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Monitor Me!

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Monitor Me!

mHealth has gained considerable momentum in recent years, but, contrary to common perception, mHealth is not limited to mobile health. It has a broad application across healthcare, including the use of biosensors, wearable personal technology, precision medicine, personalised care, patient engagement, and patient empowerment. We could say mHealth is the dream example of how technology and innovation intersect with healthcare, and it has the potential to revolutionise how we diagnose, treat, and manage patients.

The key, however, lies in realising its full potential. There is a great deal of talk about the opportunities that mHealth offers, but very little discussion on its limitations and how to effectively integrate it in healthcare. There are thousands of health applications out there, and most smartphone users have at least one mHealth app installed. But there is more to mHealth. There are nearly 300 million people in the US and the European Union with at least one chronic disease. Each could significantly benefit from wireless home monitoring and integrated medical devices - just one example of what mHealth has the potential achieve.

But how close are we to realising this potential? In Monitor Me, our contributors explore how we can make healthcare data work for both provider and patient and how we can better utilise mHealth tools to change the way cardiology is practiced. We also examine how mHealth could work in parallel with healthcare consumerism for a better patient experience plus how we can improve patient compliance through mHealth.

Our focus on mHealth makes a fitting backdrop to the theme of the 28th congress of the European Association for Hospital Managers (EAHM) in Ghent, Belgium from September 11th to 14th. The congress will bring the latest developments in Big Data and digital health, finance and health economics, architecture, and governance and ethics into focus. In our Spotlight section, we feature Danny Havenith, Congress Chairman who talks about the unique experience that the Congress will offer. We also feature Arthur Feldman, Professor of Medicine at the Lewis Katz School of Medicine who talks about the future of cardiovascular disease treatment and management.

In our Management section, experts weigh in on educating physicians to be leaders, addressing the skills and strategy gaps in HIT, nursing and cutting edge technology, and the benefits of branding your hospital. In our Winning Practices section, we explore the future of nuclear cardiology, effective cardiovascular prevention strategies, the use of inotropic agents for heart failure and recognising gender and treatment differences in cardiovascular disease. We also look at Eurosafe's journey to strengthen medical radiation protection and highlight the #pinksocks movement which helps people connect by sharing stories. Our patient perspective includes an individual's take on dealing with cancer; and the importance of reducing medical errors.

We hope this journal will provide you valuable information. As always, we welcome your news and views. ■

Happy Reading!

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DISCLOSURE
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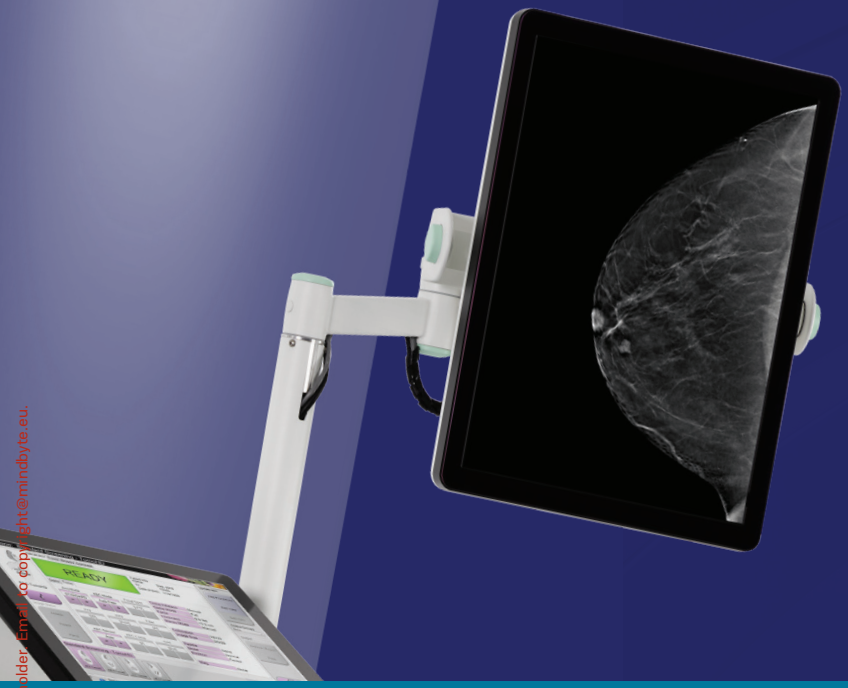

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COVER STORY : MONITOR ME

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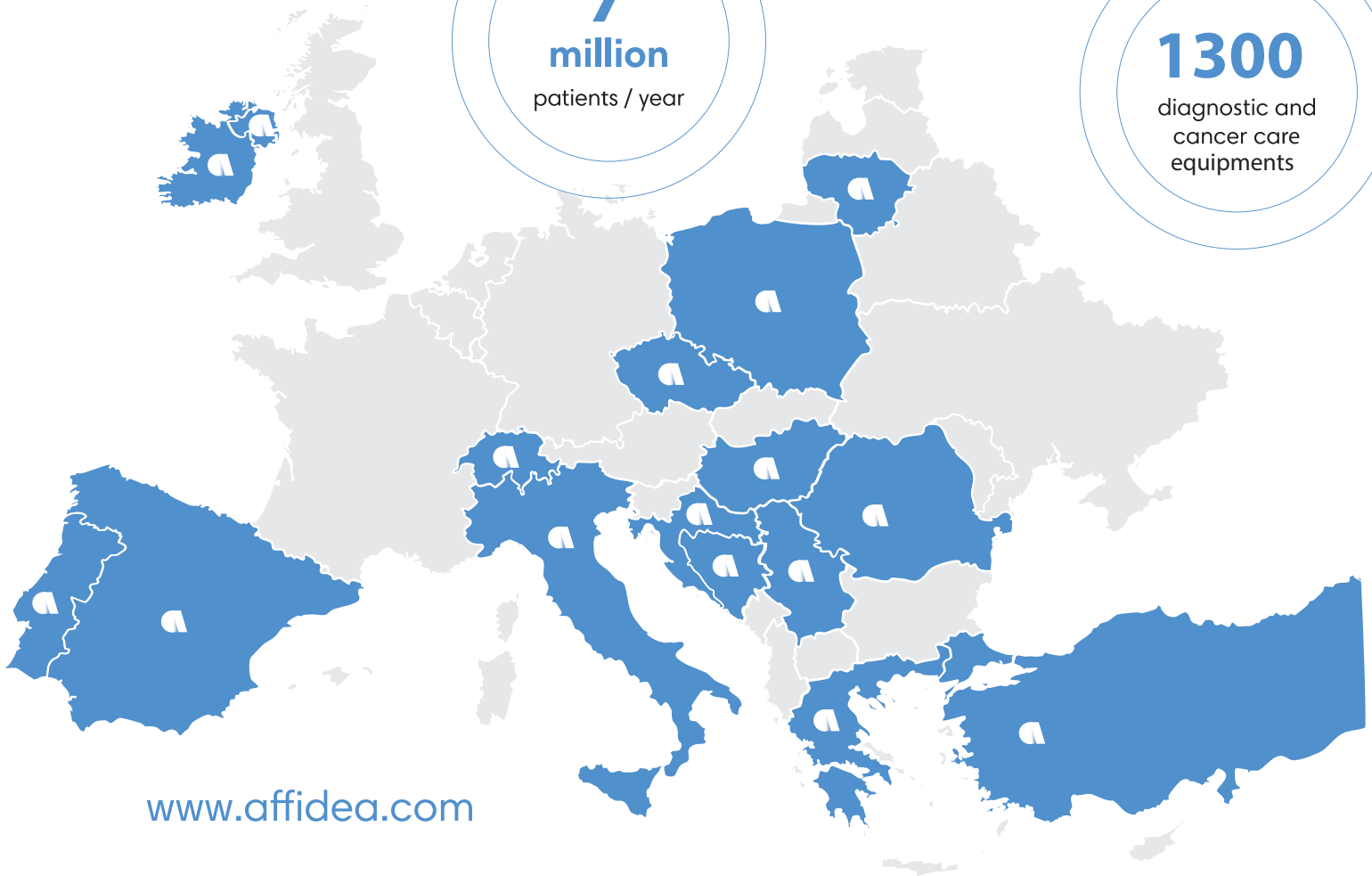

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Innovation and a Unique Experience at EAHM 2019

The 28th congress of the European Association of Hospital Managers (EAHM) will take place in Ghent in Belgium from September 11–14. Danny Havenith, congress chairman spoke to HealthManagement.org and shared the unique experience that will be offered to participants at the EAHM Congress 2019.

The congress theme of Innovative Healthcare Strategies encompasses the following areas: Big data & digital health; Finance & health economics; Smart buildings & logistics; Health management, governance & ethics; Innovation & technology; and Healing architecture. Which of these areas do you think hospital managers across Europe need to prioritise in order to improve care quality?

The theme of the EAHM 2019 Congress is: Innovative Healthcare Strategies. It sheds light on a key issue that should occupy the CEOs of hospitals in Europe, indeed throughout the world: innovation. Innovation is the engine of the future, anticipates future success, and enhances the quality of healthcare providers. Thus, all six themes are also quality issues, each of which in their own way gives the managers and guests of the Congress input for their daily actions. This is applicable to the quality in medicine and nursing, but also in technology, paramedicine, administration, and management. It is about exchanging experiences and developing visions among the participants. It is about doing the right things in the right way.

Can you give some examples of hospitals across Europe that are working effectively and leading the way in any of the above areas?

The six selected Belgian hospitals that can be visited during the Congress are places where this innovation can be seen, especially in the topics that are specifically offered there. But I am also pleased that we have found intersections in cooperation with industry. We all work towards the same goal: to provide high quality and innovative health service that puts people first.

For the Inauguration Ceremony, we have asked two people for a keynote speech - people who live this vision: Prof. Fidelos Soh, CEO of Tan Tock Seng Hospital, Singapore & Central Health, National Healthcare Group, and Paul Stoffels, Chief Strategic Officer, J & J worldwide. They will give us a glimpse into the future they already live in their businesses.

In your Congress video address, you mention the need for open minds and networking. How do you encourage this at the event?

We as organisers and members of the Belgian Hospital Managers Association have put our vision under these very keywords: to reach excellence, to remain open-minded, to follow innovation in the sector, and to cultivate friendship with colleagues. These four aspects are the cornerstones of the community of a Congress that brings together managers.

The Belgian Association of Hospital Managers has worked to create an impressive network amongst six hospitals that has addressed critical areas such as digital transformation and finances. What insights will you be sharing with delegates on how this network works?

The Congress theme is, as already indicated: Innovative Healthcare Strategies. We have also created a new concept in the organisation and pedagogy of the Congress. Instead of organising an ex-cathedra congress in which 500 participants sit together in a conference room and listen to the

lectures and impulses, we have decided on a decentralised concept.

The participants vote for two of the six proposed topics that you have already mentioned. To do this, you leave the conference centre on two half days of the three-day congress and go in smaller groups of 80 people max in new innovative hospitals. By creating small groups, we will create communication among the participants. Interested people on a particular topic will get together in a dynamic process. This offer creates a great logistical challenge for the participants' exchange and for us, organisers, which we will handle with professional partners on-site.

What will delegates see on visits to future-proof hospitals?

The participants will have special offers in hospitals. Each session is presided by a chairman, and there will be an academic contribution. The other speakers are contributing from the industry. The second part includes a visit to the hospital to present innovative projects from the hospital and industry partners. The visit starts with the bus ride — a kick-off video introduces visitors to the hospital and the subject.

Not to be forgotten and, of course, worth mentioning is also the plenary sessions in the conference centre. In addition to the inauguration ceremony, which we talked about earlier, there will be a very dynamic workshop on innovation, including spin-off ideas and other sectors, and giving input to CEOs.

Last but not the least, we are organising an Innovation Award for the first time in cooperation with the European Association EAHM. So, the Congress offers many facets, and there is something for everyone. The social programme provides an adequate framework so that the exchange between the participants is effective and sustainable.

Innovative Healthcare Strategies

Six Themes, Six Hospitals

The European Association of Hospital Managers (EAHM) Annual Congress focuses on six main themes this year, Big Data & Digital Health; Finance & Health Economics; Smart Buildings & Logistics; Health Management, Governance & Ethics; Innovation & Technology; and Healing Architecture. EAHM 2019 aims to explore these themes by linking their implementation to different hospitals and centres around Belgium.

The digitalisation of healthcare has meant that data is now more accessible. **AZ Groeninge Kortrijk** has made digital health and big data a focus by the implementation of their integrated computerised patient record. The safeguarding and coordination of health data in systems such as this will be explored at EAHM 2019.

EAHM 2019 will also aim to focus on finance and health economics and the long-term benefits of investing in technology and prevention. The efforts of **Delta CHIREC Brussels** in the investment of their new site along with their neighbourhood centres demonstrates the group's aim to offer high-quality care in a multidisciplinary approach.

The development of smart buildings will also be explored at EAHM 2019. Intelligent hospitals need to be able to utilise technology for the benefit of the patient, whilst also evolving with our constant need to provide personalised care. The new phase of construction at **AZ Delta Roeselare** shows exactly how smart architecture and logistics have been prioritised.

With the digital revolution comes a new change in priorities. At EAHM 2019, the benefits of the digital revolution to both patients and care providers are explored and the subsequent changes that are needed to take place in healthcare to accommodate this. **UZA Antwerp** prioritises these governance and ethical concerns in its continuum of care.

To make progress in the face of technology and the mass of medical data available, we need to innovate. Strategies for innovation and technology, for example, those from **AZ Maria Middelares**, will be examined at EAHM 2019. AZ Maria Middelares aims to simultaneously provide high-tech healthcare along with basic care, making it an efficient hospital constantly striving for quality.

Hospitals' aim to get patients back to their comforts and the importance of healing architecture is the final theme to be explored at EAHM 2019. **AZ Zeno Knokke** is always innovating demonstrated by its slogan 'This is not a hospital.' The centre thrives from the benefits of unique architectural designs to deliver care of high quality.

What do you hope delegates will take away from the 28th EAHM Congress in Ghent?

We hope that the delegates of EAHM2019 Congress will go back to their hospitals and do their daily business a little differently, putting ideas and vision into practice, so that the patient feels that "appropriate and optimal health care is offered here." Maybe the Congress will also help make new innovative discussions between key players in the hospitals possible. That would be a nice reward for our efforts.

What changes do you think are necessary to be implemented in hospital management by the EAHM 2020 congress in Budapest?

Each national association - the organiser of the congress, sets its priorities. We have a wonderful team in Belgium that organises the Congress. It is already in contact with the Hungarians to exchange best practices. In the same way, I thank all the Portuguese colleagues who organised the Congress in Cascais in 2018 for all the support we have received. ■

Reducing Risks and Generating Economic Benefits

Did you know that IV filtration in an intensive care unit (ICU) could help to reduce risks and generate economic benefits?

Dr. med. Lydia Unger-Hunt
lydia.unger@gmail.com

Introduction

Intravenous administration of fluids and drugs is an important part of patient care for the critically ill. However, the contamination of infusion solutions by particles is a largely unknown and underestimated side effect of intravenous therapy, which can lead to particle-induced mechanical blockage of vessels and the development of pulmonary foreign body granulomata.[1, 2, 3, 4] In an intensive care setting, the particle burden may rise up to one million infused particles per day, increasing with the complexity and quantity of the administered infusions.[3, 5]

During the EAHM congress in Cascais, Portugal in September 2018, Dr. Michael Sasse, leading senior physician of the PICU at Hannover Medical School (MHH), showed that implementing standard operating procedures for infusion management and the use of in-line IV filters significantly lowers the occurrence of SIRS and the length of stay in the ICU by 23%. Based on these results, the MHH was able to increase the capacity in its ICU, which also had important economic effects.

Particulate Contamination: Why is it a Problem?

The contamination of infusion solutions by particles is a widely unknown and underestimated side effect of intravenous therapy.[1, 2] Particulate contamination is due to drug incompatibility reactions or their incomplete reconstitution during the preparation process.[6] Various studies have demonstrated the contamination of infusion solutions with glass particles from opening glass ampoules, particles from rubber stoppers or conglomerates of the parenteral nutrition components.[7,8] Particles have also been shown to be inherent to generic drug formulation.[2]

If these particles are not eliminated, they will enter the patient, with potentially severe consequences such as organ damage (lungs, kidneys, liver, bone marrow), particularly in organs that were damaged before. It is therefore important to optimise infusion therapy in order to minimise medication errors and particle load. In-line filtration has been shown to prevent the infusion of particles almost completely.

Clinical Trial Methods

The aim of the study published by Dr. Sasse and his team was to evaluate the impact of in-line filtration of particles with respect to severe complications such as systemic inflammatory response syndrome (SIRS), sepsis, thrombosis, and organ failure in critically ill patients.

A single-centre, prospective, randomised controlled trial was conducted. A total of 807 children under 18 years of age were randomly assigned to either a control group (n = 406) or a filter group (n = 401), with the latter receiving in-line filtration.

The primary endpoint was a reduction in the rate of overall complications – SIRS, sepsis (defined according to the International Paediatric Sepsis Consensus Conference[9, 10]), organ failure, and thrombosis – whereas secondary objectives were a reduction in the length of stay in the intensive care unit and overall hospital stay.

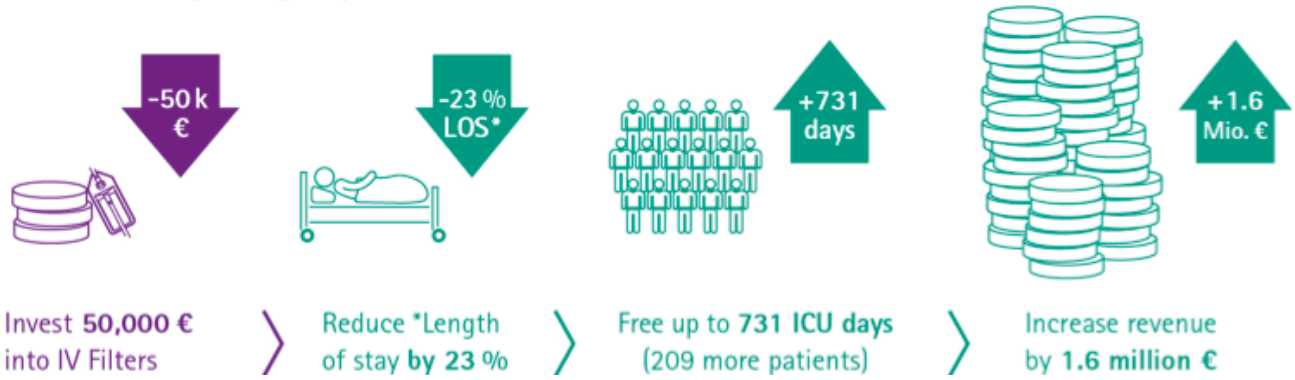
The filter group received in-line filtration throughout the period of infusion therapy, with eligible fluids administered via in-line IV filters. The appropriate IV filters –

- 1.2 µm pore size for infusion of lipid-containing admixtures;
- 0.2 µm pore size positively charged filters for aqueous solutions –

were arranged in the lumen of each venous catheter. IV filters for lipid containing infusions were replaced after 24 hours, IV filters for aqueous solutions were changed after 72 hours of regular use, or in cases of blockage.

Results of Clinical Trial

Analysis showed that in-line filtration significantly decreased the overall complication rate for the filter group (40.9% versus 30.9%; p=0.003). A significant difference (p=0.003) between the control and filter groups was detected concerning the time to first occurrence of any complication per patient: the median event-free duration for the control group (7.0 ± 0.2 days) differed significantly from that of the filter group (10.0 ± 1.9 days).



The incidence of SIRS was significantly lowered from 30.3% in the control group to 22.4% in the filter group (p= 0.01).

Additionally, the use of filters led to a significant reduction in the length of stay in the intensive care unit. The length of stay at ICU could be reduced by 23% (3.89 days versus 2.98 days; p=0.025).

"Because 12 to 18-year-olds are like adults when it comes to factors such as the capillary bed, we can safely assume that the effect must be the same in adults," comments the expert Dr. Michael Sasse.

Economic Impact of IV Filtration

Dr. Sasse can also prove that using filters make financial sense: the length of ICU stay can be decreased by an average of 21.75 hours per patient, representing a 23% drop. Almost an entire day can thus be saved – a substantial economic advantage.

Together with his team, Dr. Sasse evaluated ICU costs, which were found to be around 1,800 euros per patient per day, with an average refund of around 8,000 euros per ICU patient from the health insurers.

"The 23% shorter length of ICU stay that we found in our study translates to around 21.75 hours per patient. For 807 patients per year this would free up 731 ICU days per year, which means that we could treat 209 more patients per year." In turn, this also leads to an increase in revenue for the ICU of around 1.6 million euros per year. The additional costs for IV filters for 807 patients came to 50,000 euros per year, an amount that is somewhat dwarfed in respect to the improved outcome.

Other economic aspects should be considered as well: "Less severe complications result in fewer drugs such as antibiotics, reduction of organ replacement, medical staff workload and also a decrease in costs for diagnostic procedures. Being able to release patients sooner also increases the flexibility of ICU allocation and the capacity for surgeries."

For the ICU at Hannover Medical School, the results of the study also mean that no patients have to be turned away due to lack of capacity. Or to make it snappier: "shorter length of stay equals treat more patients equals save more lives," says the German intensive care specialist.

KRINKO, the German commission for hospital hygiene and infection prevention, which is part of the Robert-Koch-Institute and has a similar standing in Germany as the CDC or FDA, has taken on these study results. Since 2016, this body has recommended that in-line particle IV filters with pore size 0.2 µm should be used in infusion systems of intensive care patients to decrease the amount of SIRS and to eliminate air bubbles from infusion solutions (recommendation cat. II).

Conclusion

The conclusion of Dr. Sasse is clear: "Managed infusion therapy with in-line IV filters will increase patient health and significantly lower the length of stay at the ICU but also have a positive financial impact on the hospital and the national economy."

This article is based on a lecture by Dr. Michael Sasse, MHH, at the EAHM congress from 26-28.09.2018 in Cascais, Portugal. ■

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transforming Colorectal Surgery Outcomes

How End to End Enhanced Recovery and Prehabilitation Transformed Colorectal Surgery Outcomes

Dr. Gerrit Slooter
MD, PhD, Surgical Oncologist

Complications in all types of surgery place a significant burden on patients' quality of life and on all clinicians involved in the care pathway. In laparoscopic colorectal surgery, anastomotic leaks are of great concern to surgeons and can place considerable economic pressure on a hospital.

As a specialist center for colorectal surgeries in the Netherlands, the Máxima Medical Center (MMC) decided to face colorectal complications head on. In doing so they uncovered multilayer pressure being exerted on facilities with a three- to four-fold increase in the cost of care involving anastomotic leakage. Surgeons also reported a considerable mental burden associated with supporting patients and their caregivers through the complication.

Since 2004, MMC has been at the forefront of developments and quality assurance for colorectal surgery in the Netherlands as one of the country's first hospitals to offer a laparoscopic solution for all bowel operations. In the same year, they also introduced peri-operative care for laparoscopic colorectal surgery according to enhanced recovery principles, including Enhanced Recovery After Surgery (ERAS®) protocols.

To further elevate standards, in 2015 the center reflected on their results from the 2012–2014 National Dutch Institute for Clinical Auditing. Although results were average, they wanted to optimize their care pathway and ERAS® compliance by taking a multidisciplinary, value-driven approach to revitalize ways of working.

Importantly, achieving sustainable results would only be possible through multidisciplinary stakeholders' involvement in and responsibility for designing improvements. So, in 2015, MMC convened 140 hospital department members in dedication to a new colorectal care pathway and renewed focus on compliance. This session served to both raise awareness and achieve alignment on the importance of a new pathway.

A fully integrated approach to pre-, peri-, and postoperative care resulted, and the Colorectal Care 2.0 program was born, shortly followed by Colorectal Care 3.0 in 2016 incorporating a 4-week period of prehabilitation. This four-pillar, multimodal program was designed to optimize treatment outcomes by preparing patients between diagnosis and surgery.

Implementation has quickly shown a marked improvement in patient outcomes. MMC results from the National Dutch Institute for Clinical Auditing for 2015–2017 versus 2012–2014, show reduced:

- median length of hospital stay down from eight days to four
- frequency of patient complications within 30 days post-surgery down from 26.5% to 11.9%
- mean comprehensive complication index (CCI) postoperative morbidity score down from 10 to six
- incidence of anastomotic leakage down from 8% to 2.5%.

In an international randomized controlled trial, four weeks after surgery, 86.0% of patients who underwent prehabilitation reached their pre-operative health status (as measured by six strength and fitness tests) compared with 40.0% of patients in the control group. In 2018 MMC, a national and international prehabilitation leader, began introducing prehabilitation into other care pathways including liver surgery, bladder surgery, and lung surgery, amongst others.

Dr. Gerrit Slooter, MD, PhD, Surgical Oncologist and team lead of this journey to excellence at MMC, shared: "The program was an integral part of the hospital's success in driving integration to deliver improved outcomes. Introducing this protocol ensured that the care pathway encompassed treatment from the point of diagnosis to the end of patient follow-up.

"It is the condition of the patient that determines the outcome and not the quality of the surgeon. Thus, focus on prehabilitation and enhanced recovery principles for laparoscopic surgery patients at MMC has elevated outcomes to the high standards expected of a specialist center."

To learn more about what was achieved at MMC via a white paper entitled *Improving Outcomes Through the Implementation of Enhanced Recovery and Prehabilitation in Colorectal Surgery*, or to contact the Johnson & Johnson CareAdvantage team about how you'd like to enhance value in healthcare, visit:

www.jnjmedicaldevices.com/en-EMEA/service/care-advantage.

Meet the CareAdvantage team on Stand 22 at the European Association of Hospital Managers (EAHM) congress in Ghent, Belgium, 11-14 September 2019 and sign up to attend one of two *Big Data and Digital Health congress* workshops. ■

Hypertension – Prevention is Better Than Cure

How can we get the most common, costly, and modifiable cardiovascular risk factor under control?

Dr. Jürgen Fortin
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Cardiovascular disease (CVD) is the number one cause of death with an upward trend beyond 30% and a tripling in costs between 2010 and 2030, placing a significant economic burden on public healthcare services.[1,2,3] The most common risk factor for developing CVD is hypertension[1] affecting one billion individuals worldwide.[4] The challenge for specialists is that hypertension being the most "modifiable"[1] risk factor, very often remains undetected and symptom-free at an early stage and is only treated when it has already become a long-term disease.

So it is critical for cardiologists to understand the influencing factors in order to predict or detect early and prevent this widespread disease.

In a new study publication with the Task Force® Monitor (TFM) in the Journal Nature, Man et al. investigated the essential cardiovascular parameters of five large consanguineous families to find out if hypertension is heritable and if it depends on genetic and/or environmental factors. The study team described "moderate heritability for blood pressure"[5] and found environmental factors more significant.

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Other TFM studies described the positive impact of physical activity on the cardiovascular system.[4,6,7] Considering that "physical inactivity is now the fourth leading cause of death worldwide,"[8] the correlation seems obvious. Also the kind of exercise can influence efficacy as isometric exercise training has a higher positive impact on resting arterial pressure than traditional aerobic and resistance training.[4] Physical training therefore not only supports the therapy for hypertension patients but also plays an important role as an efficient preventive measure.[6]

Risk prediction approaches and powerful monitoring tools help identify potential hypertension patients "for timely prevention and treatment at an early stage before obvious symptoms happen."[3]

There is also evidence that long-term complications of undetected, untreated or ineffectively controlled hypertension can also lead to cerebrovascular diseases, an impairment of the cognitive function and even organ damage. Early detection and promptly initiated antihypertensive management can reverse these implications.[9]

We can conclude from these findings that we can contribute to a better cardiovascular health by making the "most common, costly, and preventable CVD risk factor"[2] an avoidable one. This might finally lead to the efficient reduction of the terrifying number of hypertensive patients and the high cost for health organizations. ■

REFERENCES

For full references, please email edito@healthmanagement.org or visit https://iii.hm/x5h

Better Insight*, **Better Peace of Mind**

Enhanced diagnostic accuracy of screening mammography with the use of Artificial Intelligence

Katia Katsari

Chief medical Physicist Affidea, Project Leader AI Operations and Dose Excellence

Breast cancer is the most frequent cancer among women, with an estimated incidence of 560,000 cases in 2018, in Europe.[1] The World Health Organisation (WHO) estimated that 627,000 women worldwide,[2] out of which 150.000[2] only in Europe, died from breast cancer, in the same year. In order to improve breast cancer outcomes and survival, early detection is critical. For this reason, many European countries have successfully introduced breast cancer screening programmes.

Affidea breast**Insight|Mammography** is a recently launched Artificial Intelligence (AI) clinical product to streamline and improve the clinical performance of screening mammography and drive the earlier detection of breast cancer. It is powered by TransparaTM, an FDA cleared and CE approved AI solution for breast cancer screening of ScreenPoint Medical. TransparaTM uses deep learning algorithms to automatically detect lesions suspicious for breast cancer in 2D and 3D mammograms and has been validated for multiple vendors and mammography models. The software categorises mammograms on a 10-point scale indicating the risk of cancer.

The Transpara™ Score can be used to triage examinations and help radiologists to prioritise patients for further investigation. CAD marks for calcifications, soft tissue lesions and interactive decision support are provided to support radiologists to interpret the images with higher accuracy. Studies have shown that the AI solution matches the performance of breast imaging radiologists,[3] and can be used as a second opinion. In this way, doctors can gain a better and more accurate insight[4] and patients, the peace of mind that any woman should have when undergoing a mammography examination.

Affidea breast**Insight|Mammography** brings benefits to all stakeholders, and most importantly, to both women who need to undergo screening mammography and their referring physicians:

A Faster Diagnostic Pathway for their patients

Effective triage of mammograms with low likelihood of malignancy allows radiologists to focus on the high-risk cases[5] which will allow doctors to get a faster diagnosis for their patients.

Enhanced diagnosis which results in reduction of unnecessary recall rates and false positive findings (fewer biopsies), giving women who undergo a mammography the peace of mind they deserve.

Improved clinical accuracy and diagnostic confidence[4]

The AI solution matches the performance of a breast imaging radiologist[3,4] and can be used as a second opinion reader to improve diagnostic outcomes. ■

"This is our second AI innovative project that we embed across our European Network with the goal of expanding precision medicine, improving accuracy and driving a faster, more personalised breast imaging diagnosis with the help of advanced artificial intelligence solutions. In this way, we support our doctors to take full advantage of the AI tools which allow them to foster diagnostic confidence and ultimately, to save more lives. Our vision, our digital and clinical capabilities and our experienced teams across 16 countries provide us with a unique opportunity to significantly improve the delivery of patient care."

Giuseppe Recchi
CEO, Affidea

"We are pushing the boundaries in terms of enhanced productivity, increased diagnostic accuracy, more personalised treatment and ultimately, improved clinical outcomes with an outstanding patient experience. The new AI solution that we are implementing in our countries, Transpara™, will provide our doctors with an automated clinical decision support that can boost reading performance and faster distinguish between healthy and tumour tissue, thus increasing diagnostic accuracy."

Prof. Rowland Illing
Senior VP, Chief Medical and Digital Strategy Officer, Affidea

Affidea at a glance:

- Multinational healthcare provider, with presence in 246 centres across 16 countries in Europe, providing high quality affordable care for millions of patients every year.
- Working with over 7,500 professionals, producing 13 million scans every year.
- Affidea is the only healthcare operator in Europe to sit on the Imaging Advisory Board of IBM Watson Health and also sits on Microsoft Cloud's board.
- 50% of the European winning centres awarded by the European Society of Radiology belong to Affidea.

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The Future of Cardiovascular Disease Treatment and Management

Arthur M. Feldman, MD, PhD, Laura H. Carnell Professor of Medicine at the Lewis Katz School of Medicine at Temple University, has been recognised with the 2019 Distinguished Scientist Award-Basic Domain by the American College of Cardiology. Prof. Feldman has received this honour due to his contribution towards improving cardiovascular health and enhancing patient care. His research has focused primarily on the molecular biology of dilated cardiomyopathy and heart failure. HealthManagement.org spoke to Prof. Feldman about his many contributions in the field of cardiology.

You will be receiving the 2019 Distinguished Scientist Award-Basic Domain by the American College of Cardiology (ACC) in honour of contributions to the cardiovascular profession. Can you highlight your key achievements which resulted in this honour?

The major contribution I've made is that I've trained a large number of graduate students, medical students, and particularly cardiology fellows – both in my lab and when I was either a Chief of Cardiology or a Chair of Medicine, and I've also had the opportunity to mentor some superb young scientists over the past 30 years. I think that their success has been my most important achievement. In terms of work, I've focused on understanding the molecular and cellular biology of dilated cardiomyopathy and heart failure using the human heart as the model to identify potential targets and then moving to mice and cells to understand the molecular and cellular pathways. As a result, we were one of the early cardiology labs to use transgenic mice to understand the biology of heart failure. One example occurred around 1989 or 1990 when we discovered that the hearts of patients with dilated cardiomyopathy expressed abnormal amounts of the pro-inflammatory cytokine TNFa. When we over-expressed TNFa in mice, we found that the mice developed heart failure. Unfortunately, when we tried to treat patients with heart failure with a medication to diminish circulating levels of TNFa it worked in Phase 1 and Phase 2 trials but failed in Phase 3 trials – so we had to go back to the drawing board. Although there is some evidence that the TNFa story is reigniting.

Your area of focus has been the molecular biology of dilated cardiomyopathy and heart failure. Can you highlight the areas where you have already made a difference and where you plan to make a difference in future with your research?

I think that what we are working on right now – and have been working on for the past eight years is one of the most exciting things that I've done and has the best chance of improving the health of patients with heart failure. It's a pretty incredible story that really evolved over time. In 1983 I was the resident in the cardiac care unit at the Johns Hopkins Hospital when we admitted a young woman from PA who had a markedly dilated cardiomyopathy and was only 22 years old. She sadly passed away because it was two or three years before we had heart transplantation at Hopkins when they recruited two superb surgeons from Stanford – Bruce Reitz and William Baumgartner. Move forward to 2002 when I received a call from one of my colleagues at Jefferson. He had seen a patient with a dilated cardiomyopathy who had two

children with heart failure, a sister with heart failure and a niece who had heart failure but was deceased. I worked her up, and clearly, she had a familial dilated cardiomyopathy. So I met with as many of her relatives as I could find, drew blood to extract the DNA. It took us almost 10 years, for a variety of reasons, but mostly we didn't have enough affected family members to perform traditional linkage analysis. But in 2012-2013, a colleague in Colorado named Matt Taylor had received funding from the NIH to perform whole exome sequencing, and actually, the cardiologists at Denver were caring for one of the family members. We sent all of our DNA and all the information we had to Matt, and he sequenced the DNA and found a mutation in a gene called BAG3. We were then able to show that the mutation resulted in the levels of BAG3 to be about half of normal – what we call haploinsufficiency.

But here is where the story gets interesting. I was writing the paper to report our finding, and I wanted to make sure that the young woman who was deceased had, in fact, a dilated cardiomyopathy and not some other form of heart disease. To make a long story short – the family helped me to get her chart. She had been hospitalised at Hopkins – and when I got the chart, I realised that she was the young woman who had led me to go into heart failure in the first place.

We were not the first group to identify mutations in BAG3 as causing dilated cardiomyopathy. In fact, the first was Ray Hershberger, a colleague at the University of Miami who had spent a few months in my lab when he was a cardiology fellow. But we were the first to show that the disease-causing mutations caused haploinsufficiency and we were the first to make a mouse model with a heterozygous knock out (haploinsufficiency) and show that it resulted in a dilated cardiomyopathy. But perhaps the most important finding was that patients without a BAG3 mutation – but with heart failure – also had 50% reductions in the levels of their BAG3. Because if BAG3 levels were decreased, we could possibly treat these patients by using gene therapy to increase BAG3 levels. In fact, we have demonstrated in four different mouse models of heart failure that we can cure the mice by over-expressing BAG3 in the heart. In addition, we are now working to move this technology into patients – first performing efficacy and toxicity measures in a large animal model of heart failure.

"GENE THERAPY IS THE TREATMENT STRATEGY OF THE FUTURE"

What role do you think gene therapy can play in tackling cardiovascular disease?

I think gene therapy is the treatment strategy of the future. However, it is in its infancy because we have to focus on patients with mutations that cause haploinsufficiency – where large pieces of DNA have been deleted from the gene or truncations where a large piece of the gene has been cleaved off. In both cases, gene therapy is really what we call "gene replacement therapy." In the case of BAG3 mutations, we know that the predominant genetic variant that causes HF, approximately 80% of the time, is a truncation or a deletion leading to haploinsufficiency. Thus we are putting back in something that is missing – one allele of the gene. But like anything else, gene therapy does have some limitations. About a third of the population has antibodies to the viral vectors and therefore can't receive therapy and point mutations can be associated with a dominant negative effect of the transduced gene resulting in an adverse effect. As a result, there is still a lot of work to be done. Nonetheless, for that group of patients that are amenable now to the therapy, we believe gene therapy will have an enormous impact.

Can you give your views on the role of precision medicine in heart failure?

We know that when we give a medication to a patient with heart failure – and the same can be said for many diseases – that many patients – if not most of the patients – will have no response and some may actually have a worse response. One element that causes this differential response is genetic differences. We can see a lot of examples, but the best example in heart failure is the fact that the combination of hydralazine and isosorbide dinitrate is beneficial in individuals of African ancestry but has no effect in individuals of European ancestry because it works in black heart failure patients but not in white heart failure patients. The study that showed the benefits in African ancestry was, of course, the AHeFT study. Dr. Dennis McNamara at the University of Pittsburgh, my second recruit after arriving at Pittsburgh in 1994, has been studying this phenomenon in a study called GRAFH and in GrAFH 2, and we have participated in those studies. Dennis' lab sequenced the DNA from patients enrolled in AHeFT, and we found that there were unique genetic variants that appeared to be more prevalent in individuals who responded than in patients who didn't respond. One of the most interesting was the beta subunit of the G protein – a protein that I studied back in 1986 when I first went into the lab. Dennis has just led a superb prospective and randomised study to assess prospectively whether we can really use variants in this protein to identify who will and who won't respond to this combination of drugs. Here in Philadelphia, we recently sequenced BAG3 in heart failure patients of African ancestry and found four unique genetic variants that in aggregate predicted a worse outcome – but were not causative of disease. And I think that we will find the same to be true for almost all drugs that we now use for treating patients with heart failure.

We are now the Philadelphia site for an NIH-sponsored study called All of Us – Pennsylvania which is led by Dr. Steven Reis, at the University of Pittsburgh – my first recruit who moved with me from Hopkins in 1994. Participants at centres across the country will be genotyped and will provide access to their medical records. The study is the outcome of the $100 million Precision Medicine Initiative that President Obama announced shortly before leaving office. This study will be a game changer because it will provide both genetic and phenotypic data from one million Americans – creating a resource and investigational infrastructure that will provide investigators with data for much of the rest of this century. Our focus will be on enrolling participants from the largely African Americans and Hispanic communities of North Philadelphia.

The prevalence of cardiovascular disease continues to increase. What measures do you think can be taken to reduce this prevalence?

First, we have to decrease the incidence of socio-economic factors that have been clearly shown to increase the risk of cardiovascular disease. In fact, individuals of African ancestry have a much higher incidence of non-ischaemic heart failure, and socio-economic factors appear to play a role along with potential genetic factors. Second, we have to reduce the many risk factors for cardiovascular disease that are over-represented in urban populations – smoking, obesity, diabetes, untreated hypertension, some recreational drugs, excessive alcohol, high cholesterol, and high-fat diets and inactivity. As part of our All of Us programme, we have partnered with a local church in Philadelphia and a church in Pittsburgh to test the hypothesis that a place of worship can also be a place of healing and that linking that with genetics can be a powerful tool for improving population health. Second, we need to identify individuals at risk earlier in the course of their disease – treating high blood pressure early on, sophisticated care of diabetics and therapy of hypercholesterolaemia. And then, we need to ask every patient whether they have first degree relatives who have the same disease. If they do – they likely have a genetic variant that is causing their disease. We have to recognise that different populations have different aetiologies for their disease in terms of genetics but also in terms of habits, environmental risks, and social risks. In fact, there is strong data showing that the house that a person lives in has a lot to do with their disease risk and what diseases they develop. Temples located in North Philadelphia, is the poorest urban neighborhood amongst the larger U.S. cities. We see lots of patients who can't pay for their medicines, who don't have anyone at home to help them, and can't afford the healthy foods that you and I eat regularly such as fish, fresh vegetables and fresh fruits.

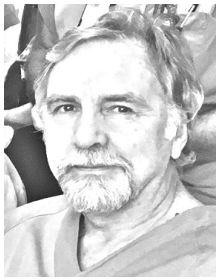
"ALL OF US IS A PROMISING INITIATIVE THAT CAN MAKE PRECISION MEDICINE A REALITY "

Based on your research, are there any new therapeutic agents and/or advanced treatment strategies that you think can be more effectively used to manage cardiovascular disease and improve patient outcomes? Any preventive strategies that you recommend?

I think that the future is precision medicine – and that the driving force that will change the way we take care of patients will be studies like All of Us that will provide the infrastructure to make precision medicine a reality. By combining genomic data with extensive phenotypic data we will one day soon be able to give the right drug to the right person and avoid giving anyone the wrong drug. In addition, the development of viral vectors that are trophic for a single organ and non-immunogenic will allow doctors to use gene replacement therapy and/or gene editing with CRISPR to cure the many rare diseases and perhaps to lower the risk of common diseases. We have been talking about the prospects for gene therapy for two decades – but its time has finally come. Two great examples – not yet in the area of the heart – but they show the power of gene therapy. Gene therapy for SMA – spinal muscle atrophy or floppy baby syndrome - has shown incredible results – preserving life in infants who had only a 5% chance of survival - AveXis . And Spark Therapeutics here in Philadelphia has developed gene therapy for the treatment of some forms of childhood blindness. In fact, the FDA has recently approved both agents. I think the next decade will be a very exciting time to be in both medicine and science. ■

A Value-Based Approach to Atrial Fibrillation

Enhancing Atrial Fibrillation Procedure Flow Garners Profound Results



Dr. Erik Kongsgård

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One year ago, Health Management published *Aiming to heal 80 percent more hearts through the power of partnership*. The article outlined the bold ambitions of Oslo University Hospital – a leading center in the treatment of Atrial Fibrillation (AF) – to expand access and enhance quality and experience for patients.

A year on, we look at the compelling results that are already being seen and what has been achieved by taking a value-based approach in collaboration with Johnson & Johnson.

Awareness of AF is increasing but the condition remains a new millennium epidemic. An estimated 11 million people in Europe have AF and, despite it more than doubling a patient's risk of stroke and mortality, only 4% of eligible patients undergo ablation treatment.

The condition is placing a critical burden on healthcare systems committed to treating patients. At Oslo University Hospital pressure to treat more patients revealed a plethora of challenges, including:

- Long waiting list times (up to six months after referral)
- Over 25% of unutilized time in electrophysiology laboratory (EP lab), where catheter ablation is carried out
- Complex scheduling processes with considerable time lost between procedures
- A 10% patient drop-out rate.

Inefficiencies meant the hospital lost time and resources and nursing staff regularly had to work overtime.

The hospital was committed to do something about this and had a clear goal – to treat more patients, safely, and improve outcomes and efficiencies. Key, measurable objectives were set to:

- Optimize EP lab utilization
- Increase the total number of ablations carried out with a focus on AF procedures
- Reduce patient drop out rate.

To achieve this, the hospital and its multidisciplinary teams partnered with the Johnson & Johnson CareAdvantage team to carry out a comprehensive review (known as 'Diagnostic Health Check'). From this, the current patient pathway was assessed through the process of 'value stream mapping' to identify the biggest hurdles and redesign an ideal pathway to deliver value and results.

First, changes were implemented in the out-patient department. Nurse coordinators were appointed to carry out more detailed and all-rounded pre-procedure assessments and patient education. A pre-defined referral management protocol was also put in place for referrals and follow-ups.

Next, in the EP lab a 'quick changeover' approach was implemented to improve changeover time between procedures to reduce unutilized time. This released time for more scheduled cases per day.

And finally, to ensure optimal uptake and implementation of the agreed procedures and protocols by all involved stakeholders, a training approach known as 'Kaizen' (a long-term approach to continuous improvement) was introduced.

Between 2017 and 2018, the results of this change have been profound. There has been a 24% increase in the number of AF cases, yet they have reduced waiting times after referral from six months to 17 weeks (less than 4 months). Unutilized time in the EP lab has reduced from 25% to 10%.

Including changeover time when using two different techniques, a 26% reduction in total procedure time for AF ablation has been achieved based on 10 observations, resulting in a significant decrease in nursing staff overtime.

Furthermore, the 10% drop out rate has now been reduced to zero.

Dr. Erik Kongsgård, Head of Electrophysiology, Oslo University Hospital, shared, "At each stage the improvements were designed to remove non-value adding activities and organize care around patients to achieve measurable and sustainable value-based change. We're delighted that we are well on our way to what we set out to achieve, and ultimately more patients will see the benefits."

To read more about what Oslo University Hospital has achieved or contact the Johnson & Johnson CareAdvantage team to discuss how you'd like to introduce a value-based healthcare approach, visit:

www.jnjmedicaldevices.com/en-EMEA/service/care-advantage.

At the European Society of Cardiology (ESC) congress in Paris, 31 Aug – 4 Sept meet the Johnson & Johnson Biosense Webster team on Stand I500 in Hall 7, Level 2.

Or, at the European Association of Hospital Managers (EAHM) congress in Ghent, 11-14 Sept, meet the CareAdvantage team on Stand 22 and sign up to attend one of two Big Data and Digital Health congress workshops. ■

Educating Physicians **to be Leaders**

Summary: For the clinician leaders healthcare desperately needs, training has to begin in medical school and continue throughout a career.

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The connection between great leaders and successful organisations that effectively innovate to remain competitive and provide shareholder value has been well demonstrated in business. To that end, many industries have, for decades, offered leadership development and training programmes as a strategy to cultivate a pipeline of leaders; leadership development as an industry is valued at over $15 billion annually.

Healthcare has lagged behind other industries in terms of leadership training, even though some have suggested that it is an essential competency for physicians to provide accessible, high quality healthcare and navigate a continually changing system (Rotenstein et al. 2018; Lerman and Jameson 2018). Since 2012, peer-reviewed literature shows a marked increase in papers discussing physician leaders. Studies have also demonstrated that training physician leaders improves physician satisfaction (Shanafelt et al. 2015). Along with an increasing demand for physician leaders, there has been a significant expansion in the number of courses to train physicians in this area. However, there are no current guidelines or requirements to mandate leadership curricula within medical education.

A former medical student and I conducted a landscape analysis that demonstrated that leadership training in medical schools falls into three categories: 1) dual degree programmes (MD/MBA); 2) longitudinal tracks with a leadership focus; and 3) classes that ranged from a one-off session to multiple, months-long components. At the same time, we also conducted a national survey of medical students and found that many believed they had insufficient experience in critical leadership skills, and particularly lacked experience and skills in managing teams. However, they expressed a desire to gain these skills and increase their competence

in being able to lead at a variety of levels: team, clinic, or health system.* At the medical residency level of training, some residency programmes have offered leadership curricula or "tracks." Post-residency, there are a few specialised leadership fellowships for physicians, and a growing number of continuing education leadership training opportunities for physicians at varied career stages.

"BY STARTING PHYSICIAN LEADERSHIP TRAINING EARLY, WE CAN IMPROVE DELIVERY OF PATIENT CARE"

In most of these examples, trainees opt-in to the leadership development track or course, which increases the likelihood that participants are actively seeking a management or leadership-oriented career. It does not account for those who might become "accidental" or "volunTOLD" leaders at some point in their lifetime. Currently, medicine selects leaders based on demonstrated clinical excellence or scientific innovation, but those forms of success do not automatically mean that a clinician is well equipped for the role of a leader. Within the literature on physician leadership there is no universal agreement on core skills and competencies physicians need to lead, and the possibilities range from problem-solving skills and communication skills to high degrees of emotional intelligence and a deep understanding of topics like quality improvement, payment, or health systems (Frich et al. 2015).

The barriers to adding leadership development to medical training are numerous and include the following (Cadieux et al. 2017; Grunberg et al. 2018):

- Disagreement on the importance of teaching leadership
- Lack of available space and time within an already packed curricula
- No predefined curricula to ease adoption of new coursework
- Minimal resources, such as faculty and funds, to implement training
- No consensus on the best time within training for leadership development

Essentially these barriers translate to the key questions of: Is teaching leadership important? Who do you teach? What do you teach? Where does it fit? How do we pay for it?

Over the last five years I've spent an increasing amount of my time thinking about, and designing programmes, that aim to educate physicians to be leaders. I do not have the solutions to all of the barriers listed above, but have felt the reality of these challenges as I've worked on programmes from design to delivery. I've taught a range of learners, from fourth-year medical students to executive leaders. The programmes have varied in terms of format: 100% virtual, blended (online and in-person), and 100% in-person. They have also been varied in length, from once per month for ten months to a three-day in-person intensive to four weeks of a block elective at the medical school. From these different experiences, I've come to four conclusions about training physicians to be leaders.

We Need to Build a Pipeline of Future Leaders

I believe it is worth investing in—and exposing medical students to—a portfolio of leadership skills and concepts despite the barriers to adding them to a medical school curriculum. This was affirmed through my experience in teaching a fourth-year elective course for medical students titled "The Physician as Leader." The course I co-direct is an intensive, month-long elective that focuses on providing students with skills to lead themselves, lead others, and better understand the organisations and systems they are about to transition into as medical residents. We use modalities such as case studies and guest lectures provide students with a glimpse into the realities of managing and leading within healthcare organisations, and convey that leaders will be needed at every level—not just in the C-suite. While the course is positioned near the end of the students' medical education, the feedback we hear from students is that the interpersonal leadership skills the course teaches and reinforces (communication, feedback, collaboration, conflict and team dynamics) are most useful to them, and would have been highly relevant and valuable had they been taught earlier in their time at medical school. Regardless, they are grateful to have more skills to use heading into residency where they will be leading medical students and working on clinical teams.

Learning to Lead Takes Practice

Leadership programmes often emphasise increasing one's knowledge. But, having knowledge does not necessarily mean that people know how to translate it into action. Learners need to have an opportunity to assimilate what they are learning, try new ways of behaving, and reflect on those actions or experiments. In the Physician as Leader course, we do this through a required team project. The final deliverable or outcome of the project is less important than the process of the student team working together over the course of the month. Longitudinal programmes with an in-person component enable participants to practice leading over

a longer period of time and afford them the opportunity to reflect and discuss challenges with peers. Our ten-month programmes typically ask learners to take on a personal leadership or improvement project for the duration of the programme. We ask that participants select projects that will impact their ability to lead within their current setting and build time into the programme for project-related reflections and feedback. This ensures participants are finding time to practice what they are learning.

Training Options Benefit Learners

The physician leadership training market is increasingly crowded, especially in terms of continuing medical education. But, I think choices in terms of programme content, timing, and format are advantageous for different learning styles as well as potential resource constraints (available time and money). I directed a 100% virtual leadership academy over a 10-month period that covered the fundamental concepts and skills for leading within a clinical practice. The audience for this programme was mainly community health centres across the U.S.; we had over 250 participants and 71% of the participants were attending alongside their clinical teams. It is unlikely that these health centres would be able to send an entire team to an in-person programme elsewhere in the U.S., but they do have the resources to attend a 90-minute webinar once per month. Contrasting with the virtual approach, I am part of the faculty team for a Medical Director Leadership Institute, which is an intensive three-day in-person programme held in Boston. The programme aims to build skills and address the challenges that medical directors face in their roles. The participants who choose this programme value the focused, time-limited nature of the programme and the ability to connect with other attendees during and after the programme.

Measuring the Impact of Training Needs to Improve

The current literature and available data demonstrates that programme evaluations of physician leadership training programmes tend to focus on participants' self-perceived changes in knowledge, skills, and attitudes (Frich et al. 2015; Miranda and Voce 2018). These changes are typically assessed at one or two specific points in time, usually before the programme begins and at the conclusion of the training. Additionally, programmes report participant satisfaction scores and, occasionally, career promotion metrics. These measures do not demonstrate the impact of training on the clinic, health system, or patients. While measuring impact beyond the individual level is ambitious, it is critical to understanding if the time and resources spent on training is a good investment.

"LEARNERS NEED THE OPPORTUNITY TO ASSIMILATE WHAT THEY ARE LEARNING AND TO REFLECT ON ACTIONS"

Healthcare needs the clinical leadership that physicians provide, both on the frontlines, but also in the C-suite. However, physicians need training to lead, and leadership skills are not currently a core part of physician training. By starting physician leadership training early, focusing on giving students and residents opportunities to practice leading, and measuring the impact of leadership curricula beyond individual learners, we can improve healthcare delivery for many stakeholders: patients, physicians, clinical teams and health systems. ■

KEY POINTS

- The demand for physician leaders is increasing
- By starting physician leadership training early, eg in medical school, we can improve delivery of patient care
- Longitudinal programmes allow more time for participants to practice the skills they are learning in their current environment
- Different training options will appeal to different audiences, allowing more participants to engage with training
- Measuring the impact of a programme beyond the individual learner is critical if we are to understand whether leadership training is a good investment

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* This work was part of Diana Wohler's 5th year Harvard Medical School project "Leadership Training in the US Medical School Curriculum."

20 Nov 2019

EUROPEAN ASSOCIATION OF HOSPITAL MANAGERS

Management Workshop

EAHM European Day at the Deutschen Krankenhaustag

9.00 – 9.15 Registration

9.15 – 9.25 Welcome / Introduction
Philippe Blua, *EAHM President, France*

Chair / Moderation
Marc Hastert, *EAHM General Secretary, Luxembourg*

9.30 – 9.45 The consequences of Brexit for Irish and European Hospitals
Gerard O'Dwyer, *Chief Executive Officer South / Southwest Hospital Group, Ireland*

9.50 – 10.05 **Healthcare in Luxembourg:** Highlights in Hospital Management
Sylvain Vitali, *Deputy Secretary General Luxembourg Hospital Federation (FHL)*

10.10 – 10.25 **Healthcare in Poland:** Highlights in Hospital Management – Focus on the Digitization of Polish Hospitals
Prof. Dr Mieczyslaw Pasowicz, *EAHM Vice-President, President of the Polish Association of Hospital Directors*

10.30 - 11.10 Patient Safety First – Procedures and Medical Devices
Dr. Ing. Peter Gausmann, *Managing Director of GRB Gesellschaft für Risik-Beratung mbH;*
Dr. Gabriela Soskuty, *B. Braun Melsungen AG*

11.10 - 11.40 Break

11.40 - 11.55 **Healthcare in Portugal:** Highlights in Hospital Management
Alexandre Lourenço, *President of the Portuguese Association of Hospital Managers*

12.00 - 12.15 **Healthcare in Sweden:** The Challenges in Hospital Care
Erik Svanfeldt, *International Coordinator Health and Social Care Division Swedish Association of Local Authorities and Regions*

12.20 - 12.35 **Healthcare in Switzerland:** Highlights in Hospital Management:
Rolf Gilgen lic. iur. Rolf Gilgen, *CEO Spital Bülach AG, Switzerland*

12.40 - 13.00 Discussion and Conclusions
Philippe Blua, *EAHM President, France*

Finance, Skills Gap, Governance: **Addressing CIO Challenges**

Summary: With finance, skills and strategy all obstacles for the healthcare CIOs, two HIT professionals weigh in on the way forward.

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When we look at the challenges facing any digital team, each one is multi-faceted coming with a chronicle of the yesteryear and a vision of the future. Considering the issues ahead, we look at some common problems through two lenses within public sector healthcare. One lens is that of a new digital healthcare leader and, the second, from an outgoing digital healthcare leader who has headed to a commercial innovation role. Sarah Moorhead is the relatively new Digital Demand Associate Director at Leeds Teaching Hospitals Trust while Richard Corbridge has just departed the same organisation after more than 20 years in health technology in the public sector.

Resources, Skills Gap and Needs

Richard Corbridge (RC): Building a team in the National Health Service (NHS) today requires a digital leader to make the most of the team they have already got around them. Coordinating the organisational culture to deliver against the new digital agenda has to be the first route to a new way of working. Enthusiasm has to be fostered and excitement nurtured. Where possible the next leaders need to be found from within the organisation to foster the feeling of potential within the team. Many teams in the NHS have a huge amount of corporate knowledge that has a significant financial worth for all NHS organisations. Harnessing this through structural change is challenging but has to be done by any 'great' leader. Lessons learnt from other digital revolutions ought to be considered. The ability to create a start-up like culture and utilise concepts like Very Clear Ideas and Design Thinking in the innovation space will assist in the gap and help enthuse growth of teams in situ.

Sarah Moorhead (SM): In the NHS we are often expected or forced into adopting archaic structures that are driven by clinical hierarchy and reputation. To be successful in delivering Digital Health for the NHS we need to look to different sectors for inspiration. It's important to build a team that is based on knowledge and skill rather than pay grade and qualifications - the NHS status quo. To find this dream team (and I believe there are now many such teams across the NHS) you must spend time listening, watching and immersing yourself on the shop floor. Doing this will help you find that hidden talent and empower staff to be part of the digital revolution. Once you have harnessed this talent, you have to ensure retention. To successfully do this in the NHS, we have to shift our focus to constant appraisals, a word that, in the NHS, sends a shiver down everyone's spine and is seen as an annual chore. If we change our approach to this to make appraising a constant daily activity that encourages people to believe in their skills and experiences that then focus them to deliver and succeed, it will be a major step forwards.

Finance

RC: The digital NHS agenda has the 'wrong' type of funding for modern technology. The desperate need to move from capital to revenue funding has been extremely well described to the centre but has yet to change or have an impact. Until it does, commitment to transformational technology that will release access to new technology, such as AI and the machine learning capability behind this, remains somewhat limited. The level of funding needed today has not been met or considered since the Wanless report more than a decade ago. At that time, 3% of the budget was recommended to be spent then on IT and this percentage still has to be met. That's even with the change to digital being so impactful and recognised by most boards as transformational to the business of healthcare delivery. As more and more of the NHS moves towards different types of contracting, moving away from commissioning as a stick to beat each other over the head with, there has to be a new potential for a better cost, spend and gain sharing within each organisation. This would assist in the removal of 'Grey IT' as well as ensuring better organisation-wide ownership of the agenda.

SM: As the investment in digitising the NHS sees no increase and our waste reduction plans have been weighing heavy, we must think differently on how we achieve introducing new technologies across the NHS landscape. We are seeing many projects pop up across the NHS, seeing the collective pooling of expertise across localities which leads to active sharing of local capabilities and funding to deliver new solutions whether that's a Master Patient Index, rostering systems or interoperability capabilities. Doing this sees Centres of Excellence emerging, allowing a bigger buying power and more resources to deliver quicker and scalable solutions.

Governance

RC: Right sizing governance is a challenge as it needs key legs of the 'stool' to be in place; engagement at the right (senior) level and the clinical engagement appropriately placed within the organisation. Very few NHS organisations have this right for digital. Clinical leaders are as essential as digital leaders to achieve the transformation. The right, balanced and respectful relationship between the two areas of expertise is actually the essential mix. The stool legs now need to include the patient/citizen. Consent for information use, input into the information itself and reuse of the information in health and wellbeing need a third, thus far hardly considered, leg to be brought into the leadership relationship.

SM: Governance is one of the biggest challenges facing digitising the NHS and is sometimes seen as a sticking point or a stick to beat innovation with. We must ensure staff are involved in governance, to build those crucial relationships and are the driver for success whilst abiding by the legislation. One of the major parts of governance for me is the softer side that sees its use in ensuring a happy workforce which is why we have and would encourage more NHS organisations to do the same. We recently encouraged our work to start a staff-side 'council'. Having this forum allows the team to feel empowered and part of every decision made whether that be office moves, the milk fund or our cloud first future, but this transparency ensures successful implementation of governance across everything required to deliver digital change.

Strategy and Change

RC: A long-term vision only becomes a plan with funding. The strategic intent of new organisations like NHSX are ambitious and being met with swathes of enthusiasm by the digital health fraternity almost universally. But there is still a sense of future dreams without central assistance on the long-term funding of the digital evolution. The nod from NHSX to support local innovation and localised strategy against a standard back drop has been seen as a giant leap forward and one that, if pushed into NHS Executive boards, could be the answer to the digital expert's 'prayers.' I remember being the IT Director of a Trust in the Midlands in the late 90s and being empowered to create a mobile strategy for social care workers going into homes of citizens to provide health and wellbeing advice. National healthcare strategy at the time stopped that local innovation from being possible, and today this 'innovation' is still largely missing from health and social care. The new strategy needs to be locally malleable to achieve this.

SM: The obvious digital platform for any healthcare setting is an EHR - whether that's an off-the-shelf or homegrown product. But the emerging part of our digital platform is that of the digital workforce. We need the right expertise, systems and training to allow our corporate function to effectively support our clinical team. Through accurate rostering, rapid recruitment, accurate finances, and upkeep of the physical estate, we will then be combining central experts with local experience. Without this, the reality of creating digital healthcare cannot be accomplished. I saw this concept first introduced in the financial sector when they identified that if staff could book leave, order a chair, or have the air conditioning altered, that the staff where content and this increased productivity overnight. As leaders we need to shift the broader thinking to enabling a digitally ready workforce across all staff groups of the NHS, not just clinical, to ensure the digital NHS of the future.

There are many challenges facing digital healthcare team. When you add the next camera lens, the one you just bought, enthusiasm for your photography bubbles up again. A new lens, one that can zoom in and out and gives a crisp and clear image of what is in front of you and the picture of tomorrow is exactly where we need to get to in digital health. Putting new brains against old problems and taking the experience of new ways of thinking and applying these, is exactly how the NHS will achieve what it needs to against the NHSX agenda. ■

KEY POINTS

- Leaders should be found from within the team to utilise the gained corporate knowledge. However, they shouldn't be afraid to look to other sectors for inspiration
- The level of funding needed today hasn't been met since the Wanless report, so if we are to introduce new technologies to the NHS we must think differently
- Clinical leaders are as essential as digital leaders in achieving transformation, although we also need to keep staff engaged in governance in order to drive success
- The right expertise, systems and training are needed to allow our corporate function to support clinicians
- New digital strategies need to have longevity and translate efficiently into the local community as well as benefitting all staff groups of the NHS, not just those who are clinical

Nurses and Cutting **Edge Technology**

Summary: Modern nursing is a multi-layered field of work with increasing work density and complexity, which requires a high level of competence, resilience and commitment from the nursing staff.

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In numerous professional situations, nursing professionals are required to have a high degree of spontaneous problem solving, abstraction skills and a safe application of highly technical specialist knowledge.

In Addition to psychosocial stresses, there are also physical overloads. Although technology in the field of medicine is accepted, there can still be resistance from the nursing sector to acknowledge and apply some of these technological advances.

On the other hand, the need for personal and social contacts of "Care Receivers," in particular, due to demographic change and as the associated shortage of specialists, continues to grow, it will be more essential for the healing process of patients than it is today. It is, therefore, apparent that the possible use of new technologies can create valuable opportunities for professional care and care receivers.

Impact Cascade

Experience in the field of technology and nursing has shown that innovative technologies in nursing are often conceived without the primary involvement of nursing staff and miss the concrete need and thus either do not represent real support for nursing staff in practice or are not known to them or are not applied (Care and Technology 2015).

It follows from this that possible potentials cannot be exploited or not sufficiently exploited by technologies and that the urgently needed additional needs for care cannot be met. Depending on the country-specific health care system, the gap between service demand and service provision will widen in favour of a two-or multi-class system, particularly in the outpatient and homecare sectors.

The following description does not deal with the occasional use of technical equipment to support the need for care, but with the strategic realignment of attention in the interaction of man-machine.

" ALTHOUGH TECHNOLOGY IN THE FIELD OF MEDICINE IS ACCEPTED, THERE CAN STILL BE RESISTANCE FROM THE NURSING SECTOR"

Traditional Solutions

The use of nursing innovations in the inpatient sector often takes place top-down without sufficient integration of the experience and demand potential of the nursing staff. In the outpatient sector, the use depends on whether, how, or which innovations are supported and financed by insurance. So there are often so-called catalogues of equipment, which promise the patients/clients a better or simple life. The associated ethical, legal and social challenges are of limited application. The subsequent user acceptance is limited.

IT2Nurse

To support nursing professionals in inpatient and outpatient care, innovations in human-technology interaction can be used to improve the performance, quality and quality of life of patients/clients (Imagining nursing practice 2050 2007).

What is that?

By IT2Nurse the author understands the use of technical innovations in three main categories:

Category 1: Assistance of qualified personnel through innovative technologies

In particular, transport and service robots (eg MiR100), lifting aids, intelligent sensors for beds and emotional robots (eg Pepper), point of care through automated data transmission, etc. is used.

Category 2: Replacement of skilled personnel by innovative technologies

As a replacement for qualified personnel, primary systems can be considered, for example, the reduction of transmission of germs through fully automatic systems (closed-loop in medication management) and UV light Robotic.

Category 3: Process support/empowerment of patients/clients/personnel through innovative technologies

From exit and fall prevention to sensor-controlled orientation lighting, standing aids and balance promotion (My colleague the robot 2016).

Cornerstones of Successful Use of Technology

There are three essential prerequisites for the successful use of technology. These include the *circulation of knowledge*, the acceptance of technology and, following this, proof of practical suitability and effectiveness *after adaptation of the operative work processes*.

1. From knowledge transfer to knowledge circulation

The original term "knowledge transfer" refers to a one-sided movement of current knowledge into practice. According to implementation science, this process does not succeed because on the one hand, no problem analysis is carried out, and on the other hand, practical knowledge is not included. The term "knowledge circulation" on the other hand, makes clear the need for equal interaction between stakeholders. With regard to the introduction of innovations, the application of the knowledge circulation of "Knowledge Triangle" (practice, research and education) (from Knowledge Circulation to the Triple Helix 2015) enables an equal exchange of knowledge from different perspectives and thus a continuous need-based further development of technologies in a useful application orientation and possible acceptance.

Quo Vadis

Innovative care technologies are urgently needed - but take time. The selection of products on the market today is already almost unmanageable. The promises of the manufacturers surpass each other in terms of potential savings and improvements. Nevertheless, realistically speaking it will still take a relatively long time until a product from a pilot phase enters everyday life. The technology is often quickly installed, but complete integration usually takes much longer. Each institution must, therefore, consider very carefully whether and for which application it decides and how it uses it. The so-called digitisation check has proven to be helpful in the run-up to the event. These are offered by various research institutes (Digitisation check eg Fraunhofer Institute for Software and Systems Engineering ISST) or private providers, among others, and usually include models of SWOT analysis, the business model Canvas and or design thinking. Digitisation checks also help to prepare the changeover processes and to set the new procedures in motion.

To ensure that the various nursing innovations in Germany can be better tested for their practical suitability and acceptance, the Federal Ministry of Education and Research has launched a comprehensive funding initiative entitled "The Future of Nursing." Nursing experts in four so-called Nursing Practice Centres (PPZ-Pflegepraxiszentrum) in Hannover, Freiburg, Nuremberg and Berlin are testing

Challenges

- Lack of patient human touch may lead to emotional problems for the patient
- Distance in Nurse-Patient Relationship
- Missing of other observations in patient's body/health due to shortage of stay in the hospital
- Shortage of patient stay may cause financial problems that may affect the overall function of the hospital
- Failure in cross verification of remote monitoring system function
- Human negligence due to nurses psychological distress and burnouts by continuous monitoring
- Inaccuracy/errors in remote monitoring parameters that may sometime increase the mortality rate
- No immediate plan in case of remote monitoring system failures
- Complexity in reset nurses routine when needed
- Full dependency of remote monitoring results

Possible Remedies

- Maintain limited and mandatory nurse's visits to patients and ensure that every patient is personally met at least 2 times during their duty period
- Plan for special rounds to identify their psychological needs
- Documentation of other observations in patients' health during the visit for better nursing care
- Compare critical paraments – Nurses observation Vs Device results
- Develop and maintain an emergency plan during improper functioning of the device
- Periodical checking and maintenance plan for the remote monitoring system
- Record regular feedback at consistent intervals and study for improvements
- Provide the technical assistance round o`clock in case of device failure
- Provide the alternative facilities (manual devices /assessment methods) for observation and treatment in case of device failure. The protocol can be useful to handle this situation
- Revising the hospital budget may be helpful to maintain/improve the financial status

Figure 1: Selection of Challenges and Possible Remedies by Introducing Patches (own representation)

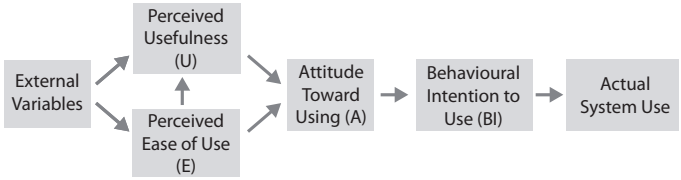

Figure 2. Technological Acceptance Model Based on Ajzen/Fishbein

Planning	• Which technologies/scenarios are suitable and where should they be applied? • Which technology is pursued with which goal? • What are the effects of the technology introduction on the company and the employees/recipients?
Implementation	• What steps need to be taken to implement it? • How can employees and stakeholders be involved at an early stage? • Will training offers of technical competence in further education and training?
Stabilisation	• How can success be implemented in the long term? • Which structural and procedural adjustments have to be made?
Evaluation	• How successful was the change process? • What can be gained from the implementation process for future technology introductions are learned?

Figure 3. Key Points for Technology Implementation (Own Illustration)

innovative nursing technologies for practical suitability, acceptance and benefits in real operation (2018-2023). The aim of the "Nursing Practice Centre (PPZ-Pflegepraxiszetrum) Hannover" project (ppz-hannover.de 2019) is to set up a sustainable ward in which technical innovations are used to support nurses and improve patient care. The redesign will take place at an accident surgery ward of the Hannover Medical School (MHH).

Within the framework of implementation, the selection and introduction of technological innovation takes place in a participatory manner, ie together with the nursing staff. The practical suitability and effectiveness are jointly tested before innovations are widely applied. Through this participatory approach, innovations in Human-Technology Interaction (MTI) in Nursing should benefit from the expertise and experience of the nursing staff.

Critical Thinking

In addition to the generally accepted approach in project and change management, particular attention must focus on the critical discussion of what influence the new technology implementation may have on the care philosophy and working culture experienced in the institution and how these should and must be applied.

Example: Single use "Patch Application" of non-invasive method to measure the vital parameters of cardiothoracic surgery patients.

There are different surveillance methods available for the post-operative patients in the hospital to measure the vital parameters. Wireless systems are widely used for ECG monitoring, SPO2 measurement and blood pressure monitoring. The usage of the non-invasive method will be helpful in preventing infection; complications induced by invasive procedure and improve patient comfort and safety. This patch is a single-use monitoring device, which can work continuously up to 10 days. The data is recorded in the device and transmitted through Wi-Fi/Cellular/Ethernet to an APP Portal. As a nursing point of view, it will reduce the workload, can increase job satisfaction, help in time management, cost reduction and balance the shortage of the nurses.

Challenges and Possible Remedies from the Nursing Perspectives

The following points are only a small selection and serve as a suggestion as to which side effects can occur through the implementation of patches and what considerations there might be to counter these.

2. Technology Acceptance

In the context of ergonomics, so-called technology acceptance (TAM) is defined as "the positive acceptance or adoption of an idea, a fact or a product, and in the sense of active willingness and not only in the sense of reactive tolerance." Ajzen/Fishbein describes two crucial variables: "Perceived Usefulness" and "Perceived Ease of Use." This can result in the behavioural intention and actual system use.

In addition to the acceptance of potential users, all relevant ELSI (Ethical, Legal and Social Implications) aspects must also be clarified satisfactorily.

3. Process Adaptation

Technological innovations and assistance systems actively interfere with familiar workflows and organisational structures. A practical added value in human-technology interaction can only succeed if the employees (users) think along with the work process and are familiar with the technical environment, accept it and use it.

Process adaptations can be made in a variety of ways. Each approach has its own advantages and disadvantages. The best known methods are: participating observation, self-observation, document analysis workshop, interview or electronic workflow presentation.

Summary

To increase potential through the use of technological innovations, it is necessary to create basic strategic prerequisites in the long term and to deal with the topic in greater depth. Technical interventions to support the nursing profession and a measurable improvement in the quality of the services offered for Care Receivers have not yet been sufficiently and effectively used. The suggestions and impulses listed above are intended to encourage people to counter them. ■

KEY POINTS

- Many in the nursing sector are resistant to understanding and using new technology
- As the shortage of health specialists grows, technology can create valuable opportunities within the nursing sector
- New technologies are often developed without any consultation with the nursing sector
- New technology often doesn't address the core needs
- The gap between service demand and service provision will widen particularly in the outpatient and homecare sectors
- Introducing new technology in the inpatient sector often takes place top-down without sufficient training for the nursing staff
- In the outpatient sector, the use of technology usually depends on if it's supported and financed by insurance
- A lot of equipment, which promises better care, cannot be used through lack of training
- Before developing new technology, it is essential to work with the nursing sector to address their requirements jointly
- When introducing technology, the focus must be on the benefits and how they will be applied.
- The most effective training is through workshops, interviews or electronic workflow presentation

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The Hospital as a Brand

Summary: The authors examine the process involved in creating a strong brand and the advantages that this can bring to an organisation and in particular hospitals by enabling them to establish a significant and distinguished position against their competitors.

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In manufacturing, retailing and the service sector, it is indisputable: in order to achieve a sustainable competitive advantage, the value of brands far exceeds that of total assets as established by conventional accounting procedures. This value also exceeds the potential "power of capital" and "market share." Brands are particularly significant in dynamic markets characterised by disruptive innovations (digital health, precision medicine), information asymmetry between customer (patient) and supplier (doctor), quality claiming demand, governmental legal interventions and serious financial limitations.

The Impact of a Brand: The Magnetic Quality

Brands are like magnets and a magnet has two remarkable characteristics: subject to certain physical conditions, it can attract things and bind them to itself. It is therefore able to attract or propel and even repel. "Magnetic hospitals" are characterised by the same capability profile (Figure 1):

- They attract more patients than they have capacity for and thus lay the foundation for future budget extensions bargained with the payers.
- These institutions are attractive to foreign patients as well (additional revenues in private and customised service area).
- They attract sponsorship funding in order to invest in improved services, building facilities, general and medical equipment as well as financing the continuing education of personnel and new recruitment.
- They are attractive cooperation partners for sickness funds with the aim to establish cost effective and value-added services for populations, for innovative industry partners in order to try out disruptive technology-based procedures, they take the role of a coordinator in specialised medical networks and are welcomed as advisors for the government.
- As cooperative partner of practising doctors and healthcare institutions, magnet hospitals are highly valued. This is the case because in future, not only individual hospitals, but regional health networks and vertical clinical performance chains as well, will compete with one another.
- They receive preferential and free samples (or use of the latest equipment), that is, innovative medical appliances. This moves them along the road to a positioning as innovative leaders.
- They assume the role of a leading hospital in model attempts to improve structures and processes.
- They enjoy a reputation as an attractive employer with interesting and secure jobs in an appealing and comfortable organisational climate and thus also attract qualified employees during a "war for talent" and lose no regular personnel.
- On the other hand, there are new business areas, which are opened up by a magnet hospital and in general, successfully. The German hospital group SANA bundled all procurement activities (purchasing and logistics; Supply Chain Management) in a separated franchise. In the meantime this firm offers a wide range of procurement services also for hospitals outside the SANA group. Actually, SANA purchasing and logistics is a dominant player in the German GPO (Group Purchasing Organisation) market place.

The Characteristics of a Brand

Products, services or institutions have a brand character, if the associations and perceptions in the minds of relevant target groups and the public have achieved a "monopoly position."

A brand represents the "best of the class" within a particular category and is therefore often identical to a description of that category. Mayo epitomises the "diagnostic clinic;" Johns Hopkins does the same for top-quality medicine in 17 and more specialist areas and has been No. 1 in the US News Top 100 Ranking for more than 10 years. Great Ormond Street stands for "The Child Clinic" and Anderson Cancer Center, "No. 1 in Cancer Care" stands for "making cancer history."

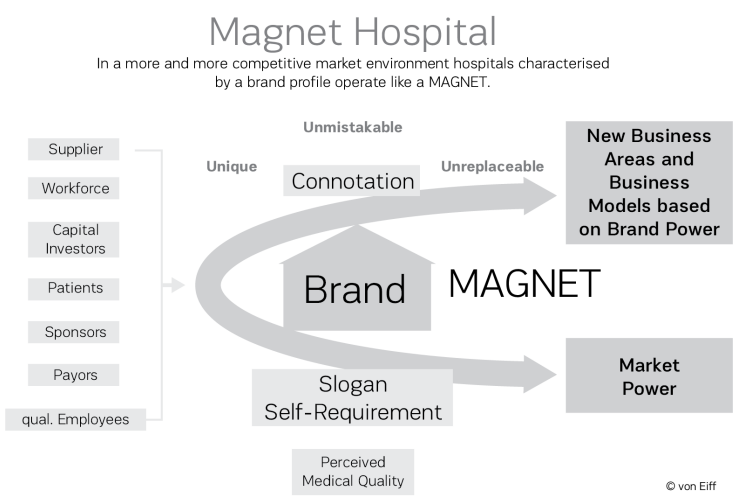

Figure 1. Magnet Hospitals are attractive co-operation partners and have a high level of competitive capability.

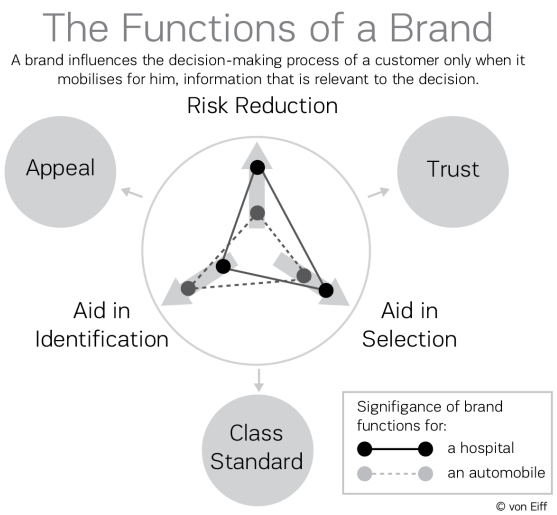

Figure 2. Brand Relevance is formed by Specific Brand Functions.

A brand is:

- unique, it cannot be copied;
- unmistakable in appearance. It stands out from the rest and the communicated message also reaches the relevant target groups undiluted;

"BRANDS ARE LIKE MAGNETS AND A MAGNET HAS TWO REMARKABLE CHARACTERISTICS"

- indispensable in terms of competence, which enables it to provide certain services to certain target groups with a higher level of qualification than any competitor;
- non-substitutable, it contains a particular emotional value to a customer which conforms to his life-orientation (for example, [religious] denominational hospitals) and the focus of the hospital sector on confidence in the medical service and individual, human communication as well as psychological support.

A brand is always linked with an offer of value that will be categorised by certain target groups as preferable to other available offerings.

The value provided by a brand to a customer derives from the basic functions of a brand (Figure 2), which provide valuable help in the purchasing decision making process:

Function of Risk Reduction

A brand stands for a "supposed or proven quality" (Q-Promise or Q-Guarantee) and signals comprehensive, exceptional competence in a specialist area. In this manner, the brand reduces the (subjectively perceived) danger of making the wrong decision. Particularly in the health market, and those for high-quality consumer and investment goods, this branding function plays a central role.

Function of Benefit (Utility) Identification

A brand offers customers the ability to express themselves or their individual lifestyles. Customers identify with the brand and want to be perceived, along with the branded product in its social environment. For medical services, this brand function has little significance, it applies more to prestige products (designer goods) and services such as exclusive.

Function of Assistance in Selection

Through its unique appearance in connection with assumed quality, brands differentiate themselves from other products or services. Brands often have a *best-in-class* status, by means of which they are used as a standard for others. Brands distinguish between products or services and aid customers in their efforts to make the right choice. The search and decision-making process becomes targeted and simplified.

In essence, it is possible to differentiate between three approaches to brand construction:

1. **The corporate design** approach treats a brand as a characteristic name and/or symbol, which enables an institution, product or service to be recognised immediately without further explanation and to be distinguished from competing offerings. A striking symbol (logo, slogan, use of colour, building, environment) aims at ensuring uniqueness. The "ideal logo" is uncomplicated and simple to construct, can be decoded rapidly, is emotional and its impact can be remembered and represents, in the ideal, the core message itself.
2. **The identity-based approach** offers customers an "emotional home" in addition to a promise of quality. Consumer goods have the characteristic that for buyers and users, apart from pure pleasure or utility value, they may also yield a so-called "identification value." This

means that the use of a brand expresses a lifestyle feeling and through the brand, the buyer defines an element of his personality.

3. **The risk-based approach** aims at instilling, in the minds of the relevant target group, confidence in quality and potential performance. This approach places two aspects in the focus of brand formation: a proven and exceptional specialist competence as well as social quality and corporate culture, as conditions for positive media reports and an increased willingness to recommend the service in question to others. In the health sector, this approach is of considerable significance.

A Brand Communicates Competence and Associations and is Represented By:

- A **symbol** which conveys the identity of a product, service or institution optically;
- A **claim of competence** (unique selling proposition) which is communicated as a service promise to the relevant target groups;
- The **actual behaviour** of the company represented by the brand, through which the customer is placed in a position to consider and compare “talk” (service promises) with “action" (actual service provided);
- **Association** which link the relevant target groups and the public with the brand.

Those associations in particular, such as pictures, visualisations, imagined images, feelings and thoughts that automatically enter people's minds when they perceive the brand, form its image and reinforce its profile over time

In the consumer goods area, this “emotional branding approach" is of considerable significance, but applies to hospital brand formation only to a very limited extent. It is possible that religious people will tend to seek out a church hospital, where they believe they will find their “emotional home” and proximity to trusted religious symbols, inner peace and psychological stability.

The Bone and Joint Hospital in Oklahoma City delivered an interesting case study referring to “emotional marketing.” This hospital started a campaign in which patients were approached after leaving the hospital (Total Hip Replacement) and asked to put a sticker on their car: “I got my hip at Bone and Joint.” The campaign was a flop. No patient was prepared to “out” himself in this manner as having an artificial hip.

However, the tendency towards a negative association in the context of hospitals, is intrinsic to the nature of the services performed.

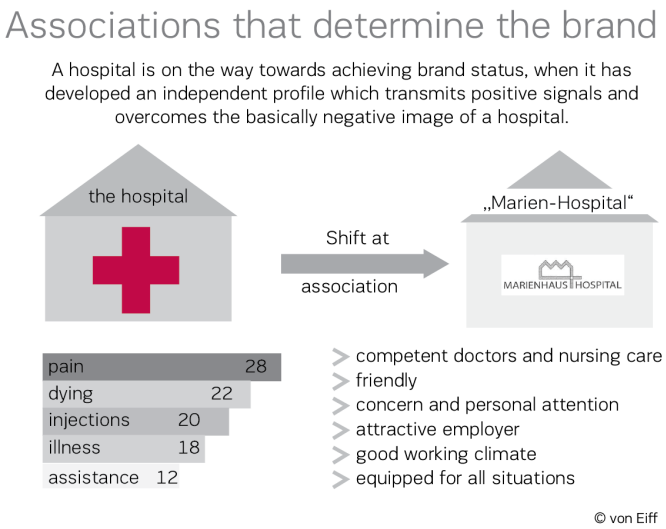

Figure 3. A hospital with a brand status ensures that there is a shift of association away from "a hospital" as an anonymous institution to one's own institution as a unique and appealing service provider.

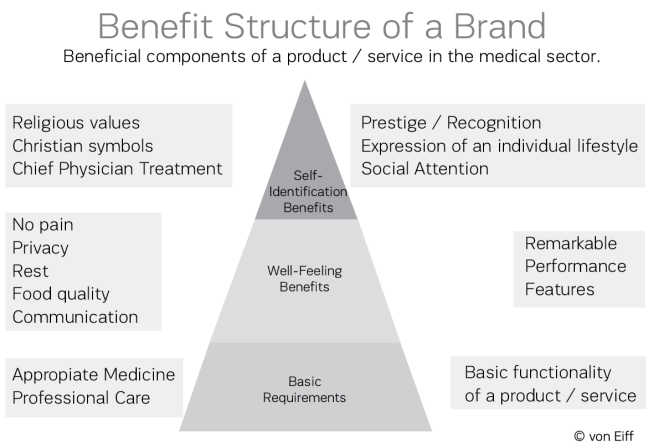

Figure 4. Typical pyramid of brand benefits from the patient´s point of view .

Hospital Services

- are, as a rule, caused by a health problem and/or, human dangers,
- entail iatrogeneous risks (anaesthesia, complications),
- give many people a feeling of vulnerability.

As a brand, a hospital must therefore attempt to create associations and confidence in the quality and the humanity of its services, without creating expectations that are unrealistic or unachievable (Figure 3).

Successful brand building happens over time by passing value-added information to the press.

Reports in the media, however, operate according to basic “brand forming” aspects:

- Medical competence
- Innovative services and cutting-edge performance
- Peer-to-peer communication to different patient groups in the community
- Sympathy

Press reports demonstrating medical competence relate to core services, through the treatment of prominent personalities such as the difficult and challenging cancer therapy of Mrs Gorbachev at the University Clinic in Muenster, Germany.

Another method to profile a brand status by cutting-edge performance is the procurement of an innovative piece of machinery that helps to extend the portfolio of medical procedures leading to better patient outcome (eg daVinci system for radical prostatectomies).

"A BRAND OFFERS CUSTOMERS THE ABILITY TO EXPRESS THEMSELVES OR THEIR INDIVIDUAL LIFESTYLES"

Another example for a brand profiling by peer-to-peer communication is the "Evening Round," an initiative of a local newspaper in the City of Muenster (Germany) in cooperation with specialised hospital physicians and family doctors. This monthly evening event provides the floor for physicians who inform the public about the nature, diagnostics and therapeutic opportunities of different kinds of illnesses (eg high blood pressure, prostate cancer, breast cancer, diabetes, stroke, acute myocardial infarction). This event is very well accepted by the public and gives the institutions involved an effective opportunity to profile their image. The public is informed by specialists about prevention, diagnosis and therapy of widespread diseases as well as orphan illnesses. These kind of reports published by neutral journalists convey competence and/or create perceptions of medical quality.

Brand profiling by sympathy refers to reports which inform the public about charity activities in the core business. So, the free operation on an eight-year old Russian girl with a heart ailment, including the organisation of a donation campaign to cover the transport and medical costs, had a clear profiling impact on the brand status.

Brand Formation: Success Factors in Developing a Brand Status for Hospitals

In order to determine the success factors that form hospital brands, the CKM *Brand Study* identified the performance criteria of a hospital considered from the point of view of patients and relatives. Medical quality was rated as the most significant evaluated criterion for the performance of the hospital, but at the same time, it was evident that few patients were able to evaluate this accurately. Nonetheless, patients and relatives did perform such an evaluation, but on the basis of *surrogate criteria: communication with patients* and the *perceived organisational climate*. Accordingly, the perceived social quality (the role of customers, handling of mistakes and errors, suggestions and attitudes towards contradiction by employees) formed a decisive success factor in increasing the willingness to recommend a hospital to other people.

- At the time of checking-in into the hospital, (assumed) medical quality plays a decisive role in the decision-making process. This process can be explained rationally: only the best medical quality provides as much as possible a successful recovery and cure. After a successful operation, there is a decline in the significance accorded to medical care in terms of evaluating the performance of a hospital and accommodation becomes more important to patients.
- If, between three and five weeks after their discharge from hospital, patients are asked about their most important (image and reputation forming) experiences, perceptions and associations, the factor *contact quality* assumes first place in the evaluation scale. The actual medical service (the results) play a significantly subordinate role in evaluating the performance effectiveness of a hospital. Former patients talk to third parties mainly about the manner of communication. In a negative case, this contact quality (dissatisfaction with the nature of communication) led between 18 and 20 patients to talk about this after their hospital stay. In the case of "customer delight" about the nature of communication with patients, only between three and five people communicated their positive experiences.
- Surprisingly, the "quality of food" also turned out as an important factor for driving the patient´s willingness for recommendation.

This closes the circle of brand formation for a hospital: experienced contact quality leads to the hospital being recommended and this in turn creates a public image and the phenomenon of *assumed medical quality*. This supposed quality leads patients and those who know them, to have confidence in a hospitals. The selection of a hospital is determined largely by confidence in the medical service that it provides.

In other words, brand status assumes a brand culture that is expressed in the management style and communicational behaviour as well as through the nature of cooperative work and the experienced *customer and service orientation*. So, the social quality is the most important quality dimension (von Eiff 2018) besides results, process and structural quality (Donebedian 2002; Donebedian 2005).

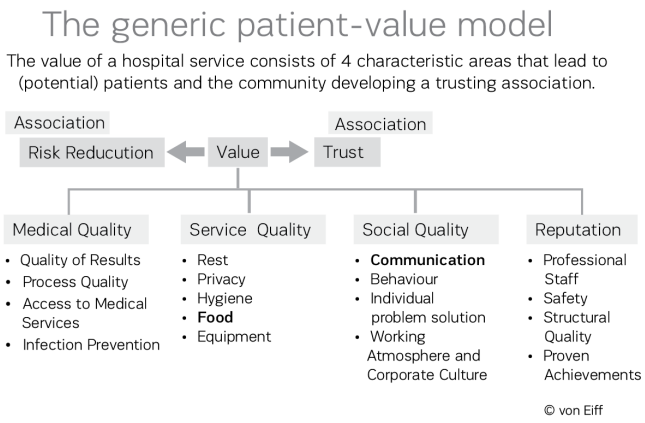

Figure 5. Success factors for creating a brand status.

Similarly, it also becomes clear that brand status does not arise over-night and neither can it be conjured up through advertising, propaganda or marketing gimmicks. Outstanding medical services, in conjunction with friendliness, a willingness to help and empathy on the part of personnel, are the real brand-forming factors.

Conclusion, Findings and Managerial Recommendations

- Brands derive from proven performance and not through promises or frenetic marketing activities.
- Brands provide clear benefits for patients and relatives (Figure 4).
- Brands are based on confidence in consistent quality. This confidence arises from tradition, competence and vision.
- Brands are characterised through an identity which arises through both “talk” and “action.” The promise of competence in an internet site, a pithy slogan with its promise of performance competence and a demanding image or philosophy must coincide with what patients actually experience.
- Brands are the result of a clear and non-substitutable image deriving from the promise of competence through the logo, symbols and advertising image, to the behaviour of individual employees.
- The most important brand formation factors are a constant, reliable service and a customer-oriented corporate culture.
- Art exhibitions, pantomimes for patients or T-shirts for the newly born are nice marketing gimmicks, but have nothing to do with the brand status of a hospital. At best, these activities promote a degree of “familiarity.”
- The brand status of a hospital is not characterised by the furniture and equipment in a room, the atmosphere in the reception hall and internet sites. Top-quality medical services and the social competence of personnel, characterise the public profile and reputation primarily and also sustainably.
- Advertising in the form of magazine/newspaper advertisements, TV spots (commercials) and billboards have very little to do with branding. Advertising in this conspicuous form will, at best, raise the degree of familiarity. The extent to which such advertising is regarded as "appropriate” in forming opinions amongst the relevant target groups is controversial and thus has a potentially disturbing impact on branding processes.
- For a hospital, the classic marketing approach to brand formation is not applicable. The brand value of a hospital (depicted in the “generic patient value model” in Figure 5) is based on medical quality (patient outcome, complications), healing environment (dignity, autonomy, safety), service quality (food, auxiliary services), communication (friendly, understandable, empathic, competent), access to treatment (waiting times) and coordination (administration, discharge management). ■

KEY POINTS

- Brands are particularly significant in dynamic markets
- Brand status does not occur overnight
- Your brand is what differentiates you in the marketplace
- Customers are attracted to brands that they share values with
- A strong, well-known brand builds recognition, loyalty, and competitiveness
- A hospital as a brand ensures it’s considered to be an appealing service provider
- A branded hospital receives preferential services, which speeds up the process to become leaders
- The brand value of a hospital is based on medical quality and outstanding service

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Lions Health 2019: **Creativity and Innovation in Healthcare**

Lions Health 2019 has offered new insights and discussions on how creativity is being embraced by the healthcare industry.

Over two days, Lions Health 2019 offered new insights and fresh ideas on how creativity can be applied to improve healthcare through focussed discussion and knowledge. This year's agenda included first-of-its-kind creativity covering a breadth of themes, from helping leap-frog healthcare initiatives in the world's poorest countries, to utilising tactics and techniques from the world of entertainment. By embracing the power of creativity, the aim of Lions Health this year was to explore some of the big issues in healthcare communications and patient experience.

A major theme that echoed throughout Lions Health was the acknowledgement that healthcare is no longer the preoccupation of those in the industry – health is the new business priority for all. Whether it's food companies, Fast Moving Consumer Goods, tech disruptors or fashion entities, a large majority of businesses are recognising the need to help educate people on the importance of good health, or learning to support those with healthcare problems. Danone's CMO, Valérie Hernando Presse, also voiced her opinion on this sentiment when speaking about their new company ethos "One Planet, One Health" – a campaign helping people improve the quality of their health through their food and drink choices. Global marketing can be a key tool to help these brands align their products and values with those of healthcare education, as demonstrated with P&G and their recent first venture into the health arena.

On stage at the festival, disruptors from the worlds of gaming, music and film explored the lessons that can support better engagement and creativity in healthcare. Level Ex, Founder Sam Glassenberg considered how psychology can transform physician education, whilst world-famous classical composer Max Richter discussed his work to develop music that enhances our sleep.

Health & Wellness Lions

The Health & Wellness Lions concentrated on discovering and celebrating work for non-prescriptive products and services aimed at promoting healthy personal care and wellbeing. The Health & Wellness Lions celebrated work in non-prescriptive products and services aimed at promoting personal care and wellbeing. Winners demonstrated the power of creativity to change lives and revolutionise healthcare services.

The ThisAbles collaboration between IKEA, product engineers and users aimed to make existing IKEA products accessible for people with special needs. The free range of open source add-ons, including handles to help open IKEA wardrobes, larger lamp switches and add-ons to raise sofa levels, took home the Grand Prix prize in the Health & Wellness Lions category. By using disability to drive innovation, ThisAbles was able to unlock the IKEA catalogue for a whole new market, providing affordable products compared to the current prices available for accessible furniture. Originating in Israel, ThisAbles has become a worldwide phenomenon through 3D printing; resulting in a 37% sales increase in products with add-ons (compared to sales in 2018) and an increase in revenue by 33%. Now downloaded in 127 countries, ThisAbles has

demonstrated how we can increase our awareness of social equality by creating accessible furniture that is readily available.

In the Health & Wellness category, StorySign, a free app developed by Huawei to help with literacy issues in the deaf community, took home Gold. As many deaf children struggle to learn letters phonetically, issues can develop when trying to match sounds to words which can lead to a higher risk of physical and mental health problems. To tackle this, Huawei developed the StorySign app which, using a Huwaei AI chip paired with OCR technology, takes the words from a children's book and transforms them into sign language using an avatar on the smartphone. StorySign has now been launched in 11 countries and, as well as being awarded a Gold Lion, has been voted the top-rated deaf app with over 128 million app film views. After reaching an audience of 1.5 billion, StoryTime has been praised globally for connecting parents with their deaf children through the power of storytelling.

Pharma Lions

The pressure of health communications within the Pharma industry to uphold the standards of care whilst trying to introduce new and innovative technology has often been met with complications. The Pharma Lions category looks to fight these challenges with creativity and push for greatness to provide the best for the healthcare community. The Pharma Lions winners demonstrated just this and proved that creativity can heal.

"CREATIVITY HAS THE POWER TO DE-STIGMATISE AND CHALLENGE TODAY'S HEALTHCARE ISSUES"

GlaxoSmithKline (GSK) was awarded the Grand Prix prize for their work on Chronic Obstructive Pulmonary Disease (COPD) awareness with the app Breath of Life. Motivated by the 100 million adults affected with COPD in China, GSK wanted to improve the number of those being properly diagnosed, which is currently less than 7%, by encouraging early check-ups. GSK developed the app through the collaboration with well-known artist and leading Pulmonologist, Dr. Yang Hu MD, PhD, to create Breath of Life, an app housed on the Chinese multi-purpose platform WeChat, which turns smartphones into a self-testing tool for COPD. By using the phone's microphone, the sound of the breath is recorded to produce a soundwave and is transformed, through an algorithm, into a tree on the screen which grows to different heights based on the strength of the breath exerted. If the result is below a certain threshold, the user is advised to seek medical attention for possible COPD. The app also allows an element of personalisation and socialisation as individuals can pick their tree style and flower colour and share their results on social media. This has encouraged others to participate on a wide scale, connecting a lost generation affected by COPD.

De-stigmatising Healthcare Issues

The role of creativity to help de-stigmatise healthcare issues was also a much-discussed topic in both talks and during on-stage discussions. A panel led by Kathy Delaney, Publicis Health Global CCO, highlighted initiatives encouraging better mental health care, particularly in the creative industries. The 'Viva La Vulva' campaign by Essity, created for Libresse/Bodyform was awarded Silver and Gold Lions in the Health & Wellness category for their brave, new approach to busting current taboos.

With the combination of the Festival attracting more brand leaders from top Pharma companies (eg Merck, Roche, GSK, Johnson & Johnson and Pfizer) and out-of-industry players moving into the healthcare space, it is becoming more evident that the healthcare industry is ready to embrace the benefits and solutions that creativity can bring. Crucially, festivals such as Cannes Lions and its dedicated Grand Prix for the sector, are critical in reminding us that creativity has the power to de-stigmatise and challenge today's healthcare issues. ■

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Consumer Tech Promotes **Patient Engagement**

Summary: How can healthcare leverage mHealth and the parallel movement towards consumerism to better patient engagement?

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In 2012, my passion for healthcare deepened when my wife, Janet, was diagnosed with Stage 1 breast cancer. She received wonderful care from her healthcare providers, but Janet and I often felt that we were left to make critical decisions—such as treatment types and the number of chemotherapy doses—all on our own.

Janet and I were ready to put our lives on hold for this healthcare journey, but we found that the process was tedious, confusing, and frustrating. We needed more information and more collaboration from Janet's providers. We wanted engaging to be easy.

These and other experiences have confirmed to me that patient engagement and the entire healthcare industry must be improved. Knowing that, I'm increasingly grateful that mHealth has come into the picture.

What exactly is mHealth? I like the following explanation: As defined at the [mHealth Summit], mHealth is 'the delivery of healthcare services via mobile communication devices.' Much more than just a subset of eHealth, mHealth offers an unparalleled opportunity to reach individuals and affect change" (Torgan 2009).

mHealth has the potential to make healthcare what most people wish it could be: simple, clear, and effective. With so many mHealth tools entering the market, providers wonder whether mHealth will revolutionise patient engagement.

The concept of patient engagement has been around for quite some time, but with consumer-grade technologies have come enhanced expectations. Patients and providers have grown accustomed to interacting with data, businesses, and each other in new ways. All parties must leverage mHealth if they are to create strong partnerships.

With that being said, mHealth is no silver bullet. It introduces unique challenges and may frustrate healthcare IT leaders who don't understand how to leverage it. Healthcare providers make it clear: The key to the successful use of mHealth technology is to incorporate it as one piece of a foundationally sound patient engagement strategy.

What makes an effective patient engagement strategy? What do early mHealth trends tell us? How can adopters of mHealth technology avoid potholes and find benefits? The following are some answers from hundreds of providers throughout the U.S.

The Pillars of Patient Engagement

In October 2018, a group of healthcare IT leaders gathered to establish a framework for patient engagement. That framework is shown below and available in the Patient Engagement Keystone Summit Whitepaper (Cherrington and Buckley 2018).

While best practices will be discussed later on, this chart gives an outline of what falls under the patient engagement umbrella and what should be included in a patient engagement strategy.

Only a limited imagination and cursory look at the chart are needed to see that each task listed could be accomplished, at least in part, with the help of a mobile device. But what is actually being done with mHealth today?

Current Trends in mHealth

Tools Being Created

Many vendors are simplifying healthcare by cutting out the middleman and going straight to patients' devices. Some examples include real-time updates on appointments and wait times, automated referral outreach, remote check-in processes, real-time status boards, and cloud-based platforms that integrate with third-party data sources.

Tools Being Used and Considered

In the research for a recent report, KLAS asked providers which patient engagement HIT tools they were currently using and considering using in the future. The tools were grouped based on the patient engagement pillar from which they originated (Cherrington and Buckley 2019b).

It was interesting to note that the tools that fell under all three aspects of the Partnership pillar (Knowing the Patient, Patient Empowerment, and Patient Experience) are being highly considered by provider organisations. Encouraging tools that patients are ready to use is critical to helping patients become healthier. For many patients, those tools are their mobile devices.

Apple Health Records

Healthcare stakeholders moved to the edge of their seats when Apple announced their Apple Health Records feature in January 2018. Four months later, KLAS published a report entitled, "Apple Health Records 2018: Early Participants Weigh In" (Cherrington and Buckley 2019a). For this report, KLAS interviewed executives from all 12 of the early adopter health systems that had partnered with Apple by that point in time.

Many are convinced that Apple truly created this tool for patients. Despite the highly competitive nature of the IT market, Apple doesn't charge provider partners any money for their Apple Health Record partnerships. Today, hundreds of institutions support health records on the iPhone (Applecom 2019). The following excerpt from KLAS' Apple Health Records report gives a good overview of providers' feelings about Apple's offering:

"Early participants say that Apple's move is not just a marketing ploy and that it has both short-term benefits and long-term potential to impact how provider organisations interact with patients and how patients manage their health. Immediately, Health Records is expected to help solve the intractable challenge of interoperability by allowing iPhone users to store their health records on a device that is already omnipresent in their lives. This convenience is expected to increase patient satisfaction and also engender in patients an expanding sense of self-ownership and self-involvement in their own care. In the long term, making health records available on the iPhone promises to speed innovation by breaking down the door between healthcare and consumer fields" (Cherrington and Buckley 2019a).

Potential Potholes

Despite (and sometimes because of) the increasing technology in the world of mHealth, provider organisations face many significant challenges. The following are some worries commonly expressed by healthcare providers.

Agreeing on a Strategy

New tools mean new questions from providers: How can we best engage our patients in their care? Which patients should we focus on? What about the family and insurance company? Is it best to jump right in with mHealth or wait and watch what other organisations do with it? The answers will be critical but possibly difficult to determine.

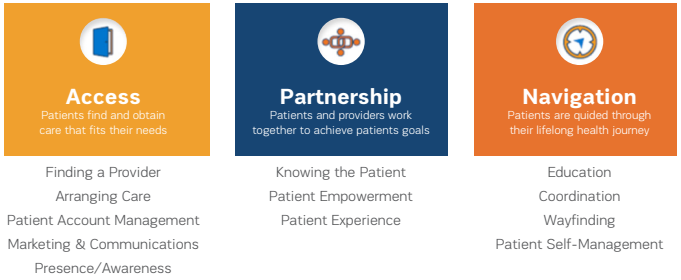
Too Many Options

As one CIO friend recently told me, "There are too many shiny, new objects." Many healthcare IT leaders are overwhelmed by the number and variety of tools available. That's one reason that agreeing on a strategy is so important. Provider organisations should set patient engagement and mHealth goals and then choose the technologies that will help them achieve those goals, not the other way around.

Education and Adoption

Some patients are confused or intimidated by the option to access their records via mobile devices. This worries healthcare IT leaders. In fact, according to the attendees of the Patient Engagement Summit, patients' lack of education is the second most significant obstacle to activating individuals in their own care. First on the list was a lack of convenience for patients (Cherrington and Buckley 2019a).

Pillars of Patient Engagement



Pillars of Patient Engagement, from the Patient Engagement Keystone Summit Whitepaper

When asked what healthcare hurdle would be most difficult for their organisation, 45% of the providers surveyed for the Apple Health Records 2018 report said educating and onboarding patients would be their top challenge. Second on the list was educating and onboarding providers (Cherrington and Buckley 2019a). Clinicians might not immediately grasp what mobile tools can do and which use cases could be helpful.

Data Ownership and Security

Most Apple Health Records partners and users are confident that the patient data is safe because Apple never actually holds the data (Cherrington and Buckley, 2019a,). However, providers don't necessarily have the same peace of mind about other mHealth tools. In KLAS' 2018 report about the security of medical devices (several of which fall under the umbrella of mHealth), about 20% of the surveyed providers said that "the inherent risks of medical devices—several of which are outside of their control—will prevent them from ever feeling confident" about the security of those devices (VanDeGraaff and Czech 2018).

In addition, the ownership of patient data is still being disputed. One CMO put it this way: "When we look at national surveys, physicians on the whole are not interested in people having full transparency into their medical records even

though they legally belong to the patients. The law says that I can get a complete copy of my medical record. However, we make it difficult for patients to do that" (Cherrington and Buckley 2019a). Provider organisations with this mindset won't succeed with mHealth; a primary need driving effective patient engagement is to help patients interact easily with their own data.

Success Principles Applicable to Both Patient Engagement and mHealth

The best way to navigate the aforementioned potholes of mHealth is to create a robust patient engagement strategy. Such a strategy must be based on an understanding that mHealth is simply a means to improved engagement and not the end goal itself. Participants at the Patient Engagement Summit created the following list of principles that create the foundation of a successful patient engagement strategy (Cherrington and Buckley 2018). The principles also apply to the use of mHealth and cover many of the provider-reported best practices KLAS has heard in our research.

Patient-centric

Too often, providers force tools on the patient to fit the needs of the healthcare organisation. Health systems should gather patients' feedback about which mHealth tools would be most meaningful to them.

Personalised

A provider organisation should plan for different patient personas. They should offer patients the option to use mHealth tools according to their needs and try to choose tools that patients can easily personalise.

Connected

Ideally, a provider organisation's mHealth tools will integrate with the EMR or other relevant systems. If nothing else, the tools should help patients feel connected to their caregivers and healthcare organisation.

Simple

Healthcare IT leaders should choose mHealth tools that are easy to use and explain to patients. Consumerism is here to stay, and now that patients have experienced the simplicity of platforms like Amazon's, they want healthcare to catch up.

Timely

In the world of mHealth, only real-time data is timely data. Healthcare IT leaders should implement tools that help patients and providers upload and access real-time data.

Continuous

Healthcare organisations should make sure their mHealth strategy focuses on assisting patients in their everyday lives, as well as at multiple stages of care. Patients need guidance before, during, and after episodes of care. Solutions that can promote a holistic relationship between the provider and patient will be successful.

Measured

Healthcare IT leaders should track not only their utilisation of mHealth tools, but more importantly, whether they are spurring changes in patient behaviour and ultimately achieving the needed outcomes. This will show which tools are effective and which tools should not be emphasised.

Leveraging mHealth to Improve Patient Experience

Some stakeholders argue that mHealth is pushing "consumerism in healthcare" and therefore removing compassion from the industry. I disagree. I think the vast majority of physicians really care about patients' health; they just aren't yet as good at engaging with patients about healthcare as they'd like to be. mHealth can only help with that.

No provider organisation can do everything for all of their patients. However, by graduating from basic patient engagement to a well-thought out strategy that capitalises on mHealth, health systems can help make a patient's healthcare experience almost as easy as ordering an Uber ride. ■

KEY POINTS

- Citizens are the holders of their personal data
- Consent and anonymity should be mandatory when it comes to protecting patients' data
- Data generated by patients is invaluable to the public and private healthcare sectors
- Saluscoop aims to give citizens management rights over how their data is used by researchers

Patient Trust Needed **for Healthcare Data Success**

Summary: Health data holds the promise of healing a plethora of healthcare operational woes. Saluscoop looks at how we can make data work for provider and patient.

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More and More Data for a Healthier Society

We are experiencing a period of data explosion: the digitalisation of health records, the increasing use of smartphones, portable devices, sensorisation and genome sequencing exponentially increase the quantity and quality of personal data related to health.

The health sector is one of those that generates great volumes of data, whether related to health or the lifestyles of citizens. Data, from multiple sources, is recorded through different devices and systems, such as Electronic Health Record (EHR) systems, Apps, Social Networks, Personal Health Records Systems (PHR), Hospital Information Systems (HIS), Laboratory Systems (LIS) and Radiological Information Systems (RIS-PACS).

The increasing computational capacity of computer systems allows processing a large amount of data, which becomes increasingly useful and valuable information. This data is of enormous value for companies and institutions to the point that to obtain our data they offer services at low cost or free in exchange for accepting legal agreements that tend to be very extensive and difficult to understand. This competition for our data means that they are in silos and that they are not readily available or accessible, hindering and slowing down any investigation. Even so, the trend, owing to social changes and mentality, is that the citizen, the owner of personal information and his/her own health history, can increasingly access health information from anywhwere at any time.

The future of medical research lies in the possibility of combining and integrating all these sources of data, from medical, genetic records to data from social networks. The knowledge generated by combining and analysing the large volumes of existing information (our clinical data, habits, lifestyles and circumstances, genetic profile) will represent a qualitative leap in the knowledge of diseases. The benefits of using data in research are tangible and significant: if the paradigm of scarcity were changed to the abundance of data, it would undoubtedly be a great opportunity, a great accelerator for research. The potential improvement in the provision of services is also significant: not only will it help us to define more personalised and effective treatments, in addition, the resource allows for the possibility of overcoming physical barriers and providing healthcare to groups and areas with less accessibility.

Property and Availability of "My Data"

But this new panorama raises some questions that we must consider, make decisions about and legislate on. The first question is whose data is it? If a patient is x-rayed, is that person the owner of the data obtained or is the public hospital, which, paid with our taxes, could make use of it and use it in an investigation that would benefit everyone? Citizens are the holders of personal data. Since May 2018, European citizens, under the General Data Protection Regulation (GDPR), and as holders of data have the right to access and to obtain a copy of it in a common format (eg PDF). We also have the right to the portability of our data (if we change company, we can request that our data be passed to the new company, through a mechanism similar to what happens when we change telephone operator and keep the number). This includes the availability of our health records for research.

Salus: Citizen Cooperative of Health Data for Research

Saluscoop wants to contribute to accelerate the development of research in the field of health by making more and more diverse data available to more researchers in more accessible conditions. For this Saluscoop aims to provide citizens with the possibility of setting the conditions under which they make the data relevant to their health, clinical, lifestyle and socio-demographic available to researchers.

In this way, the citizens can exercise their management rights over the data and influence the research agenda. Saluscoop can only contribute to fulfilling its mission to generate an abundance of data

for health research if it is capable of attracting a critical mass of citizens and a sufficient diversity of data to become a relevant player in this environment.

The advantageous position of Saluscoop in the data market for health research should be based on the following factors:

- Cost of access to data is zero through donation of citizens.
- Data diversity: clinical, habits for a holistic view of health.
- "Light" technological development that does not store data for management of data access keys.
- Non-profit so all surpluses are reinvested.

The way to achieve this critical mass and to finance the technological developments and human resources needed to achieve it are the most important critical decisions of the Saluscoop development plan. Saluscoop is a citizen cooperative of health data for research. Its objective is to help citizens to manage their health data and to share them for scientific research projects that are of interest to them. Cooperatives and data donors will not receive personal financial compensation for the use of their data. The surpluses of the cooperative will be used to finance research projects and services for members.

The last contribution of Saluscoop is SALUS Common Good License trying to introduce a citizen-led license to manage health data.

How can citizens take ownership of their data and have an active role in medical research? In order to provide an answer to this question, Saluscoop, citizen cooperative of health data, introduced this year the Salus Common Good License for medical research. Based on an open study (TRIEM) to find out under what conditions citizens would be willing to donate their health data, this license provides a tool to advance management of data in medical research and improve collective health.

The five guarantees of the Salus Common Good License for medical research are:

- Only health: your data will only be used for research of any disease, especially chronic and rare illnesses
- Non-commercial: research projects will be promoted by entities that support general interest such as public institutions, universities and foundations.
- Shared results: results of the research will be accessible at no cost.
- Maximum privacy: all data will be anonymised prior to use.
- Complete control: you will be able to cancel or change the conditions under which your data can be accessed at any time.

Conditional Donation: Consent and Anonymisation

Through the sharing or donation of data we are facing a great opportunity, but not without problems, dilemmas and risks that we must understand and discuss. Patients are usually very generous with their data when it comes to helping clinical research, but they, rightly, promote the protection of their privacy. On the other hand, there is an atmosphere of opacity that leads companies to make unethical uses of the data, generating distrust in the citizens who decide not to share their data with those who could contribute to generating a significant collective return - for example, in the discovery of new treatments. It seems indisputable that the patient should give an informed consent for the use of their data, similar to that required for other less sensitive services than the health service. However, it is not clear what the scope of that consent is, and the question is whether it could be used in any type of investigation of any disease, in any circumstance. Probably the answer would be no, but it is also unreasonable to limit the scope of consent so much that it makes future research unfeasible. The data related to health is of maximum sensitivity, may contain information about the most intimate aspects of our life and may expose us to multiple risks, for example, the risk of being discriminated against or even manipulated.

Consent, then, on its own, isn't enough. It is necessary that the privacy of patients is also protected with the anonymisation of the data, that is, the elimination of any data that allows identifying the person. This process raises a new debate: who should be the guardian and with what guarantees? How can citizens make informed decisions about the conditions of sharing and use of their data? The decision to share our data requires balancing many risks, including privacy and security and possible misuse of data, in relation to the enormous potential value of accelerating innovation in medicine and even improving the planning and provision of public services. Only citizens can make those decisions, considering their beliefs, their fears and motivations. The more knowledge they have about the nature of the data and the technological operations that allow them

to extract value from them, the more capable they will be of making decisions that minimise the risks and increase the collective return. We have to give an express consent to donate our data to third parties. In this consent, it must be detailed under what conditions and for what purposes the cession of data takes place. If third parties use our data, they should treat only those that are relevant to the purpose of the analysis and, when possible, dissociate them from our personal data.

"DATA IS THE GOLD OF OUR TIME, A GIGANTIC BUSINESS FOR THOSE WHO KNOW HOW TO TAKE ADVANTAGE OF IT"

Conditions for the Use of Medical Information for Research Purposes

What we understand as "health data" is changing and will continue to change significantly. What it increasingly means is integration and linking to a particular person, information as diverse as patient medical records, data generated by patients, biological data of portable monitors, fitness, mood and symptom tracking data, video data and sensors of people, genome data. Data is the gold of our time, a gigantic business for those who know how to take advantage of it. And just as public health systems collect the vast majority of our health data, the private sector wants to access it to carry out clinical research. Although it may be a beneficial relationship for both, it is evident that only the public sector will put the citizen at the head of the priorities of that investigation. All these issues should be addressed for the design of genuine health data governance. The benefits that digitalisation will bring to the health sector are indisputable and should not hinder clinical research. But it is essential that public and private systems are custodians and guarantors of our health data. In reality, administration and private companies are failing in the attempt to protect the privacy of the individual. It looks like they care very little. But to develop better and fairer health services, to improve and make universal health services free of charge, organisations and researchers need to have quality, representative information about patients.

The use of Big Data and the revolution that will result in more effective, better quality and completely personalised health services, is also an opportunity to ensure the sustainability of public systems if the return on public investment is guaranteed. The data can be used to heal if it is well used. We must therefore overcome the current crisis of confidence in relation to the use of personal health data. The only way to move towards a better health system is by having people control their health data. Citizens could easily access and share their health data in a standardised and real-time format with specific research projects and studies that work on a large or small scale by organisations of all types, including communities of people engaged in particular conditions.

The next step would be to make these large and varied datasets useful for people and professionals in the health system. It consists of using new tools and skills to analyse large amounts of data, interpret them at the individual level, through the development of continuous learning algorithms, fed by millions of historical health data and advance new research for a better understanding of diseases and health. All these attempts to increase, from our data, the knowledge of what is health and how to achieve a healthier life requires that citizens feel comfortable with the use made of their data. Health services should move gradually from the medical care of diseases to actions that improve the health of the population. Providers should be rewarded based on the results of the care they provide and on whether they help citizens live well and stay healthy. Universal and free health services should not discriminate based on whether citizens share their data as well as not discriminate against certain unhealthy behaviors. The sector has to maintain trust and clearly explain the benefits of sharing.

The health system must work to extract the full potential of health data, be more transparent about what happens with health data, how it is processed and what the results are, generating confidence that the data will not fall wrong hands and will not be used without the citizen's permission. ■

KEY POINTS

- Citizens are the holders of their personal data
- Consent and anonymity should be mandatory when it comes to protecting patients' data
- Data generated by patients is invaluable to the public and private healthcare sectors
- Saluscoop aims to give citizens management rights over how their data is used by researchers

Cardiology and mHealth – **Rethink About Monitoring**

Summary: Overview about the value of mHealth in cardiology exemplified by some promising tools that for sure will change the way cardiology is practiced, especially in the management of rhythm disturbances like atrial fibrillation.

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Where Are We Now?

Nowadays, there is a lot of hype about the role of wearables and mobile health (mHealth) in the field of cardiology (McConnell 2018). Only recently has the medical community started to embrace the certainty that most "health" takes place outside the healthcare facilities (ie the daily activities and clinical events that occur "the other 360 days" per year when people are not seen by a clinician).

Some authors like Steinhubl and Topol (Steinhubl 2015) highlighted some years ago that we were in the process of moving from digitalisation to digitisation in cardiovascular care, and this change will have a lot of meanings for patients and providers. These new tools could give us a much more high-definition view of our patients; one good example is the wearable sensors that track a wide range of important physiologic parameters continuously. This digitisation of health can also markedly improve the physician-patient relationship, sharing the data obtained through the digital technologies

The role of mHealth in improving outcomes in the early phase, proof-of-concept studies targeting lifestyle are well established (Ganesan 2016). The topic of mHealth has been the focus of a formal scientific statement (Eapen 2016) and its potential in clinical trials is currently explored, in any case, but has yet to be fully explored and realised. A systematic approach is needed to balance the promises and opportunities afforded by mHealth with the maintenance of privacy, safety, and regulatory standards in the conduct of emerging clinical trials

How to incorporate technology successfully into the health care system remains a test yet has the potential to yield huge societal and individual benefits.

Two interesting approaches in the field of cardiology are currently driving the conversation on mHealth: one is the measurement of physical activity, and the other is arrhythmia detection.

mHealth for Promotion of Physical Activity and Fitness

Physical fitness, not just the amount of regular physical activity, has also been revealed to be an independent risk factor for CV disease and longevity (Arena 2015). This research has led to a call for assessing cardiorespiratory fitness as a vital sign in daily practice (Ross 2016). Mobile devices can be used to assess fitness (Coolbaugh 2014), with the most straightforward form as a self-administered 6-minute walk test. This was validated as part of the Health eHeart study, where the smartphone-measured distance was accurate to within 15% in more than 90% of participants (Brooks 2015).

"ALTERING A BEHAVIOUR SUCH AS PHYSICAL ACTIVITY IS MORE CHALLENGING AND COMPLEX THAN ACQUIRING A MOBILE DEVICE OR APP"

But using a device/wearable is not going to make you exercise, and there are many proofs of this which should be noted. Two good examples are the IDEA (Innovative Approaches to Diet, Exercise and Activity) trial (Jakicic 2016) and the TRIPPA (Effectiveness of activity trackers with and without incentives to increase physical activity) trial (Finkelstein 2016).

The IDEA (Jakicic 2016) was a long-term study of weight loss, with physical activity and fitness as

components. Young adults were prescribed a low-calorie diet, increased physical activity, and group counselling for 6 months before being randomised to "enhanced" intervention with a wearable (that tracked calories and physical activity). Paradoxically, at the end of the 24 months, the enhanced group lost less weight. Without any doubt, the wearable in this study did not show the expected benefit in maintaining weight loss, but its contribution to behaviour change was difficult to determine.

The TRIPPA (Finkelstein 2016) was a randomised controlled trial where employees from 13 organisations in Singapore were randomly assigned to control (no tracker or incentives), activity tracker, tracker plus charity incentives, or tracker plus cash incentives. The cash incentive was most effective at increasing moderate to vigorous physical activity per week at 6 months, but this effect was not sustained 6 months after the incentives were discontinued. The authors identified no evidence of improvements in health outcomes, either with or without incentives, calling into question the value of these devices for health promotion.

A critical issue, highlighted in these and other studies, is the recognition that altering a behaviour such as physical activity is more challenging and complex than acquiring a mobile device or app.

Even more challenging is the limited integration of physical activity assessment into the clinical workflow. Consumer devices provide near-continuous daily measures of physical activity, which would be overwhelming for a provider to review. Thus, software solutions are needed to summarise clinically relevant physical activity measures and integrate into the electronic health records to allow review with similar ease as viewing a vital sign or lab result

Another interesting point about monitoring is the accuracy of wearables used by consumers; a lot of publications about this topic are available (Thomson 2019) showing in comparisons that the accuracy of real-time heart rate monitoring by different devices is reduced as exercise intensity increases. This finding, unfortunately, is common in literature with many other devices that are suboptimal at moderate exercise (Cadmus-Bertram 2017; Wang 2017).

In summary, we have great tools for fitness in the field of wearables for consumers, but accuracy needs to be improved.

Cardiovascular mHEALTH for Atrial Fibrillation Detection and Management

A great chance for mHealth beyond prevention is enabling earlier disease detection and helping both patients and providers better manage the cardiovascular disease - working together for proactive rather than reactive health care (McConnell 2018). One field where mHealth and cardiology are getting together is arrhythmia detection.

The detection and management of the most common arrhythmia - atrial fibrillation (AF) - represents a major cardiovascular mHealth opportunity to prevent strokes, manage symptoms, and reduce hospitalisations. AF has been challenging to detect and manage, as episodes can be paroxysmal or asymptomatic. Office visits or short-term monitoring devices provide only limited "snapshots" as to disease presence and burden. This can result in complications of stroke, tachycardia-related left ventricular dysfunction, and heart failure, as well as ever-increasing AF-related hospitalisations and health care costs (Kim 2011). The prevalence of undiagnosed AF in the United States alone is estimated to be almost 600,000 patients, with an economic burden of more than $3 billion (Turakhia 2015).

The occult AF - a risk for primary or secondary stroke - has incited efforts to implement AF-screening strategies in at-risk populations. For example the study REVEAL AF (Reveal Atrial Fibrillation) included high-risk patients with an implantable loop recorder (not a wearable, needs surgery for implantation) showed a detection rate of 29% for new AF at 18 months, and 40% at 30 months, with a median of 4 months until AF detection (Reiffel 2017). This kind of research is the one that is motivating the development of smartphone and wearable devices for AF detection to empower broader patient and consumer access (Freedman 2017).

One could discuss that the classic Holter monitors, although bulky, were one of the first "mHealth" devices available. Their redesign led to the emergence of small patch ECG monitors that led us to longer monitoring and increased diagnostic yield (Haberman 2015). This has been followed by the development of multiple consumer-friendly, smartphone-connected handheld or wearable ECG monitors for mobile use. Smartphones and wearable devices have also leveraged optical detection of photoplethysmographic (PPG) signals to track heart rate and rhythm from the finger, face, and wrist (McConnell 2018). These advances make us rethink the monitoring strategy of individuals.

Recent studies of both mobile ECG- and PPG-based AF detection show high rates of accuracy. Automated analysis of handheld single-lead ECGs in a diverse population of 381 participants yielded a 94% sensitivity and 99% specificity (Haberman 2015). A screening study performed using both ECG and PPG methods in more than 1,000 at-risk primary-care clinic patients found a 3% incidence of AF (Chan 2016). Using the PPG signal from placing the finger over the phone's camera had 98% specificity and 93% sensitivity for AF detection, compared with 71% and 99% for the automated handheld ECG-based app

Despite these promising early results, we must highlight that there is a major concern for broader use of AF detection algorithms. This concern is the possible loss of specificity, as other rhythms that create irregularity (eg premature atrial

or ventricular contractions, supraventricular tachycardia, atrioventricular block) could potentially be misclassified as AF, leading to improper diagnosis and treatment.

Also artificial intelligence could help us in rhythm monitoring through machine learning algorithms. One example was founded on smartwatch PPG-based heart rate measurements plus step counts used to train an AF-detection algorithm obtained from more than 9,000 Health eHeart participants, with high accuracy (98% sensitivity, 90% specificity) when tested in patients before and after cardioversion, but limited accuracy (68% sensitivity and specificity, 8% positive predictive value) when tested in a broader ambulatory cohort that self-reported AF status (Tison 2018).

The next step in this kind of research was the Apple Heart Study that was recently finalised and tried to prospectively detect irregular rhythms via smartwatch PPG, with ECG patch follow up (Turakhia 2019). The objective was to help provide a foundation for how wearable technology can inform the clinical approach to AF identification and screening. The results were communicated in the scientific sessions of the American College of Cardiology and are worth reading (acc.org/education-and-meetings/image-and-slide-gallery/media-detail?id=a8c5540539d34a00bdd50cd72b5d2691).

To summarise the results of the Apple Heart Study, this strategy could work accurately but needs some improvements. From my point of view, it was a nice way to start clinical trials with digital tools, but the selection process of the participants needs several improvements. Another important point was that this was tested with an old technology as the new versions of this device are able to perform ECG that will be better than an algorithm based on PPG; for sure new studies will come out in the next years.

Conclusion

Cardiology and mHealth are good partners to show the value of these technologies. There are very good examples of mHealth value in the cardiology field. These tools are promising, and for sure they will change the way in which cardiology is practiced, especially in the management of rhythm disturbances, with special focus on AF, but physicians need to be prepared for the upcoming technologies and the implementation of artificial intelligence also in this arena for the daily practice. We need better results of performance to ensure the implementation of these technologies in our clinical pathways.

I believe that we are in times to rethink how we must monitor our patients and empower them through wearables that had shown accuracy in their performance in clinical trials. ■

KEY POINTS

- Nowadays there is a lot of hype about the role of wearables and mobile health in the field of cardiology
- We have great tools for fitness in the field of wearables for consumers, but accuracy needs to improve
- Studies like Apple Heart Study are a nice way to start clinical trials with digital tools but the selection process of the participants needs several improvements
- We need to rethink how we must monitor patients and empower them through wearables that show accuracy in their performance

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Sensors in Everyday Objects **for Dementia Care**

Summary: The past, present & future of dementia care using sensors in everyday life objects through four use cases from research labs to large-scale pilots & adoption by pharmaceutical companies.

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Alzheimer's Disease (AD) is a progressive neurodegenerative disorder. It is the main cause of dementia, a syndrome defined by loss of cognitive capacities and independence in daily life. Approximately two thirds of all dementia cases are caused by AD. Patients with AD dementia typically suffer from progressive memory loss.

The societal and economic impact of dementia is enormous. Currently, 50 million people in the world are diagnosed with dementia. As the world's population ages, this number is expected to triple by 2050. At this moment, the costs associated with dementia are estimated at one trillion US dollars per year. These costs are expected to double by 2030 (The World Alzheimer Report 2018).

Alzheimer's Disease poses numerous clinical and scientific challenges, as well as several unmet medical needs. First and foremost, there is no cure for AD. Available medication may alleviate the symptoms of AD dementia. However, treatments to slow or stop disease progression have not been developed successfully to date. Second, diagnosing patients in an early disease stage is very difficult. Typically, patients consult a physician for the first time when they experience memory problems. Unfortunately, at that point, the brain has already suffered a lot of neural damage.

Technology can play a central role in earlier identification of disease and healthy ageing. Smartphones, wearables and smart home sensors can measure and extract activity, behaviour and daily living parameters relevant to the disease. At some point these digital biomarkers can be used for both assessment and treatment. In the former case, detection of signs combined with predictive analysis can lead to prevention as early as five years before AD's onset. In the latter case, monitoring can reveal trends and patterns pointing to personalised and per-case intervention. Non-pharmaceutical interventions and lifestyle change, such as consumption of natural products, physical and cognitive exercise, serious games, relaxation, meditation and other forms of Cognitive Behavioral Treatment (CBT) have proved their effectiveness in slowing down or reversing the progress of mental decline (Livingston et al. 2017). This way, patients can self-manage and feel included in their care but, most importantly, (formal and informal) carers and doctors can monitor progress and re-adapt interventions. Still, technological advancements are diverse, heterogeneous and often not suitable for large-scale adoption and end-user acceptance by such a sensitive demographic.

In this article we present the evolution of sensor-based technology for the care of elders and dementia in time and variety through four use cases, beginning with research lab prototype development, to large-scale pilots and adoption by the pharmaceutical industry.

Wearables, Multimedia, Object and Appliance Sensors

The Dem@Care platform for sophisticated multi-sensor monitoring

Dem@Care (**demcare.eu**) is a platform developed at the early onset of affordable wearable and smart home technology, between 2010 and 2015. The platform managed to interconnect not only heterogeneous devices but also sophisticated algorithms for processing multimedia (Stavropoulos et al. 2017). Wearable device prototypes by Philips, speech analysis for dementia biomarkers by IBM, image analysis from 3D depth cameras to understand activities, wearable GoPro cameras to recognise objects, sensors on everyday objects and electrical appliances were all integrated in the same software platform.

Dem@Care was piloted in lab trials in Thessaloniki, Greece and Nice, France in technology-facilitated and accelerated trials for cognitive state assessment with three hundred participants and an accuracy of 80%. The system was then deployed in nursing homes in Sweden and homes in Ireland and in Greece. Six home users in Thessaloniki, Greece successfully piloted the system for an extended period of time (between six months and a year), demonstrating its ability to

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co-exist with a patient at home, support and improve personalised interventions and, in turn, stabilise or even improve their cognitive state (when compared to control groups of interventions not supported by the system) (Lazarou et al. 2016). However, the sophisticated design of the platform, the installation and maintenance cost of the equipment prevented its large-scale deployment and adoption.

Smart Home Monitoring in Large Scale

The ACTIVAGE IoT platform for large-scale pilots

ACTIVAGE (activageproject.eu) in 2017 came to expedite findings of research technology similar to Dem@Care to be piloted in the large-scale for validation and greater impact. However, several IoT integration platforms have already emerged, presenting technological barriers and market fragmentation. Therefore, the primary goal of the new platform is still to unite and integrate open IoT platforms, including FIWARE (**fiware.org**), universal (**universaal.info**) and OpenIoT (openiot.eu). Through the united platform and focusing on Active and Healthy Ageing (AHA) applications, an ecosystem of App and IoT developers, healthcare providers and business stakeholders will emerge. Open calls invite third parties to develop and to cross-deploy ACTIVAGE solutions in Europe, with the ACTIVAGE Marketplace (**marketplace.activage.iti.gr**) being the central hub for ecosystem growth.

Deployments in ACTIVAGE span across nine sites in seven countries: Spain, France, Italy, Germany, Greece, Finland and United Kingdom. A mixture of several scenarios is demonstrated in each site, not limited to dementia care but also AHA: activity and behavioural monitoring, mobility and transport, emergency situations and more. Reaching thousands of people, ACTIVAGE deployments include an unrestricted range of devices due to the unified platform.

In Greece, smart home sensors provide presence in a room, environmental temperature, humidity, luminance and door usage (for going out) to extract patterns of behaviour at home. An additional emergency button provides elders with the means to call their relatives, doctors or even the authorities for help. Still, a drawback of the platform is the requirement of experts for installation and maintenance, as it is still under development.

Easy-to-Deploy Smartphone and Wearable Monitoring

The Support2LIVE smartphone app for telecom providers

Support2LIVE (**ypostirizo-project.gr**) is a monitoring app to support dementia care for elders using a smartphone and a wearable wristwatch combination. With its minimum equipment requirements, the app remains affordable, easy to install and maintain for virtually every elder. Beginning development in 2018, Support2LIVE leverages the penetration of smartphones, with a rising percentage of owners around 30% (66% in Greece), but also wearable fitness trackers, which now come in tens of brands and models. With this momentum, Support2LIVE aims to surpass limitations of more complex IoT platforms (such as ACTIVAGE and Dem@Care) and be disseminated through telecom providers to every home in Greece.

Reduced to a smartphone and an (off-the-shelf) wearable, the platform is still able to measure movement, heart rate, sleep duration, stages, and interruptions and interpret them to stress, physical activity level, sleep quality highly relevant to AD symptoms and quality of life. Meanwhile, the smartphone app can interact with the user delivering brain games and interactive questions both as an assessment and as an improvement tool for effective interventions.

While behavioural monitoring is covered, activity monitoring is excluded, due to the absence of smart home monitoring. This highlights the need for further developments in technology and the market to deploy object-monitoring sensors just as easily as wearables to enable fast-track adoption and greater societal impact.

Wearables, Apps and Everyday Objects in Clinical Settings

The RADAR-AD digital biomarker trials for pharmaceutical research

The technological development of AHA and AD care through technology has meanwhile and quite naturally caught the attention of the pharmaceutical industry. Besides accelerated trials (as in Dem@Care), the metrics and features extracted by monitoring equipment and analysis can be further exploited as an emerging kind of "digital biomarkers" in a clinical setting.

RADAR-AD (**radar-ad.org**) started in 2018, co-funded by and co-developed with major pharmaceutical companies as an attempt to capture these biomarkers and put them to use for early detection and medicine development. RADAR-AD works closely not only with the industry but also with patient and carer representatives in Alzheimer Europe to try and identify the best equipment for them.

It will deploy technology-aided trials in three

different settings in homes: lightly equipped (as in Support2LIVE), moderately equipped (as in ACTIVAGE) and heavily equipped experimental prototypes (as in Dem@Care). The heavier the equipment deployed, the fewer the participants. This showcases how different levels of monitoring are needed according to case, needs and aspirations for scale. Smartphone apps ALTOIDA (**altoida.com**) and Mezurio (**joingamechanger.org/information**) are central to patient interaction. They already count millions of users outside the project and proven to be reliable biomarkers for the disease. Still, they will be accompanied by smart home sensors, such as presence in a room, proximity to items and indoor location, appliance and object usage, to capture and understand activities performed, ie functional domains interesting for clinicians. Besides the different levels of installation and monitoring capabilities, the project's breakthrough is adoption by pharma, which shines hope for a future of more effective treatment.

Conclusion

We are only just starting to understand the possibilities of mobile technology in health care. Evolution in the past decade has shown different levels of equipment are needed according to each use case and aspirations for scale. Heavier installations can work in a clinical setting where patients visit for an assessment. However, lighter more affordable and self-deployable solutions are needed to reach greater societal impact. Currently, such solutions are limited to smartphones and wearable wristwatches, which, in turn, limit monitoring to behavioural qualities such as physical activity level, stress and sleep quality. Monitoring of everyday objects is required to monitor daily activities such as chores, cooking, adherence to medicine and thus actual quantification of one's functional capabilities. Besides and even before pilots, inclusion and co-design with user representatives are needed. Working with patients, caregivers and regulators can ensure that users are comfortable and safe using the developed technology and adequate regulatory frameworks are developed. Overall, from research labs to large-scale and recently to adoption by and co-development with the pharmaceutical industry, technology promises a brighter future of more affordable, accessible and more effective care of dementia.

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KEY POINTS

- Technology plays a central role in earlier identification of disease & healthy ageing
- The integration of multimedia, wearable and smart home sensor analytics can accelerate dementia assessment trials and support clinical interventions at home
- Large-scale pilots for a plethora of use case scenarios for behavioural and activity monitoring, mobility and transport, and emergency are possible through IoT platforms
- Smartphone and wearable combinations are highly deployable solutions to reach high societal impact
- The pharmaceutical industry is starting to adopt and co-develop digital biomarkers using smartphone, wearable and smart home monitoring solutions
- Daily object sensors are needed to monitor functional capabilities and, thus, further advances in technology to reach effective deployment

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Improving Patient Compliance with Future **mHealth**

Summary: Combine the characteristic of our engagement with social media with existing technology and how could we improve patient compliance in the not so distant future?

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Patient treatment compliance is a significant barrier and a challenge for healthcare professionals the world over. While several studies have been conducted leading to techniques being developed to improve compliance and treatment outcomes, not enough seems to have been done to bring new technologies into play.

While we have seen an explosive growth in harnessing new technologies through the invention of diagnostic equipment, laboratory and radiology investigation techniques and molecular technologies for the pharmaceutical industry, attempts to overcome some of the most mundane barriers to patient compliance have been slow or tentative at best.

Frustration with (Non)Compliance

From the patient point of view, barriers to treatment compliance include inadequate knowledge of illness and prescribed medication, poor discipline in taking medication and a fear of drugs. Review of medication information taking too much time and difficulty in obtaining knowledge of home medication constitute just two of the difficulties for physicians. When it comes to the healthcare system at large, treatment compliance can be undermined by a shortage of GP appointments and poor hospital communication (British Medical Journal 2017).

Monitoring Technology

Now let us look at what technologies are viable for monitoring and influencing better patient compliance and health outcomes.

Technologies already mature and in use such as NFC, RFID, QR Code, embedded electronic chip, microprocessors, the IoT, are excellent candidates for more expansive applications in patient treatment protocol. We are already using several of these new technologies in monitoring, educating and serving as electronic "butlers" as part of the treatment in areas of medication and post-discharge self-care of patients. Examples are monitored heart rate reporting, monitored blood pressure reporting, and monitored blood sugar reporting using smart phone apps that can upload data stream to a secure cloud storage location. The said storage location is given access via secure login to the physician's office or the hospital that the patient is receiving care from.

I'd like to imagine a world where bolder and more effective treatment compliance would become mainstream. I think this is possible by harnessing an amalgam of contemporary technologies and newer technologies that leverage individual biomarkers and combine those with software driven hardware.

Tech for Future Compliance

Recent developments in the way biomarkers are identified and used in developing treatment protocols have been exceedingly encouraging and exciting. Moving the process from the research bench to the patient bedside is already underway in some cases and a helping hand from molecular sciences, and powerful imaging technologies, is a boon to patients and medical professionals alike. That the biomarker discovery is an evolving ongoing process only bolsters the prospects for other hardware and software technologies to join the party.

A microprocessor is like a miniature computer central processing unit.

Microprocessors are key to marrying biomarkers with implantable chips that can happily live inside our bodies while silently monitoring and relaying what the biomarkers are telling them about our bodies. Since biomarkers are very specific in what they pick up in our bodies. A clever software-driven hardware chip that can "talk" to the biomarkers would significantly improve the monitoring and reporting loop both to the patient and the provider.

Artificial Intelligence also has a role to play. Let's consider a combination of Natural Language Processing (NLP) and Machine Learning (ML) for a stern virtual nurse that will not let you off easy on your physiotherapy. With ML, the software is aware of how many of the exercise routines you have completed and the degree of effectiveness of the routine. Over time, ML can look for and detect your areas of weaknesses or laziness and devise prompts that would help you or encourage you with improvement charts that would be displayed on the smart phone app that you would record your exercise start-stop events. If you ignore these helpful attempts by your virtual nurse, he/she would report your delinquencies to your provider. A carrot-stick approach that would have been setup at the time of your treatment planning would immediately come into effect. Nowhere to run. Nowhere to hide. Add Alexa from Amazon to your tribulations and now you have a duo of chips badgering you until you comply.

Compliance of physiotherapy is external and can be effectively monitored, assisted and reported. What about medication administration? There are some clever devices and operational approaches to medication dispensation and monitored reporting in the market. However, a clever patient who strongly objects to the side effects of his/her prescribed medication can find ways to cheat any system. A patient who simply forgets to take medications also loses out on the treatment outcomes and causes worry for the family and the provider. Added complications come up when the patient lives alone and does not have the luxury of an aide or a neighbor who can administer the medication if the patient is suffering from other complications such as dementia.

A combination of biomarkers and implanted chips can help such patients. Not unlike external infusion pumps, chips can be used to trigger medications that are attached to the patient in the form of dermal patches or pouches. These can be taped to the abdomen or lower back or any other discreet external location on the patient's body. When the biomarker picks up a value that is indicative of a drop in the medication's dosage, it signals the chip and the chip can trigger a mechanism attached to the said patch or pouch that would allow the right dosage to be released for a set duration.

The Power of Data

Data when it is collected and indexed into useful categories can be invaluable to the patient and the provider. All the technologies discussed here, gather mountains of data. Edge computing can help sift through the heaps and collate and upload only the relevant pieces saving storage space and valuable time for the provider. Such data can also be aggregated to provide further analysis for understanding what challenges are not met and what techniques and technologies engender best outcomes. A closed feedback loop would enable leaps and bounds of progress for providers in devising ever-expanding use of technology into their treatment planning.

Patients and their families would spend less energy on compliance, leaving the heavy lifting to the "butlers" in their bodies and look toward a healthy future. Providers would fare better in their profession deriving a much-desired satisfaction of seeing their patients recovering well. Job satisfaction will soar and employee turnover rate will fall.

Unlimited Possibilities

Let's imagine we can bypass the, often cumbersome, present-day legal roadblocks without compromising ethical standards. What solutions could we come up with for effective patient compliance? If we were to imagine technologies and assistive devices coming together to become part of the human anatomy, the prospects of designing a near-perfect methodology that would combine activities of daily living (ADL) with a subliminal behavior modification through technologies that would seamlessly "guide" the patient along the treatment protocol with the patient not even realising it. Consider our obsessive engagement with the social media platforms with little or no financial or professional gains and yet, through this, we have been modifying our ADL, with considerable detriment to many dimensions of our lives.

If we were to harness a similar approach but for beneficial outcomes, technology would prove a better servant than a surreptitious master. ■

KEY POINTS

- Lack of information and communication with healthcare professionals is a leading cause of patient treatment non-compliance
- Effective treatment compliance could become mainstream by incorporating technologies to monitor health outcomes
- Microprocessors, biomarkers, AI and implanted chips are all mHealth tools that could be used to increase treatment compliance
- The data collected from mHealth can be invaluable to the patient and the provider
- mHealth solutions for patient compliance would require using technology to adjust activities of daily living (ADL) to benefit patient health

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In Data We Trust

An efficient mHealth network relies on patient data but provision of such data requires confidence that it is being sourced and used with integrity. HealthManagement.org spoke to three health data experts for their views on what healthcare can do to secure patient trust when it comes to accessing and using their data.

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

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

These are crucial dimensions even when planning for one-stop shop for data. For winning the trust from the researchers and companies aiming to use the data, we need to ensure transparency and an audit trail to the data sources, and maintain good quality of data management tools and processes.

The same applies for enriching data sets with personal data for more tailored digital services. An international survey reveals that people's lack of trust presents an obstacle to the growth of digital business. The progress enabled by artificial intelligence is also at risk if access to data is compromised or transparency is not ensured.

There are three types of data: personal, collective and identification. Personal data must be treated as part of the individual's body and integrity. It belongs to them and must only be taken and used with consent. It must be treated with respect and collected, used and disposed of in that spirit. Collective data is something else. We as a society need that data to understand and learn more about the human condition and how to protect and support our common good. In both cases we must be able to trust those who have access to the data. Trust is easily lost and hard to rebuild. The data will inevitably be lost, stolen and abused so those charged with its safe keeping must develop agility in responding to these failures with integrity and transparency. The third type of data is more difficult; it is that concerned with identification: fingerprints, DNA, facial recognition etc, often collected for public protection and collective security reasons but the question of trust remains. There is also a fourth: social media and the mistakes we all make in casually releasing too much information. Good Governance requires us to tackle all of these from the first principle that all data about me is mine forever and only I can determine who uses it and to what ends. We may have to compromise that principle but we must do so thoughtfully and transparently.

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One of the best ways healthcare can protect patient data and maintain their trust is by ensuring that access to this data is restricted to only those who require it. Information related to a patient's personal health and body is very sensitive and private. In order to ensure that this information is secure and accessible only to people who need it to provide quality patient care, the healthcare system needs to be proactive. They need to educate their staff and make them understand the meaning of privacy; they need to put measures in place that would restrict access; they need to mitigate network-related and device-related risks; they need to implement controls regarding data usage, and they need to closely monitor and conduct regular assessments. Only with a proper system in place can you secure patient trust when it comes to information that is related to them.

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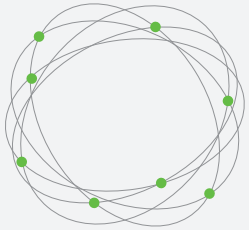
MONITOR ME!

WHAT IS mHEALTH?

The use of mobile and wireless technologies to support the achievement of health objectives (WHO).
Source: https://iii.hm/wq6

The use of mobile and wireless devices to improve health outcomes, healthcare services, and health research (NIH).
Source: https://iii.hm/wq7



"The science of today is the technology of tomorrow."
Edward Teller

mHEALTH APP TYPES

- Fitness
- Lifestyle Management
- Nutrition & Diet
- Disease Management
- Women's Health
- Medication Adherence
- Healthcare Providers/Payors

Source: https://iii.hm/wvj

PROMISING DIGITAL HEALTHCARE IDEAS

- Artificial Intelligence
- Voice Technology
- At-Home Diagnostics
- Siteless Clinical Trials
- Digital Biomarkers
- Digital Therapeutics

Source: https://iii.hm/wvm

mHEALTH FACTS

The Global Mobile Health Market is expected to grow at a CAGR of approximately **33.8%** and will reach around **$181.52** billion by **2025**.
Source: https://iii.hm/wq5

There are approximately **318,000** mHealth apps available in app stores today. Over **200** apps are added each day. The primary driving factor is increased smartphone adoption and heavy investment in the digital health market.
Source: https://iii.hm/wvi

mHealth is a more common activity **(62%)** than online banking **(57%)**, job search **(42%)** or accessing educational content **(30%)**.
Source: https://iii.hm/wvk

74% of patients say using mobile apps, wearables, and mHealth tools helps them cope and manage their medical conditions.
Source: https://iii.hm/wvl

CHALLENGES OF mHEALTH IMPLEMENTATION

- **Usability**
- System Integration
- **Data Security and Privacy**
- Network Access and Quality
- **Reliability**

Source: https://iii.hm/wvn

Cardiovascular Disease Prevention 2019: **Quo Vadis?**

summary: Cardiovascular disease prevention strategies in 2019 remain a major healthcare issue, requiring an individualised approach for diagnostic and therapeutic decision making.

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Introduction

Since investigators from the Framingham Heart Study first confirmed the existence and importance of cardiovascular disease (CVD) risk factors in 1961 (Kannel et al. 1961), scientists and clinicians have been seeking to refine the prediction of risk for CVD. More than 50 years later, age, gender, and traditional CVD risk factors, including hypertension, diabetes, hypercholesterinaemia, smoking, and adiposity are predominantly used in daily clinical routine for risk prediction and stratification into risk groups. Based on these risk factors, multiple risk scoring algorithms (eg the Framingham Heart Score, the European SCORE, or the ASCVD-Score) have been established over the last decades. These allow the classification of patients into risk groups (low, middle, high), combining the information from traditional risk factors. However, the current algorithms only imprecisely predict the individual's future risk, especially in the intermediate-risk group, which is also acknowledged by current guidelines (Grundy et al. 2018). For further risk stratification, risk enhancement via assessment of carotid artery plaque burden, ankle brachial index, and most importantly, the coronary artery calcification (CAC) score is suggested by current guidelines (Grundy et al. 2018; Piepoli et al. 2016). The present article provides an overview of state of the art cardiovascular risk prediction strategies in 2019 and gives a perspective on innovative approaches that may improve future prevention algorithms.

Risk Scores

Risk scoring algorithms are established in clinical routine for assessment of cardiovascular disease risk based on traditional risk factors. For many years, the Framingham Risk Score was the leading risk score in clinical routine (Pencina et al. 2009). However, several studies have outlined its limitations to distinguish the risk for CVD (Ajani and Ford 2006; Brindle et al. 2003; Akosah et al. 2003). In the U.S., the Framingham Risk Score has been widely replaced by the Pooled Risk Equation, which is recommended according to the current AHA/ACC guidelines (Grundy et al. 2018). In Europe, the ESC advises the utilisation of the SCORE, which has been established based on European cohort studies and differentiates into high and low-risk countries. In contrast to most other algorithms, the SCORE assesses the risk of cardiovascular mortality only instead of overall cardiovascular event risk (Piepoli et al. 2016). Based on different approaches, multiple additional risk scores are available, eg for estimation of lifetime risk (Jaspers et al. 2019). However, the predictive ability of risk scores based on traditional risk factors is limited, providing an area under the ROC curve of around 0.7. Inclusion of modern risk markers such as the CAC score may improve the predictive ability (McClelland et al. 2015), but need to find their way into daily clinical routine.

Statin Therapy for Primary Prevention – Differences in European vs. U.S. Guidelines

In patients aged ≥40 years without known cardiovascular disease, AHA/ACC-guidelines advise statin therapy when the risk for atherosclerotic cardiovascular disease (ASCVD) is ≥7.5% in 10 years, while statin therapy can be considered in patients with 10-year ASCVD risk of ≥5% (Grundy et al. 2018). But the ASCVD-Score, which is based on U.S. population-based studies, leads to a relevant overestimation of 10-year risk in European cohorts (de Las Heras Gala et al. 2016). Therefore, application of AHA/ACC compared to ESC-guidelines results in a tremendously higher rate of indication for statin therapy (Mahabadi et al. 2017; Kavousi et al. 2014). In contrast, according to European guidelines, a relevant amount of patients experiencing cardiovascular events would have been classified into low or intermediate risk groups prior to disease manifestation (Mahabadi et al. 2017). This makes approaches for individualised risk estimation and personalised treatment recommendations indispensable, allowing improved prevention strategies in the future.

Imaging for Reclassification of Cardiovascular Risk

Several measures of subclinical atherosclerosis have been suggested for potential risk reclassification in primary prevention cohorts. Most importantly, the

CAC score, quantified from non-contrast cardiac computed tomography (CT), has demonstrated its ability to improve the prediction of cardiovascular events as well as allows reclassification of risk groups (Mahabadi et al. 2017; Yeboah et al. 2012). The CAC score also outperforms other markers of subclinical atherosclerosis such as the ankle brachial index and the carotid intima media thickness (Geisel et al. 2017). A CAC score of zero reclassifies patients to a category in which guidelines no longer recommend treatment according to population-based cohort studies (Nasir et al. 2015; Mahabadi et al. 2017). Therefore, CAC scoring can be used to down-classify selective patients as statin therapy in primary prevention cohorts may be withheld or delayed if the CAC score is zero. In contrast, recent data suggests that the detection of subclinical atherosclerosis by a CAC score of greater than zero increases the likelihood of lifestyle modification and initiation or continuation of pharmacological therapy (Gupta et al. 2017). Likewise, within the framework of ESC-guidelines, one in three individuals with a recommendation for lipid-lowering therapy can be reclassified to a lower risk group by CAC scoring (Bittencourt et al. 2018). But in addition, assessment of the CAC score also has the added value of identifying patients without indication for statin therapy, who indeed are at increased risk (Mahabadi et al. 2017). When following ESC recommendations, CAC scoring can be used to both down- and up-classify patients with and without indication for statin therapy in appropriate risk groups. Therefore, CAC scoring has the ability to improve the prediction of cardiovascular risk on an individualised level and leads to a significant improvement in reclassification, allowing personalised treatment decisions in primary prevention settings.

Innovative Imaging Technologies for Risk Prediction

The CAC score is quantified based on the Agatston method, which was described in 1990 and accounts for size and density of calcified lesions (Agatston et al. 1990). However, over the last 30 years, imaging technology for visualisation of cardiovascular structures has relevantly improved. In addition, once cardiac CT is performed, assessment of other structures of the heart and the vasculature may improve risk prediction in addition to the CAC score. These include the sizes of cardiac chambers and the great vessels as well as visceral adipose tissues within the thorax (Dykun et al. 2015; Kalsch et al. 2013). Most importantly, the epicardial adipose tissues have gained interest over the last two decades as a potential modulator of local inflammation. Epicardial fat can be quantified from computed tomography, magnetic resonance imaging, or echocardiography of the heart. Recent data suggests that both the volume as well as the CT derived attenuation of epicardial fat is associated with cardiovascular risk, independent of traditional cardiovascular risk factors and the CAC score (Oikonomou et al. 2018; Mahabadi et al. 2013; Balcer et al. 2018). When contrast-enhanced CT coronary angiography is performed, information on the presence or absence of obstructive CAD can be obtained, which may improve the patient's outcome in high-risk cohorts (Scot-Heart Investigators et al. 2018). Moreover, from contrast-enhanced CT, composition of plaque burden can be evaluated, allowing the detection of established high-risk plaque features, which may further increase the predictive value of this imaging technology (Ferencik et al. 2018). In addition, novel imaging technologies such as molecular imaging on inflammation and metabolism provide first promising results and may play a relevant role in the future (Schlosser et al. 2013; Nensa et al. 2015).

Conclusion

Despite cardiovascular disease being the number one reason for morbidity and mortality in the industrialised world, primary prevention strategies remain a major challenge in both research as well as clinical practice. Based on traditional risk factors, multiple risk scoring algorithms are established and broadly used in daily routine. However, these algorithms only imprecisely assess the individual patient's risk. The CAC score currently is the best imaging derived measure for redefining risk, allowing personalised treatment decisions in primary prevention. But multiple new approaches are on the horizon that will challenge the role of CAC scoring in the future. ■

Conflict of Interest

There are no conflicts of interest to disclose.

KEY POINTS

- The predictive ability of risk scores based on traditional risk factors is limited
- Inclusion of modern risk markers may improve cardiovascular risk prediction in daily clinical routine
- Application of AHA/ACC compared to ESC-guidelines results in a tremendously higher rate of indication for statin therapy
- CAC scoring has the ability to improve the prediction of cardiovascular risk on an individualised level and can allow personalised treatment decisions in primary prevention settings
- Novel imaging technologies such as molecular imaging on inflammation and metabolism provide first promising results and may play a relevant role in the future

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For full references, please email editor@healthmanagement.org or visit **https://iii.hm/wnp**.

Sex and Gender Impacts in Cardiovascular Disease: **A "Typical" Presentation of Cardiovascular Disease?**

Summary: Differences in sex and gender may account for gaps in treatment and prevention of cardiovascular disease, but at the same time, it also gives the opportunity for personalised sex and gender-specific medicine.

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Typical presentations in medicine are defined in ways that health care professionals can draw on past experiences and education to adequately diagnose, treat, and heal. Yet, when it comes to cardiovascular disease (CVD), a "typical presentation" may not be accurate for half of the population. CVD is the leading cause of death in the United States of both men and women according to the Center for Disease Control (CDC), yet the typical risks factors and presentation for the disease differ in clinically important ways. The impact of sex and gender in health and disease is especially illustrated with CVD as the "typical" criteria for presentation chest pain, diaphoresis, nausea, radiating pain to the left shoulder and jaw, were developed from research on men.

Sex and Gender Impacts on Quality of Care

Sex differences between men and women begin at the cellular level, affecting cellular gene expression and function that is unique to the chromosomes present in the cell (Garcia et al. 2016). Gender is a person's socialisation that may extend beyond the binary to a larger range of association, expression, and identification. In CVD, sex and gender differences contribute to a lower perceived risk of morbidity in women than in men. When women, their physicians or other non-physician providers, are less aware and less proficient in identifying CVD because the "typical" presentation does not match their male counterparts (Saeed et al. 2017), mortality increases. In the United States, one out of five deaths in women is due to CVD.

"PHYSICIAN GENDER BIAS IN PREVENTION AND TREATMENT STRATEGIES CAN LEAD TO SERIOUS CONSEQUENCES"

When CVD risks are not recognised, women are also less likely to be given aggressive treatment for the prevention of CVD such as lipid-lowering therapy, aspirin, and therapeutic lifestyle changes even when they present with the same risk for atherosclerotic CVD (Abuful et al. 2005). Abuful also noted that physicians suspected chest pain as having an actual cardiac origin more often in men than in women. Physician gender bias in prevention and treatment strategies can lead to serious consequences. While differences in sex and gender may account for gaps in treatment and prevention of cardiovascular disease, it also gives the opportunity for personalised sex and gender-specific medicine.

Risk Factors for Cardiovascular Disease: Traditional and Non-Traditional

Traditional risk factors for CVD impact both men and women and include age, smoking habits, obesity, high blood pressure, elevated cholesterol levels, and diabetes (Saeed et al. 2017). In a 2017 review by Saeed, these indications themselves present differences in the risk associated with their contribution to the development of CVD in men and women. In a meta-analysis of 75 cohort studies, women smokers showed a 25% greater risk of coronary artery disease than male smokers. Women with type 1 diabetes mellitus had a 37% increased risk of all mortality, and twice the risk of fatal and non-fatal vascular events compared to male counterparts, also with type 1 diabetes. The typical

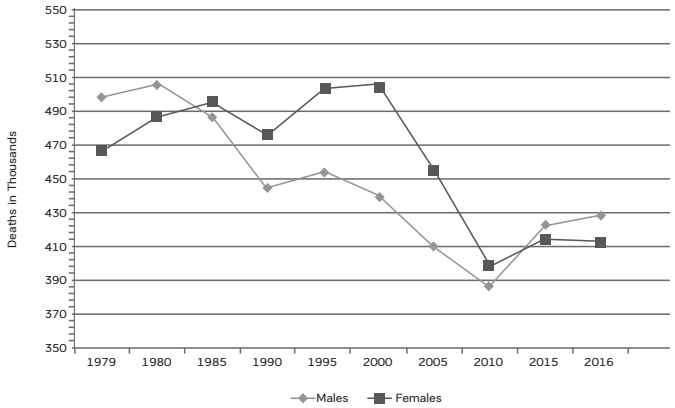

Figure 1. Cardiovascular disease mortality trends for males and females (United States: 1979–2016) Circulation. 2019;139:e56–e528. ©2019 American Heart Association, Inc. Available at ahajournals.org/doi/10.1161/CIR.0000000000000659.

presentation of CVD falls short here, as the calculated risks associated with traditional factors do not treat men and women equally.

Non-traditional risk factors for CVD are associated with the ability of women to bear children, associated with higher oestrogen levels in women, and associated with social and economic stressors. These include gestational hypertensive disorders, preeclampsia, gestational diabetes, autoimmune disorders, depression, and declining oestrogen levels (Saeed et al. 2017). Having increased blood pressure in pregnancy not only contributes to a greater risk for mortality in both the mother and baby, but also puts the mother at risk later on in life for developing high blood pressure and cardiovascular related disease (Ferranti et al. 2016). As women reach menopause, their oestrogen levels decline. Oestrogen protects and enhances the survival of cardiomyocytes within a woman's heart when placed under stress (Kim et al. 2006). These risks support the notion that a typical presentation of CVD must be further defined to include the sex that it describes.

Risk for heart disease for both men and women:

- Smoking
- Diabetes
- High Cholesterol (high HD and/or low HDL
- High Blood Pressure
- Obesity
- Sedentary Lifestyle

For women only

- Menopause
- Birth Control Pills in conjunction with smoking

Ischaemia in the setting of no obstructive coronary artery disease (INOCA) is associated with coronary microvascular dysfunction and adverse cardiac outcomes. More common in women, INOCA may explain the difference in heart attack symptoms and complicates the diagnosis and treatment of CVD. For example, if a cardiac catheterisation is the gold standard for diagnosis of CVD, but women have INOCA then some may be wrongly categorised as having no significant disease. Without using criteria that accounts for the impact of sex and gender, blood tests such as troponin may lead to patients wrongly "ruled out" from having CVD.

While both men and women may have chest pain when having a myocardial infarction, women are more likely to have ischaemia without "typical" chest pain symptoms and are more likely to face mortality without this traditional presentation (Canto et al. 2012). We need to reclassify "typical and atypical" presentations of CVD as this terminology contributes to bias that may lead to incorrect diagnoses. Instead, the development of guidelines and criteria that are sex and gender-specific will improve diagnosis and treatment options, and with increased recognition, we can decrease the mortality from CVD in women.

Stress and CVD Risk

Mental and physical stress, whether experienced early or later in life, is increasingly recognised as significantly influencing the development of chronic diseases. Studies available show that the correlation between stress and CVD risk do not treat the sexes equally. Investigating the effect of socioeconomic status in puberty, a sub-study of the Ovarian Aging Study found that lower socioeconomic status for women in puberty correlated with lower levels of sex hormone-binding globulin (SHBG). SHBG is derived from an index of bioavailable testosterone, and is related to CVD associated hormone profiles (Bleil et al. 2015). Therefore, women that experienced lower socioeconomic status (SES), and the stressors that come with it, have a greater risk for CVD as they age from pubescence into adulthood. In a model by Miller, stress associated with lower SES early on in life heightens the response of macrophages and monocytes, creating a state of chronic inflammation. This inflammation, along with genetic susceptibility, can lead to chronic diseases such as chronic heart disease (Miller et al. 2011). In a study of the prevalence of Adverse Childhood Events (ACEs) over 23 states between 2011-2014, the mean score of ACEs was higher for women than in men, and was higher

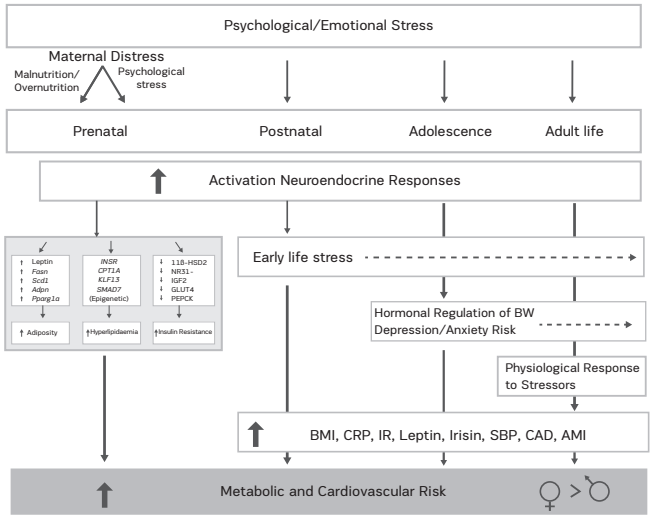

Figure 2. Origins of greater metabolic and cardiovascular diseases through the lifespan in women. BMI, body mass index; CRP, C reactive protein; SBP, systolic blood pressure; IR, insulin resistance; CAD, coronary artery disease; AMI, acute myocardial ischaemic disease.

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for multiracial communities than other races (Merrick et al. 2018). Women report experiencing adverse events in childhood more than men and these adverse events and stressors can lead to higher risks for CVD as they reach adulthood. These additional risk factors for women should heighten our awareness of the potential for CVD. Limited studies have purposefully looked into sex-related correlations on stress and cardiovascular risk, further qualifying the need for such research (Murphy & Loria 2017).

In a perspective from Murphy, there is substantial evidence pointing to several psychosocial disadvantages impacting young women, and this condition will most likely affect the metabolic and CVD risk in the next generation (Murphy & Loria 2017).

Conclusion

The overall decline in death from CVD between 1979 and 2010 can be correlated to the use of evidence-based strategies and implementation of guidelines that decrease risk factors. With increasing rates of death from CVD since 2010, where are the evidenced-based guidelines that take sex and gender into consideration? Including the impact of sex and gender in the development of diagnostic algorithms and treatment options could change the upward trend of mortality in CVD. We must have research that includes the differences in presentations and risk factors for both men and women. In 2014, the NIH released a policy requiring all preclinical research to include sex as a biological variable, and to require adequate justification to only study one sex. Policy is helpful; however, we must have implementation in research and medical school curricula to ensure that the future generation of women is included in our definition of CVD. As we understand CVD differences due to sex and gender, we can tailor therapy, management, and preventive care to gain maximum use of medical care dollars and improve morbidity and mortality overall. ■

KEY POINTS

- When it comes to CVD, a typical presentation may not be accurate for half of the population
- In CVD, sex and gender differences contribute to a lower perceived risk of morbidity in women than in men
- A typical presentation of CVD must be further defined to include the sex that it describes
- We need to reclassify typical and atypical presentations of CVD as this terminology contributes to bias that may lead to incorrect diagnoses

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Inotropic Agents for Heart Failure - **Wishful Thinking?**

Summary: Calcium activation and calcium sensitivity in the failing myocardium.

Historically, treatment of heart failure with inotropic agents started with the employment of extracts of foxglove, which contained a mixture of cardiac glycosides. With their low therapeutic margin due to a resulting ionic dysbalance though, cardiac glycosides have meanwhile nearly completely disappeared from the therapeutic tableau. As clinical alternatives, adrenergic agonists had been introduced, but, due to internalisation of adrenergic receptors, their therapeutic efficacy tends to vanish over time, so that at best an intermittent therapy is employed. Alternatively, phosphodiesterase inhibitors exert their effects beyond the adrenergic receptor but can impose calcium overload and energetic exhaustion of the cardiac myocyte. Thus, inotropic agents of the types of cardiac glycosides, adrenergic agonists or phosphodiesterase inhibitors have to be seen as therapeutic approaches to be taken only with great care and under strict clinical observation, not well suited for chronic medication in heart failure. As it appears, the reduced cardiac contractility in heart failure is not necessarily due to a lack of intracellular calcium ions. Therefore, in such cases, agents enhancing the sensitivity of the contractile proteins to calcium appear to be a potentially safer way to the therapy of heart failure.

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Introduction

Heart failure is characterised by the inability of the heart to produce sufficient blood flow through vital organs of the body. As the heart is part of the cardiovascular system, impairment of perfusion of parts of the arterial system, due to, eg atherosclerotic plaques or vasoconstriction, increase afterload and may, in the long run, affect the pumping capacity of the heart. Systemic symptoms like oedema and shortness of breath may arise and reduce the exercise capacity of the body progressively. ACE inhibitors, angiotensin receptor blockers, calcium entry blockers and the like are successfully used to reduce the afterload on the heart and can improve survival, but as exercise capacity depends critically on myocardial performance, positive inotropic agents are still needed to support the pump function of the heart.

Cardiac Glycosides for Heart Failure

The accumulation of water in oedema has historically been dubbed "Dropsy" and was successfully treated already in the 18th century by the application of extracts from the foxglove Digitalis purpurea (Withering 1785). It took, though, 168 years until the underlying mechanism of action was discovered. Schatzmann (1953) reported that cardiac glycosides inhibit the Na/K ATPase (NKA), the enzyme responsible for exchanging sodium (Na) that had entered the cardiac cell during the depolarisation phase of the action potential for potassium (K) that had left the cell during repolarisation. By this, an additional Na load is imposed on the myocardial cell. Coupled to the passive transporter (Sodium Calcium Exchanger, NCX) that exchanges intracellular Na for extracellular Calcium (Ca), an inhibition of the Na/K ATPase results therefore in a net increase in the amount of Ca ions available intracellularly for contractile activation (Figure 1, Ca fluxes 2 and 3). This results in a positive inotropic response that is principally aiding pump function, but also in an ionic imbalance that can lead to severe proarrhythmic complications.

Adrenergic Agonists for Heart Failure

During bodily exercise, an increased outflow from the adrenergic system helps the heart to cope

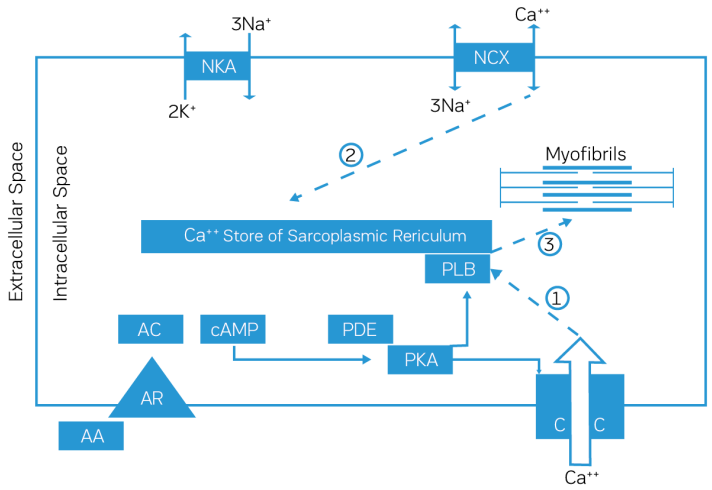

Figure 1. Schematic Representation of a Myocardial Cell

NKA = Na/K-ATPase; NCX = Na/Ca-Exchanger
AR = Adrenergic receptor; AC = Adenylylcyclase
PKA = Protein Kinase A; PDE = Phosphodiesterase
AA = Adrenergic agonist; CC = Calcium-Channel
PLB = Phospholamban; - - - = Calcium Flux

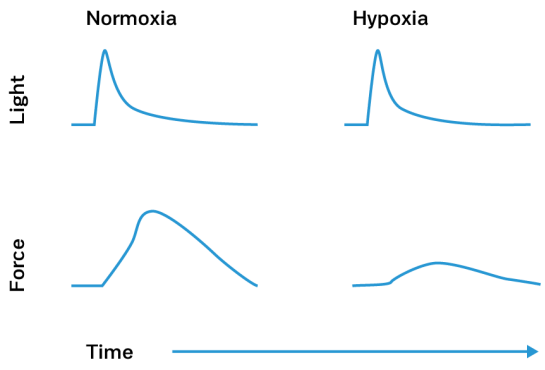

Figure 2. Force and Intracellular Free Calcium in Electrically Stimulated Ferret Papillary Muscle in Normoxia and Hypoxia

Light emitted from injected Aequorin as a measure of intracellular free Calcium ions (after Allen and Orchard 1976).

with increased circulatory needs of muscles and other organs, eg during the "fight or flight" reflex reaction. Understanding of the actions of adrenergic agonists on cardiac performance has, therefore, consequently, led to the concept of therapeutic application of adrenergic agonists in heart failure. Stimulation of adrenergic receptors triggers the production of cyclic AMP (cAMP) by adenylyl cyclase (AC) (Figure 1), which activates a cyclic AMP-dependent protein kinase (PKA) that phosphorylates a couple of proteins that are involved in handling of intracellular calcium, like the sarcolemmal calcium channel (CC) (Figure 1, Ca flux 1) and phospholamban (PLB) on the sarcoplasmic reticulum. All this together results in an increased availability of calcium ions for contractile activation and therefore a positive inotropic effect. Chronic application of adrenergic agonists, though, entails a chronically enhanced calcium activation and hence a metabolic load which the heart is not capable to cope with in the long run. The positive inotropic effect of adrenergic agonists tends, though, to fade progressively over time. The underlying cause has been identified as an intrinsic protective mechanism, namely the progressive down-regulation of adrenergic receptors by endocytosis and internalisation into the myocardial cells (for an overview, see Ferguson 2001). One way out of this dilemma is the intermittent clinical application of adrenergic agonists in chronic heart failure, which means to accept intermittent periods of no treatment (Mauro and Mauro 1986). Such observations resulted in the need for alternatives, circumventing the involvement of adrenergic receptors.

Phosphodiesterase Inhibitors for Heart Failure

As shown in Figure 1, the production of cAMP in the myocardial cells is governed by adenylyl cyclase (AC), while phosphodiesterase III (PDE) cleaves cAMP. As activation of AC and production of cAMP depend critically on stimulation of the adrenergic receptor, down-regulation of the receptor leads to a loss of the inotropic effect. On the other hand, inhibition of PDE would be a therapeutic principle to protect cAMP from cleavage and is, therefore, to be expected to preserve the positive inotropic effect. At the same time, this would lead to a cAMP-dependent vasodilation in resistance vessels, thereby reducing afterload (Arnold 1993).

"CONGESTIVE HEART FAILURE IS CLINICALLY EXTREMELY DIFFICULT TO HANDLE"

Although the beneficial effects of PDE inhibitors on cardiac performance and haemodynamics have been observed in heart failure patients, PDE inhibitors tend to negatively affect morbidity and mortality upon prolonged application (Packer et al. 1991). Like with adrenergic agonists, metabolic exhaustion and arrhythmias are certainly contributing to the observed increase in

morbidity and mortality. Strikingly, cAMP, when applied to cardiac skinned fibres (Figure 3), induces a rightward shift of the calcium activation curve toward higher calcium concentrations, ie cAMP leads to a decrease in the sensitivity of the contractile structures for calcium ions through phosphorylation of Troponin I on the cardiac myofibrils (Herzig and Rüegg 1980). This at least partly explains the acceleration of diastolic relaxation in cardiac muscle under the influence of adrenergic agonists or PDE inhibitors, but it also entails a limitation of systolic force at the physiological intracellular calcium concentration of 1 µmol/l, thus this effect partly counteracts the positive inotropic action of adrenergic agonists or PDE inhibitors. Congestive heart failure is, therefore, still a disease which is clinically extremely difficult to handle. This has even led to the rather desperate judgment that trying to stimulate the failing heart with inotropic agents may be as hopeless as "flogging a dead horse." While increases in intracellular calcium certainly increase cardiac force, Allen and Orchard (1976) showed that hypoxia in intact papillary muscles leads to a loss of contractility, which is not associated with a decrease in intracellular free calcium (Figure 2). This means that in hypoxia it is not calcium that is lacking, but the sensitivity for calcium is reduced. This observation called for a search for pharmacological agents that increase the sensitivity for calcium.

"LEVOSIMENDAN HAS BEEN WELL INVESTIGATED IN HEART FAILURE PATIENTS"

Calcium Sensitisers for Heart Failure

As PDE inhibitors have to pass through the myocardial sarcolemma to access their locus of action intracellularly (Figure 1), it appears logical to investigate whether PDE inhibitors would also exert additional actions within the myocardial cell. One elegant way to study such actions is to remove the diffusion barriers of membrane systems like the outer cell membrane (sarcolemma) and the sarcoplasmic reticulum (the intracellular storage organelle for Ca ions). This can be done in myocardial preparations by dissolving the phospholipid bilayers of these membrane systems by exposing the myocardial preparation to detergents, like Lubrol WX or Saponin. The resulting "Skinned Fibres" can then be activated by the addition of Mg-ATP as an energy source and Ca ions as "trigger" for mechanical activity (Figure 3). The skinned fibres then produce sustained contractions the amplitudes of which depend on the free Ca ion concentration in the range of 0.1 to 10 µmol/l (Figures 4 and 5).

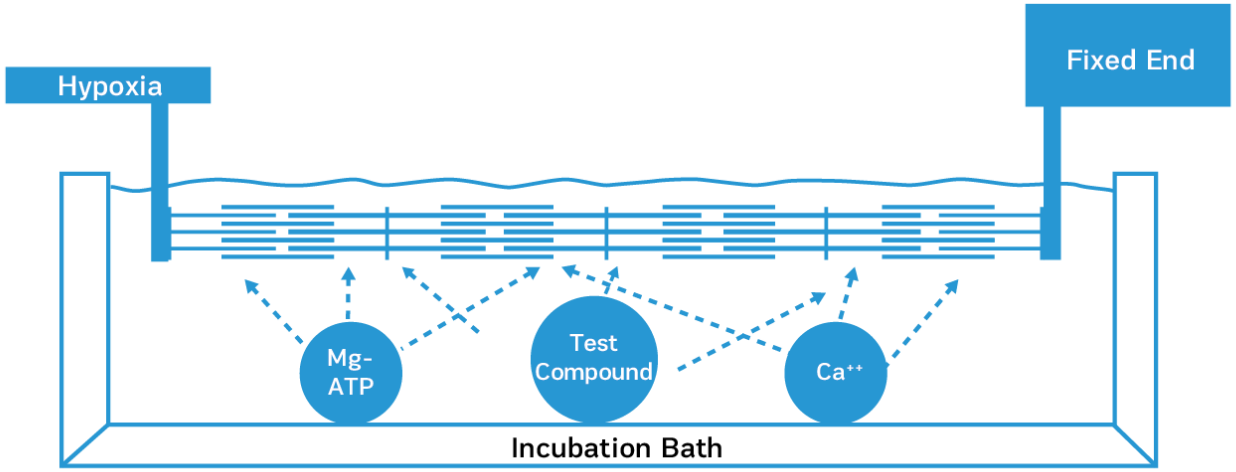

Figure 3. Schematic Representation of a "Skinned Fibre" from Cardiac Muscle in an Incubation Bath

The skinned fibre is deprived of membrane systems like, eg sarcolemma and sarcoplasmic reticulum by treatment with detergents. The incubation bath contains a salt solution with Mg-ATP as energy source, Calcium ions as activator of contraction and a test compound whose action on the myofibrils is to be investigated. All constituents of the incubation medium can freely diffuse into the myofibrils of the skinned fibre. Force development and ATP consumption can be measured simultaneously.

The first positive inotropic agent that was tested in such a model was ARL-115 BS, a cardiotonic PDE inhibitor (Herzig et al. 1981). As in this model membrane targets for cAMP-dependent phosphorylation are removed, and as PDE is washed out, only mechanisms that would lead to positive inotropism independent of membrane effects of the adrenergic cascade and of PDE inhibition can show up in the skinned fibre model. ARL-115 BS, in the concentration range of 350 µmol/l, leads to an increase in calcium sensitivity, ie the calcium activation curve of the skinned fibres is shifted to the left, toward lower concentrations of free calcium (Herzig

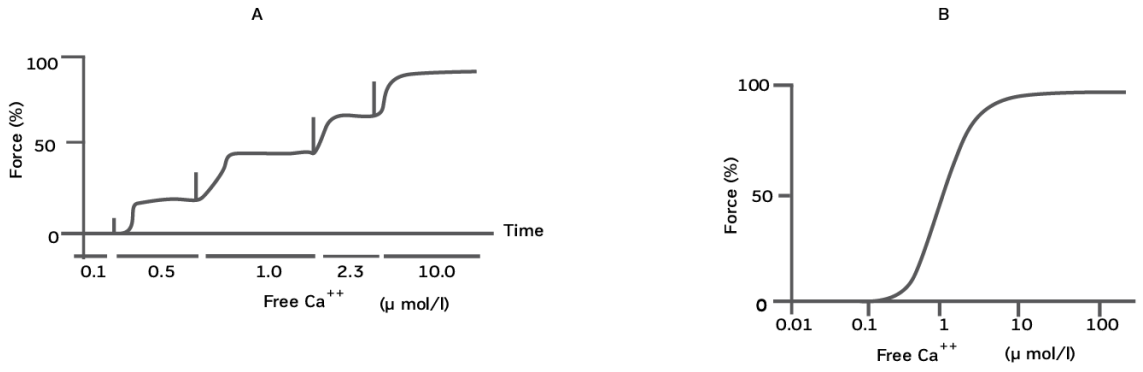

Figure 4. Time Course of Calcium-Dependent Force in Cardiac Skinned Fibres (A) and Calcium Dependence of Force in Cardiac Skinned Fibres (B)

Free Calcium ion concentrations are buffered with EGTA / Ca-EGTA, 10 µmol/l Mg-ATP as energy source, room temperature, pH 6.7 (after Herzig et al. 1981).

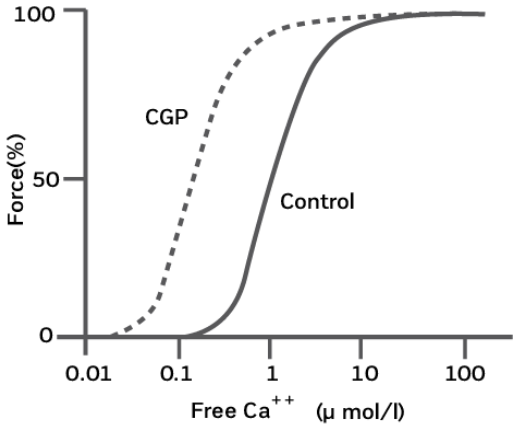

Figure 5. Dependence of Isometric Force Development on the Free Calcium Ion Concentration in Detergent Treated Porcine Cardiac Muscle

Control = no drug added; CGP = 10 µmol/l CGP 48506 (after Herzig et al. 1996).

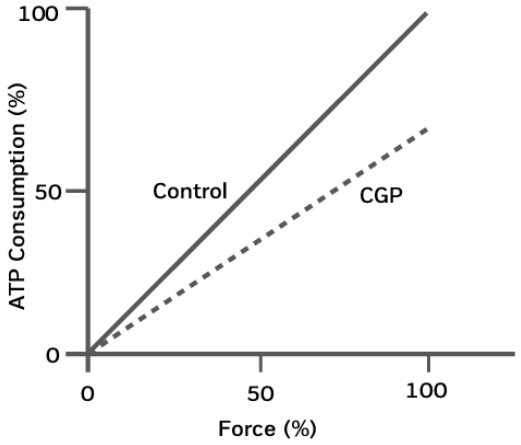

Figure 6. Relationship between Calcium-activated Force and ATP Consumption in Cardiac Skinned Fibres

Control = no drug added; CGP=10 µmol/l CGP48506. Note that with 10 µmol/l CGP 48506 any given force is reached at reduced ATP consumption as compared to Control (Herzig unpublished).

et al. 1981). This observation initiated a further search for calcium sensitising agents, and the most obvious candidates for such investigations had initially been other PDE inhibitors. We (Salzmann et al. 1985) published the calcium sensitising effect of the PDE inhibitor APP 201-533 where, most importantly, we saw evidence for a concomitant effect on the economy of the contractile process, ie the calcium sensitising effect of APP 201-533 is associated with a relative reduction in the consumption of ATP by the contractile structures. This effect on cardiac economy is even more pronounced in BA 41899 and its active enantiomer CGP 48506, the first ever described calcium sensitising agent that is completely devoid of additional PDE inhibitory activity (Herold et al. 1995; Zimmermann et al. 1998) (Figures 5, 6 and 7). CGP 48506 at 10 µmol/l reduces the energy requirement from ATP for contractile activity by about 40% (Herzig unpublished). Concomitantly, systolic calcium concentrations as measured with Fluo-3 in intact papillary muscles explanted from human hearts are unaffected, while systolic shortening is increased, and diastolic relaxation is decelerated (Herzig et al. 1996).

"PDE INHIBITION BLUNTS THE INOTROPIC EFFECT OF CALCIUM SENSITISATION"

Thus, there is evidence that the calcium sensitiser CGP 48506 prolongs the attached state of the myocardial myosin cross-bridges on the actin filaments, thereby increasing the force-time-integral associated with each ATP cleavage on the contractile system, comparable to shifting the contractile system of the heart into an energy saving "overdrive."

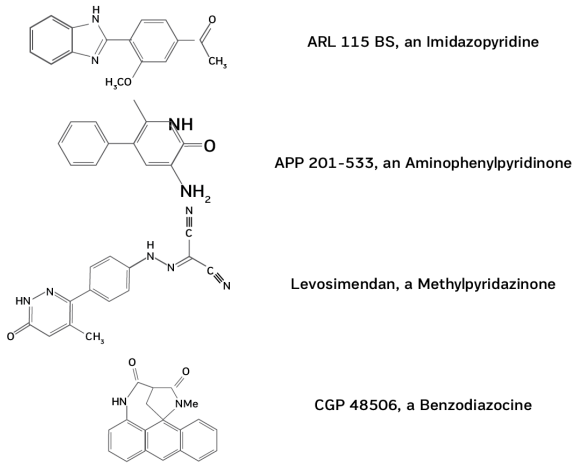

Figure 7. Chemical Structures of Calcium Sensitising Agents

Note that ARL 115 BS, APP 201-533 and Levosimendan are all primarily PDE inhibitors with additional effect on calcium sensitivity, while CGP 48506 is the only calcium sensitising agent without PDE inhibitory effect.

Some calcium sensitising agents have been tested clinically, but all of them are primarily PDE inhibitors with additional effects on calcium sensitivity (Kass and Solaro 2006). Levosimendan (Figure 7) has been particularly well investigated in heart failure patients. Mebazaa et al. reported in the SURVIVE Trial 2007 that levosimendan did not improve survival as compared to the adrenergic agonist dobutamine. According to Endoh (2015), the clinical observations under levosimendan can be fully explained on the basis of its PDE inhibitory effect alone. CGP 48506 (Figures 5, 6 and 7), on the other hand, is the only calcium sensitising agent without any effect on phosphodiesterase. Despite its proven efficacy as a positive inotropic agent in a variety of models, this agent has, so far, not yet been tested clinically in heart failure patients.

Conclusion

"Classical" inotropic agents of the types of cardiac glycosides, adrenergic agonists, and PDE inhibitors are acutely aiding heart failure patients, but fail in chronic application. As far as current clinical experience with those PDE inhibitors is concerned which concomitantly increase calcium sensitivity, PDE inhibition appears to, at least partially, blunt the inotropic effect of calcium sensitisation. Next to the novel myosin activators (Cleland et al. 2011), it will, therefore, be important to investigate "pure" calcium sensitisers like CGP 48506 clinically, in order to understand the true potential of the concept of calcium sensitisation, including its impact on myocardial energy demand (Salzmann et al. 1985; see also Figure 6), independent of other inotropic mechanisms. Such studies are still missing and should be undertaken with priority. With such information, inotropic agents for heart failure may, in the end, become more than just wishful thinking. ■

KEY POINTS

- Mixed clinical experience with cardiac glycosides, adrenergic agonists and PDE inhibitors
- Calcium activates the heart, but is calcium lacking in heart failure?
- Don`t increase calcium, try calcium sensitising agents

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Nuclear Cardiology: **Molecular Insights into the Heart**

Summary: Nuclear cardiology is a promising field located between research, imaging, and patient care. Through close interdisciplinary cooperation, a variety of cardiovascular diseases (eg coronary artery, inflammatory and infiltrative cardiac diseases) can not only be investigated, but also efficiently treated in daily clinical routine.

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What is Nuclear Cardiology?

In nuclear medicine, molecular probes are administered to patients at nano- or picomolar concentrations in order to visualise processes non-invasively in the body. This principle is applicable in different medical fields such as oncology (eg glucose metabolism of tumour cells), neurology (eg amyloid plaques in dementia) or cardiology (eg myocardial perfusion). In general, only low amounts of weak radioactivity are given, which result in low radiation to the patient. In addition, the administered radiotracer do not usually cause pharmacological effects. Single-photon-emission-computed-tomography (SPECT) and positron-emission-tomography (PET) are scintillation cameras which detect the emitted radiation from the patient. The functional images generated by those cameras are usually combined with computed tomography (CT) or magnetic resonance imaging (MRI) for morphological correlation. Nuclear medicine also offers therapeutic interventions such as Peptide Receptor Radionuclide Therapy (PRRT) for neuroendocrine tumours; however, this is not the subject of this manuscript.

Nuclear cardiology represents a dynamic subspecialty which is dedicated to develop approaches in a variety of cardiac diseases including atherosclerosis (eg coronary artery disease, ischaemic heart failure), infectious diseases (eg myocarditis, endocarditis, cardiac implantable electronic device (CIED) - infection) and infiltrative cardiac conditions (eg amyloidosis, sarcoidosis, Morbus Fabry). Since these are complex disease entities, it is of high importance in nuclear cardiology to set up an interdisciplinary team of experts. As an example at the University Hospital Essen, a close collaboration between the Clinic for Nuclear Medicine/Institute of Radiology at the University Hospital Essen and the West German Heart and Vascular Center has been established. Patients are examined by state-of-the-art molecular imaging approaches using SPECT/CT, PET/CT, and PET/MRI. In addition, a preclinical imaging facility including micro-PET/CT was set up to pursue new, promising research approaches and translate them from basic research into clinical application. Last but not least, a professorship for nuclear cardiology has been implemented to promote this promising field. The aim is for all these approaches to lead to the promotion of cutting-edge research and patient care.

What Heart Diseases Can We Image?

Using nuclear cardiology, a variety of cardiovascular diseases can be non-invasively assessed. The most important ones include imaging of ischaemia due to coronary artery disease, viability testing in ischaemic cardiomyopathy, and imaging of infective and infiltrative cardiac diseases such as endocarditis and sarcoidosis.

Coronary Artery Disease

Coronary heart disease remains the leading cause of death in the Western world despite improvements in acute care for myocardial infarction through rapid revascularisation and optimal drug therapy. In coronary heart disease, an increasing narrowing of the coronary arteries leads to a reduced perfusion of the dependent myocardium. As the disease progresses, the probability of a sudden blockage of a coronary artery due to thrombus formation increases, leading to myocardial infarction. Stenoses of the coronary arteries can be treated with percutaneous transluminal angioplasty and stenting, but numerous studies have shown that stenoses are the most likely to benefit from an intervention that impedes

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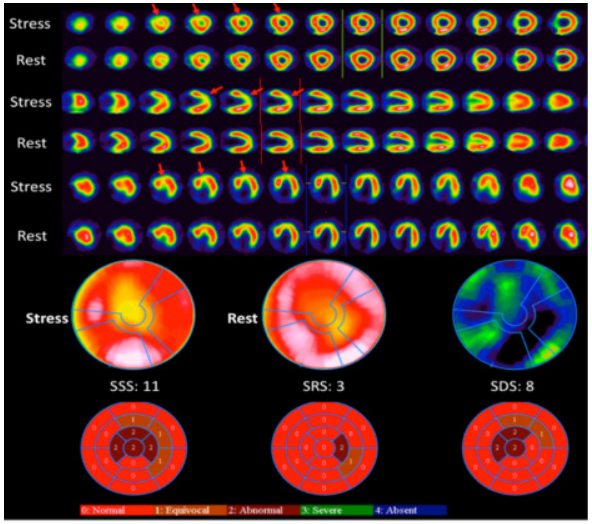

Figure 1. Myocardial perfusion scintigraphy demonstrating ischaemia.

This patient was examined using Tc-99m sestamibi SPECT/CT to rule out perfusion abnormalities. A reversible perfusion defect in the anterior wall and the apex (red arrows) was found, indicating ischaemia due to haemodynamic stenosis in the left anterior descending (LAD) territory. As the extent of ischaemia is more than 10%, revascularisation should be considered. SSS = summed stress score, SRS = summed rest score, SDS = summed difference score

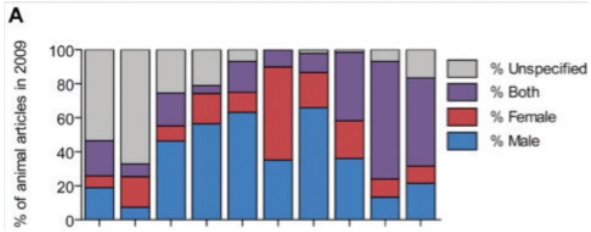

Figure 2. FDG PET/MRI of a patient with active cardiac sarcoidosis.

The examination was performed in case of suspected cardiac involvement in known systemic sarcoidosis. The MRI images show a midmyocardial LGE of the basal lateral wall with corresponding FDG uptake in PET (red arrow), which can be interpreted as an active myocardial sarcoidosis with beginning fibrosis. In addition, myocardial areas with intensive FDG accumulation without correlate in the LGE MRT can be detected (blue arrows), which are to be evaluated as active cardiac sarcoidosis without initiated fibrotic transformation of the myocardium. The green arrow also indicates active myocardial sarcoidosis of the basal septum, while the contrast enhancement in this area is most likely not due to myocardial damage, but rather fibrotic fibers of the upper part of the interventricular septum.

myocardial blood flow and causes ischaemia. With the help of myocardial perfusion scintigraphy as a non-invasive ischaemia test of the myocardium, the necessity of a cardiac catheter examination can be determined. In other words, myocardial perfusion scintigraphy has a gatekeeper function in the diagnosis of patients with coronary heart disease. A perfusion tracer is injected once under hyperaemic and once under resting conditions. Hyperaemia can be caused by physical stress (treadmill or bicycle ergometer) or pharmacological stress (adenosine, regadenoson, or dobutamine). After tracer injection, the stress or rest images are acquired using PET or SPECT. Based on the images obtained, a distinction can be made between normal findings, myocardial scar tissue, ischaemia, and mixed findings (Figure 1). Depending on the result, a decision must be made together with the cardiologist as to whether revascularisation is necessary or whether drug therapy and lifestyle changes with optimisation of the risk factors are sufficient.

"NUCLEAR CARDIOLOGY REPRESENTS A DYNAMIC SUBSPECIALTY WHICH IS DEDICATED TO DEVELOP APPROACHES IN A VARIETY OF CARDIAC DISEASES"

Viability Imaging of the Heart

Coronary artery disease may result in ischaemia or myocardial infarction of the heart. Chronic or repetitive hypoperfusion of the heart may cause the heart muscle to stop contracting properly and lead to a syndrome called ischaemic cardiomyopathy. This typically manifests itself in symptoms such as shortness of breath, leg oedema, or pleural effusions. If the heart is hypoperfused but still vital, this is called 'hibernating myocardium.' Hibernating myocardium is characterised by a wall motion abnormality that is reversible after revascularisation. A typical characteristic of hibernating myocardial areas is also that they prefer the metabolisation of glucose instead of free fatty acids. It is also known that the presence and extent of hibernating myocardium is associated with cardiac events and poor prognosis, if no revascularisation is performed.

There are several approaches to non-invasively visualise myocardial vitality, which include stress echocardiography and stress MRI, myocardial perfusion scintigraphy by SPECT using perfusion tracers, glucose metabolism imaging by F-18 fluorodeoxyglucose (FDG, a glucose analogue) PET, and late-gadolinium enhancement (LGE) MRI, which is ultimately imaging of myocardial scar tissue. In order to create ideal examination conditions, the patient must be specially prepared for FDG PET. Among the various methods used to achieve the best possible FDG uptake of the heart are oral glucose administration and simultaneous intravenous administration of glucose and insulin. If the FDG PET is combined with a perfusion study, the proportion of hibernating myocardium, ie the proportion of myocardium that is hypoperfused but has a normal or increased glucose metabolism, can be determined. LGE MRI, on the other hand, allows myocardial scar tissue to be visualised with contrast medium, since

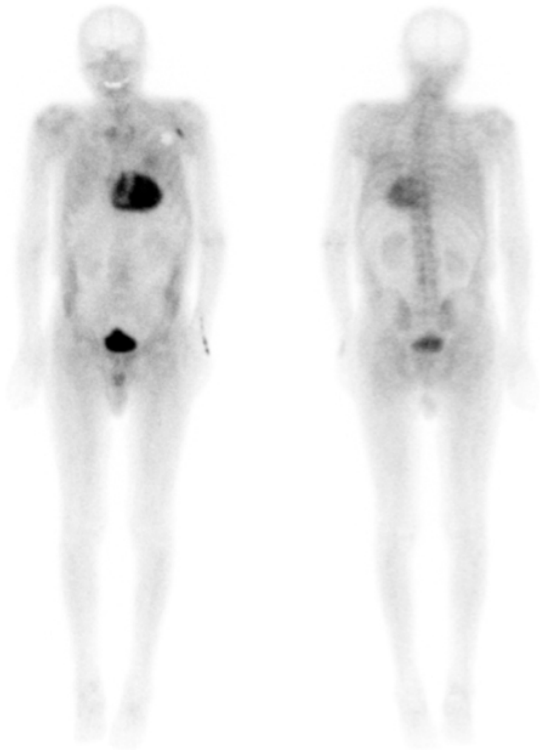

Figure 3. Tc-99m DPD scintigraphy of an 83-year old male patient with ATTR amyloidosis.

The delayed phase images of the skeletal scintigraphy show an intensive tracer accumulation of the heart (Perugini score 3), which allows the diagnosis of cardiac involvement of ATTR amyloidosis. Consequently, an endomyocardial biopsy is not required in this case

MRI contrast medium is washed out of scar tissue more slowly than from healthy myocardial tissue. FDG-PET is considered to have the highest sensitivity for the detection of vital myocardial tissue, while the MRI has a higher specificity. Therefore, it is expected that a combined PET/MRI will provide a very high diagnostic value and accuracy.

Infection and Inflammation

Both PET and MRI allow visualising inflammatory processes that play an important role in a variety of cardiac diseases such as myocarditis, cardiac sarcoidosis, or infectious endocarditis. With the help of MRI, myocardial fibrosis or oedema, pericardial effusions, and wall motion abnormalities can be detected with high sensitivity. In recent years, FDG PET has also been used with increasing frequency to visualise inflammatory processes in the heart. In particular, FDG PET allows to determine the extent of inflammatory processes and to distinguish between highly active, low-grad, or no longer active myocardial inflammation. As described in the previous section, cardiomyocytes also metabolise glucose and may therefore also show an intense FDG uptake. For this reason, it is necessary to minimise myocardial glucose metabolism prior to FDG PET if inflammatory processes are to be visualised. This is achieved by different methods to reduce the blood glucose level and to increase the free fatty acid level. These include an 'Atkins diet' (high-fat/low carb diet) the day before the examination, a longer fasting period (usually longer than 12 hours) immediately prior to the examination and the injection of unfractionated heparin prior to FDG. If the FDG is injected after such preparation, it is almost exclusively taken up by inflammation cells, and an FDG accumulation in the area of the heart thus represents inflammatory processes.

Myocarditis is an inflammatory, potentially life-threatening disease that can have several causes, the most common being a (viral) infection. The symptoms are often non-specific and of limited help in diagnosing the disease. While endomyocardial biopsy as an invasive procedure with a relatively high complication rate but only limited accuracy remains the reference procedure for the diagnosis of myocarditis, non-invasive imaging procedures are increasingly used. In a study at our institution, 65 patients with suspected myocarditis were examined by FDG PET/MRT, and a very high accuracy of the procedure was found. For this reason, FDG PET/MRT is regularly used in patients with suspected myocarditis at the University Hospital Essen.

Another inflammatory disease of the heart in which FDG PET/MRT is regularly used is cardiac sarcoidosis. Sarcoidosis is a multisystemic disease whose cause is unknown. Cardiac involvement is one of the most common causes of death in patients suffering from sarcoidosis and must, therefore, be excluded with a high degree of certainty. An increasing number of articles proves the value of the combined examination of LGE MRI and FDG PET.

FDG PET can not only represent inflammatory processes of myocardial sections that are not yet scarred, but may also be used to graduate the acuteness of the disease. The LGE MRI reflects already scarred myocardium - information that may be helpful in the context of implantation of a possibly required ICD due to cardiac arrhythmias. An example of a patient with active cardiac sarcoidosis is shown in Figure 2.

"BY APPLYING COMBINED FUNCTIONAL AND MORPHOLOGICAL IMAGING MODALITIES, PATHOPHYSIOLOGICAL PROCESSES OF CARDIAC DISEASES CAN BE VISUALISED"

Cardiac Amyloidosis

Cardiac amyloidosis is another disease that has recently become increasingly important in cardiology and nuclear cardiology. Amyloidosis is a systemic disease that can ultimately involve any organ, with the heart, kidneys, liver, and autonomic nervous system most commonly affected. The vast majority of cardiac involvement in amyloidosis is monoclonal light chain (AL) or transthyretin (ATTR) amyloidosis. In patients with heart failure but preserved ejection fraction (HFpEF), cardiac amyloidosis is a common and often unrecognised cause, and the disease must, therefore, be safely excluded. Scintigraphy using osteotropic tracers (eg Tc-99m dicarboxypropane diphosphonate [DPD]) shows very high sensitivity, specificity, and positive predictive value for the diagnosis of cardiac ATTR amyloidosis. Cardiac AL amyloidosis, on the other hand, is usually negative in this examination and is therefore often diagnosed by endomyocardial biopsy. Using amyloid-specific PET tracers such as F-18 florbetaben or F-18 florbetapir, both AL and ATTR amyloidosis can be diagnosed and differentiated by the intensity of tracer accumulation. PET/MRI, therefore, has the potential to reliably diagnose cardiac amyloidosis: the extent of cardiac impairment can be quantified by MRI (eg impairment of left ventricular pump function, wall movement abnormalities, myocardial fibrosis) and the different amyloidosis subtypes can be differentiated by PET. An example of skeletal scintigraphy of a patient with ATTR amyloidosis and cardiac involvement is shown in Figure 3.

Conclusion

Nuclear cardiology has proven to be an important subspecialty of nuclear medicine. The main fields of application using imaging techniques such as SPECT/CT, PET/CT, and PET/MRT are coronary heart disease, heart failure, and inflammatory/infiltrative cardiac diseases. By applying combined functional and morphological imaging modalities, pathophysiological processes of cardiac diseases can be visualised, resulting in improved diagnostics with high accuracy and confidence. ■

KEY POINTS

- Nuclear cardiology is a dynamic subspecialty in nuclear medicine which allows non-invasive assessment of a variety of cardiac diseases
- Established methods include myocardial perfusion scintigraphy using Single-Photon Emission Computed Tomography (SPECT) and viability imaging of the heart using F-18 fluorodeoxyglucose (FDG) Positron-Emission Tomography (PET)
- Imaging of inflammation and infection (eg in cardiac sarcoidosis or myocarditis) or non-invasive diagnosis of cardiac amyloidosis are additional fields of application and the subject of current research

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For full references, please email editor@healthmanagement.org or visit **https://iii.hm/wdz.**

Putting Medical Radiation **Protection First**

Summary: How a European Society of Radiology flagship initiative is addressing quality and safety in medical imaging.

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EUROSAFE IMAGING has celebrated five years of success in its mission to support and strengthen medical radiation protection across Europe. Through its Stars network, EUROSAFE IMAGING makes efforts to give radiation protection greater visibility with a holistic, inclusive approach, while simultaneously having a positive impact on clinical practice. The flagship initiative, created by the European Society of Radiology, continues its vital mission of promoting quality and safety in medical imaging and to support and strengthen medical radiation protection across Europe. HealthManagement.org talked with Professor Guy Frija, Chair of EUROSAFE IMAGING on the success of the initiative and what plans are in the works for the future.

How have you seen EuroSafe Imaging develop, what important milestones have you reached in the establishment of the diagnostic reference levels and what challenges have you encountered?

We have finished the data collection of the EUCLID project and it's already a great achievement. As far as our survey is concerned, we knew that having the same understanding about the indications for which we establish clinical DRLs was very important. There was strong participation from the scientific advisory board and other experts to select the indications and prepare the surveys to collect data from the participating centres. I would like to mention, although we did manage to do it, it was not easy. It is extremely difficult work, and several centres experienced difficulties getting the ethical authorisation from their committees as we are managing health data. The issues arising are now more complex, especially with the establishment of the EU General Data Protection Regulation (GDPR). Due to GDPR, it is now far more time consuming when we undertake a new clinical study.

"EUROSAFE PROVIDES 'TRANSLATION' OF LEGISLATION TO SUPPORT WORK OF CLINICAL PRACTITIONERS"

How has EuroSafe Imaging expanded, developed and gone cross –border?

When we started, we were in contact with other countries. We would let them know that EUROSAFE IMAGING would like to launch some "safe campaigns." The EuroSafe Imaging call for action provides radiologists with a simple tool and specific actions to follow for successful implementation for other campaigns worldwide. We supported Africa in developing a radiation protection (AFROSAFE) campaign, followed by Canada (CANADA SAFE) and Japan (JAPAN SAFE). Through EUROSAFE IMAGING we were able to explain the main challenges of radiation protection, which is one of the main areas of the EUROSAFE IMAGING campaign. In addition, during the European Congress of Radiology (ECR 2019), we saw an increasing interest in radiation protection topics. For example, the number of posters submitted for the EUROSAFE IMAGING exhibition and accepted for presentation at ECR 2019, demonstrated an exponential increase breaking previous records. This year we welcomed over 120 posters from experts worldwide, while last year, we had fewer than 90 and the year before only 70. The interest among professionals on the issues of radiation protection has grown. It's a matter of fact that, parallel to EUROSAFE IMAGING, there has been a strong increase of presentations related to medical radiation protection topics at ECR.

The Euratom Basic Safety Standards Directive (Council directive 2013) lays down Basic Safety Standards (BSS) to guard against the dangers arising from exposure to ionising radiation. The requirements of the BSS Directive affect healthcare professionals in radiology in all aspects related to the safety and quality of procedures using ionising radiation. Thus, the BSS Directive provides the legal framework for most criteria of the EuroSafe Imaging Stars self-

assessment. However, many of the criteria used in the self-assessment go beyond the BSS Directive's explicit requirements, which have had to be observed by all imaging departments in the European Union since February 2018. It is important to understand that the EUROSAFE IMAGING Call for Action is not the BSS Directive. With EUROSAFE we provide a 'translation' of the legislation into concrete actions, which are very much in stride within the clinical activity of clinical practitioners.

You chaired the open forum access to medical physics experts in the imaging department: use cases. How will this reinforce the goal to bring the radiologist into the centre of care?

I think it is extremely important to have access to medical physicists. There is a strong shortage of medical physicists in Europe and other countries. It is important to listen to professionals who are working in centres with medical physicists, professionals who are working without medical physicists, and also some companies that are providing medical physicist services. I invited one company like that from my country, France, and showed the attendees that if you don't have access to medical physicists because there is a shortage in your country, you could try to buy medical physicist services.

How do you see Artificial Intelligence (AI) can help reduce the doses for imaging procedures that rely on ionising radiation?

I believe AI is a starting point. It is not only a tool for radiation protection, but it is also a tool for improving quality and safety at large. This is very important. We can address some aspects with AI, which are very important but completely overlooked. Consider the radiologist interpretation of variability. You can take what they learn from a paper published in the last 5 years, comparing radiologists - for example, heart radiologists assisting in developing a new sequence - and we see a very wide variation between each of them. This variability is a non-quality factor, and by using AI, you smooth this variation out. Then, you'll have no variation as the AI system response is always the same, and this is a very important aspect. One other important aspect is the radiology workflow. The workflow is like working in a kind of cockpit. You are not always aware of what is happening in the working room; in particular, you are not aware of emergencies. It is extremely important to have a system which connects with the emergency and which puts this emergency on top of a working list for the radiologists. Our top priority is quality and safety, and AI can help, because you can significantly reduce radiation dosage with AI tools. There are several papers that examine where dosing has been reduced by at least 50% in CT scans. If you consider digital breast tomosynthesis imaging cases, you could reduce the dose by as much as 70%. It is clear AI will help to reduce the dose and can help deal with the difficulty of dose exposure, but also help to reduce the dose of contrast agent, which is extremely important. There is very interesting work from researchers in Stanford that has shown administering an MRI using a 10% dose of gadolinium, provides the same contrast as the full dose. For the moment, there is nothing about CT, but I'm sure it will come.

What other advantages can this technology offer?

AI is a vehicle for improving patient outcomes, and thus it will change the practice of radiology in the next few years and will enhance radiation protection in medical imaging. AI will be a method of demonstrating the clinical value of radiology and will allow for faster and more accurate image assessment and hence diagnosis. AI will also support the training of radiologists, improve clinical knowledge, and contribute to research in medical imaging. Furthermore, AI could have knock-on impacts on radiation protection by reducing the incidence of unnecessary procedures, reducing the doses administered, increasing the image quality, and improving patient safety in general. The transformative potential of AI for the radiology profession cannot be ignored: rather practitioners must be prepared to embrace it. ■

KEY POINTS

- The EUROSAFE IMAGING "safe campaigns" launch is the role model for other campaigns worldwide
- EUROSAFE IMAGING Call for Action provides radiologists with a simple tool and specific actions to follow so that its implementation can be more successful
- The transformative potential of AI for the radiology profession cannot be ignored: rather practitioners must be prepared to embrace it
- Artificial intelligence (AI) is a vehicle for improving patient outcomes, and thus it will change the practice of radiology in the future

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Closing the Loop: **The Road to Zero Medication Errors**

Summary: It is estimated that even today, medical errors are the third leading cause of deaths in the US, costing the health system several billions of dollars a year. Many of these deaths can be attributed to the misuse of medication.

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When used properly, medications save lives. Unfortunately, medication and dosing errors are one of the top challenges that hospitals face and can lead to patient harm and even death. Hospitals implemented electronic infusion pumps in the 1970's to provide more precise flow control of fluids, medications and nutrients than manual adjustment of gravity infusions alone could provide. But along with these benefits to patients came pump-related errors in the tens of thousands. Indeed, the prestigious ECRI Institute's "Top Ten Health Technology Hazards" list has included infusion pumps in eight out of the past ten years, including 2019, and in 2010, the US FDA changed guidance about infusion pump design, based on five years of adverse events and recalls reported to the FDA by hospitals and manufacturers.

In 1985, a multidisciplinary team at Massachusetts General Hospital, motivated by a near-miss event involving a life-critical infusion in a newborn, started working on creating better, more portable drug infusion pumps, using recent advances in low power microprocessors and other technical advances permitting equipment miniaturisation. Our first device was a small syringe infusion pump that assisted users in making complex dose calculations. Subsequently, we developed, patented, and then widely licensed to industry the concept for "smart drug infusion pumps." These allow a hospital to embed in the pump's user interface a table, called a "drug library," of their own, customised list of drugs, together with the best practices by which they are given. The pumps had the capability to prompt a user for correct practices, and to detect and prevent programming errors before they reached the patient. In 2002, ECRI Institute named this feature a "Dose Error Reduction System."

"HOSPITALS IMPLEMENTED ELECTRONIC INFUSION PUMPS IN THE 1970'S TO PROVIDE MORE PRECISE FLOW CONTROL OF FLUIDS"

The advent of "smart pumps" and other patient safety technologies, such as bar-code-assisted-medication-administration (BCMA) prompted leading healthcare systems to launch ambitious initiatives to achieve continuous excellence, and to target "Zero Medication Errors" as achievable goals. In 2005, Partners Healthcare System, in Boston, Massachusetts, where I work, set a goal of reducing medication errors through technology by 2010. We implemented multiple technological systems and changes to the workflow of front-line caregivers and support staff. These included computerised order entry with decision support and the development of our own electronic medication administration record system with bar coding. We worked with our insurers and payers to mandate and implement smart drug infusion pumps at every patient bedside. By 2010, modern versions of "smart pumps" were wireless-capable, permitting drug libraries to be updated more frequently. However, the full electronic integration of the pumps with our clinical information systems, for example with patient-specific order entry, the pharmacy information systems, and the care documentation systems, could not actually be completed by the target date of 2010, for a host of reasons including cybersecurity, the sophistication of wireless information networks, lack of harmonisation of the drug libraries with the formulary, and the sophistication of the pump programming screens.

In 2014, Bill Churchill, Pharmacy Director at Brigham and Women's Hospital, and I proposed a new timeline for "pump integration" in our Boston hospitals, at the World Patient Safety, Science & Technology Summit. The revised goal was to have a system in place by the year 2018 that could exchange data in real-time between pumps and clinical information systems, while providing auto-programming and auto-

documentation. In January of 2019, we affirmed this timeline with the Patient Safety Movement Foundation, because our organisation had made a system wide decision to implement one single infusion pump platform across all 13 of our hospitals … to fully integrate clinical systems to minimise medication errors and close the loop with intravenous drug pumps.

As I write this in the late spring of 2019, it is the "go-live" date for implementation of the new, closed-loop-capable pump platform, at the second largest of the 13 hospitals at Partners Healthcare System (Brigham and Women's - BWH). 3,800 infusion pumps are being replaced in one day, with large teams of support staff in constant attendance to ensure patient safety and continuity of care at the transition moment. All the team members have special T-Shirts with the hospital logo and "Pump Go Live Team – Leading Innovation!!" The Hospital's public-facing newsletter makes it clear that "failure is not an option" even if glitches arise, as is inevitable: "The transition is part of a system-wide goal of wireless, auto-pump programming and auto-documentation in Partners 'eCare'" (**bwhbulletin.org/2019/05/23/get-pumped-brigham-completes-infusion-pump-transition**). After BWH is settled, the other 12 hospitals will follow in a pre-defined sequence. And at each hospital, the target features of "auto-programming" and "auto-documentation" will be achieved according to the implementation plan.

In 1985, our team stepped out of our 'day-job' descriptions, to set aside time to design and to develop entirely new kinds of drug infusion pumps, effectively partnering with mainstream industry and with start-ups, too. We are proud of this effort, prompted by the incident with the newborn baby, and by the desire to have better technology with which to do the best possible patient care.

In 2005, Our Partners Healthcare System Leadership Wrote Defining a Pathway That Has Been Emulated Widely

"By 2010, most Partners hospitals will have fully integrated clinical systems to minimise medication errors. These integrated systems will allow physicians to order medications and tests electronically via a computerised order entry system. With "medication decision support" software integrated into Partners' computerised order entry systems, physicians will be able to reconcile medications and identify

possible adverse drug interactions and patient allergies electronically - before an order is placed. These systems will also enable nurses to electronically record medications administered to patients and ensure that the right patient gets the right drug at the right dose at the right time. By scanning their own bar-coded staff identification, the patient's bar-coded identification, and the patient's unit dose bar-coded medication into the electronic medication administration records (eMAR) system, nurses will verify the accuracy of the medication administered and document the transaction electronically. Similarly, if the medication is intravenous, "smart intravenous pumps" will document the administration of these drugs in the eMAR system" (**partners.org**).

"3,800 INFUSION PUMPS ARE BEING REPLACED IN ONE DAY, WITH LARGE TEAMS OF SUPPORT STAFF IN CONSTANT ATTENDANCE"

In 2013 ECRI Wrote

"Another important consideration is to recognise the limits of safety technologies. Many pumps today are equipped with on-board drug libraries that trigger alert warnings for gross miss-programming. Such "smart" technologies do a good (not perfect) job of helping to get the dose correct. This requires, however, that appropriate drug libraries are developed (and maintained) and that staff use the available safeguards appropriately. In addition, these technologies don't help prevent errors such as administering an order to the wrong patient or selecting the wrong drug. Infusion pump integration – that is, connecting the servers for the infusion pumps with other information systems – can provide additional protections, such as helping verify that both the right patient and the right drug have been selected. Thus, we recommend that healthcare facilities begin (or continue) to implement infusion pump integration with relevant information systems" (**ecri.org/Resources/Whitepapers_and_reports/2014_Top_10_Hazards_Executive_Brief.pdf**).

This Year ECRI Wrote

"Even "smart pumps" that incorporate a dose error reduction system can be misprogrammed in a way that could lead to patient harm. The surest way to eliminate manual-entry errors is to implement auto-programming of your infusion pumps" (**ecri.org/Resources/Whitepapers_and_reports/Haz_19.pdf**).

It was a long road to this point, but I truly believe we have had, and by our leadership will continue to have, the opportunity to significantly reduce harm and death from medication errors around the world.

There is certainly more to be done. We will continue to find, fund, and facilitate pilot projects (particularly in oncology, anaesthesia, and critical care) that permit rigorous testing, verification, validation, and user acceptance of such integration, prioritised according to their impact on patient safety and capability of being scaled across the U.S. and global healthcare landscape. Of importance is continuing to refine the use of bar coding or other automatic identification technologies to assure automatic drug identification by drug infusion systems in every care setting. We also seek to assure that adequate online, highly scalable training and education technologies are available to all caregivers as they learn to use these advanced technologies. And we envision a future state in which human physiology, such as the depth of anaesthesia, can be precisely adjusted by drug infusion devices that are responsive to signals that measure each patient's brain state in real time.

As Churchill said during World War II, "Now this is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning" (Winston Churchill 1942). This quote is applicable to our goal of ZERO preventable deaths from medication errors. ■

KEY POINTS

- Medication and dosing errors can lead to patient deaths
- In 1992, a team at Massachusetts General created and licenced a "smart drug infusion pump"
- "Smart pumps" along with other safety technologies inspired "Zero Medication Errors" as goals
- The target date of 2010 could not be achieved because of a host of reasons
- A revised goal for 2018 was made to have a system that could exchange data in real-time between pumps and clinical information systems
- In January 2019, this timeline was shared with the Patient Safety Movement Foundation
- Spring 2019, the "go-live" date for implementation of the new, closed-loop-capable pump platform, took place
- 3,800 infusion pumps were replaced in one day

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‘The Death of Cancer’ **The Patient Perspective**

Summary: Cancer affects everybody's life at some point. ‘The Death of Cancer,' written by one of oncology's leading figures, Dr Vincent T. DeVita, documents his own journey for the cure. Dr Peter Kapitein gives his personal review on the book.

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In 2005 I was diagnosed with lymph gland cancer and became interested in the medical industrial complex: everything that has to do with healthcare and especially the care of cancer. As a patient advocate, I am empowered through Inspire2Live to improve the quality of life of cancer patients by working on the best treatments for patients and by making these treatments even better. We connect patients, doctors and scientists and initiate projects.

Recently I read the book 'The death of cancer' by Vince DeVita (DeVita and DeVita-Raeburn 2015). Although it was written in 2015, I became aware of its existence recently. Vince DeVita is a pioneer and someone who thinks and always investigates with the patient in mind. He starts with the patient in front of him and, by taking the story of this patient as the starting point, he takes the steps needed to treat them. Science should start with the patient: what does it need for them to survive and what do we need to study for that best outcome? Science should serve our needs and be there for the patient and not the other way around.

Each page resonates the conversations I have had with Dr Bob Pinedo and still have. DeVita: 'You did not give up and you never let go just because a patient has a fatal illness' (DeVita and DeVita-Raeburn 2015).Pinedo resembles DeVita: 'You do not give up on a patient, the patient can stop by themself, but a doctor never does’ (Pinedo 2017). That qualifies a good doctor and DeVita argues more and more against the 'Dr No's.' Doctors who stop treatment because they, themselves, do not know or refuse to consult a colleague for advice or to take over the patient, or because standard practise fails in this patient. Protocols have brought us a long way, but not every patient fits into the protocol. What then fits is 'evidence-based medicine,’ as David Sacket intended: 'Evidence-based medicine includes the integration of clinical expertise with the best available external evidence in addition to the patient's preference' (Sackett et al. 2000).

What is described beautifully and impressively is the pioneering work with the first chemotherapy for blood cancers. While reading, I realise that I am still alive because people like Vince DeVita have done their job and they did not always do that with a helpful and encouraging tailwind. The opposition was heavy. Cancer was treated with surgery and radiation and it was not considered ethical to treat patients with chemotherapy and make them suffer. These are arguments that you still hear now, but from people that do not speak out anymore. Chemotherapy has been proven to contribute to its treatment for cancer patients. DeVita shows beautifully how we get cancer under control, through the three paradigm shifts that have taken place: the recognition that combination chemotherapy can cure cancer, that targeted therapy is successful and that immunotherapy works in most patients.

What DeVita explains is why it is so difficult to cure cancer. Many treatments focus on one particular hallmark of cancer; then it does not work or only for a short while, then the disease returns and the patient dies. DeVita shows this on the basis of a simple explanation of the famous article in Cell 'Hallmarks of cancer: the next generation' by Douglas Hanahan and Robert Weinberg (2011). Initially there were six hallmarks; in an amended version it has been brought to eight. Treatment must focus on all of these eight hallmarks. For the time being, this is impossible (according to DeVita) under the current regulation. If you want to treat according to these hallmarks, you will have to use all information available during the trial or initial treatment in order to be able to use all the information that is currently available and to help the patient. 'Combination anti-hallmark therapy? Forget it’ (DeVita and DeVita-Raeburn 2015). This is of course extremely frustrating for patients and certainly for patients with 'unmet medical need.' They benefit from personalised medicine and if the regulation is a barrier, they die, while there is a well-defined strategy and opportunity based on

the results of the research of top scientists such as Hanahan and Weinberg.

"PEOPLE ARE NOT DYING BECAUSE DRUGS DO NOT EXIST BUT BECAUSE THEY CANNOT ACCESS THEM"

While reading, you increasingly have to think about the 'War on cancer' and that is for good reason. In a beautiful chapter DeVita describes his role and especially his collaboration with Mary Lasker. This widow of the rich philanthropist Albert Lasker, who died of cancer, had a mission and that was to get cancer under control. She was not only rich, but also had an influence at the highest level and arranged the 'War on cancer' under Nixon. The NCI came out of the NIH and got its own budget. DeVita became the director. What unfortunately did not work, was to free the FDA from the NIH and transfer it to the NCI. If you read this and the other chapters, you will feel uncomfortable. DeVita had a powerful position, a lot of money to spend on research and the people to change the working method. And yet many did not succeed or did, but slowly. We can clearly see this at a time when we know of better treatments and we know there is a better approach. Painful is the description of Bernie Fischer who shows that with a limited operation of breast cancer patients, followed by adjuvant chemotherapy, the survival is equal to that of a total mastectomy, where women are seriously mutilated. Even DeVita only managed to change this after six years, while Fischer's work was scientifically regarded as solid, but it jeopardised the income of the surgeons and radiotherapists. 'Most surgeons and radiotherapists would never admit that they opposed Fisher's findings because they threatened the doctor's income; instead, they questioned his integrity' (DeVita and DeVita-Raeburn 2015). If I see, for example, the resistance nowadays that exists to have intervention radiology replace certain surgical procedures and for which there is also proof that this is better for the patient, you would not be happy. When I see how much effort we have to make in order to change the way we work for cancers with unmet medical need, such as pancreatic cancer and brain tumours 'People are not dying because drugs do not exist but because they cannot access them' (DeVita and DeVita-Raeburn 2015), you would not be happy.

So has nothing changed or improved? It appears not, but the good news is that DeVita comes to the conclusion that 'The death of cancer' will be realised by personalised medicine. We will treat patients on all eight (and perhaps Hanahan and Weinberg will discover one or two more) hallmarks and adjust the method in the trials and treatments. Phase three studies are no longer necessary. It simply does not relate to the definition(s) of personalised medicine that have in common that we have to give an individual patient with her specific form of cancer, presently a unique treatment. This is an uphill battle, but I know that this is going to happen.

The 'war on cancer' was a success, although many trivialised it. It was a success because survival made a huge leap. And let's not pretend that the money was wasted. DeVita shows in a beautiful way that cancer research has always cost little when compared with other things: per inhabitant the United States spent $125 in 1969 on the war in Vietnam. For cancer research only $0.89. Let's turn this around and spend more money for saving lives than for destroying them.

Verdict

Vince DaVita is a hero and never left a patient alone. An example for Dr. No. A must-read for the students who are still unspoiled and not biased and for whom this applies: 'Nothing is impossible' (DeVita and DeVita-Raeburn 2015). ■

KEY POINTS

- Cancer will affect us all directly or indirectly
- ✓ A good doctor will not give up on a patient. A bad one will also avoid admitting the treatment isn't working
- ✓ The verdict of what is a fatal illness is subjective on both the patient and the physician side
- ✓ Cancer is difficult to cure because most therapy focuses on one type of treatment.
- ✓ 'The death of cancer' will be effective with the use of personalised medicine
- Inspire2Live encourages patients, clinicians and researchers to work together to get cancer under control by 2021

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#Pinksocks: Changing the World With Heart Speak, **Hugs and Gifting**

Summary: HealthManagement spoke to Nick Adkins, founder of #pinksocks, a movement that began in healthcare and spreading like wildfire in all industries by activating people to connect by sharing each other's stories with compassion and empathy to work together as one.

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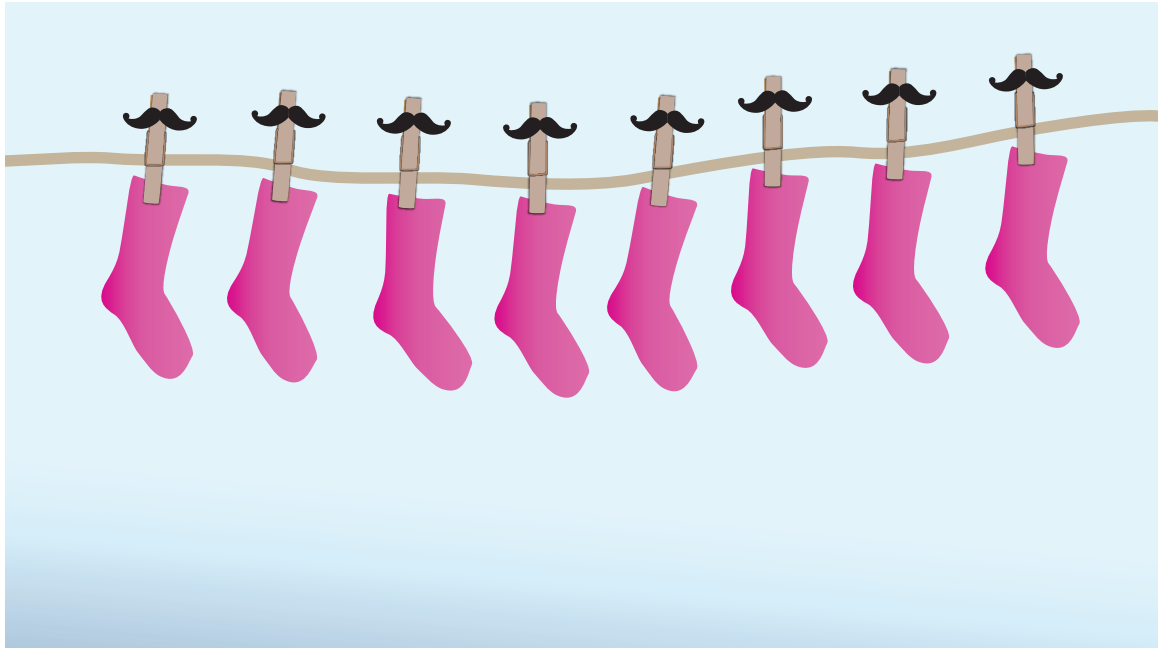

What does it mean to be part of the pink socks tribe?

It means there's a bunch of happy smiling people around the world trying to do good things to make the world a better place. The label on the socks says the world is full of good and when you believe that, you see it. We're making a choice to focus on the good positive things and celebrate them. It doesn't take a lot of effort to focus on the negative. What does take effort is people who are full of light and love and joy. To rise above the negative stuff and to be a voice and echo for good positive and happy things. When you follow the #pinksocks hashtag on Twitter, it's a steady stream of happy stories. People post things that have to do with kindness and love and empathy. It started in healthcare but it's transcended healthcare.

When I give people their pinksocks in person I say you can't always control governance and politics, but what we can control is how we interact with people. One person at a time, one smile at a time, one pair of pinksocks at a time. Every time you wear them, you connect with somebody new because somebody sees those in the market or on the train or bus and they comment on it. That's the universe tapping you on the shoulder and giving you an opportunity to connect with someone. If you were not wearing the pinksocks that day you would have missed that.

You stop doing what you were doing, get off your phone, stay and introduce yourself and in that moment of connection you see each other just as you are—as fellow humans. You don't know them, what their job title is, where they work, what they have or don't have. In that moment we see each other and realise that we're all trying to get through this moment together. That's the real message of pinksocks—we're all in this together and we will focus on what's good. Digital stuff has made us so

connected that we've become disconnected. Pinksocks allows us to have a real connection.

How did the pinksocks movement begin?

It's from the principle of gifting that the pinksocks were born. I started wearing kilts in 2012 and when you wear a kilt, you have to wear fun socks. My friend, and co-founder at a healthtech startup, Andrew Richards (@andrewintech) and I were on a business trip to San Francisco. There was an older couple from Israel we met at the hotel one morning over coffee. The husband's name was Shlomo and he had one of the most contagious smiles! He was crazy about the robot monkey socks I was wearing. I had a new pair in my bag that I hadn't worn yet, so I gave them to him as a gift. And, I remembered I felt—how amazing the connection between two people can be from gifting!

So it all began by accident—I started giving them away. Andrew and I we packed our bags full of what had turned out to be the crowd favourites every time I wore them – the pinksocks with the moustaches. Every time someone came up to us and commented on our socks- we gave them a pair of pinksocks. When I gift the socks, I always look the other person in the eyes and say, Every time you wear your pinksocks you're going to make people smile! People will come up to you and ask you about your pinksocks. That's your opportunity to connect with another person that had you not have been wearing your pinksocks that day, the two of you would have missed each other in the universe. Don't miss that moment to connect and share space! Get off your bike, stay on the train or bus for another stop, look each other in the eyes and connect. That's what we're here for! Don't miss each of those moments!

The pinksocks aren't about one company, brand, logo or mission. There's no money in them. They are just a fun gift. Someone gifted your socks to you and somebody gifted those socks to them. There is probably only one or two degrees of separation from where your pinksocks came from. It's really awesome to see how it's grown since 2015. Three and half years roughly and over 40,000 people around the world who have gifted pinksocks.

"THAT'S THE POWER OF CONNECTION AND IT TOOK A FUN PAIR OF PINK SOCKS TO DO THAT"

We had the conferences for a year and had a great time on Twitter with it. I was like let's just be done. Kind of like Elvis. There's young Elvis and there's fat old Elvis. And I was like let the pinksocks go out as young Elvis.

Somebody reached out to me on Twitter and said, "did you send some picksocks to this group over in the Netherlands?" There's a group that's gifting pinksocks to help increase awareness for dementia care and Alzheimer's. We got another message a group in Wales that's gifting pinksocks for drug awareness for the work they're doing for ataxia, which is a rare disease. At that point we knew we had gone organic and people were sourcing pinksocks and gifting them on their own to celebrate whatever work they were doing. And people on Twitter were starting to follow, like, tweet and retweet #pinksocks. The next thing you know, it's a thing.

Are there are any standout cases where pinksocks has effected change in the healthcare setting?

If you look at hospitals, pharmaceutical companies, start-ups, IT companies, everything, it's not really that the pinksocks are effecting the change, but that people who have pinksocks connect with each other. Like attracts like. I encourage people to give pinksocks as a gift. It's about wearing them, gifting them; wear a pair, gift a pair. Don't walk up to someone and say I would like to give you these. Wait for the person to say, "cool socks." When that happens, the pinksocks have just found their next person. All of these people said I want to think outside the box, I want to be celebrated, I want to be part of this, I want people to know I am doing this.

In healthcare you have burnout, and the phenomenon of professionals just becoming machines, just performing the task. There was another movement "Hello my name is" movement because it's come to the point that professionals don't even introduce themselves to patients. Has the pinksocks movement inspired them or created even a small shift in their approach?

Yes, pinksocks helps start a conversation in small organisations and very large global organisations, primarily around empathy and connection and kindness and there's a lot of conversation on physician burnout. I've seen the pinksocks in different groups be a catalyst to say hey it's okay that you're not okay. That you want to talk about this. The connection with the person you have, we're all just trying to survive this thing. I've been in talks where we break into spontaneous hugging, I have seen people cry. Each time I go somewhere I know that at least one person that I have never met before, at least one person, is going to come up to me and they'll say, "I need to tell you a story," and I will look them right in the eye, and I will get a little closer to them, and I will say, "I need to hear a story."

And they'll tell me stories: my wife just died of cancer, I just found out I have stage 4 cancer, my son just had to go to rehab, my daughter just killed herself. A stranger that I've never met is telling me the most intimate, heart-wrenching story of their life. That's the power of connection and it took a pair of pinksocks to do that.

There's over 40,000 people that have pinksocks, and then there are other people who make badges and buttons, if we could build just one connection a day, if we meet five people a day, stop and connect with that person, ten, oh we're almost at half a million people creating good energy, love. I mean can that effect change? Does that have a ripple effect? Is there some exponential piece to that? Absolutely! And so when you blow it out, it's not really about healthcare. It's about humanity. It's about you and me. It's about all of us. In the beginning it was the pinksocks but now you've trained yourself, retrained yourself to think, I need to talk to this person, I need to say hi, I need to listen to their story.

There are a couple of things that help the movement spread. One is that it is totally decommodified. It's not about money, it's not about one brand logo, mission, no sponsorships, no corporate stuff on this. It's all about gifting. There is no one definition as to what it is so it can be what you need it to be. It's fluid and dynamic and so you watch it just grow and thrive at its own will.

You're involved with artificial intelligence (AI) and AI powered medical research. There's this whole debate about AI versus humans especially in healthcare. How has pinksocks shaped your point of view?

I don't really know if pinksocks has influenced this but there will be functions where AI will replace humans altogether. We're not going to see that in our lifetime, but definitely AI is going to augment a lot of work, and it should. There's no reason why we shouldn't be using technology to its fullest to help us. There are so many awesome things that AI can do right now and it's only growing exponentially. I'm a huge fan of AI.

You say that we've allowed tech to get in the way versus using it as a tool. Do you think there will be harmony using tech as a tool and enhancing it with empathy?

Look up #applewon on Twitter and you will see that Apple is already doing that here in the U.S. Everything we've been talking about for years, about getting rid of fax machines, and finding an easy way for patients to communicate with their families and their care team. Apple is already doing that. The harmony is already there. So I tell people if I have to go to a hospital, take me to one that has partnered with Apple.

Empathy. Saying yes. Disconnecting, giving yourself permission to see each other, to hear each other, to feel somebody else's story or see someone feel your story. Have you seen this applied in healthcare?

I see stories. I read stories. I hear stories in person. I read things on Twitter. I see doctors wearing pinkocks, nurses wearing pinksocks. It lightens the mood. They can begin a conversation and change the tone of the conversation, encounter or meeting. In a way sometimes it's so simple, it's surprising. A simple pair of pinksocks can change the attitude of a room. If you're an executive and you come in and everybody is dressed like a bunch of bankers, in suits and all of a sudden you have these bright pinksocks popping out, it changes the energy. It takes it from being so serious to lighten up and really talk. Get to what matters. Let's get out of our head and more into our heart. Let's just talk as humans. What we really want to talk about is what's real for you in your life. Pinksocks starts off that conversation a lot of times.

If you're planning a trip and you search #pinksocks and whatever city, country, Denver, London, Paris, New Zealand, etc., you will find your tribe there. People are having pinksocks meetups all around the world. Not just conferences. They just get together. All these like minded people that are out there. People will see each other hugging and smiling and people will come up and ask hey what's going on here and they will say we're the pinksocks tribe and they will give them pinksocks and so it goes on. It's really awesome to watch.

You say there's a difference between having the socks and wearing the socks. What is it?

I stole that from Morpheus in The Matrix: "There's a difference between knowing the path and walking the path." There's a difference between having pinksocks and wearing pinksocks. Someone gifts you pinksocks. You may take a picture on Twitter holding your pinksocks and tweet that. Yeah that's fun. But the real magic comes when you wear them. Because every time you wear them you're going to have a connection with someone new.

And, it's also making a statement to yourself: "I am going to be an agent of change. I'm going to wear these pinksocks and go out in the world and make some connections." ■

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TOP QUOTE FROM THE BLOG 'Addressing Overall Expenditures in the U.S. Healthcare'

"One approach to cost containment is reducing the need for physician services, regarding, the providence of primary and secondary prevention, health promotion and education, health behaviour based premiums and patient safety and reduce medical errors."

See more at: https://iii.hm/xdo

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VICE PRESIDENT MARKETING, AIDOC LTD., ISRAEL

TOP QUOTE FROM THE BLOG 'What Does the Competitive Landscape for Your Areas of Specialisation Look Like?'

"The radiology workflow is ripe for AI disruption at various stages, including patient scheduling, image acquisition, workflow orchestration, detection, diagnosis, reporting, follow up and peer review. The opportunity is here – it's up to vendors to come up with the best possible solutions."

See more at: https://iii.hm/xdq

DR. MICHAEL D. CATTEN

PRIVATE PRACTITIONER, SALT LAKE CITY, USA

TOP QUOTE FROM THE BLOG 'Taking Responsibility for Avoidable Patient Deaths'

"The patient safety concessions can finally be repaired. Our ability to provide home safety nets is cheap, readily available, and easy to use. Tragically, these safety nets are almost never offered or even considered."

See more at: https://iii.hm/xds

MICHAEL JOHNSON-ELLIS

MANAGING DIRECTOR, HEALTHIER RECRUITMENT, UK

TOP QUOTE FROM THE BLOG 'The Urgent Need for Digital Skills in Healthcare'

"The role of digitally competent staff is only going to become more important as technology improves, and the thousands inadequately prepared staff could be left behind. Training staff to be proficient in digital skills can also play a large role in job satisfaction, and therefore staff retention."

See more at: https://iii.hm/xdr

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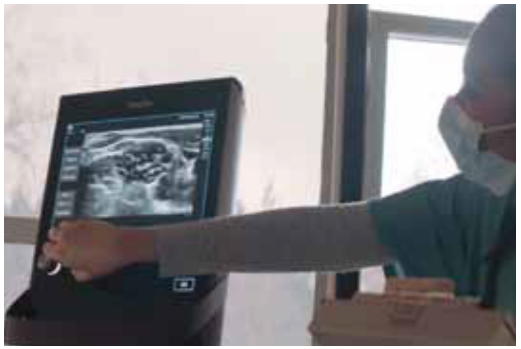

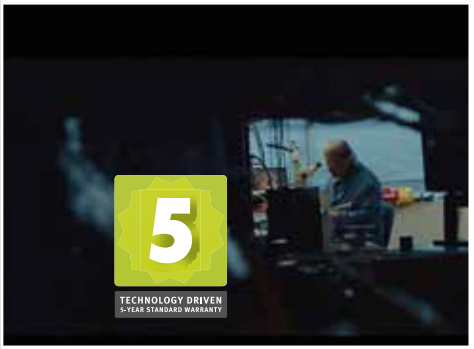

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