefulness in automated segmentation of not only normal brain tissue and structures but also lesions (Akkus et al. 2017). Finally, interesting results have been shown on automated segmentation of whole-body scans, such as CT exams performed for staging purposes (Polan et al. 2016). The development of automated segmentation technologies provides the basis for further expansion of clinical applicability of machine learning as it contributes to solving one of its main limiting factors: time-consuming post-processing of exams.

Radiologists must examine a large number of images, and therefore support tools for the detection and localisation of relevant findings are desired. Automated detection of findings within medical images based on machine learning applications goes beyond classical computer-aided detection and computer-aided diagnosis, which have been used for decades.

For example, the introduction of lung cancer screening programmes will produce an unprecedented amount of chest CT scans in the near future, which radiologists will have to read in order to decide on a patient follow-up strategy. Several studies have been published exploring but also validating AI tools in the extraction of incidental findings such as pulmonary and thyroid nodules, in breast cancer screening and bone age analysis. Other applications include prostate cancer detection at MRI, determination of coronary artery calcium score, or

detection and segmentation of brain lesions (Choy et al. 2018).

Image interpretation can be one of the most challenging moments in daily radiological practice. A high level of expertise and knowledge in a specific field may be required to make the correct evaluation. One of the most common applications of machine learning is tied to the evaluation of pulmonary nodules, with studies showing good accuracy in cancer detection (Causey et al. 2018). Another field in which radiomic evaluation with advanced machine learning algorithms has produced interesting results is the classification of brain tumours. There are many studies showing the potential for molecular subtyping of gliomas using MRI, contributing to the choice of therapeutic approach while potentially avoiding use of invasive techniques (Lu et al. 2018). Breast cancer diagnosis has also shown potential as a clinical application of AI, both on mammographic and MRI exams after radiomic feature extraction. Classification of adrenal lesions is another setting in which machine learning has shown promising results, possibly reducing the need for intravenous contrast administration during MRI exams (Romeo et al. 2018). Currently, there is software already approved for clinical use that can diagnose, for example, the presence of intracranial haemorrhage, prioritising the exam reading in the context of daily practice, or identifying potential stroke patients, pre-alerting stroke unit members prior to regular radiological evaluation, reducing potential time waste in a critical setting

## Conclusion

The increasing inclusion of AI and machine learning applications in the daily radiological workflow could lead to improved quality of life and patient satisfaction. Timeconsuming tasks such as image segmentation could be automatised while better support for detection and interpretation of findings can be achieved.

# KFY POINTS



- Among the first applications of artificial intelligence is screening detection, decreasing false positive results
- The number of publications on artificial intelligence developed for medical imaging applications has dramatically increased in recent years
- Another objective of artificial intelligence in diagnostics is to classify diseases, enabling quantitative characterisation of local and diffuse disease
- Machine learning algorithms and neural networks will permit analysis of not only imaging findings but also electronic patient records and genomic data, to propose classifications and recommendations to radiologists to incorporate into their interpretation



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# Would you use a dirty ultrasound probe on yourself?

Making the ultrasound scan a safer examination

A sonographer and a microbiologist working together to increase awareness of infection control in the ultrasound world

ver the past few years, these two Australians have published extensively in the field of infection control in medical ultrasound practice. Whilst Sue performs ultrasound scans in her role as a research sonographer, Jocelyne has a PhD in microbiology and is passionate about infection prevention and control (IPC). It is this combination of these two professions that has been the key to the relevance of their articles. Their research journey began with Sue questioning what germs could be found on the ultrasound probes, cords, keyboards or in the coupling gel. Needing an offsider with a knowledge of microbiology. Jocelyne collaborated with Sue and used her networking skills to bring the project to reality. Swabs were taken of hundreds of surfaces across multiple ultrasound practices and the results revealed a magnitude of bacterial species, many posing a health risk to ultrasound patients (Westerway et al. 2017).

Following this research project, Jocelyne, as the Australasian Society for Ultrasound in Medicine's policy officer initiated a collaborative project to create guidelines with infection control experts from the Australasian College for Infection Prevention and Control (ACIPC). She co-led a working committee with ASUM and ACIPC and together both organisations produced the Joint Guidelines for Reprocessing Ultrasound Transducers (Basseal et al. 2017). These guidelines, published in the Australasian Journal of Ultrasound in Medicine (AJUM), were a world first collaborative team effort consisting of ultrasound practitioners, infection control experts and microbiologists.

Another major project has been with the World Federation for Ultrasound in Medicine and Biology (WFUMB) where, as members of the infection control task force, they created, dispersed and analysed a worldwide survey on IPC habits amongst ultrasound practitioners from every continent of the world. Over 1,000 respondents answered the global survey from developed and developing countries. Analysis of the data revealed that there was a lack of compliance of high-level disinfection, varied usage of probe covers and sterile gel for procedures. Furthermore. ultrasound practitioners had differing levels of training and knowledge in basic infection control practices. The results of this global survey will be published in Ultrasound in Medicine and Biology (UMB) (accepted; in press).

Recently, they completed a probe cover integrity research study, where commercial probe covers and condoms were assessed post-transvaginal ultrasound examination for any breaks. The results were presented at the recent International Society for Ultrasound in Obstetrics and Gynaecology (ISUOG) world congress (Basseal et al. 2018).

Both Sue and Jocelyne continue to research into best practices in infection prevention and control

within ultrasound. They have presented their data at numerous local and international conferences along with running interactive hands-on infection control sessions with trade at the ASUM conferences.

Their signature message "Would you use a dirty ultrasound probe on yourself?" has raised awareness of this important issue in ultrasound.



Would you use a dirty ultrasound probe on yourself?

They are changing the ultrasound world one probe at a time.

# How safe are the millions of ultrasound examinations that are performed daily around the world?

The literature suggests that the routine ultrasound scan may be a potential source of bacterial and viral contamination and that significant healthcare-related infections could be spread by failure of the operator to appropriately clean the probe and other ultrasound machine components such as the keyboard. handles and probe cords. Low level disinfection (LLD) should be performed on all surface probes used on clean, intact skin whilst probes used for intracavity scans, infected skin or open wounds require high level disinfection (HLD).

# Probes do not need to be visibly soiled to be contaminated with blood, bacteria or viruses viruses (Keys et al. 2015)

Although countries may have regulations in place that govern the appropriate disinfection and reprocessing of ultrasound probes, recent international surveys of ultrasound users have revealed a lack of understanding of the importance of, or poor knowledge of infection control issues. The infectious status of patients may not be disclosed to ultrasound operators at the time of scanning and so poses a potential risk to both the operator and subsequent patients if the probe has not undergone adequate disinfection. The surveys also looked at current reprocessing habits for transvaginal and transrectal probes which revealed that a common decontamination method was to remove the probe cover and wipe with alcohol. Some operators only cleaned the probe at the end of the patient list, relying on covers to protect the patient from cross-contamination. Would you like to be the last patient on that list?

With so many international organisations and societies producing guidelines, there is some consensus on disinfection recommendations following the Spaulding classification system (based on probes for non-critical, semicritical and critical items). Good guidelines for reprocessing ultrasound equipment should refer to relevant literature, incorporate local/national regulations, have collaboration between ultrasound societies and infection control experts. should include alternative methods for both LLD and HLD and consider the cost of compliance. Most importantly, ultrasound operators should undertake a basic infection prevention and control training programme to further their understanding and ensure that any potential risk of acquiring a healthcare-associated infection is minimised.

# Conclusion

To make the ultrasound scan a safer examination we need to address the lack of access, or operator compliance to, ultrasound infection control guidelines or protocols. Unfortunately, it may take a major infection incident to draw awareness to the importance of infection control standards for ultrasound practice.

# **KEY POINTS**



- The infectious status of patients may not be disclosed to ultrasound operators at the time of scanning and so poses a potential risk to both the operator and subsequent patients if the transducer has not undergone adequate disinfection
- A visibly clean probe may still be contaminated with blood, bacteria or viruses
- Efficient disinfection will significantly reduce the risk of crosscontamination for the ultrasound patient
- Good guidelines for infection prevention in ultrasound practice should be a priority
- Basic infection prevention and control training should be provided to all ultrasound operators



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#### Dirk-Andre Clevert

Head of Interdisciplinary Ultrasound Center Munich University Hospital

# US-elastography for superficial organs: update

US-elastography, introduced to clinical practice in the early 2000s, is today considered a useful additional tool to baseline ultrasound in different clinical fields.

everal papers, as well as the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB) and the World Federation for Ultrasound in Medicine and Biology (WFUMB) have published guidelines reporting on clinical value, recommendations, limitations and tips and tricks for the use of US-elastography. Furthermore, this year at EUROSON 2018, held in Poznan, the joint ESR/EFSUMB session had the title "Elastography of Superficial Structures: Where are we now?"

# Elastography of superficial structures: Where are we now?

The session, moderated by EFSUMB President Prof. Paul Sidhu and Chairman of the EFSUMB Publication Committee Dr Vito Cantisani was organised into four lectures:

- Thyroid US-elastography: indications and limitations
- Elastography of the breast: when should we assess tumour stiffness?
- Is there any value in tendon and nerve assessment?
- Scrotal elastography: hype or real?

The session was very well attended and the room was crowded. The stimulating discussion was animated by several questions which enabled better audience understanding. The session facilitated full appreciation of the widespread use of elastography of superficial structures, understanding of the strengths and limitations of current applications, appreciation of the potential in many fields, and finally the ablility to incorporate elastography into clinical practice.

# Strain- and shear-wave elastography

Dr. Cantisani provided his personal experience and an overview of the current literature, chiefly focusing on the published recommendations by EFSUMB and WFUMB, and some further insights into the upcoming EFSUMB guidelines concerning US-elastography thyroid nodule characterisation. To date, only a few published papers compare the accuracy of strain- and shear-wave elastographic techniques. Both the techniques appear to be useful in the multiparametric ultrasound evaluation, increasing the accuracy in this setting, explained Dr. Cantisani. Some promise has been shown by means of 2D and mechanical 3D US-elastography, postulated to be useful especially for the planning and follow-up of mini-invasive treatments. Dr. Cantisani explained that multiparametric evaluation remains warranted for the following:

 For breast tumour diagnostics it was stressed that elastography should be used in combination with

B-mode examination. Both strain- and shear-wave elastography can be used, and it was discussed whether strain-wave elastography may be preferable for evaluation of stiff tumours, whilst shear-wave elastography may be more reliable in soft tumours. The ways of combining elastography with the BI-RADS classification has been the topic of many articles, and for comparative evaluations of breast elastography studies, the awareness of the different combinations used is pivotal. Dr. Jonathan Carlsen. Rigshospitalet, Copenhagen, concluded that both strain- and shear-wave elastography should mainly be used as an adjunct for assessing probably benign (BIRADS 3) and low-suspicion tumours (BIRADS 4a), where elastography can be used to either upgrade or downgrade tumours.

#### Musculoskeletal disorders

Despite the increased number of articles about musculoskeletal diseases in the last few years, a limited increase in evidence level is observed. For Achilles tendinopathy, ultrasound elastography increased in evidence level from D to B with an expert indication grade of 3. In addition, the use of ultrasound elastography was scored with evidence level B and an indication grade of 1 for soft-tissue tumour examination. This is understandable as ultrasound elastography is designed to distinguish tissues with different stiffness, and it is believed that ultrasound elastography for soft tissue masses and nerve entrapment is a promising technique.

We have to acknowledge that most published studies related to ultrasound elastography are pre-clinical or feasibility studies currently insufficient to increase the clinical evidence level. However, the progressive implementation of musculoskeletal ultrasound with ultrasound elastography should produce studies with the potential to impact clinical practice. Prof. Klauser from Medical University of Innsbruck concluded that, at the moment, elastography impacts on tendon disease with Level 1b, recommendation 1, whereas nerves show a lower level of 2b. Further longitudinal studies in order to verify impact of elastography in musculoskeletal disorders in clinical routine examination is still demanded.

# Testis US-elastography

Finally, Prof. Bertolotto from University of Trieste updated the

current knowledge on testis US-elastography. He concluded that testicular lesions need a multiparametric assessment, mainly based on Colour Doppler US and CEUS, reserving the application of US-elastography to additional role. US-elastography, as reported in literature and discussed at Euroson 2018, is really an active research field, especially for superificial organs; experts should be aware of the indications, limitations and tips and trikcs to increase accuracy and reduce interobserver variability.

# **KEY POINTS**



- ✓ Published guidelines from WFUMB and EFSUMB were discussed, as were upcoming EFSUMB guidelines concerning US-elastography thyroid nodule characterisation
- Only few papers compare the accuracy of strain- and shear-wave elastographic techniques. The session discussed this
- The session updated the knowledge on the use of US-elastography in breast tumour diagnostics, mulsculoskeletal disorders and testicular lesions



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