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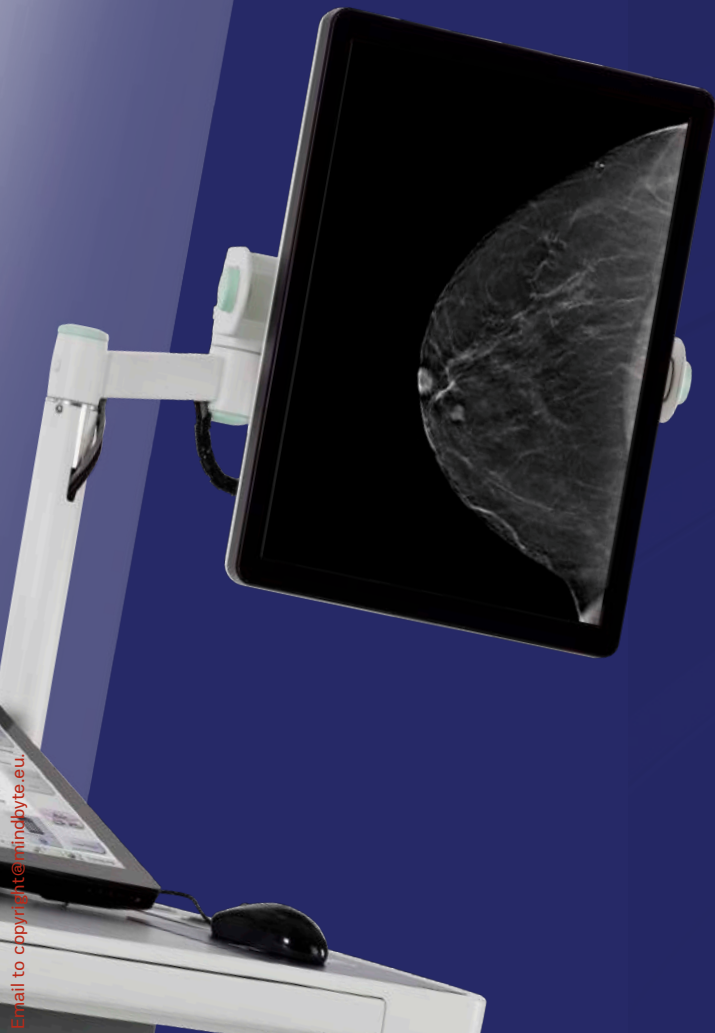
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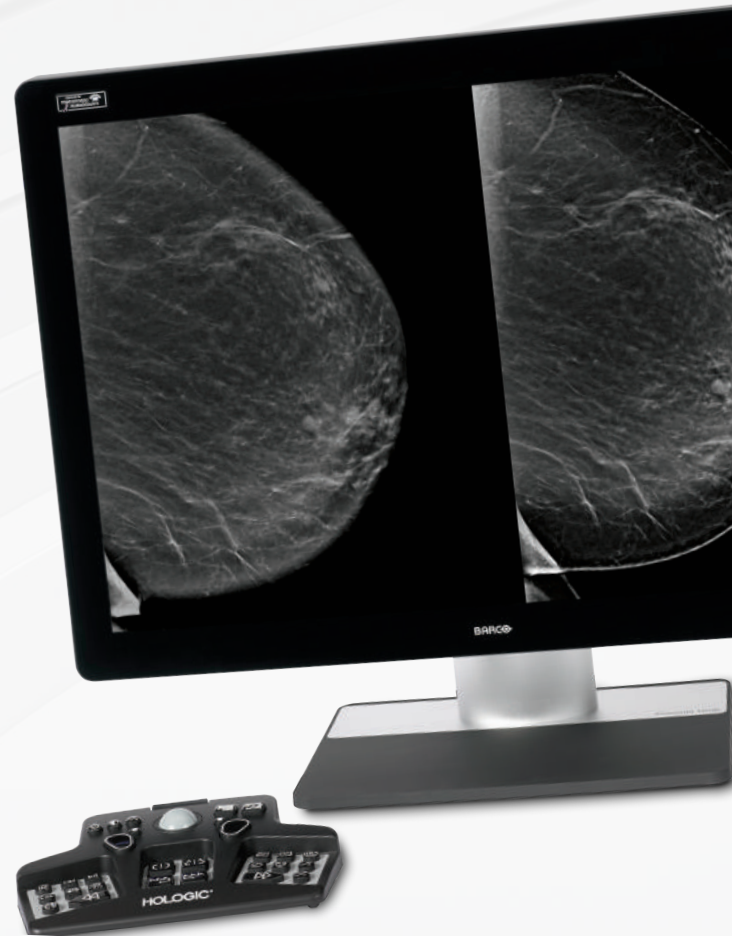
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Top Target Treatments

On paper, it looks straightforward; the basis of personalised care and targeted therapy lies in the realisation that every patient has a different level of susceptibility to disease, responds differently to the same treatment, and needs different doses for the same effect. Over the last ten years, healthcare has made huge progress in linking genetics with disease prevalence and drug response. What makes personalised medicine distinct as a concept is the fact that it is not only focused on genetics but also takes into consideration clinical and environmental influences, providing more meaningful and more personalised data and information regarding disease prevention and treatment. Let's also not forget the question of Pharma; the study of genes can help drug developers create targeted treatments which would revolutionise patient care.

Research is booming. The Human Genome Project in the U.S., the world's largest biological project, mapped out the genetic code of human life, thus triggering off a series of studies and research on identifying and isolating disease risk factors on an individual basis. We've seen similar programmes launching in the UK with The 100,000 Genomes Project and massive cross-border genomics cooperation in Europe.

With personalised medicine's potential to eradicate so many of healthcare's bottom line woes, what is there not to like?

But there are obstacles ahead. How can personalised medicine move from piloted research to an accepted standard of care that the entire population can benefit from? What will it take for physicians to accept that personalised medicine has enough value for them to give it their support? Will policy makers react

in time to allow for its smoother implementation and where could the science have the most valuable impact.

Ultimately, is the outcome really worth the cost – in research, time, resources and even patient hope?

In this issue, HealthManagement.org explores the promise of personalised medicine. Healthcare experts highlight these very challenges, discuss where it could have the greatest potential, and provide signposts along the path to the application of personalised medicine in the real world.

Our contributors talk about next-generation sequencing, a human-centric approach on data use, the FAIR4Health data sharing project, phenotyping imaging, the application of personalised medicine in radiology, cardiology, and oncology, humanism in personalised medicine, the role of telehealth, and how personalised medicine intersects with public health for optimal care.

In our Management section, we focus on the influence of sex and gender in medicine and the importance of integrating creativity in organisations through diverse approaches to teamwork. The latest Winning Practices in healthcare cover emerging healthcare technologies and their cutting-edge implementation and making a success of cross-border hiring. Also in focus is the people-powered health movement, where patients are equal partners with healthcare personnel in the care continuum, and the use of artificial intelligence in diagnostic neuroradiology.

We hope this journal will inspire you to make new and fruitful steps in your practice. As always, we welcome your feedback.

Happy Reading! ■



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EUROSON 2019 welcomes world of ultrasound

Initiatives to expand the meeting globally

Prof. Sidhu, talks to Healthmanagement.org about EUROSON 2019 and EFSUMB initiatives in the pipeline.



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EFSUMB and FESUMB welcome the imaging and ultrasound community to Granada for EUROSON 2019. This year EUROSON will be held simultaneously with the XXX Annual Meeting of AEED (Asociación Española de Ecografía Digestiva) and the 35th International Course of SEUS (Sociedad Española de Ultrasonidos). What highlights can physicians look forward to?

The congress will be held in Granada this year, which is a splendid city with a magnificent history. The conference centre is well designed to accommodate a large manufacturing industry exhibition. The conference halls are nicely arranged around the congress centre itself to allow delegates easy access. There are many different sites to visit in Granada, but hopefully the programme that we have arranged for the EUROSON congress will keep all delegates within the congress hall at all times.

The conference centre is excellent with good facilities, and we have up to six parallel sessions each day at the conference, over three days.

At the EUROSON 2019 congress we will launch the newly published, non-liver elastography guidelines, which go through all the various areas for which elastography can be used outside of the liver. This will be one of the highlights of the meeting. These guidelines are very comprehensive and we are confident that once again EFSUMB has produced a world-leading set of guidelines on the use of this new technique. In addition, we will also publicise the most recent publication of the gastrointestinal ultrasound guidelines which are due to be released very shortly in *Ultraschall in der Medizin* and this is a part of a series of components dealing with gastrointestinal ultrasound again hopefully will be well received.

There will be discussions on all aspects concerning ultrasound, from gynaecology, liver, small parts,

physics, safety right through to the newest advances in contrast-enhanced ultrasound (CEUS). Breakthroughs from new scientific evidence will be presented in the scientific sessions. In addition, we will have a Young Investigators section where the cream of the young investigator participants of the European societies will battle it out for the chance to win a substantial prize awarded to the best investigator. This is a very popular section of the meeting.

This year we have arranged between European Society of Radiology and EFSUMB that we repeat certain sessions presented during the ECR 2019. Essentially the topics are unchanged, and we are introducing these topics to a different audience on this occasion.

At EUROSON 2019 you will be chairing the session: "Ultrasound simulation models in training and ultrasound: where are we going?" Which technical procedures do you see applied in a radiology curriculum?

There's a lot of simulation-based scanning at the moment, and it's really the abdominal and pelvic imaging that's becoming quite popular, including intracavity ultrasound, transvaginal and transvaginal procedures that can be usefully applied using these stimulation models as a basis to teach people. The country that's doing most of this work, at the moment, is Denmark. It's quite exciting because the studies have shown that simulators work just as well when applied in training as do live models and of course the benefit is that this is not live patient-dependent and it's uniform, so it's a good aspect for education particularly early in the learning process.

You have dedicated sessions and lectures on safety presenting a line-up of 'hot topics' such

as “10 tips of safety” and “which interactions could occur.” Which aspects of safety assurance do you consider most important?

Certainly safety is a very important issue with the use of ultrasound. Many practitioners pick up the ultrasound transducer and start using it without giving much attention to the fact that even though ultrasound is a very safe technique there are issues surrounding safety, particularly with the newer more sophisticated aspects of ultrasound, such as Contrast Enhanced Ultrasound and the more recent use of Elastography.

If you put a push pulse of elastography into a structure like the liver, you can raise the temperature, momentarily in that tissue. It is very important to have an understanding of the limitations of your use of ultrasound, and one of the abstracts dealing with nerve block is an area where some of the safety issues surrounding ultrasound use are very important with delicate structures such as nerves.

Another substantial session you are introducing this year is “Professionalism professional standards in ultrasound.” What will be the focus of these presentations?

I hope this session is going to generate a lot of debate. There’s been a lot of discussion in Europe, over a number of years, about who should be performing ultrasound. There are two viewpoints here, one viewpoint that is held by many European countries and a number of other countries across the world, that it should only be a physician-led tool. But countries such as United Kingdom, Canada, The United States of America, Australia and New Zealand and some South East Asian countries, non-physicians perform ultrasound.

These are highly trained technicians who perform ultrasound all the time to produce images for either physicians to report, or these technicians produce a report themselves. A lot of physicians, in countries such as Germany and Italy, feel that it should be a

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physician-led and interpreted service and it's an extension of the clinical examination. This subject was brought to a head, a couple of years ago, with an editorial in *Ultraschall in der Medizin*, which outlined the practice across the world of different countries; some using non-physician sonographers or technicians to perform the ultrasound and other countries relying solely on physicians to perform ultrasound. So, this session will open up, hopefully, a debate.

I will be presenting the United Kingdom viewpoint where sonographers or technicians have been doing ultrasound for over 40 years and they are a great asset to the National Health Service, where we are almost overwhelmed with the number of examinations that need to be performed. We will present other viewpoints where ultrasound is seen as a valuable extension of the clinical examination and a very important clinical tool in the right hands. It is going to be an interesting debate and I'm sure there are going to be many opinions from the different ends of the spectrum regarding this aspect of the practice of ultrasound.

What are the new initiatives you are working on with EFSUMB?

In this meeting in EUROSON, the Board of Delegates will be presented with constitutional changes to enact the previous points we discussed regarding opening up the membership and changing the infrastructure of the society. This is an important meeting to take this initiative forward and hopefully if this is voted and approved, we will see a different society emerging over the next couple of years.

We are also launching a number of new initiatives. In particular, we are working on many new guidelines including specific ones for point-of-care-ultrasound (POCUS), musculoskeletal guidelines and continuing with the renowned gastrointestinal guidelines. Assessment of the gastrointestinal tract will be the fifth and sixth set of new guidelines. This compliments the recently published statement on the use of handheld ultrasound devices.

Looking to the future, we are working on restructuring the society itself, hopefully opening up to more membership, not just in Europe, but across the world and making it a very attractive organisation in ultrasound education throughout the world. In addition, we are looking at the EUROSON Congress trying to upgrade it and update it to make it more attractive worldwide to physicians and people interested in ultrasound.

Exciting times! With even more improvement

planned for the future, we are very excited about the potential to opening up the society in general, helping to spread good practice, information and sharing expertise.

What role does ultrasound play in precision medicine and personalised care?

The areas of personalised care and precision medicine are with our ultrasound community at the moment. We are working with precision targeting- with targeting microbubbles for prostate cancer, or targeting it to thrombus, but this is very much in the early stages and is not really a clinical tool as yet.

Ultrasound contrast in children is now becoming more established. There'll be some sessions on paediatrics and this will incorporate contrast-enhanced ultrasound. We are working, at EFSUMB, towards increasing the use of contrast in children, this is a slow process but hopefully we will progress at this meeting.

This year at EUROSON 2019, you are introducing: "EFSUMB meets China" for the first time.

One of the things I do want to highlight at this meeting of EUROSON 2019 is that we inaugurate "EFSUMB meets China," which is an important initiative for EFSUMB. China is the most populous country in the world. In China the practitioners of ultrasound perform all aspects of ultrasound and only ultrasound. They are highly skilled and bring extensive knowledge to the ultrasound community. Furthermore, they are very interested in the educational opportunities offered by EFSUMB, not just only for providing the guidelines but also in attending the EUROSON meeting. This year, for the first time, we have invited three very eminent Chinese doctors who will deliver presentations in combination with EFSUMB. Hopefully we will see more collaboration.

In addition, EFSUMB has started conducting EUROSON schools in China; last year we were involved with a EUROSON school in Hong Kong, which was very successful. Later on this year, or hopefully next year, we will have a second EUROSON school, possibly in Beijing or Shanghai- which will have a combination of Chinese and European speakers, and take this aspect forward in a manner of collaboration. The transfer of knowledge is both ways.

EUROSON 2019 will be a big meeting for us constitutional wise so hopefully we will be successful in altering some of the structure. We are very pleased in the direction we're going to head. ■

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BREXIT means BREXIT: Radiologists without borders

An in depth interview with UEMS Secretary General
Prof. Vassilios Papalois

Prof. Papalois talks to Healthmanagement.org about BREXIT and the potential repercussions the break from the EU may bring to patients and medical professionals



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Secretary General of The European Union of Medical Specialists (UEMS) Prof. Vassilios Papalois, talks to Healthmanagement.org about his powerful ECR 2019 presentation: “BREXIT means BREXIT: Radiologists without borders.” We also discuss the potential repercussions the break from the EU may bring to patients and medical professionals as well as the consequences to the development and implementation of personalised medicine and population health in the UK.

HM: You presented "BREXIT means BREXIT: Radiologists without borders" a comprehensively supported case on the serious repercussions in radiology and why withdrawal from the EU is a "huge mistake." What does BREXIT mean for radiology and radiologists?

VP: BREXIT is essentially a political decision of the United Kingdom to leave the European Union- the EU has been a major political agreement and a major peace project connecting EU states over the last 70 years or so. This will affect, radiologists and all healthcare professionals, if, in the case of a ‘hard’ BREXIT, there will be a stop of free movement of healthcare professionals. This will consequently lead to a stop in the exchange of resources, of people, of expertise, of experience. Eventually progress in the field of all specialities will suffer greatly. Of course radiology will severely be impacted, as it is one of the most rapidly developing specialities technologically- including all of its sub-competencies across Europe and beyond.

HM: Having experienced EU’s influence in fostering collaboration in radiology & health, how will physicians & management leaders face "the day after" outside the Union?

VP: The global political environment, not only in the United Kingdom, in Europe and across the world is very fluid and very challenging to say the least. At the moment, especially as it relates to BREXIT nobody knows what “the day after” is going to look like. First of all with the new extension to October we still do not know if it will ever come. This lack of clarity is the biggest challenge we face as no one can prepare for a new structure that, in reality, has not been planned in any way. People are guessing but they have no idea what it is going to be.

“ MY FIRST
CONCERN IS ABOUT
THE PATIENTS ”

It is a major challenge and brings paralysis to certain elements of our planning for the future, which is anything but desirable. This is where we stand. The only way I see medical professionals may work around this potential exit from the EU is to be able to approach healthcare- that is the provision of healthcare both in the clinical and academic arena, beyond the political problems. I think it is our duty as doctors to be able to see how we can ensure continued collaboration in the present, in the future,

well beyond the current challenges and politics. We cannot solve the politics, they influence us but we cannot convince national leaders or solve EU issues arising between member states. What we can do within our power and is in our hands is to vigilantly build as many collaborations as possible, assure all the channels of communication remain open to help share our aspirations for the future and plan to face them together.

HM: What do you consider to be the most dangerous and detrimental consequences in the aftermath of BREXIT for radiology & professionals affected?

VP: My first concern is about the patients. We must not forget there are many people from continental Europe living in the United Kingdom. There are many people from the United Kingdom living in continental Europe. These people have well-established lives, either in the UK or in Europe spanning many, many years. As they are human, they will eventually face health problems- at the moment we have no clarity as to how these people are going to be treated.

When you are a doctor, politics is one element of it- but your main care is about the patient. In this situation, we have no clarity whatsoever of what type of care we will be able to offer our patients and this is a major, major issue and my biggest concern. Parallel to this, fall the issues affecting health professionals, because you have many professionals who have moved on both sides of the English Channel, either to the UK or in continental Europe. Again, they have very well established professional and personal lives and they don't know what will become of the status of their employment, and career progression, or the status of their family in the years ahead of us. This lack of clarity is crucial for the practice of those people, not only for radiology but all medical specialities. I will stress again, mainly for specialities like radiology that have a galloping development in all aspects of the field.

HM: As Secretary General of The European Union of Medical Specialists how do you predict BREXIT will alter UEMS mandates & what actions can the UEMS take to help prevent/alleviate negative repercussions?

VP: The way healthcare is provided in the 21st century, especially in Europe, has a holistic and universal character. It's beyond countries, beyond borders, and it is beyond specific hospitals and

universities. Healthcare is totally universal. We are inter-dependent, we rely on each other and this is a blessing. We learn from each other, support each other and collectively we can progress. Trying to fragment this to build up walls and borders and cut out pieces of it will only prove terrible for patients and doctors alike.

The first thing that was made very clear, not only in the UEMS but in all the other European Medical Organisations is that the British Medical Association will remain as a full member just as it has been for decades, ensuring nothing will change in this respect. Our British colleagues will continue to enjoy full membership, full access and full participation in all European Medical Organisations in which they've had a very, very, very productive presence for decades. This is absolutely paramount and all European organisations have worked very hard to secure it.

“ IN THE CASE OF A ‘HARD’ BREXIT, THERE WILL BE A STOP OF FREE MOVEMENT OF HEALTHCARE PROFESSIONALS ”

When it comes to how it may change and how we are working around these changes, the answer is we tried not to change anything at all. We tried to work in the same collaborative way and ensure whatever initiatives we produce such as: European training requirements, our processes of accreditation of doctors, centres and educational events, our collaborative projects between different countries and different institutions, all this stays exactly the same and, if anything, will be enhanced in any way we can. Our reaction to this very fluent and challenging political climate is to continue with 'business as usual' and additionally enhance the collaboration of health professionals across Europe. This is our answer to the complicated issues that may arise.

HM: Precision health and population health: how can they intersect effectively after BREXIT?

VP: BREXIT is one of the elements that could potentially cause fragmentation in the provision of healthcare. It is not the only factor; there are many factors actually. We plan to ensure healthcare continues

to be provided in a holistic and universal way, in a harmonised way across Europe and this is the way we doctors see it. There are many challenges out there, not only BREXIT, there are the financial challenges that come into play in many European countries, specific social needs and specific political interventions which can all cause fragmentation to the way we treat our patients. We try to go over this and say that for us healthcare is one thing, it should be harmonised and it should be of the highest possible standards in terms of the way we train and support our doctors and the way we treat our patients.

“RADIOLOGY WILL SEVERELY BE IMPACTED, AS IT IS ONE OF THE MOST RAPIDLY DEVELOPING SPECIALITIES TECHNOLOGICALLY”

HM: Having over two decades of surgical experience, numerous awards & achievements, what in your opinion are the most promising developments in precision medicine and personalised care in the fields of radiology, interventional radiology and imaging?

VP: The main theme of all the projects that the UEMS has developed over the last 60 years, especially in collaboration with major European Scientific Societies, like the European Society of Radiology, which is one of the biggest societies in Europe and in the world, is to create quality assurance projects for everything that we do. The European training requirements that set the standards of training and European requirements we have for accreditation of educational events are derived from the projects of collaboration of doctors across Europe. These quality assurance projects safeguard the quality of practice of physicians across Europe and allow them to go to the next level. When you have quality assurance, when you have people practicing with high standards, you can deliver holistic care, you can deliver precision medicine, you can deliver all the innovations that are needed and are expected by patients in the 21st century.

HM: You've talked about "Invasion of Technology and Digitisation of Healthcare," what

do you consider the benefits of these in integrating precision medicine & personalised care in radiology?

VP: Overall in medicine, and specifically in specialties like radiology, which are very heavily involved with technology, the patient is at the centre of healthcare now. Patients have enormous power in selecting among different modalities of care and a very strong say in which one is most suitable for them. The focus on outcome not only correlates to medical outcome but also to the quality-of-life outcome for patients, for the ultimate receivers and end users of healthcare. This has changed completely, dramatically, the way we were used to practice. Healthcare was very much doctor-orientated, paternalistic, with very limited involvement on the side of the patient. I believe the big revolution is patients are now at the centre of healthcare with enormous power in their hands, with enormous say in the decision making process, with very clear demands, not only for an excellent medical outcome but for the overall quality of their lives.

It allows the patient to be part of the care continuum. For example, the way it works nowadays in most modern departments, after the clinic appointment the patients don't wait for another appointment or a phone call, they can access their data directly. They access their outcomes quickly by checking electronic links that they have with the hospital, which have changed the whole picture dramatically. They can even communicate any kind of upcoming symptoms, and changes in their status sent to the clinical team and they can get responses. Technology has empowered patients to take a much more active role in the process of provision of healthcare, irrefutably.

The advances of technology to the level we are witnessing today have brought the radiologist and patient much closer. Precisely because this requires a very close 'partnership' between the healthcare professional, the available technology, all the potential of these technologies, and the receiver of this care which is the patient.

HM: What is your advice to radiology colleagues & leadership on dealing with BREXIT?

VP: We must ensure in any way we can, with the support of all our colleagues, the support of our patients and the support of other organisations, to keep the channels for provision of healthcare open across borders. This means the free movement of

healthcare professionals, patients (which is absolutely crucial), movement of experience, expertise, ideas, information and networking which is imperative for us to progress. This should be our focus. Not to build borders that will lead to fragmented healthcare, which is catastrophic.

HM: In the event of BREXIT what are the key asks you, and by extension radiologists, have in order to ensure continued quality of care, training, and patient outcomes?

VP: What I can say which we are advising through the British Medical Association (BMA) which is our voice, as doctors in the United Kingdom- is “keep the channels open.” We will continue to say it because if we don’t every channel we close down effects the quality of healthcare we have to offer our patients. It harms professionals and it harms patients. This we know is going to happen if we are not extremely, extremely careful. I hope it will not happen, we continue to vigilantly advocate and hopefully common sense will prevail.

“IT’S OUR DUTY AS DOCTORS TO ENSURE CONTINUED COLLABORATION IN THE PRESENT, FUTURE, WELL BEYOND CURRENT CHALLENGES & POLITICS”

The collaboration between the UEMS and the European Society of Radiology serves as a model that we project across Europe. We have lasting collaborations with all major European Scientific Societies and the ESR is one of the biggest examples of how collaboration between the professional organisations and scientific societies benefits doctors and patients. It’s a model we build on and a model we project across Europe and beyond. It is impressive to see how all the quality assurance projects we have developed in Europe over the years are rapidly gaining popularity beyond Europe. This proves the value, quality and the power of European collaboration.

HM: Concluding, what would be your advice to UK decision makers to convince them to decline

to withdraw from the EU?

VP: My advice would be to keep our focus on the two big elements, which are: the patients and the healthcare professionals who serve the patients; this in combination with the absolutely crucial need to keep the walls down and the channels of healthcare collaboration wide open. This is the ball and we need to keep our eyes on it. To the credit of the European Society of Radiology – and we are very proud of the collaboration that we have between the UEMS and the ESR – the focus on this task in Radiology across Europe becomes stronger and stronger producing one project after another that advances the quality provision of healthcare. I think this is what helps us overcome the fluid and challenging political environment. ■

Conflicts of Interest

None.

KEY POINTS



- ✓ 21st century is totally universal, has a holistic and universal character beyond countries, borders, and it is beyond specific hospitals and universities especially in Europe.
- ✓ A 'hard' BREXIT will stop free movement of healthcare professionals and will be detrimental for patients and doctors alike.
- ✓ Radiology will be severely impacted, the most rapidly developing specialities technologically across Europe and beyond.
- ✓ Our British colleagues will have full membership, full access and full participation in the UEMS and all European Medical Organisations in which they’ve had a very productive presence for decades.
- ✓ We will continue with ‘business as usual’ and enhance the collaboration of health professionals across Europe.

Fighting cyber threats with a global community

Denise Anderson, President of the Health Information Sharing and Analysis Center (H-ISAC), spoke to HealthManagement.org about this growing global organisation's aim to fight cyber threats through cooperation among healthcare stakeholders.

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H-ISAC aims to foster trust and cooperation amongst members with the objective of achieving a more secure digital health environment. How does H-ISAC achieve this and where are the greatest challenges?

I actually think, in general, that the sharing is fairly good within healthcare and the ISAC, especially amongst the larger organisations. It's harder for smaller organisations which either, don't have a security operation or resources, don't understand the importance of sharing information or being part of a trust community, or don't prioritise security. I think that education and sharing experiences among members is the best way to make the smaller organisations aware of the opportunities the ISAC offers.

When it comes to medical device security, the issue is very complex. Manufacturers and healthcare delivery organisations (HDOs) can have contentious relationships. Within HDOs there are a number of stakeholders that often operate in silos. The regulators are also different for manufacturers and HDOs so the entire ecosystem is fragmented. It is very important that all stakeholders work together to solve security problems. In H-ISAC, we have a Medical Device Security Information Sharing Council which is co-chaired by a manufacturer and an HDO. We purposely did this and the goal is to ensure that both parties understand each other's issues and perspectives so that everyone can work on challenges together.

Is healthcare management sufficiently concerned with cyber security?

In some organisations, there is focus. But really what we should be doing across industry is to change the conversation from one of cyber security to one of enterprise risk management (ERM). Cyber is just one component of the risk to the enterprise. If an organisation deploys ERM correctly, it will understand the 'crown jewels' and build its risk management strategy out from there. Of course it also means knowing what the threats are, who the threat actors are and what their motivations are - which is part of information sharing - as part of the equation. I don't think healthcare, in general, is able to tackle that yet.

When it comes to physical security, are the issues of developing trust similar to those of cyber security?

I actually think the sharing in cyber is better for a variety of reasons. One is that there is machine-to-machine sharing so those indicators get shared automatically. Second, most of the infrastructure is within the private sector and industry understands one person's defence becomes everyone else's offence. Traditionally, the physical security teams have been mostly former law enforcement and the community has tended to be very close fisted. Also, government had access to intelligence that wasn't available to the private sector so, unless one had a clearance or need to know, information wasn't freely shared. Trust exists but it isn't as broad.

What do you anticipate for both cyber and physical threats in healthcare in the next five to ten years and how can they be addressed?

We see incidents stemming from old malware and vulnerabilities that will most likely still be around five years from now. The Nigerian prince and romance schemes still exist because they work! That being said, attackers will always find ways to take new technologies that come into play and that are connected to the Internet to achieve their goals. We just need to be aware and always mindful of the potential risks that can come from a lack of availability of resources and integrity of data. We also need to be very cognisant of cascading impacts from incidents that target other organisations, such as an attack like Petya/Not Petya that targeted a country but ended up affecting numerous large and small organisations to the tune of billions of dollars. Hurricane Maria in Puerto Rico was another example of

cascading impacts from other sectors on the pharmaceutical and medical supply chain.

You have experience in a number of sectors, including finance. As far as security is concerned, do you think there are any lessons healthcare could learn from other industries?

I think any sector can certainly always learn from other sectors. Obviously the financial sector has been dealing with cyber attacks and incidents for decades because of the electronic nature of global finance and the fact that they are a target. So yes, healthcare can learn from finance and can see the benefits of their lessons learned, especially when it comes to information sharing. But it is more than just technology; it is also people and process and until there is awareness and acceptance from the leadership of an organisation/sector, lessons learned only go so far.

What are some of the key objectives you have for your continued tenure as President of H-ISAC?

Primarily I want to make sure that we are delivering value to our members. There are a number of things that we are doing to help assess what members want and what we can deliver. One area in particular is in building our Security Operations Center (SOC) to do more analytics on what members are seeing, create threat trending and other reports and build a 'visit programme' at the SOC among other things. We are hiring a Chief Security Officer this year to help accomplish this vision.

Another area is global expansion. As part of the expansion we have established an H-ISAC EU Council and are creating an H-ISAC Japan Council to establish regional forums for sharing and collaborating. We will look to hold summits in each region within the next year. I consider myself an evangelist for global information sharing and collaboration and the more we can get the world to share the better off everyone will be.

Finally, we will continue to grow the membership so that more organisations can benefit from being a part of the great community we have in place. ■



Innovation and collaboration: FT Digital Health Summit

The FT Digital Health Summit, is a one-day conference focusing on how innovation can help address healthcare's increasing bottom line and how the issues of security, engagement and fragmentation can be tackled.

Now in its fifth year, the summit brings together leading speakers from the patient, hospital manager and practitioner, investor and innovator fields to discuss how technology/innovation are meeting and addressing the growing challenges facing healthcare.

The agenda is simple: where and how can digital technologies, devices and applications, and the data they produce have the most meaningful and effective impact within patient care?

"People's perception of the healthcare sector can be very niche," says Daniel Mahony, Healthcare Fund Manager of Polar Capital Partners and summit speaker. "It is often focused on the big pharma companies who can be seen driving the news agenda. The reality is that there are a variety of themes, innovations and developments happening in the healthcare sector and events like these help us to communicate the exciting investment opportunities available."

The FT Digital Health Summit will explore ways to implement digital transformation and improve the impact of innovation. Some of the key topics on the agenda are the hospital of the future, the challenges of security, engagement and integration in digital health and the role of preventative solutions in promoting wellness and collaboration as a catalyst for transformation.

An additional key focus area is the ongoing issue of finding the skills and leadership needed to spearhead transformation.

"Based on almost 15 years of experience from health sector, I still feel that professional mindset, and clinicians lacking interest of technology is still a main issue for big breakthroughs," says Jaana Sinipuro, Project Director at the Finnish Innovation Fund Sitra and speaker at the FT Digital Health Summit. "In order to adjust technology to serve people, and not opposite, we need to motivate

clinicians and healthcare professionals to become curious about technology and make them innovate together with tech professionals."

Industry is also on the agenda with a look at best practices for closing the gap between product development and adoption and the critical need to move pharma into the digital age.

"In the Life Science industry, more and more pharma companies are willing to invest in generating new data sources for real world evidence. Real-world data, together with patient reported outcomes is needed to implement value-based healthcare practices. The Life Science industry is working on new collaboration models with authorities and societies," says Sinipuro.

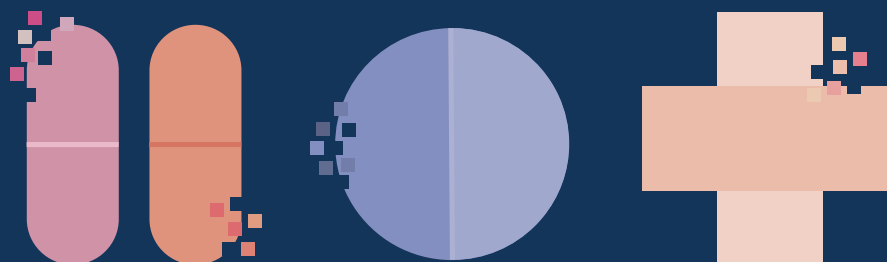
"Data could be described as one of the healthcare sector's biggest catchwords at present and rightly so - the potential it holds to transform both practices and processes and patient outcomes is revolutionary. Harnessing this potential in practical and practiceable ways is another theme of the FT Digital Health Summit.

"Rising costs of healthcare, due to ageing population and cost-pressures from targeted medicines, will maintain the focus in data interoperability and skills and tools to enable better use of data and analytics," says Sinipuro. "It will be necessary to find means for data exploitation and combining different sources of data, like measuring patient reported outcomes, combining personal data to clinical data and evaluate direction towards value-based healthcare."

Looking to the future, an industry event on healthcare cannot ignore the impact Artificial Intelligence (AI) is also having and will continue to have on processes and patient care.

"We are entering a new phase of structural disruption that is not just about a new therapy – be it drug or device. The next phase of disruption requires a realignment of interests across the value change and relies on collaboration," says Mahony.

The FT Digital Health Summit takes place in Berlin on June 18, 2019. For further details go to: live.ft.com/DigitalHealth ■



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The fifth edition of the **FT Digital Health Summit** will bring together industry leaders and experts and look at ways to implement transformation and improve the impact of innovation.

Speakers confirmed include:

Jens Spahn, Minister, *Federal Ministry of Health, Germany*

Michael Dahlweid, Chief Technology and Innovation Officer, *Insel Group*

Stephan Holzinger, CEO and Chief Financial Officer, *Rhön-Klinikum*

Ilona Kickbusch, Director, *Global Health Centre, The Graduate Institute Geneva*

Kalle Killar, Deputy Secretary General E-services and Innovation, *Ministry of Social Affairs, Estonia*

Neville Koopowitz, CEO, *VitalityHealth*

Anja Langenbacher, Europe Director, *Bill & Melinda Gates Foundation*

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The two-day forum presents its 2019 themes

Lions Health focuses on the creation, conception and execution of awe-inspiring life-changing creativity that has a verifiable impact on healthcare outcomes. It takes place during the Cannes Lions International Festival of Creativity on the 17-18 June 2019, in Cannes, France.

Seminars, round-table discussions, inspiring activations, networking and an evening awards event foster discussion around the power of creativity to change lives. Delegates will leave armed with new inspiration and proof of the positive role of creativity to shape healthcare communications – whether it's to improve awareness about global health issues, or support individuals in their disease management.

CMOs, brand leaders and award-winning creatives from healthcare marketing agencies, founders of new disruptive players and the investors who are facilitating change are coming together for two days of inspiration, learning and making new connections.

Cannes Lions consulted the entire industry to understand what big issues in the sector should be answered and have outlined four key themes that will be explored at this year's festival.

Using Creativity to Improve healthcare outcomes

Creativity has the power to transform complex scientific, statistical and technical information into arresting narratives, content and advice that connects and engages with everyday people. It permits divergent thinking, experimentation, storytelling and empathy. But compared to hard medical facts, it is often deemed intangible and unmeasurable.

Hear from the world's largest healthcare brand leaders and award-winning creatives on the transformative power of creativity and its capacity to change behaviours, to change dialogue and change attitudes towards healthcare for the better. We'll go behind the scenes on the most effective work, and prove its power to enhance healthcare outcomes.

Speakers include:

- **Maithreyi Jagannathan**, Associate Marketing Director Healthcare, Procter & Gamble
- **Ajay Vikram**, Chief Creative Officer, Publicis Singapore

Ajay and Maithreyi go behind the scenes of Vicks' ground-breaking, award-winning work '#TouchOf-Care' which challenged taboos and redefined stereotypes around family and social values.

The future healthcare company

With the onward march of technologies including big data, machine learning and predictive analytics and the growth of the B2C model, the healthcare industry is experiencing a large-scale structural evolution. How, where and when we access healthcare is fundamentally changing as new entrants strive to make it more convenient and affordable to serve healthcare needs.

What does this shift mean for Big Pharma and long-standing providers? Will the entrance of consumer tech companies and B2C models help empower patients to focus more on their health? How can creativity support this transformation? Speakers from global pharma entities, and new B2C entrants will explore the creative capabilities shaping the healthcare companies of the future.

Speakers include:

- **Anirudh Koul**, Former scientist at Microsoft Research and Founder of Seeing AI, Head of AI & Research, Aira

Anirudh will provide a deep dive into his work at startup Aira – where experiments making use of advances in artificial intelligence, 5G, and wearable computing, married with creativity are opening a

myriad of life-changing, "first-time" experiences for the blind community -- from blind marathoners, to blind photographers and even blind drivers.

Designing human-centred healthcare experiences

For an industry focused on improving the health of human beings, healthcare businesses and services are notoriously poor at customer experience. As experience design becomes a priority for all consumer facing companies, so too is the healthcare industry following suit. There is new focus on designing exceptional experiences for patients with a focus on empathy, seamlessness and empowerment.

Hear from designers and technologists who will explore the use of design methodologies paired with experiments in voice tech and chatbots to gaming and music to shape better healthcare experiences, improving education, adherence and overall well-being in healthcare.

Speakers include:

- **Andrew Barraclough**, Vice-President of Global Design and Innovation, GlaxoSmithKline (GSK)
GSK's Vice-President of Global Design and Innovation Andrew Barraclough will follow on from GSK's talk at last year's Lions Health exploring its digital transformation to discuss how design is now playing a crucial role in the execution of this transformation. He considers how design enables the creation of distinctive and memorable customer experiences across all touch points in this new digital journey

Cut-through storytelling in healthcare

Healthcare might well be based on fact and science, but the human experience of it is emotional; feelings of anxiety, hope, relief and fear are all intrinsically linked to situations focused on our health. Good storytelling triggers an emotional response that provokes action and awareness in a far more powerful form than charts and statistics – and is therefore vital.

Leading artists, writers, directors and creatives will share how they shape narratives about healthcare issues that cut through and change behaviour. We discuss how storytelling, supported by good craft can transcend demographics, geographies and language to engender awareness for public health issues, and speak to healthcare professionals as humans.

Speakers under this theme:

- **Atilla Cansun**, Chief Marketing Officer P&G Health

- **Atilla Justyna Dettmer**, Head of HCP Communication P&G Health

Cansun, CMO of P&G Health, and Justyna Head of HCP Communication for P&G Health will explore how we can improve engagement with healthcare professionals through insight-based emotional campaigns that speak to these people as humans, and help incite more empathy within the doctor-patient relationship.

Lions Health Awards

The Lions Health Awards - Health & Wellness Lions and Pharma Lions - celebrate creativity in branded communications with the unique power to truly change lives. The winners are announced and celebrated at the Awards Ceremony on the 18 June 2019.

The Health & Wellness Lions celebrate creativity for personal wellbeing.

The winning work demonstrates an inspired approach to consumer healthcare; that is exceptionally engaging work which promotes non-prescription products and services, publically educates to allow self-diagnosis or facilitates pro-active personal care. All work entered in Health & Wellness has been created specifically for or by a health and personal wellbeing related brand/service.

The Health & Wellness Lions Jury is led by President Shaheed Peera, Executive Creative Director, Publicis LifeBrands, Publicis Resolute and Real Science.

Pharma Lions

The Pharma Lions celebrate creative communications from pharmaceutical clients and services surrounding this highly-regulated industry.

Communications in this arena bear the responsibility of introducing new innovations, establishing standards of care and advocating for the industry within a context that is often emotionally charged and sometimes full of controversy. These communications must navigate debates about patient rights, policies and politics, society and humanity. Often delivered in healthcare settings, they require a significant level of appropriateness and respect for the people who treat or suffer from medical conditions.

The Pharma Lions Jury is led by President Robin Shapiro, Global President, TBWA\WorldHealth. Robin leads disruptive teams in creating award-winning work that contributes to a more purposeful future. ■

When does striking out alone work best?

The case for the lone wolf and pack of wolves

Author of lauded book 'The Art of Innovation – Integrating Creativity in Organisations', Dimis Michaelides puts forth how to get the balance right with sole and group creative problem solving.



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Health professionals are well aware of the value of collaboration. The surgery and the emergency room, the care of a single patient always call for different competencies working together in an organised way. Health professionals are also well aware of the value of a single expert - a specialist diagnostician, a skilled surgeon, a researcher inventing new treatments. In an organised health establishment people will at times complain of poor collaboration, at other times of too many people meddling in their work and causing delays. They will complain that they have no help when they need it and too much interference when they want to get on with their work. We will argue that from the perspective of innovation, they are usually always right.

In the early years of the twenty-first century countless human beings are thinking up new products and services and new ways of producing and selling them. The cult of the individual thrives. The great inventors, the great marketers and the great entrepreneurs who spearhead change make great heroes in business folklore.

Yet even the most rugged individualist will admit that innovation is never a solo act. Different schools of thought, place, communities, nations or social classes are at the centre of their thinking. They argue that wealth can only be created by people working together, with know-how generated by many others before them and around them.

Notwithstanding, the star power of exceptionally creative persons, innovation is almost always

implemented by groups of people with common goals. Teams. Families. Task forces. Think tanks. Idea exchange forums. As ideas circulate, in the right environments they thrive.

Most people will work on new ideas on their own as well as with others. What proportions of solitude and togetherness works best depends on the task at hand as well as individual preferences. Acknowledging different personal styles and alternating between individual and team modes will help address organisational challenges more effectively.

Individuals: The lone wolf

The lone wolf can offer highly original ideas. Some are pretty weird. Many don't work. He loves what he does. She works odd hours, mostly alone. He hates meetings. She has unusual hobbies. Being different is high on their set of values.

“ IN A HEALTH ESTABLISHMENT,
PEOPLE WILL AT TIMES COMPLAIN
OF POOR COLLABORATION, AT OTHER
TIMES OF TOO MANY
PEOPLE MEDDLING ”

This caricature is of a highly creative person, a radical thinker who might generate a breakthrough or two. Such people imagine new futures and open new paths. They are valuable assets for the organisations that accept them.

Many rare, game-changing ideas are generated by individuals thinking alone. Precious insights come from the mind during sleep, in the shower, under the tree, on that walk by the seaside. Such thinking is hard to reproduce at the office, in meetings or in groups. Noise, interruptions and sometimes just the physical presence of other people can impede creativity.

The lone wolf has a storm in his brain, but does not thrive in a brainstorm. The very process of group idea generation managed by a facilitator does not resonate well in her mind. He thinks meetings are time-wasting, even counter-productive. She believes too much emphasis on teamwork can lead to lower performance, social loafing, excessive conformity and groupthink. It can kill good ideas. He is convinced that not all crowds have wisdom.

The environment often seems to conspire against the lone wolf. Many people in organisations find it difficult to accept non-conformist ideas, attitudes

or lifestyles. Most managers will not tolerate behaviors that threaten their team's spirit. They are more comfortable when all people are aligned. Corporate norms are not always flexible enough to accommodate mavericks. The lone wolf has to make a huge effort to sell his methods to the pack.

But deep down the lone wolf knows her ideas will never see the light of day if she wants to go it alone all the way.

Teams: packs of wolves

In the creativity lab, people engage in innovation together. They have common goals. They brainstorm. They share ideas. They test them. They define roles and responsibilities, tasks and deadlines. They are committed. They take action. They monitor progress. They hold each other accountable. They take pride in good communication. Coordination is high on their set of values. So is camaraderie.

Organisations are born of cooperation and effective teamwork is a non-negotiable reality of organisational life. All innovation is in some ways the outcome of many minds and bodies. With this in mind Alex Osborn (1953) and Sydney Parnes (1992) published the first creative problem-solving model from the 1950s onwards. This has two key features: thinking in structured sequential stages and alternating between creative and critical thinking at each stage. The stages involve exploring the context and defining the problem, finding solutions, evaluating them and implementing the best. At each stage, people actively engage in creative thinking (stretching the mind to generate many ideas without judgment) followed by critical thinking (evaluating and choosing the best ideas).

Brainstorming is team idea generation situated firmly within this model. Its practice has been codified by Osborn, also known as the father of brainstorming. A plethora of techniques that stimulate the imagination in unconventional ways and tools to analyse ideas and guide choices further enrich brainstorming. And there are plenty of variations too. Design thinking, a contemporary refinement of creative problem-solving, adds rapid prototyping as an essential step before full-fledged implementation. Other collaborative creativity methods include TRIZ from Genrikh Altshuller (1984) and Six Thinking Hats from Edward de Bono (1985).

Like Osborn and Parnes, most practitioners of creative methods recognise that producing new ideas is only part of the story. Preparing the ground

for new ideas and following up on them are necessary too. They are best done collaboratively, because the sum of knowledge, experiences and skills of many surpasses what any person can do alone. An additional benefit is that challenges defined early on and action plans implemented later on are shared and co-owned.

Nonetheless, it is rare for truly breakthrough ideas to emerge from brainstorming. This is because breakthrough ideas are by definition rare and because the spark is more often generated by individuals working alone.

“ WHAT PROPORTIONS OF SOLITUDE AND TOGETHERNESS WORKS BEST DEPENDS ON THE TASK AT HAND AS WELL AS INDIVIDUAL PREFERENCES ”

Leadership tips

While each health establishment will have its own legacy, culture and approach to innovation, striking a balance between good individual contribution and effective teamwork will always be a key responsibility of leadership.

Tip 1

Provide time and space for creativity, to individuals. Set challenging expectations for creative ideas to all individuals and offer them time to work on their ideas. Design office space that enables each person to indulge in uninterrupted bouts of thinking, research and experimentation alone. Have flexible hours for people to organise their own creative time and place.

Tip 2

Provide time and space for creativity, to teams. Set clear innovation deliverables for expert and multi-disciplinary teams and insist on high trust and

clear accountabilities within teams. Design office spaces to facilitate good teamwork and provide good collaborative software for online idea exchange. Such software allows people to work together asynchronously, so contributing to group outcomes at times of their choice.

Tip 3

Train people, in creativity and teamwork.

Establish training programmes in both creativity and teamwork. Help people learn creative methods, tools and techniques and the basics of good collaboration.

Tip 4

Provide recognition for innovation, to individuals and to teams.

Reward both on an individual and on a team basis. Announce that:

“Our company values and rewards both individual and team achievements. We call on each and every person to constantly seek new ways of confronting our innovation challenges. We call on your teams to welcome diversity and new thinking and to make original new ideas go live. Each one of you is a creative genius. Together, we are an innovation powerhouse.”

Anonymous CEO ■

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KEY POINTS



- ✓ Successful collaboration is critical to healthcare operations
- ✓ All innovation is a result of input from multiple sources and team members
- ✓ There is creative value in both people working alone and in teams



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VALUE-BASED
HEALTHCARE

Value-oriented management

A leadership model for the health care sector

In medical institutions, leaders are required to ensure, through delegation of responsibility, that working conditions are characterised by interdisciplinary thinking, team-oriented work and ongoing improvement.



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Leaders in the health sector must be aware of the fact that hospitals operate in a market, which is not in fact a market in the classic competitive economic sense. Nevertheless, in a medical world characterised by increasing patient expectations, expensive innovative treatment opportunities and limited budgets hospital managers are forced to perform higher medical quality and containing costs simultaneously.

In this complex VUCA world (volatile, uncertain, complex, ambiguous), convincing and successful leadership conveys binding values and norms (why do we do something?) and creates legitimation (for whom do we create what value-added?), provides orientation (what are we doing?) and how to transform plans into successful organisational development (how do we do it?).

Those in leadership positions can obtain assistance through the leadership and organisational approach of the CKM leadership model for value-oriented management. It serves as an orientation for action and a compass for managing medical organisations.

Initial situation

Internationalisation, digitalisation, changing societal values, the impact of the economy on medicine, and demands for ecological sustainability are all confronting “leadership” with new challenges. What constitutes “good” leadership? When can leadership be regarded as “successful” and what characterises a good leader? Can one learn to lead, what leadership instruments have stood the test of time and what behavioural rules provide support along the path to successful leadership? Leadership is also always a reflection of the political, societal and economic framework and prevailing situation.

It is also influenced by the specifics of a particular industry, which applies all the more to the health care sector (see **Figure 1**).

Below, the CKM Leadership Model is described in terms of its basic dimensions and design elements (see **Figure 2**).

External conditions, that is, political, economic and societal trends, as well as the dynamics of the health sector, substantially determine the nature and organisation of leadership in medical institutions.

In this context, the management of hospitals, rehabilitation clinics and nursing homes find themselves in a difficult balance between financial constraints, a shortage of qualified personnel, digitalisation, employee expectations and calls for family-friendly working conditions. In addition, there are rising quality requirements and a growing demand for medical services by multimorbid, chronically ill and aged people. As a reaction to such developments, there are changes in the content and nature of work, qualification profiles, work processes and forms of cooperative work. Furthermore, altogether new forms of jobs are also emerging.

Values and behavioural guidelines for leadership are represented through the formational dimensions of sense and purpose, responsibility, entrepreneurial thinking and resource orientation (= efficiency and effectiveness; evidence-based practice).

The following questions are to be answered: “What mode of thinking characterises leadership?” and “What ethical rules guide leadership?” and “How can the efficiency and effectiveness of clinical processes be ensured in order to achieve sustainable financing for a medical business?” and “What are the key performance indicators for measuring and evidence-based steering of all medical and nursing activities?”

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Sense and purpose determine the legitimation of an enterprise in a competitive market and within the community. The sense and purpose demonstrate what the client (patient, relatives, referring doctor, cooperation and business partner, community) can justifiably expect from an enterprise. And this is an internally fundamental source of intrinsic motivation for employees. In dilemma situations of decision-making where managers are forced to decide, for instance between financial limitations and patient needs, “sense and purpose” assumes the role of “referee institution,” in terms of a “meta level goal:” In case of doubt, patient comes first!

“CAN ONE LEARN TO LEAD, WHAT LEADERSHIP INSTRUMENTS HAVE STOOD THE TEST OF TIME AND WHAT BEHAVIOURAL RULES PROVIDE SUPPORT ALONG THE PATH TO SUCCESSFUL LEADERSHIP?”

In an exceptional situation, customers (patients and relatives) experience such “moments of truth” and sense the social quality of a corporate culture.

The CKM leadership model advises “sense and purpose” to focus not primarily on economic constraints, but on patient and family-centredness, as well as on patient experience (see **Figure 3**).

Responsibility on the part of leaders in the medical business are primarily concerned with the wellbeing of the patient. Their decisions and actions are subject to the medical ethics principle: primum nihil nocere (first do no harm), patient wellbeing, autonomy and dignity. They use economic principles (eg causality principle, equal-treatment principle) in order to overcome the challenges presented by the health system with regard to sustainable finance, as well as an equitable allocation of health services.

The patient is not an autonomous, decision-making client, but a sick person with anxiety and pain, often in a physical and psychological borderline situation. Accordingly, the service process is particularly subject to ethical and behavioural guidelines. The leadership principle of shareholder value is the short-term orientation as a managerial philosophy, and revenue maximisation and thinking in terms of quarterly results is entirely inappropriate for the medical industry. By contrast, the stakeholder-value approach, with particular attention being paid to patient risks and fairness within a solidarity-oriented

Leadership

The CKM Leadership Model incorporates the holistic interaction between individual, organisation and environment.



Figure 1. Leadership transforms the influences and requirements of the socio-political and economic corporate environment into strategies and interventions for corporate development.

CKM Model: Value-driven Leadership

A Leadership Model is like a compass and provides direction in a disruptive health care system challenged by economic pressure, patients' needs and ethical conduct.

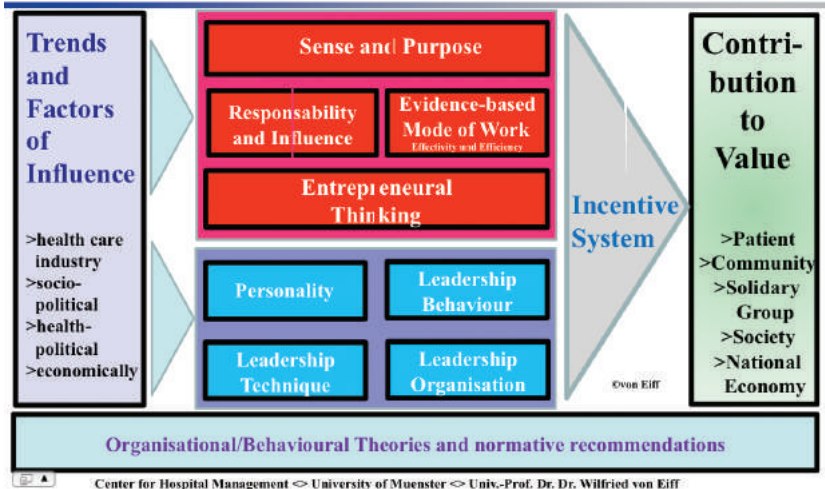


Figure 2. The leadership model is a compass for “credible” and “successful” leadership.

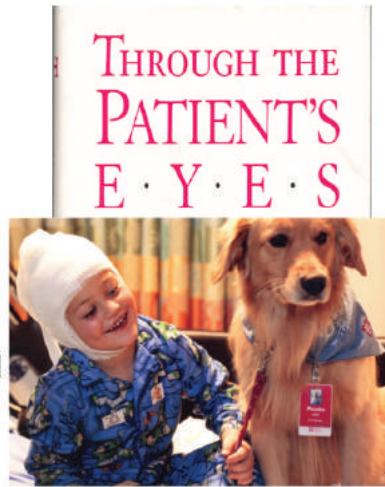
financial system, is the philosophy of choice.

Responsibility is the central controlling instrument of an entrepreneurial incentive system: the assumption of responsibility is both expected and rewarded (financially and ideally), and structures associated with an organised lack of responsibility will not be tolerated. Value-oriented leadership in the medical business is committed to medical-ethics principles.

Sense and Purpose: Patient and Family Centeredness

The patient desires...

- Painless Procedures
- Risk-free Environment
- Fast Procedures
- Privacy
- Individual Service and communication, informed consent
- Autonomy and Dignity



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Figure 3. What patients can justifiably expect from a hospital stay.

Patient Risks and non-ethical decisions in health care

Hospital decision-makers have to manage the balancing act between appropriate medical provision, controllable risks and cost restrictions.

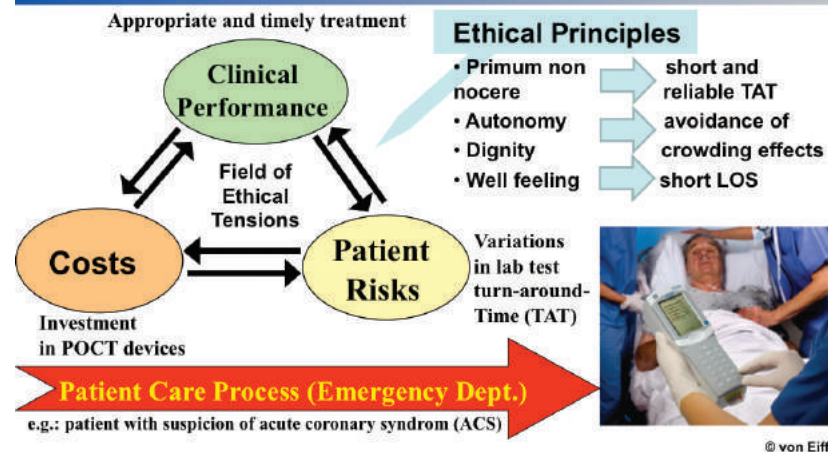


Figure 4. Value-oriented leadership overcomes the problems associated with economically motivated decisions, through taking into account patient risk as a primary decision-making criterion.

As a criterion of ethical evaluation for each managerial decision, what matters is the extent of risk that the patient bears, if, for example, there is rationing of medical services needed for appropriate treatment for cost reasons (see **Figure 4**). The more emphasis hospital manager's place on cost containment, budget restrictions and economic criteria, the more medical quality will decrease and, simultaneously, the risk of the patient suffering harm rises.

Entrepreneurial thinking and behaviour aims at securing innovation and the ability of the organisation and of the community to survive. An organisational culture, in which entrepreneurial thinking has a compelling value, is characterised by a constructive handling of errors, and oriented towards problem solving and contributing to continuous improvement.

Entrepreneurial leadership is constructively aligned with the "New Management Paradigm", according to which rising quality in the medical industry, together with a tendency towards declining cost, is to be achieved. Entrepreneurial leadership is also constructively aligned with "New Management-Entrepreneurial Awareness and Behaviour" and is necessary at all levels of an organisation and has to apply across professional groups and boundaries. This is conditional on the assumption of responsibility by colleagues as well ("Every Employee a Manager").

“ THERE ARE RISING QUALITY REQUIREMENTS AND A GROWING DEMAND FOR MEDICAL SERVICES BY MULTIMORBID, CHRONICALLY ILL AND AGED PEOPLE ”

The process is ensured through the participation of colleagues who are capable of delegation in decision-making processes, through setting up task areas, which are suitable for delegation, with clearly defined decision-making autonomy, as well as through clinically oriented compliance management. Entrepreneurial leadership also aims at including and integrating employees in decision-making processes, in order to solve problems and contribute to continuous improvement.

Resource-orientation commits the institutions within the health system to ensuring efficiency and effectiveness, because, in the health sector, wastage, redundant (double) work and errors lead to investment and quality gaps, which jeopardise the sustainability of financing. In the health sector, the generally accepted principle for a market economy of "creative destruction" leads to patient risks and is associated with additional costs, which ultimately cause the care situation to deteriorate in the future. Effective leadership converts "sense and aim" into goal-oriented behaviour, overcoming complexity through coordination and resolving goal conflicts constructively.

The dimension of leadership competence comprises the formational attributes of leadership techniques, leader behaviour & personality and leadership organisation. The central questions are: “What attributes characterise leadership and how can they be influenced and formed? What leadership instruments have proven their worth over time? What relationship prevails between successful leadership and personality?”

Leadership techniques

Leadership techniques subsume leadership methods and instruments into goal-oriented, transparent and understandable control of colleagues and employees. One method is that of using structured processes to recognise a problem and solve it in a systematically understandable and transparent manner. An appropriate methodology, as a systematic approach supporting decision-makers in managing the process from identifying a problem-to-problem solving, ensures that a leader can understand at any stage of the decision-making process, how an intermediate result arises. By so doing, learning processes for future decision-making, in the sense of experience formation, are possible. Suitable instruments include surveys, analysis, communication and decision-making techniques, which can all provide tangible support in achieving leadership objectives.

The leadership technique of “Management by Objectives” (MbO) entails a recommendation for a structured process of objective formation, agreement and control, and further employee development on the basis of constructive criticism. As leadership instruments, the documented agreement on objectives, evaluation systems, reward systems and personal development systems, are used.

The MbO concept works on the basis that agreed-upon objectives, in combination with a reward and personal-development system that is regarded as fair, foster the intrinsic motivation of employees. The basic condition for the successful implementation of MbO is firstly the establishment of organisational units that are capable of delegation, and which create congruence between task (objective), competence and responsibility. Secondly, a transparent system comprises agreement on objectives, and is accompanied by performance control and employee development.

The CKM leadership model provides leaders in the institutions of medical service providers with

INSIGHTS Leadership Check

People align their way to act and communicate to dominant guidelines. That makes behaviour predictable.

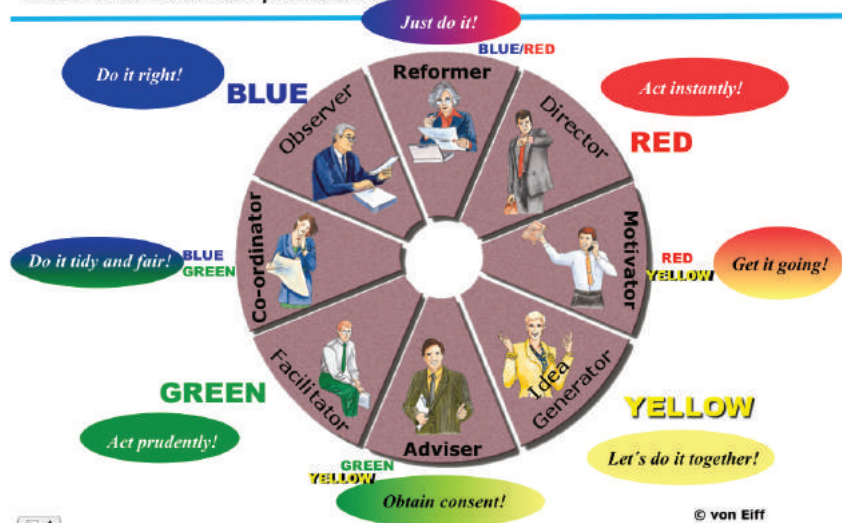


Figure 5. The eight personality types of the INSIGHTS concept

Organisational Change

Behaviour cannot be changed by appeals, but by establishing an organisational framework that meets both the requirements of the organisation (task, responsibility, competence) and the preferences of the employees (working conditions).

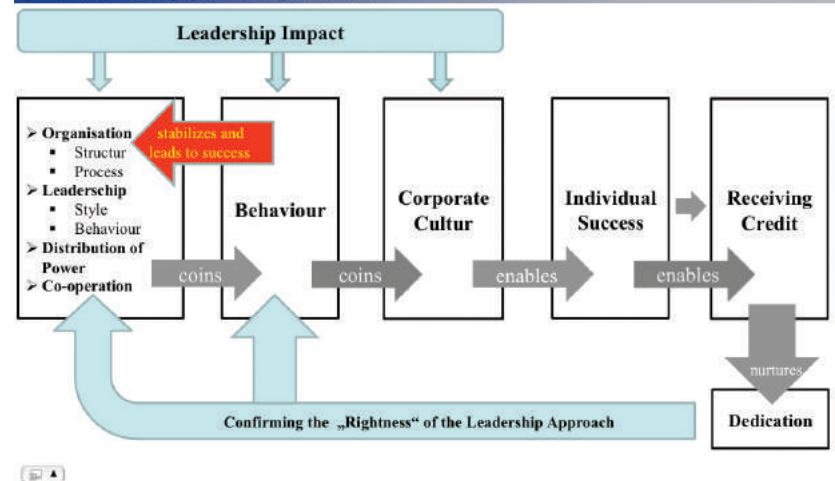


Figure 6. Leadership and organisational structure determine behaviour

the normative, strategic behavioural recommendation not to form any goal-agreements with an exclusively economic focus, because this would generally lead to ethical conflicts. Thus, agreements on the quantity of certain types of operation (eg total hip replacement) run contrary to the requirements of indications quality, and transgress the ethical maxim of “primum nihil nocere.”

Behavioral elements of successful leadership

Successful leadership ...

- transforms resources into results
- creates direction and determines objectives
- explains the point (of actions and behavior)
- gives FEEDBACK and conveys what is expected
- creates positive working conditions
- creates rules and promotes adherence to them
- has a clear position and basic orientation
- is calculable
- enables employees to develop themselves further
- prevails in conflict situations (through setting meta-objectives)
- communicates directly (I - messages)
- is emphatic and takes things seriously
- establishes a balance between autonomy and obligation
- respects individual life paths
- ensures clarity and transparency
- ensures employee responsibility
- bonds through rituals.



Florence Nightingale

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Figure 7. Leadership and "managerial competence" in the medical industry: How successful leaders are recommended to behave, act and communicate

Leadership behaviour

Leadership behaviour characterises the active communicative impact of a leader on employees in terms of goal attainment. This also entails the balancing act of harmonising an employee orientation (degree of fulfilment of employee expectations) and a task orientation (importance of the enterprise's requirements of its employees). Successful leadership behaviour is based on proven rules of communication, eg establishing rituals, providing feedback and ensuring transparency pertaining institutional needs, as well as employee expectations (career opportunities, family-friendly workplace conditions, work life balance).

Personality and leadership

All individuals have their own unique personality profile. Even in antiquity, philosophers such as Hippocrates and Empedocles attempted to create a typology of human behaviour, in order to predict how certain personality types could be expected to behave. The early typologies so derived entailed four basic types: choleric, sanguine, melancholic and phlegmatic.

The personality type determined the work, communication and behavioural style. This style is situational and influenced particularly by work stress,

“RESPONSIBILITY ON THE PART OF LEADERS IN THE MEDICAL BUSINESS ARE PRIMARILY CONCERNED WITH THE WELLBEING OF THE PATIENT”

time pressure, errors and so on. As an instrument for analysing and predicting the work, communication and behavioural style of a particular person, the INSIGHTS Leadership Check has proven its worth.

INSIGHTS refer to the interrelationship between personality and successful leadership on the basis of eight standardised personality types (see **Figure 5**), whose typical modes of behaviour in typical situations can be categorised into normal situations, stressful situations and those with extreme stress.

In the context of the dimension of an incentive-contribution system, the following question is posed: “what function and significance does the corporate culture have and how is it possible to develop a goal-oriented incentive system that is regarded as fair by all participants?”

The incentive system comprises monetary components (salary, special payments, bonuses, overtime), contains fringe benefits (child care, employer-sponsored housing benefits, public transport tickets), includes the working conditions (work

place design and equipment, working times, holiday regulations) and also regulations for personal development (continuing education, career opportunities as specialists or in management) as well as a system for internal company suggestions.

The corporate culture is characterised by the manner in which the following are dealt with: conflicting opinions, suggestions for improvement, employee initiatives, errors, resource wastage and a failure to disclose information. Formulated behavioural principles and leadership guidelines render an enterprise's culture transparent and understandable. What is important is that any contravention of the corporate culture values be followed up and investigated. The incentive-contribution system and corporate culture are the sources of motivation and willingness to perform.

The CKM model is based on the "Structure-Behaviour Theory of Motivation" (von Eiff 2018). According to this theory, behaviour is not changed through appeals alone, but rather through the formulation of conditions (organisational structure, work conditions, rules of corporate culture, forms of cooperative work, power relationships), all of which enable employees to develop enthusiasm for their work.

Leadership has the primary function of avoiding demotivation (lack of feedback, no evident purpose of the work, the expertise of employees is not utilised, obviously dysfunctional work processes are not improved). Through partial autonomy, the formation of work and decision-making processes of employees can be experienced successfully within defined competence fields through their own decisions, which fosters recognition and commitment (see **Figure 6**).

The dimension of valued added through leadership (with regard to the patient, community, solidarity system, economy) considers the following question: "What value is added by leaders in terms of reasonable stakeholder expectations?" Accordingly, leaders not only have a responsibility for employees and enterprises, but must also take account of the impact of their decisions on society and the community.

A hospital is part of the infrastructure of a region and contributes to the security and quality of life of the citizens. As an employer, its duty is to provide attractive, stimulating and secure jobs, and such enterprises constitute an important economic factor within a region. With regard to health policy, the value added by leadership is concretised through the

Triple Aim Strategy (> quality-oriented remuneration; > population-oriented care; > patient experience/patient care in a recovery-promoting environment) (von Eiff 2018).

From the five dimensions of the leadership model, specific recommendations for action can be derived, which provide the basis for internal organisational discussion between current and potential leaders. Through such recommendations on leadership techniques and behaviour (see **Figure 7**), leaders obtain assistance in dealing with classic leadership situations. That is: How do leaders communicate in a manner that is clear and unambivalent? What typical leadership errors should one avoid? What organisational conditions support goal-oriented leadership? What is the significance of rituals for determining a stable corporate culture and how should they be formed and formulated? ■

Conflicts of Interest

None.

KEY POINTS



- ✓ Leadership is a reflection of the political, societal and economic framework and prevailing situation
- ✓ In the health sector, managers must provide a high level of medical, economic and ethical competence to deal with the balance between a limited budget and a demand for suitably qualified medical services
- ✓ Before every decision, the leader must ask the question: Does my decision conform to the ethical guideline "Above all, do no harm!" or "To what risk could my decision expose the patient?"
- ✓ The CKM Leadership Model is a compass, with the help of which requirements can be targeted, structured and implemented in a sector-specific manner.



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Sex and gender in medicine

The need for more attention to how sex and gender influences healthcare

Healthcare has not been immune to the gender gap, but the implications go deeper than one would expect.



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Biological differences between males and females have a profound impact on how we approach their healthcare needs in terms of pathophysiology and treatment for a vast array of diseases. However, health education and research currently do not adequately highlight these differences. Sex and gender are an essential aspect of precision health, where every cell has a sex and can influence pathophysiology and gender is reflective of environmental factors. Understanding both leads to optimal treatment and is essential to a better understanding of the disease process.

Sex? Gender?

A person's sex is genetically influenced and, based on external genitalia, is usually assigned when born. Gender refers to an individual's socialisation leading to both identity and expression and has a much broader expanse of possibilities. Understanding these differences, summarised pictographically by the Canadian Institutes of Health Research in **Figure 1**, is essential as we strive for more individualised patient care and an increased knowledge of health and disease.



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Research limitations

Research has been wildly behind in understanding the differences between sex and gender. This is evident even starting at the preclinical phases of clinical trials, which tests drugs on non-human subjects. A review article looked at sex bias in research on mammals in 10 biological fields and found that a male bias was noted in 8 disciplines. This was most prominent in neuroscience, with single-sex studies of males occurring 5.5 times more often than females (Beery and Zucker 2010). An underlying foundation of excluding females has been that females have more biologic variables, particularly with hormone cycles and pregnancy, which can create more confounding variables and make data analysis more difficult.

However, it is essential that we address these

variables so that we can ensure that this data is applicable to human females when clinical trials progress to further phases. For example, women are diagnosed with anxiety disorders 2.25 times more often than men, but most animal studies on pharmacology for anxiety are done on male rats. Similar trends have been noted in other studies discussing strokes, multiple sclerosis, and pain (Beery and Zucker 2010).

“SEX AND GENDER ARE AN ESSENTIAL ASPECT OF PRECISION HEALTH; UNDERSTANDING BOTH LEADS TO OPTIMAL TREATMENT”

Even in human articles, as evidenced by **Figure 2**, we can see a clear bias for male subjects in almost every field, except three: reproduction, endocrinology, and behaviour physiology. This perpetuates the idea that female subjects are only relevant when determining reproductive value and analysing hormonal differences (Beery and Zucker 2010).

Gender gap amongst physicians

The gender imbalance in healthcare is mostly at the leadership level. Up to 80% of those that provide healthcare are women, but only 3-9% actually make it into leadership positions. This lack of women in leadership may be due to unconscious bias and outdated societal stereotypes and has a negative influence on patient outcomes (Rotenstein 2018).

Rock Health, a venture fund that has been surveying women about gender diversity since 2012, has noted that the percentage of women on healthcare executive teams and boards has remained stable since 2015 (Tecco and Huang 2018). These findings, shown in **Table 1**, make it clear that the fight for gender equality is still pervasive even within the medical field, which in turn, has made it more difficult to push for the attention to gender gaps in medical

knowledge. It's essential that women play a central role on these boards so that more diverse ideas and suggestions about how research and medical practice can be put forth and older notions can be challenged.

It has been shown in corporations that with increase in diversity at the senior leadership level, there is a reported increase of up to 74% more in equity and assets. Recognising that high performing women physicians are less likely to stay in an organisation where they perceive a glass ceiling and the cost for decreased physician engagement and increased burnout should lead the health care industry to work on mechanisms for promoting more women into traditionally male-dominated leadership roles (Kimball 2015).

Lives could be saved by evaluating the differences, not only in the disease process but in the management provided by physicians. In a study by Tsugawa, there was a decrease in mortality for Medicare patients cared for by female physicians (Tsugawa 2017). Interestingly though, female physicians score lower in patient satisfaction scores than their male colleagues as reported by Sotto (Sotto-Santiago 2019). Just as in understanding what the drivers are for differences in disease states, we should learn what female physicians are doing differently that may increase care quality (Tecco 2018).

Education reform

In a survey conducted by the American Medical Women's Association (AMWA) between September 2004 and June 2005, students were asked to rank the extent of how certain topics across several disciplines were included in their curriculum and how prepared they were in certain clinical skills. The most frequently mentioned topics students would have liked to see more of, included abortion and contraception (42%), sex/gender-specific information on any topic (20%), and rape and domestic violence (20%). Other highly-ranked topics included female sexuality, sexual orientation, and gender identification, and adolescent girls' issues. Furthermore, some students commented about how there are also deficiencies in many aspects of male healthcare, and some of the survey topics were not addressed in men. A couple of students also commented on how women's healthcare topics were isolated when they should be approached with a balance between both sexes.

This information suggests that not only do medical schools not spend enough time addressing gender



Figure 1: Sex vs. Gender

Image Source: Canadian Institutes of Health Research

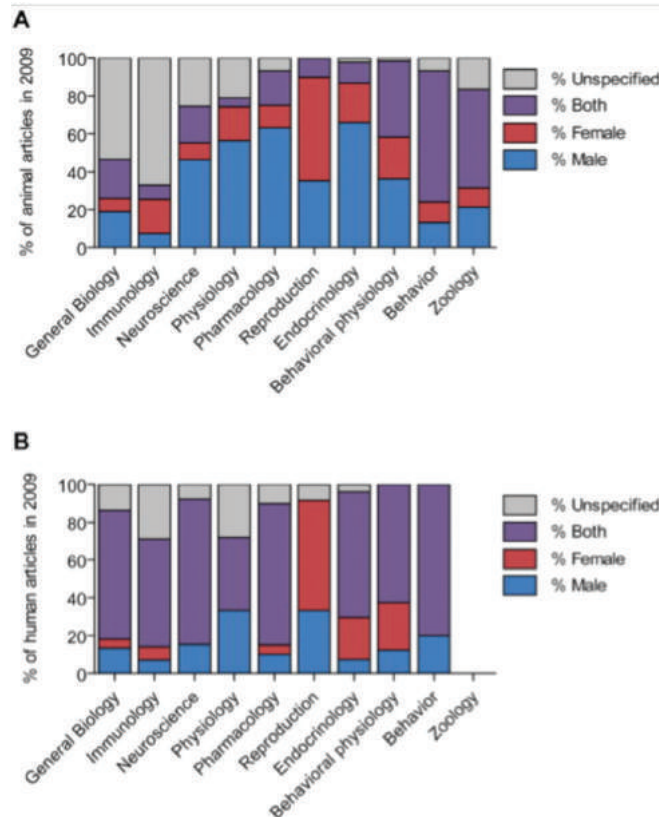
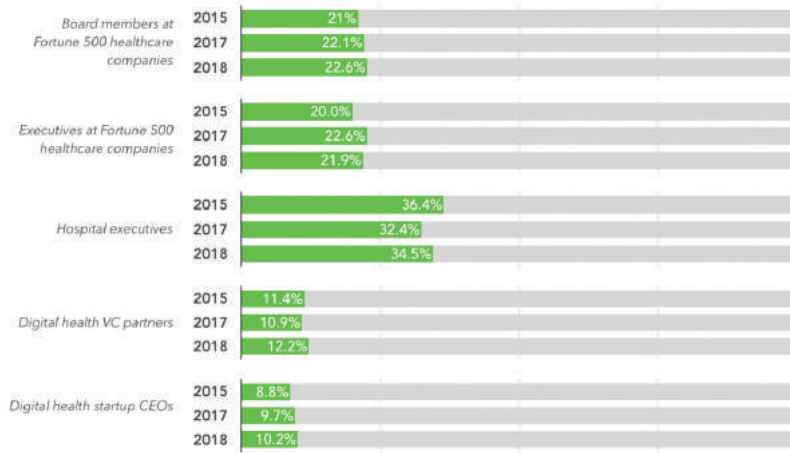


Figure 2: Distribution of studies by sex and field in 2009 (Beery and Zucker 2010)

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THE PERCENT OF WOMEN IN HEALTHCARE LEADERSHIP IS GROWING, ALBEIT SLOWLY

Women as a percentage of each of the following categories in 2015, 2017, and 2018



Source: Fortune 500 List, Rock Health Funding Database, company websites

Table 1: Percentage of Women in Healthcare Leadership Roles (Tecco and Huang 2018)

Reprinted with permission from Rock Health

disparities in healthcare, but also students actually want to know more about these topics. It is no secret that each new generation has an increased awareness and personal connections to problems such as the ones mentioned above. However, physicians continue to lack serious training in addressing these topics at any level. These conversations are never easy, and that makes it essential to start talking about how to approach patients with sensitive subjects early on in medical training to make it a more empathetic process. Furthermore, physicians also should be aware of what resources exist at their institutions to help support patients for long-term healthcare impacts that will persist beyond their first visit.

“LACK OF WOMEN IN LEADERSHIP MAY BE DUE TO UNCONSCIOUS BIAS AND OUTDATED SOCIETAL STEREOTYPES AND HAS A NEGATIVE INFLUENCE ON PATIENT OUTCOMES”

So where do we go from here?

Research focusing on both human male and female participants has been increasingly emphasised and has improved over the past few decades, especially with pressure from national and international organisations to do so. However, while the sex bias has a

relatively easy fix, addressing gender bias has its own sets of limitations. How do we measure gender when it exists on a spectrum of possibilities? With the ever-changing landscape on how we view gender, how do we attempt to avoid stereotypes and come up with an unbiased scale? Furthermore, how do we analyse the intersection of sex and gender to understand how to individualise therapy? These questions certainly have no easy solution, but it is important to start the conversation and push for a solution through greater inclusion of women as leaders and addressing the gender inequality at every level of medical training. ■

Conflicts of Interest

None.

KEY POINTS



- ✓ Medical research has long neglected sex and gender as variables, but it can have profound impacts on what we know about treatment plans.
- ✓ Women represent less than 10% of leadership positions in hospitals, but evidence suggests that more women in these positions would increase company satisfaction and profits.
- ✓ The drive to change how we include sex and gender in medicine should be implemented in medical schools, so that future physicians have the foundation to examine pathophysiology and treatment options with an educated knowledge base of the impact of sex and gender on health and disease.



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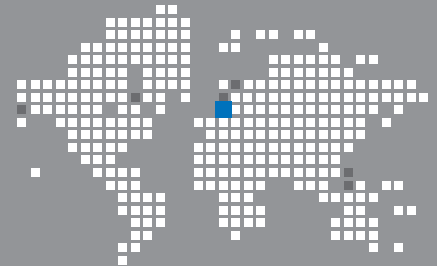
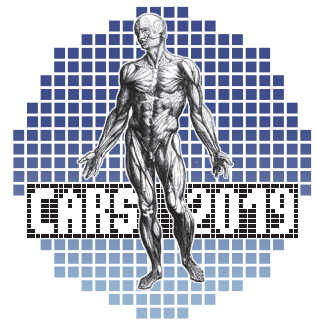
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Precision health and population health: can they intersect effectively?

How and where can precision medicine and public health join forces to improve patient care and outcomes and, ultimately, lead to more efficient healthcare. HealthManagement.org spoke to four precision medicine experts for their views.



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We are facing a revolution in cardiovascular medicine. Big data, from wearables, social media, omics, gene analyses etc. cannot be analysed, using standard techniques, which makes the data more or less useless. Using artificial intelligence has the potential to make a significant impact in cardiovascular medicine. Initiatives specifically designed to improve diagnosis and treatment of rhythm disorders, coronary artery disease, hypertension, and heart failure could go a long way in helping reduce the global

burden of cardiovascular disease. We are in acute need of targeted therapies in cardiovascular care, and we also need precision medicine approaches that would provide us with more advanced drugs that not only treat patients better, but could potentially prevent cardiovascular disease altogether. The premise of personalised medicine, and its focus on understanding the human genome can enable healthcare providers to look deeper into the causes of heart disease. Spotting biomarkers that could help clinicians identify patients at high risk for future issues such as heart failure, arrhythmia and atherosclerosis could go a long way in helping curtail the increasing prevalence of cardiovascular disease. This is especially true since a large majority of cases of coronary artery disease are linked to the patient's genetics. I strongly believe that genetic insights and the increasing use of personalised medicine can change the way we prevent, diagnose and treat cardiovascular disease.

What the critics really focus on is the use of PM at a population level. They need to see the clinical advantages to the full population of patients with a given disease – for example, breast cancer. Will we see benefits by using this technology and using this therapeutic target at a population level? Will it bring down costs? Will it incur higher costs and does the cost equal the benefit we're getting? These are the questions that critics are asking. To those critics I would say, like any system, we need to develop the regular use of PM so it can be implemented most effectively and efficiently in order to fully realise its value to both the patient and the population.

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Make no mistake, broad precision medicine implementation will happen. We're already seeing substantial, real-world evidence of progress and outcomes. Pioneering healthcare organisations have deployed various models, many of which focus on engaging underrepresented, minority, and disadvantaged patient groups. For now, reliable applications are limited to use cases for which significant clinical findings have been demonstrated. In such cases, payers, pharma, major vendors, and well-funded health systems are beginning to work creatively together. Over the past 18 months, KLAS has worked with dozens of leaders to validate the activities of leading precision medicine programs. The majority of healthcare leaders believe a business case exists today,

and that the most impactful priorities for success in building a programme include provider education and engagement, multi-specialty collaboration, and stakeholder buy-in. Most do not feel the market lacks science or applicability. Success is primarily measured today by lives saved, enhanced quality of life, and disease prevention. Despite a growing consensus on how best to approach and scale a structured precision medicine programme, providers largely feel that widespread adoption remains several years out. Progress remains stifled by lack of agreement on reimbursement policy, education, and knowledge. Despite these challenges, provider organisations are highly optimistic about partnership opportunities in the industry. Precision medicine will supplement and complement current efforts to develop population health programmes by specifying and adapting care management to fit unique needs. In many ways precision medicine practice is informed somewhat by the robust analytics and stratification of information demanded by population health. However, the practice of precision medicine turns population health on its head primarily by systematically putting individual patients at the centre of analysis rather than a condition or risk state, and then scaling learnings across a population or sub-group.

We are beginning to see the intersection between precision health and population health through new strategies for predictive prevention – for example, efforts are underway to use genomics to predict individuals' risk of common diseases such as cardiovascular disease or type 2 diabetes. Ensuring the effective use of genomics and other types of patient data for predictive prevention at scale will require the health system to collect, manage and store data from healthy individuals, which could inform population-wide strategies to delay or prevent ill-health.



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Personalised Medicine: The road ahead

How can healthcare accelerate the implementation of the science?

Where is Personalised Medicine (PM) already improving the lives of patients and what is needed to make it the standard of care across multiple conditions?



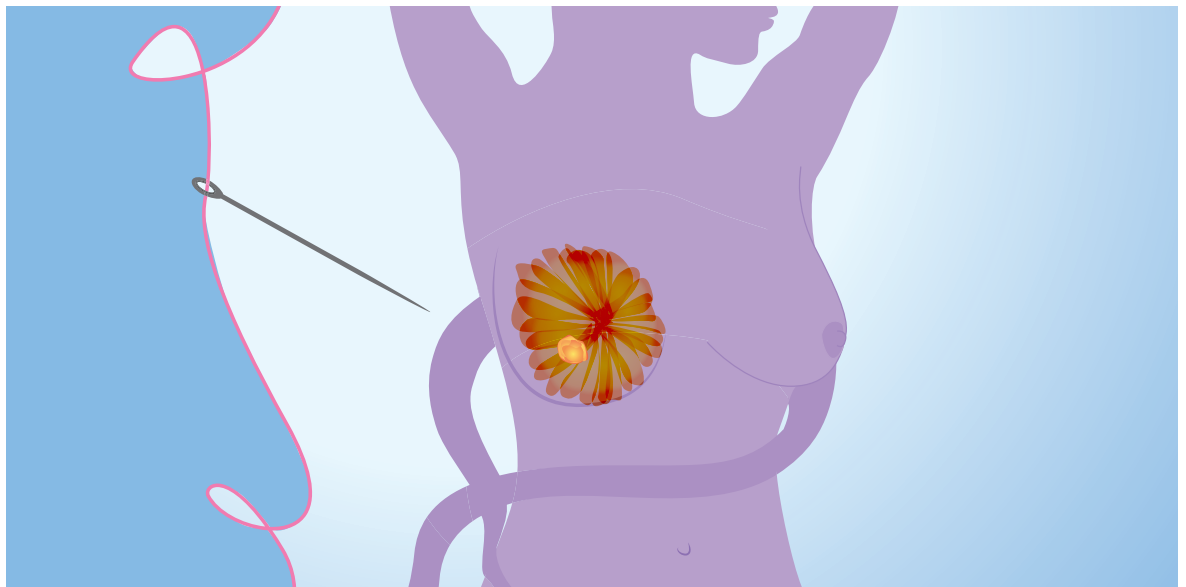
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What's your brief at the PMC?

I have a science and genetics background and bring scientific expertise to the PMC. I'm leading the programme and initiatives that try to make a case for PM, show scientific validity, understand trends and show how to implement it in clinical care. Alongside my work, the public policy portfolio works with different policymakers throughout Washington DC.

Together our goal is to advance PM, facilitate access to PM for patients and help healthcare providers implement it.

The potential of genomics and PM, for example, with the Human Genome Project (HGP) has been presented as having huge potential for tailoring and improving healthcare. However, some critics claim that PM is not delivering on its promise and funds would be better spent on population

health. Can you please cite two or three examples of where PM is already making a tangible impact?

The HGP and the growth of the tech in the field is something that is ongoing and, as more technologies are developed and beginning to be implemented in healthcare, we are seeing an increased rate of technology implementation and development. The PMC strongly feels that PM is the future of medicine and we need to establish the environment for it. It has already made an impact in several areas.

Firstly, we have seen utility in breast cancer with the use of biomarkers that identify candidates for targeted therapies in care. This has been so beneficial in treating patients, it has now become the standard of care in breast cancer therapy. For those patients who have certain biomarkers that make them eligible for targeted therapies, the long-term survival rates have increased dramatically and breast cancer is less of a

death sentence than it used to be. It is now more of a chronic disease.

Outside of the oncology space, there is progress with cystic fibrosis. This is a rare disease where patients have difficulty in clearing mucus from their chest and have a long progression into a continuously degenerative lung situation that, previously, had led to very early deaths and a difficult end. Today, because of testing and understanding the ‘biomolecular’ pathways for this condition and development of new therapies that target those pathways, the vast majority of cystic fibrosis patients are getting targeted treatments that have allowed them to live normal life spans and to breathe freely.

A therapy that is relatively new but is showing remarkable benefits to patients is gene therapy for retinal disease. This has allowed patients with inherited degenerative vision disorder to regain sight by directly targeting the gene that is mutated in the molecular pathway that leads to disease.

Is PM scalability a challenge and, if so, what are some ways you are seeing healthcare organisations overcoming this?

It’s certainly a problem. In a lot of areas we are seeing PM being implemented or inducted through pilot protocols (which are really research protocols). Scaling that to become regular care in healthcare and care delivery systems has been a clear challenge. IT management has played a huge role in the strategies that are bringing PM research to regular care. Sometimes there are massive amounts of data involved in PM therapeutics strategy and this has to be integrated into the system. It’s important that accurate information gets to the physician through a clinical decision support mechanism. The aim is that it’s ultimately a net time save for decision making. As with all new technologies, there is inevitably a lag time as physicians begin to understand personalised medicine and how to implement it and there’s reluctance by many to do things differently until they know that it works. We need to make sure that the IT management systems are in place that can bring PM forward. This is already directly linked to EHR integration.

With your experience and insights into the practicalities of PM, what would you say to any critics of this healthcare movement?

I don’t think that there is a large-scale critique about the concept of PM, the idea that if you understand the biological mechanism of disease you can target that

for treatment. I think that it’s a strong concept that is widely accepted. What the critics really focus on is the use of PM at a population level. They need to see the clinical advantages to the full population of patients with a given disease – for example, breast cancer. Will we see benefits by using this technology and using this therapeutic target at a population level? Will it bring down costs? Will it incur higher costs and does the cost equal the benefit we’re getting? These are the questions that critics are asking.

To those critics I would say, like any system, we need to develop the regular use of PM so it can be implemented most effectively and efficiently in order to fully realise its value to both the patient and the population. What we’re seeing are practice gaps – the reluctance to use the technology until the value of the technology is clear. As we develop the evidence of PM’s value and implement the supporting technology, we’ll begin to see those population level value elements come to the fore. We’re clearly seeing individual level benefits. To realise these individual patient level value elements benefits at a population level we need to implement the system more fully and effectively and that will come with time, I’m certain.

Where does PM have the most near-term potential?

That will depend on each condition and how rapidly new technologies are developed and implemented. I feel that within five to ten years, PM will be a standard of care in three areas in particular: oncology, inherited rare diseases and pharmacogenetics. In areas such as cardiology, asthma, Alzheimer’s, multiple sclerosis and in other autoimmune diseases, we are also seeing the advance of PM.

What are the pitfalls?

The real danger is that PM science is moving more rapidly than policy, so if we don’t develop and implement policies for both regulatory approval and coverage and reimbursement, we’ll see an unnecessarily slow implementation of PM. This would be to the detriment of patients. We need sound regulatory oversight and reimbursement policies in place.

How will PM become more accepted in the world of medicine?

What critics are looking for is evidence that PM has value. We need practice-based evidence. Research only goes so far and the sector needs to know how PM is going to work in practice. These are the steps now being taken. ■

A human-centric approach for data collection

The promise of personalised medicine



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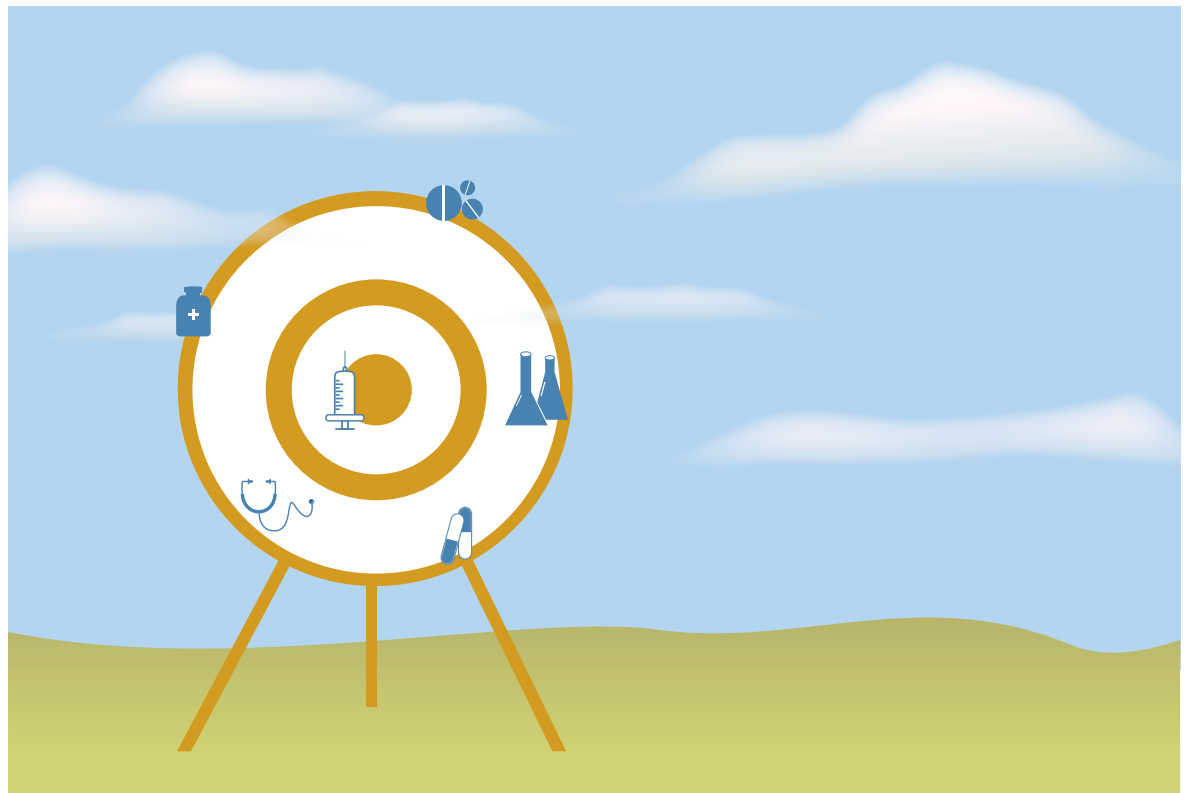
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Based on extensive market research, the precision medicine sector is fast becoming a multibillion market. It consists of innumerable companies involved in the research and development, manufacturing and commercialisation of several novel drugs and diagnostic kits to boost the precision medicine workflow (BIS Research, 2019).

Countries are competing for investments with different approaches. The Health Sector Growth Strategy was created for Finland a few years ago,

pinpointing the health sector as one of the core industries for the Finnish future. The promise of precision medicine will be fulfilled with unique data reserves, technological know-how and broad public-private collaboration, like The FinnGen study that plans to tap into 500,000 unique blood samples collected by a nation-wide network of Finnish biobanks (FinnGen.fi 2019).

Legislative reforms were seen as an important enabler in the Health Sector Growth Strategy.

One of the reforms was to bring Secondary Use of Health and Social Data into compliance with EU's General Data Protection Regulation (the GDPR). GDPR was applied in all EU Member States as of 25 May 2018. After few years of preparation, the Act on the Secondary Use of Health and Social Data (Government proposal HE 159/2017) was scheduled to enter into force in April 2019. Research and innovation will get an additional boost from fresh legislation as a new licensing authority is born, which will allow social welfare and healthcare data to be used more smoothly and securely.

“INCREASING THE AMOUNT OF PERSONAL DATA RAISES NEW QUESTIONS ON DATA ETHICS, TRUST AND TRANSPARENCY – MANDATORY PREREQUISITES FOR THE PHARMA AND LIFE SCIENCE INDUSTRY TO SUCCEED”

In such a complex world one approach is not enough. Many organisations are already testing near real-time data processing technologies (aka data lakes) for making more use of AI and developing new AI-based solutions. More and more data are generated outside traditional registers and EHRs. For targeted treatments and research to be a reality, growth of personal healthcare devices and integration of smart technologies in the healthcare system is an important enabler. Increasing the amount of personal data raises new questions on data ethics, trust and transparency – mandatory prerequisites for the Pharma and Life science industry to succeed. According to a survey of the general public conducted in 2018 (four countries and 8,002 respondents), two in five respondents discontinued their use of digital services because of a lack of trust in the service provider (Sitra, 2019). In a 2018 Mobile Ecosystem Forum (MEF) Consumer Trust survey (10 countries and 6,500 respondents), the same response was given by 39% of respondents (MEF, 2019). This is a clear message to companies: the best way for fair companies to stand out positively is to offer clear and comprehensible terms of use that state what

the data is collected for and why, and what it will be ultimately used for.

One of the human-centric paradigms for trustworthy handling of personal data is MyData. The main objectives of The MyData movement are: 1) formal to actionable rights, 2) data protection to data empowerment and 3) closed to open ecosystems. This movement is aimed to build a fair, sustainable, and prosperous digital society, where the sharing of personal data is based on trust as well as a balanced and fair relationship between individuals and organisations (MyData.org, 2019).

Also, an increasing number of analysts are becoming interested about this kind of paradigm and the potential ecosystems being built around it. MyData is a human-centric approach to data management and well aligned with an idea of “data minimalism.” In the future, more transparency is needed for consumers to trust necessary use of their data needed for new products and services. Data should also be used and stored responsibly (Trends.fjordnet.com 2019).

Sitra is now working with a new cross-sectoral initiative, known as IHAN, on a fair data economy. A fair data economy is fair for all: individuals, businesses and society. It is about just treatment of people's privacy and about sharing data in an ecosystem with consent from individuals to create new services. Sitra believes that consent-based data sharing could be something for pharma companies to ensure trust and positive attitudes for future. A human-centric data exchange may also provide new means for data interoperability.

When it comes to interoperability, it should be considered in its broadest sense - information exchange not only between domains of industry, but also spanning several countries.

One of the most impressive examples of this fair data economy is a story of a teenage girl named Alva, who suffers from type-1 diabetes. Even though the burden of the disease has an impact on her daily life, she still wants to live an active life with all the activities that teenagers of her age would normally take part in - attending school, being active with hobbies etc. When Alva travels between Nordic countries, she should be confident of receiving quality services wherever she goes.

By giving consent for the use of her data, her parents are helping their daughter to have her critical safe glucose data flow secured by bullet-proof Blockchain technology. This comes from

open-source-based metering solutions to the caring doctor, but also to other authorised parties, such as a school teacher or a basketball coach, that have been given consent earlier by the family. This “ring of trust” provided by the consent identifier in a wallet of services, can be expanded by a new set of service providers as the number of fair-data services grow.

Another interesting fair data pilot case also contains cross-border elements. A bold pilot is going to be experimented with where Finnish citizens travelling to the Tokyo 2020 Olympics download a mobile app that can be used in case of the need for medical attention while travelling. The app itself will fetch travellers’ medical and prescription records from the national health register, KANTA. This app will contain a translation service that will decipher, for example, ICD-10 diagnosis codes and prescription information to the target language and coding systems (eg SNOMED CT) using elaborate algorithms and metadata. This leads to better and quicker treatment if something happens while travelling. This is all made possible because of a fair data environment where the end-user is empowered and rewarded by the new set of value-add services provided by user consent.

When it comes to sports, one can also take the athletes’ viewpoints. A solution is being created by the Olympic committee to gather athletes’ training and wellness information from selected data sources. This consent-based data can then be used by authorised coaches and other supporting staff. This can also be extended to a national health level. The Finnish Defence Forces are recreating overall conscript training as part of their Training 2020 Programme. In the pilot the conscript’s consent-based personal data can be shared to various stakeholders during the service period.

Let’s imagine a case where a research pharmacy takes up a role as a service provider and, along with the pharma company, launches a study to combine target group participants’ health data from national

registers with self-reported data. This Patient Reported Outcome data combined with register data can describe regional differences in, for instance, rare disease prevalence, characteristics, resource use and nationwide costs. A participating person is directed to create a digital ‘wallet’ for managing personal consents.

This new era of a data-based gold rush is ongoing, where pharma companies are investing enormous amounts of money into value-based healthcare and real-world evidence, where customer-related data, MyData, should be incorporated into the Research and Development process for accelerated drug development processes.

These types of new services will flourish in Europe and in the Nordic countries particularly, as fair data services grow. A brand new legislation for secondary-use of health data in Finland gives a good foundation for new service providers and data operators to thrive if the most important asset of this new economy is taken care of – the trust of citizens in these new fair data services. ■

KEY POINTS



- ✓ Citizen trust is key to efficient use of data for healthcare purposes
- ✓ Organisations which have a human-centric approach on data use will have more success with their healthcare research and delivery objectives
- ✓ A human-centric approach to personal data can lead to a fair, sustainable, and prosperous digital society



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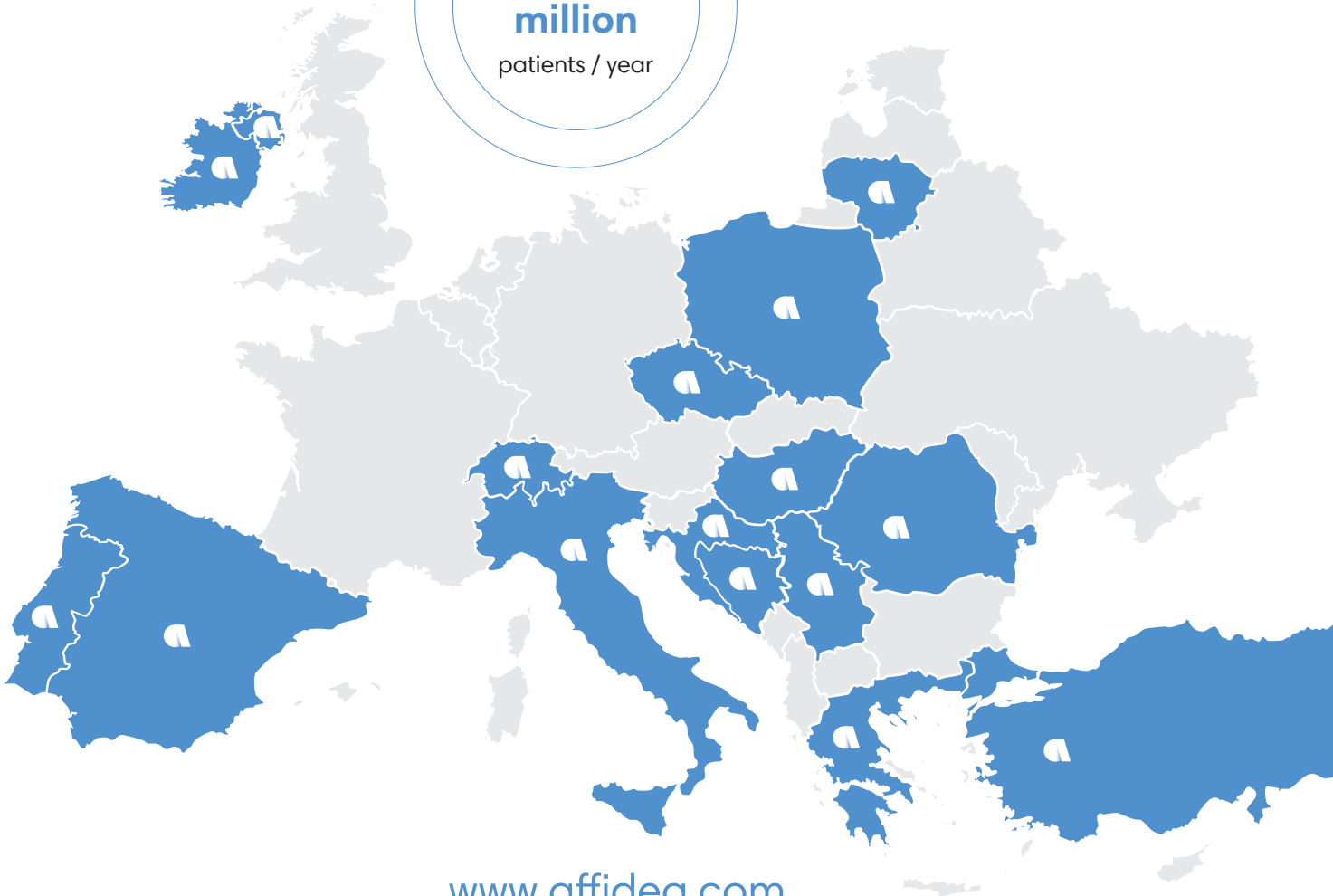
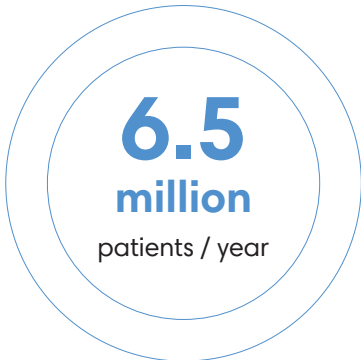
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Leading European provider of advanced diagnostic imaging, outpatient and cancer care services.



Know more, treat better

Affidea applies ground-breaking AI technology on Brain MRI examinations for people with Multiple Sclerosis



Katia Katsari
Chief Medical Physicist and
AI Operations Affidea

Affidea has entered into a partnership with **icometrix**, a data science company that develops Artificial Intelligence (AI) solutions for healthcare, to standardise and improve the care of patients with neurological disorders. The official announcement of the partnership has been made at ECR 2019 on the application of a ground-breaking AI tool on Brain MRI examinations for people with Multiple Sclerosis (MS).

As the leading European provider of advanced diagnostic imaging services, we are well-positioned to transform healthcare and the way we diagnose, monitor and treat people with multiple sclerosis, benefitting from a pan-European network of medical centres, reputed medical professionals and a committed ownership. Our own investor, the Waypoint Capital Group, which manages the funds of the Bertarelli family, has a deep heritage in the healthcare sector and a focus on innovative, forward-looking industries. It also owns the new digital tech fund, Forestay Capital, which recently announced an investment in icometrix to support its ambitions for growth and to transform patient care through imaging AI.

“OUR AMBITION IS TO LEAD THE IMPLEMENTATION OF AI CAPABILITIES IN HEALTHCARE”

Studies have demonstrated that up to 26% of people with MS have suboptimal response to treatment and due to the complexity of the disease progression assessment it can take up to 4 years to identify the optimal therapy¹. Delaying any disease

modifying treatment, even for a few years, can lead to a decrease in treatment efficacy that cannot be easily regained by opting for more aggressive treatments at a later age². This can result in higher rates of disability for patients with MS and to higher costs for payors, be they private or public.

The new Affidea clinical product, **neuroInsight|MS**, ensures accurate and standardised measurements to monitor Multiple Sclerosis, resulting in an earlier prediction of disability, disease progression and treatment response. Affidea **neuroInsight|MS** has been implemented in clinical routine and is available in four Affidea countries – Italy, Portugal, Switzerland and Serbia.

Affidea **neuroInsight|MS** utilises the FDA cleared and CE approved AI software, “**icobrain ms**”, that is used by radiologists to enhance the reporting of Brain MRI examinations for people with MS. The enhanced report provides unique and quantifiable information about the patient’s evolution of white matter abnormalities and brain volume changes, including population graphs and statistics that can be used to objectively track the disease progression and identify the optimal bespoke treatment for each patient with MS.

Another key component of Affidea’s **neuroInsight|MS** is the “icompanion” application. This application is a patient reported outcome measurement (PROM) tool as well as an educational tool on the use of MRI in MS that patients can access via their smart device or through the web. People with MS are able to track symptoms in real time, and this information is then available to their treating physician between visits.

NeuroInsight|MS brings benefits to all stakeholders, and most importantly, to both doctors and people with MS.

Benefits To Doctors

- **Objective Reporting**
Using the AI software as first reading, can reduce error rate by a factor of 5 to 8
- **Earlier estimation of disease progression, disability and treatment response³**
Monitor subclinical parameters in individual patients
- **Reduced time on costly suboptimal treatment regimens**
Faster treatment evaluation can reduce time on suboptimal treatments⁴
- **Improved patient care and communication**
Normative reference values and color-coded segmentations to help the clinician conceptualise patient's condition

Benefits To Patients:

- **Patients can take control of their disease through self-tracking of symptoms**
They can track and upload their symptoms between consultant visits via icompanion
- **Earlier prediction of disability progression, relapses and treatment response⁵**
AI technology enables early detection of sub-clinical brain volume changes
- **Improved quality of life through personalised treatment**
By using the AI software, the time on suboptimal treatments can be reduced by 2.5 years⁶

Giuseppe Recchi, CEO Affidea, stated: *“This partnership signals our first foray into the incredibly exciting new world of AI and we look forward to expand the application of this new software for the benefit of our patients and doctors. Our ambition is to lead the implementation of AI capabilities in healthcare by working collaboratively with our partners across the healthcare industry, from national health services to main hospital hubs and the pharmaceutical industry, helping to develop the very best clinical solutions for patients all over Europe. Our vision, our digital and clinical capabilities, and our experienced teams across 16 countries provide Affidea with a unique opportunity to significantly improve the delivery of care for patients – at a time when they need it most.”*

Prof. Rowland Illing, Chief Medical and Digital Strategy Officer of Affidea, added: *“Clinical excellence is of paramount importance for Affidea, and this transformative partnership will greatly benefit our patients. The new AI service will allow us to offer objective and consistent brain imaging measures throughout our network. By using AI algorithms for MS patients, we can automatically measure the volume of a patient’s brain that defines the progression of the disease – as well as the lesions, their size, and their location, to compare the scans with other patients and the wider population. By automating the measuring of lesions, we can substantially reduce the time it takes for neurologists to track the progress of the disease and recommend the best personalised treatment for each patient with MS.”* ■



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Enhancing precision medicine: sharing and reusing data

The FAIR4Health project supports wider publicly-funded health data use

How FAIR4Health aims to enable safe and ethical sharing of all data and metadata derived from publicly-funded research



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The FAIR principles are intended to ensure that people and machines can reuse data. These principles are designed to be applied to data and metadata across all scientific disciplines and has been taken over by the OECD for Access to Publicly Funded Research Data and by the European Commission's initiative in the framework of the European Open Science Cloud (EOSC).

The overall objective of FAIR4Health is to facilitate and encourage the European health research community to FAIR and share and reuse their data sets derived from publicly-funded research initiatives by demonstrating the potential impact that such a strategy will have on health research and health outcomes.

FAIR4Health will focus on the area of Health. According to FAIRsharing statistics, life sciences and biomedical sciences are one of the top five domains in the standards, databases, and policies development regarding FAIR.

Nonetheless, this is not a common practice for the vast majority of health research institutions. Health data is particularly sensitive for reuse since such a strategy is a key enabler to develop Learning Health-care Systems and Real-World Data (RWD) for precision medicine and healthcare delivery, and further analysis and prototyping of reuse is required.

The pillars of FAIR4Health

- Development of an open community of health research institutions and data scientists in synergy with related national and international initiatives and projects and based on innovative public participation strategies.

- Effective dissemination strategy at European level. This will include awareness raising and training on the exchange and re-use of health research data, including web and social network visibility, scientific publications and dissemination activities targeting both stakeholders and the general public.

“THESE PRINCIPLES ARE DESIGNED TO BE APPLIED TO DATA AND METADATA ACROSS ALL SCIENTIFIC DISCIPLINES”

- Improving the quality of health research data. This is a result of the implementation of FAIR data certification preparation developed in conjunction with international initiatives leading the management of FAIR data based on a thorough analysis of all relevant aspects related to FAIRification, exchange and reuse of health research data. The purpose is to develop a set of recommendations on how to effectively implement a FAIR health data policy.
- A set of technological tools (FAIR4Health platform and agents), developed in a secure and reliable framework that supports and facilitates the implementation of FAIR data policy in health research institutions, while enabling the development of innovative new data-based services

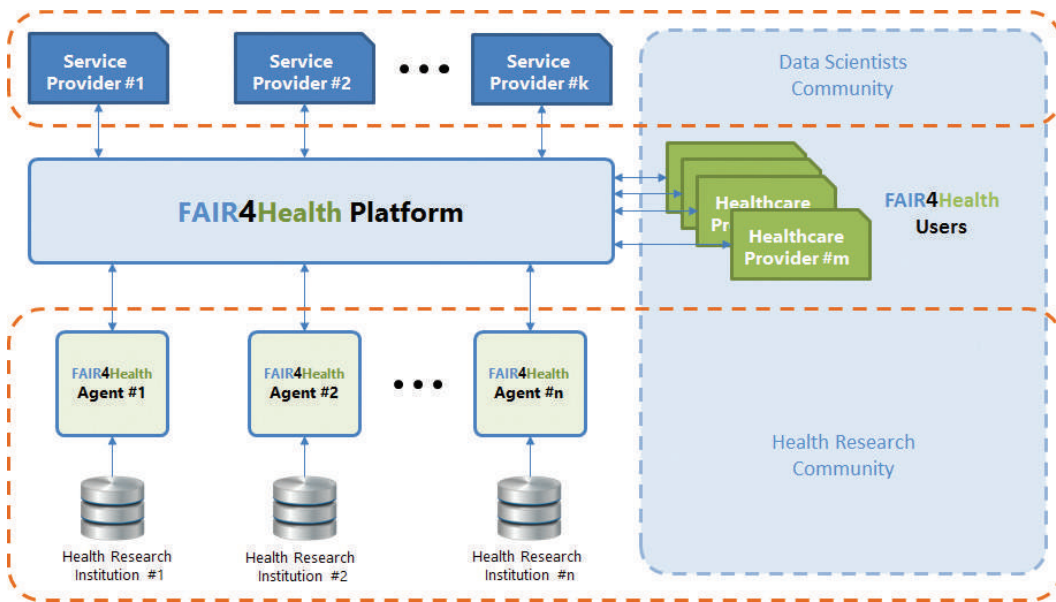


Figure 1. Interactions among FAIR4Health community users

while preserving privacy in a federated data environment.

- Demonstrating the potential impact that the implementation of a FAIR data policy can have for health and health research in real environments that will serve as a lever for the sustainability of FAIR4Health beyond the duration of the project.

Health researchers contribute new FAIRified data and can access other datasets with information relevant to their research, thanks to the use of standard ontologies and vocabularies of each specific domain. Data-based service providers can develop innovative eHealth services based on FAIR information, while healthcare providers can access this innovative set of services through the platform.

FAIR4Health will trigger a step forward to advance the overcoming of one of the major challenges in the health of our time: Precision Health. This will be made possible thanks to the increase in the availability of high-quality health research data provided by FAIR4Health. In this sense, data science research will be able to face theoretical and practical challenges related to the advanced exploitation and

knowledge extraction from federated, heterogeneous resources while preserving the privacy of the data subjects in order to develop the necessary computational tools to address this major challenge. Moreover, health research will benefit from the multiplier effect of aggregating cohorts when testing hypotheses on larger stratified cohorts of subjects to produce unbiased and stronger evidence.

Acknowledgments

FAIR4Health has been funded by the European Union's Horizon 2020 research and innovation programme (GA 824666). ■

KEY POINTS

- ✓ The FAIR principles are designed to ensure that people and machines can reuse data
- ✓ FAIR4Health will help overcome the challenge of Precision Health.
- ✓ FAIR4Health will encourage the European health research community to share and reuse their data



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Personalised medicine and cardiovascular disease

An overview of the application of personalised medicine in cardiology and the potential benefits it offers for improved cardiovascular care.



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The term “personalised medicine” was first introduced in the late 1990s. The Council of Advisors on Science and Technology of USA defined personalised medicine as “the tailoring of medical treatment to the individual characteristics of each patient. It does not literally mean the creation of drugs or medical devices that are unique to a patient, but rather the ability to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment. Preventive or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not” (PCAST 2008).

Personalised medicine has made great strides in the treatment of cancer. But the same cannot be said for cardiovascular disease. When we talk about cardiovascular disease and precision medicine, we mean an approach to CVD prevention and treatment that is based on the patient’s genetics, lifestyle, and exposures.

Over the years, significant focus has been placed on increasing awareness about measures that can prevent the onset of cardiovascular disease. These measures include lifestyle modifications, and the use of evidence-based therapies. However, despite this focus, cardiovascular diseases continue to be the leading cause of disease burden and deaths worldwide. There are approximately 92.1 million adults in the US alone who have been diagnosed with cardiovascular disease. It is projected that by 2030, 44% of the adult population will have this diagnosis (Leopold and Loscalzo 2018).

Cardiovascular disease is quite complex. The traditional approach of treatment of cardiovascular disease currently focuses on treating large patient groups with similar therapies. The focus at present is to treat established cardiovascular disease without addressing individual characteristics. But now, with the advancement in panomics and a greater focus on data analysis, clinicians can personalise treatment based on clinical,

biological, and molecular phenotyping. Precision medicine could thus be a more effective strategy to prevent and treat cardiovascular disease. This strategy would be based on genetics, exposures, lifestyles and health factors. Based on these elements, clinicians will be able to determine the optimal treatment strategy for the patients.

“ THE EFFECTIVE APPLICATION OF PERSONALISED MEDICINE IN CARDIOLOGY COULD HELP EASE THE BURDEN OF CARDIOVASCULAR DISEASE AND WOULD ALSO PROVIDE A MORE COMPREHENSIVE SOLUTION FOR ITS PREVENTION AND TREATMENT ”

The effective application of personalised medicine in cardiology could help ease the burden of cardiovascular disease and would also provide a more comprehensive solution for its prevention and treatment. This would include a) the traditional risk factor assessment, overview of family history, and diagnostic testing; b) genetic testing; c) proteomics to identify novel biomarkers; and d) identifying personalised treatment solutions (Moo-Sik et al. 2012).

The practical application of personalised medicine would require an analysis of a patient’s genetic makeup, family history, and genetic information as well as the effect of the disease on the patient. Extrinsic factors such as smoking and air pollution would also have to be considered. Other external factors such as



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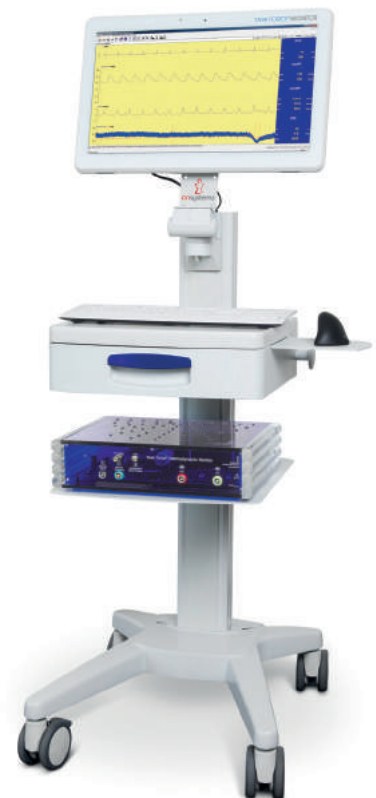
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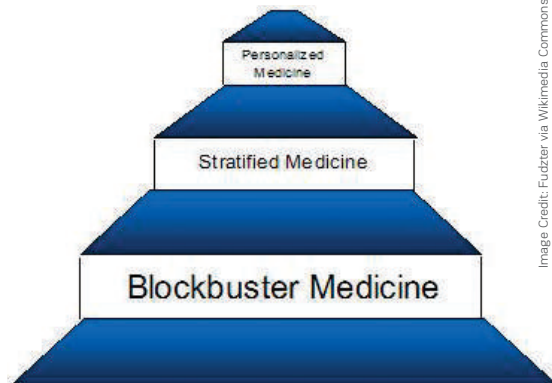


Image Credit: Fudzter via Wikimedia Commons

Figure 1. The path towards personalised medicine

poverty, difficulty in access to care, inadequate care, etc. should also be taken into account since they have an impact on morbidity (Ruben 2011). Cardiovascular disease increases the health burden globally as well as the total cost of care. The use and application of personalised medicine for the treatment of cardiovascular disease makes perfect sense because genetics is an important contributor. However, its application in cardiology still faces some challenges. While the use of genomics research is already happening, there is still a need to understand that as far as cardiovascular disease is concerned, there are other factors that must be considered. As already stated, cardiovascular disease is complex; there are multiple interactions between genes, environmental factors, and socioeconomic factors that must be considered. There is also a need to better understand epidemiological issues. We are still focused on the treatment of cardiovascular disease whereas what we need is an increased emphasis on prevention.

Personalised medicine still has a long way to go. The healthcare regulatory system related to the use and application of personalised medicine is still in its infancy. There is still a lot that needs to be done with respect to the development of appropriate healthcare technologies that could potentially make the theoretical benefits of personalised medicine a reality. Finally, we still need to align research efforts in this area with investment and education.

The path to personalised medicine is a stepwise process. We've already crossed the first step - that of developing blockbuster medicines, and we are currently moving towards stratified medicine, which involves the identification of subgroups of patients with clearly identifiable manifestation of disease, or have demonstrated a certain response to treatment. The next step in this journey is personalised medicine (**Figure 1**). We are not there yet, at least not in cardiology.

This discussion is not meant to dismiss personalised medicine. On the contrary, it has the potential to completely change the way we perceive cardiovascular disease. But in order to be able to do so, we still have to utilise the right people, identify the relevant areas of research, focus on connecting and linking genetics with other factors and come up with solutions that are not only geared towards treating cardiovascular disease, but preventing it. ■

Conflicts of Interest

None.

KEY POINTS

- ✓ Personalised medicine refers to the tailoring of medical treatment to the individual characteristics of each patient
- ✓ There are approximately 92.1 million adults in the US alone who have been diagnosed with cardiovascular disease. By 2030, 44% of the adult population will have this diagnosis
- ✓ Application of personalised medicine in cardiology would include a) the traditional risk factor assessment, overview of family history, and diagnostic testing; b) genetic testing; c) proteomics to identify novel biomarkers; and d) identifying personalised treatment solutions.
- ✓ The path to personalised medicine is a stepwise process. The first step is blockbuster medicine, followed by stratified medicine, and then personalised medicine.



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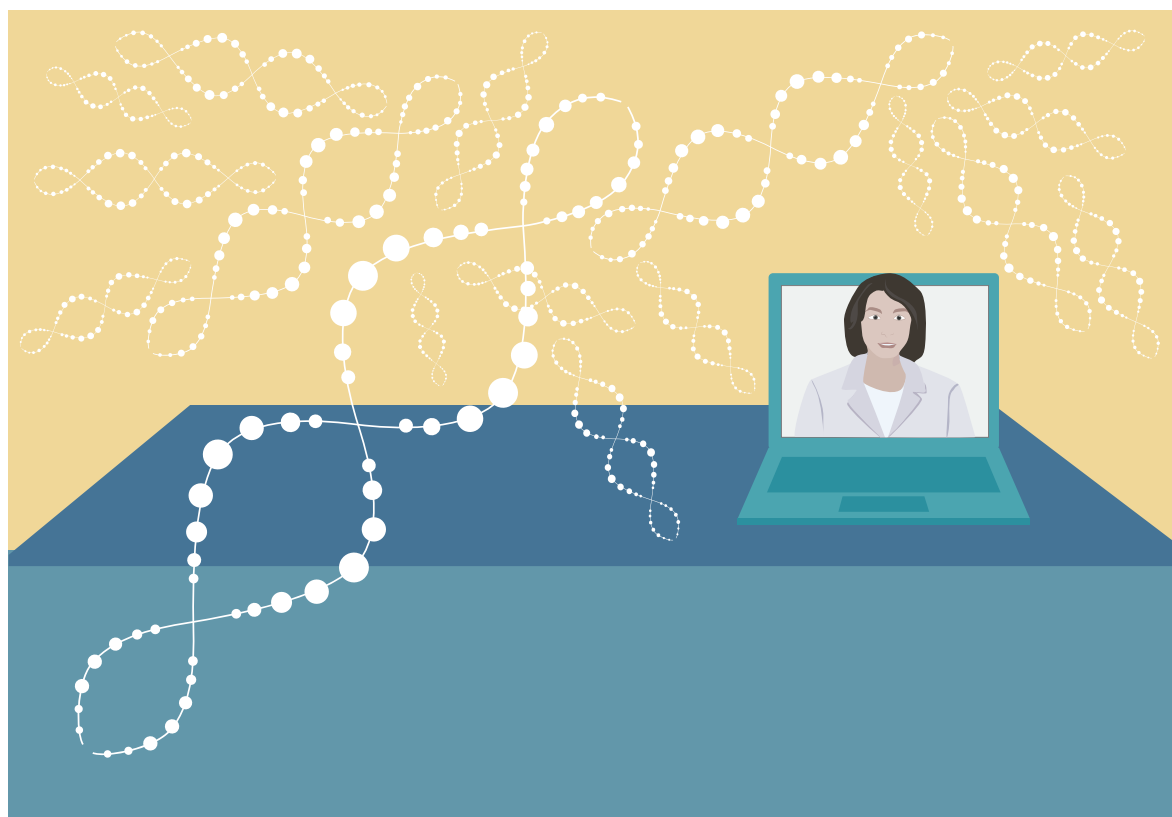
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Telehealth bringing Personalised Medicine closer

What role is telehealth playing in improving the genomics playing field?

How one company is breaking down barriers to implementation of genomics to make Personalised Medicine a growing daily reality in healthcare provision.



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What is Genome Medical's mid to long-term objective in the field of genomics and Personalised Medicine (PM)?

Imagine a day in which your genome is a critical part of your medical record, referred back to often by your provider when making care decisions. This is our long-term objective. Genome Medical cuts through

the administrative challenges associated with making genomics part of the standard of care, through a combination of telehealth technology and services.

We help healthcare providers and their patients navigate the rapidly expanding field of genetics and utilise test results to understand the risk for disease, accelerate disease diagnosis, make informed

treatment decisions and lower the cost of care. We are shepherding in a new era of genomic medicine by creating easy access, via our telehealth platform, to top clinical genomics specialists for patients and clinicians all around the country.

What are the challenges in your field and how are you overcoming them?

Genomics is one of the most exciting advancements in health care today. It has tremendous promise for the improved health and wellbeing for all through more precise diagnosis, greater risk awareness and more personalised treatment plans. At the same time, there is a nationwide shortage of genetic experts that makes it impossible for the majority of patients and providers to take advantage of appropriate genetic tests and data. In fact, there are only about 1,500 geneticists and about 2,500 genetic counsellors in clinical practice today in the U.S.

“THERE IS A NATIONWIDE SHORTAGE OF GENETIC EXPERTS MAKING IT IMPOSSIBLE FOR PATIENTS AND PROVIDERS TO TAKE ADVANTAGE OF GENETIC TESTS AND DATA”

Additionally, there are over 600 labs that provide more than 70,000 genomic tests. This, combined with a rapidly evolving standard of care, makes it really challenging for physicians to keep up. A staggering 90% of primary care physicians say they don't know who to test or what to test for. This results in both under-utilisation and waste as non-genetics professionals often order the wrong test.

Genome Medical exists to solve these problems. We are the first and only nationwide medical practice focused on genomics. We deliver our services via telehealth and work with health systems, providers, employers and health plans to meet the ever-growing needs for our services.

What is the “Understand Your Genome?” programme?

The Understand Your Genome (UYG) programme was started by Illumina in 2012 and is being continued by Genome Medical with the goal of advancing awareness

and access to personal genomic medicine. More than 2,000 pioneers have received whole genome sequencing through the programme and more than 40 symposia have been held across seven countries.

The UYG programme enables individuals to not only learn about the latest advancements in the field of genomic medicine but also gain access to a diverse set of genomic services, including whole genome sequencing, for improved health through more personalised treatment plans. We are seeing a strong response to the UYG programme, including from prior participants who wish to receive clinical expertise from Genome Medical. More information is available at understandyourgenome.com.

Do you think there is a danger of genomics/ PM becoming exclusive or do you see evidence of it being used in public health settings?

I strongly believe in a future where genomic medicine will be a part of routine medical care for all. Genomic medicine is being applied in clinical care today for cancer, cardiovascular disease, paediatric genetics and reproductive health. This is helping us to better understand disease risk and can be used for faster diagnosis and a more informed selection of therapeutics.

You can imagine there was a day where we were not able to draw and analyse blood to inform patient care even though, today, it is fundamental to the practice of medicine. Similarly, I believe we will look back on medical practice today and ask ourselves, how did we diagnose disease and select therapies without the benefit of looking at the molecular make-up of the individual? This is important information to inform clinical care.

The challenge today is that there is a large divide between the community setting and leading academic centres in terms of access to genomic medicine. Genome Medical seeks to bridge this divide. We are the front door to genomics for patients everywhere and we support providers to appropriately utilise genomic medicine for the benefit of their patients.

Today, we service patients in all 50 states and offer next day appointments. We will soon be expanding access to our clinical experts for health systems and providers outside of the United States.

How do you see the scalability of genomics/PM?

Clinical utility for genomics is vastly outpacing clinical expertise. Many providers are ill equipped to meet the demand, in turn preventing the integration of genomics into the practice of medicine.

Most leading academic medical centres have a genetics department with one to two geneticists and three to four genetic counselors on staff. Community hospitals typically have zero geneticists on staff and few (only 17%) have a genetic counselor.

So, there remains a huge gap between the appropriate utilisation of genetics in the clinical setting, and the number of experts who can select, interpret and guide providers and their patients on how to use these tests and their results effectively.

This prompts a massive issue of scale, and one that Genome Medical is uniquely suited to solve with our virtual telehealth and genomic care delivery platform. We provide services for hospitals, health systems, employers and consumers in all 50 states. We can deliver on-demand access to genetic experts for virtual visits and provider-to-provider consults, in addition to educational and training services such as patient risk assessment tools and consumer e-learning resources.

“ WE BRING GENETIC EXPERTISE TO HEALTHCARE EASILY AND SEAMLESSLY SO THAT GENOMIC MEDICINE BECOMES A FASTER REALITY ”

When do you see genomics being a part of daily medical care?

The demonstrated clinical utility for genomics is rapidly expanding. I expect that within three to five years, every cancer patient will receive genetic services and genetic testing at diagnosis. We can see progress towards this goal. For example, the American Society of Breast Surgeons is now recommending that all breast cancer patients receive genetic testing. This updates guidelines that otherwise cut that recommended population in half.

This is great news for patients – genetic services and appropriate genetic testing can help with selecting better, more targeted treatments and ensuring patients comply with routine screenings. On the downside, it also presents a major issue of scale. Right now, it's estimated that roughly one in 100,000 people has access to a genetic counsellor. Genetic specialists are critical in guiding patients and doctors (PCPs, oncologists and other specialists) on which patients

would benefit, what test to order, and what to do with the results.

How can genomics impact favourably on the bottom line aim in healthcare, ie, better outcomes at lower costs?

As a whole, a personalised approach to medicine will almost always lead to better outcomes at a lower cost. Here are several examples of that:

- Broad carrier screening prior to conception can improve likelihood of having a healthy child. Approximately one out of every 50 children born has a complication resulting from genetics. It can cost \$1 million annually to treat a child with a genetic disorder.
- Using a patient's genetic information to select the appropriate therapy faster improves efficacy and reduces adverse drug response.
- Identifying an individual at high risk for cancer provides the opportunity to alter clinical care for more active surveillance and early detection. For example, it is more cost effective to provide a colonoscopy to a high-risk colorectal cancer patient, detect and remove a polyp, rather than later treating advanced stage colon cancer.
- Utilising somatic cancer testing can help inform appropriate care for cancer patients. For example, the majority of breast cancer patients may not respond to chemotherapy. With accurate genomic information readily available, providers and their patients can assess whether chemotherapy, which has well-known side effects, is likely to have efficacy, and make more informed treatment decisions.

At the end of the day, a future in which genomics is a seamless part of everyday care delivery will not be realised until we solve the gap between the current clinical application of genomics and access to genetic expertise. Genome Medical is actively working to eliminate the traditional barriers associated with having genetic experts immediately available for making informed decisions about genetics and genomics. That's how we're different—we bring genetic expertise to healthcare in a way that's easy and seamless, so that genomic medicine becomes a faster reality than the field can currently deliver. ■

A primer on next-generation sequencing data analytics

Next Generation Sequencing (NGS) is rapidly becoming more and more standardised in terms of sequencing techniques.

With Precision Medicine coming into the clinical forefront, it is important to know the steps and possibilities associated with Next-Generation Sequencing techniques.

Introduction

Next Generation Sequencing (NGS) is rapidly becoming more and more standardised in terms of sequencing techniques, library preparations and assay development. The main challenges arising in running a good NGS lab focus around data management and making sense out of that data. The amount of data produced in a single NGS run is magnanimous thanks to the high throughput associated with sequencing, reduced cost of sequencing per base pair and high quality library preparation kits which have enabled the creation of larger multigene panels (example – TSO500, which is a 523 gene panel).

The nature of this data, makes its analysis and interpretation time consuming and thus increases the turn-around time and cost in clinical settings. Hence data analysis and interpretation have become the problem areas and differentiating factor between good and average clinical NGS labs. Nowadays, several companies and research groups have developed tools for easier and much more efficient analysis and interpretation of the sea of data produced by sequencing. One would think that in today's day and age, the analysis of such data would be trivial- yet, NGS data analysis is different from other forms of data because of multiple reasons: the amount of data produced, the quality of the data produced and the impact of this data in the broader clinical perspective. For example, even a simple clinical exome identifies around 20,000-30,000 variants from around 6,000 genes. The main hurdle, and therefore opportunity, in NGS data interpretation is to zero in on a single or few variants responsible for the patient's phenotype.

Advanced bioinformatics solutions have significantly improved the data analysis and clinical interpretation of genetic variants. These user-friendly tools can augment the efficiency of a bioinformatics expert, data analyst and clinical interpreter. These programmes use a series of filters which can be manually selected and help to identify the causal variants. These filters can help answer questions such as “which of the mutations found in this patient have pathogenic findings for breast cancer and have an FDA approved therapeutic option” – consequently paving the way for precision medicine in oncology.

Data quality check

NGS data analysis software consists of various steps including quality assessment of the data, alignment, variant calling, annotation and visualisation. After the sequencing run is complete, the data is evaluated based on quality of raw reads- low quality reads are trimmed or removed to avoid wrong clinical interpretation. Various tools used for this quality check include FastQC, NGSQC, ContEst etc with each of these having specific roles. Integrated tools have also been developed which provide summary statistics as well as filtering and trimming functions. Now, platform specific tools have also been developed.

Alignment

After the reads have passed specific quality checks, they are aligned to a reference genome to check for 'deviations' from the reference genomes. There are two main sources of human genome assembly: University of Santa Cruz (UCSC) and Genome Reference Consortium



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(GRC). Out of these two, UCSC offers 'hg19', which is currently used as a reference. The most commonly used alignment programs are Bowtie, Novoalign, BWA, MAQ, mrFAST. Reads which present with multiple mismatches are discarded from further analysis and after alignment the software removes PCR duplicates to avoid errors in variant calling.

Variant identification

The next important step is variant identification. It is influenced by all the steps of the test- from test design and coverage, to the bioinformatics tools used for data alignment and analysis. Tools to identify these 'variants' are called 'Variant Calling' tools, and their choice is determined by the kind of variants one is searching for. Major types of variants are Germline, Somatic and Structural. Germline variants are typically found in hereditary and rare diseases, somatic generally signify cancer related mutations and structural variants include Copy Number Variants (CNVs), insertions and deletions (INDELs), translocations etc.

Variant annotation

After identification, the variants are 'annotated' to filter those variants which the phenotype can be attributed using a computational tool. The phenotype in this case refers to the 'reason' why the test is ordered- for example, it can be the presence of a particular type of cancer, or a child with a suspected hereditary condition. There are different annotation tools focussing on SNPs (most common) and INDELs. The limitation of these tools is their use in structural variants as currently they are well developed only for CNVs. These tools mostly provide links to public databases for functional classification of the variant into accepted or deleterious mutations. There are now both web-based and offline applications for annotation. Although the web-based applications are easy to use and do not require physical hardware, they are dependent on service availability and require analysis of single variants entered manually. While the offline tools solve these issues, they require good user technical skills.

Data visualisation

Visualisation of generated data is very helpful in data interpretation. Examples include genome browsers to compare data with different annotations and viewers to compare sequences between different organisms. Like annotation tools, genome browsers can be web-based or offline, and can be accessed on standard platforms like Windows, MacOS and Linux. Apart from being

extremely user friendly, web-based browsers provide access to a variety of annotations from various databases. An obvious risk is in the form of potential security and legal issues that might arise with uploading of patient data to external servers – this aspect needs to be dealt with differently according to each country's regulatory restrictions and mandates. Offline browsers, naturally, are safer in terms of data security but require highly skilled personnel who have to download annotation files, update the annotations regularly and perform complex calculations which are automatically done by the web-based browsers.

Summary

In summary, NGS data analysis is extremely complex and requires a series of computational steps which must be conducted and completed sequentially and accurately. Historically, NGS has remained a tool for research, but with the advent of precision medicine and personalised therapeutics, it is coming into mainstream clinical work, making it important for doctors and managers to know how to handle the data generated by these machines. To make things faster and more efficient, it is generally advised to create and establish end-to-end pipelines for managing the data. These pipelines have algorithms which require expertise to build, but once created are extremely helpful in data analysis and interpretation. There are now several companies that provide bioinformatics solutions taking care of all the steps of analysis of NGS data making the use of NGS in clinical scenarios a much more viable option in terms of time needed for analysis and cost effectiveness. ■

KEY POINTS

- ✓ NGS data analysis is extremely complex and requires a series of computational steps which must be conducted & completed sequentially and accurately.
- ✓ Main challenges in running a good NGS lab focus around data management and making sense out of that data.
- ✓ The amount of data produced in a single NGS run is magnanimous thanks to the high throughput associated with sequencing, reduced cost of sequencing per base pair and high quality library preparation kits.
- ✓ With the advent of precision medicine and personalised therapeutics, NGS is coming into mainstream clinical work, making it important for doctors & managers to know how to handle data generated by these machines.



Leveraging advanced methods to evaluate AI-Pharma companies

The level of sophistication used in due diligence should be on par with the level of complexity in a given industry.

AI-Pharma companies are 100 times as complex as FinTech companies. Methodologies used to assess them should be 100 times as rigorous.



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Discovering new drugs using AI is one of the most challenging areas in biological sciences. Top tier AI for Drug Discovery companies have distinguishing characteristics that include high levels of expertise in biopharmaceutical science, advanced proficiency in AI, very specialised teams, and constantly evolving internal knowledge. Companies in this sector are developing very advanced AI techniques that may enable them to produce the next blockbuster drugs, making them the new unicorns of the Pharma industry.

Due to the complexity, companies in this sector sometimes appear to be enigmatic black boxes to investors. Since most investment funds have not developed sufficiently robust methods to evaluate AI for Drug Discovery companies, they erroneously treat these companies as traditional biotech companies. There could be and should be better assessment methods for evaluating these companies. Even the most advanced companies should be scrutinised, and many parameters should be taken into account. Very few investment firms are capable of applying efficient due diligence to assess investment targets in this sector because they fail to use approaches that match the sophistication of the sector.

The drug discovery environment

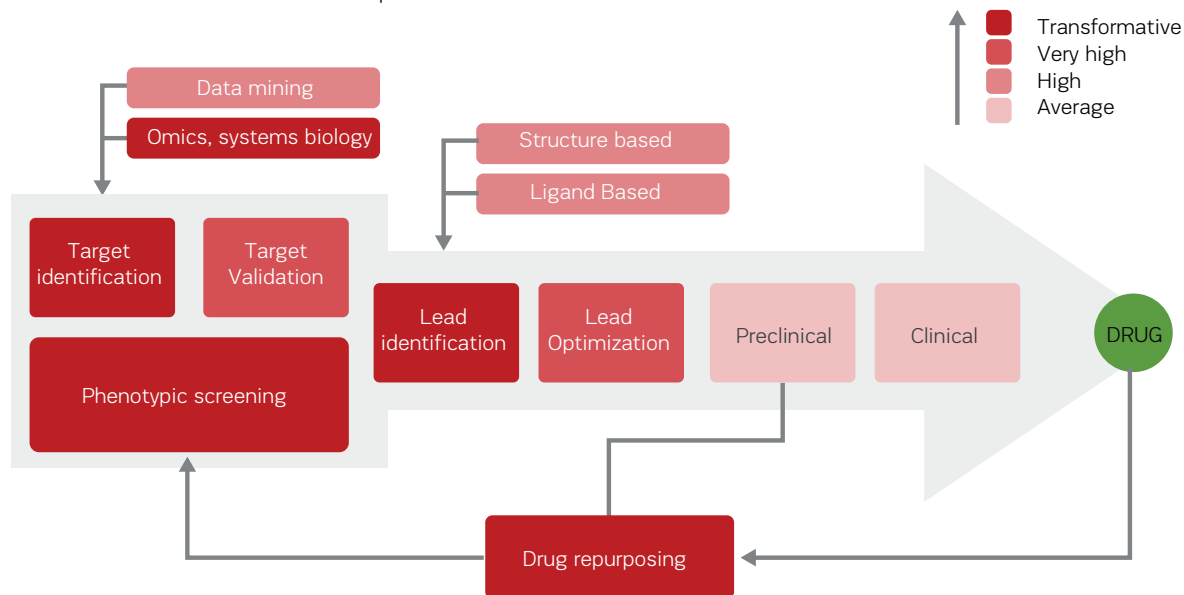
The drug discovery environment is big. It includes advanced AI for drug discovery teams and startups, pharmaceutical companies, venture investors, healthcare providers and governments. Interactions in this

environment are extremely inefficient. There are very few examples of high functioning relationships between AI startups, pharmaceutical companies and healthcare systems. Most of the venture investors are profiting on disproportions and inconsistencies in the sector, rather than through proactive adoption and use of the most advanced technologies available. This is why venture capital firms can generate profits without being sophisticated investors in this area. This scenario is far from ideal.

“ MOST INVESTMENT FUNDS ERRONEOUSLY TREAT AI FOR DRUG DISCOVERY COMPANIES AS TRADITIONAL BIOTECH COMPANIES ”

The pace of innovation in AI for Drug Discovery is unprecedented. These companies are using fundamentally different techniques than those used as standard practice 20 years ago. At the same time, the majority of investment funds are still using the same techniques that were used 20 years ago. The venture investment industry is not evolving at the pace required to match the rate of progress in DeepTech. The pace of progress in the investment technology industry (InvestTech) must keep up with the

The Heat Map of AI Potential Value for Various R&D Areas



pace of progress in advanced science and technology. Investment funds that leverage progressive techniques to update their business models, exit strategies, and underlying assessment methodologies, will have a big advantage over funds that don't.

Specialised metrics for valuation and forecasting

Although there are about 150 AI companies in the Drug Discovery space, very few of them are capable of building end-to-end solutions. Companies such as WuXi NextCODE, BenevolentAI, DeepMind Health, and Insilico Medicine are leaders in this area. Insilico Medicine was the first company to apply generative adversarial networks for generating new molecular structures with specified parameters and published a seminal peer-reviewed paper (oncotarget.com/index.php?journal=oncotarget&page=article&op=view&path%5B%5D=14073&path%5B%5D=44886) submitted in June 2016.

Deep Knowledge Ventures invested in Insilico Medicine in 2014, years before the AI for Drug Discovery sector rose to prominence. In 2018, Deep Knowledge Ventures' analytical subsidiary, Deep Knowledge Analytics, developed industry-specific due diligence methods to determine which AI for Drug Discovery companies are overvalued, balanced (from a technological and financial perspective) and undervalued (where technology significantly exceeds financials).

Deep comparative analysis

Deep Knowledge Analytics uses multiple parameters and applies quantified metrics to perform deep comparative analysis to differentiate levels of maturity, business development, scientific advantages, and technological levels in a very objective way.

Early stage startups are assessed using 100 parameters. Advanced stage companies are assessed using more than 300 parameters.

10 fundamental parameters used by Deep Knowledge Analytics

1. Team structure

The number of specialists and balance in the company's team structure. Generally the best structure is 1/3 biochemistry specialists, 1/3 AI specialists, and 1/3 business development and investment relations experts, including former Pharma executives to assist in establishing contact and cooperation with Pharma companies. In practice what constitutes a sufficient number depends on the scope of the company's target applications. As a general rule, the number of specialists should be more than 10.

2. Independent scientific validation

Evidence of independent scientific validation including peer-reviewed scientific papers published in high-impact journals, and visibility within the scientific community through frequent presentations at scientific conferences.



3. Partnerships with Pharma companies

The company should have several contracts in place with Pharma companies. This serves as additional validation that the company has something practical and tangible in its pipeline.

4. AI strength

There must be evidence that the company uses state-of-the-art AI techniques and consistently absorbs ongoing innovation in novel AI technologies and methodologies. If the company claims that it is an AI company, then it should be particularly strong in AI.

5. Investors

The company should have world-class investment funds as investors in their Series A or B rounds. There are fewer than 20 world-class investment funds recognised as being top funds globally by the entire investment community.

6. Molecules

The company should have a large number of target molecules discovered, and a sufficient number of molecules currently in clinical trials.

7. Target applications

The number of target applications the company pursuing (eg drug discovery, biomarker development, toxicity and ADME prediction, compound generation, compound binding, etc).

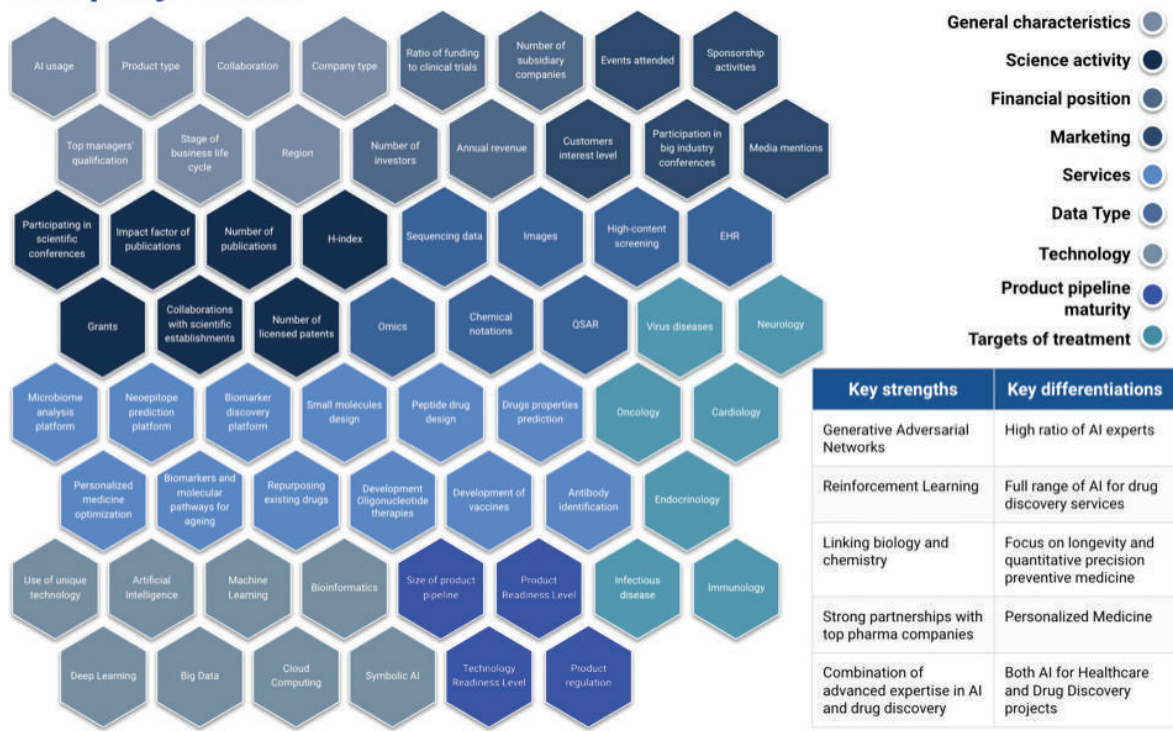
8. Technology development scope

Whether the company is developing an end-to-end clinical pipeline, or focusing on just one particular segment in the overall drug discovery and development process.

9. R&D depth

The proportion of the company's funds dedicated

Company Profile



to its R&D activities, as opposed to completing the development of products near the end of their development cycle. A high proportion of funds devoted to R&D indicates proactive innovation and new technology adoption.

10. Ratio of investment to IP produced

The ratio of the amount of money invested in the company to the amount of IP produced by the company. This is indicative of the performance of the company's R&D activities and the company's future prospects, and reflects how intelligently and efficiently the company has utilised its funding to date.

Progressive InvestTech

The business model traditionally used by venture funds has stagnated and will be ineffective going forward. To achieve success, investment firms operating in DeepTech industries will need advanced science and technology assessment capabilities and new approaches to venture capital business models and exit strategies. Deep Knowledge Ventures is developing a novel InvestTech solution which will be particularly relevant for the AI for Drug Discovery sector. The thematic AI-Pharma investment fund is designed with one purpose - to invest in the best AI

for Drug Discovery companies. The Pharma AI - Index Hedge Fund will use hybrid investment technologies combining the profitability of venture funds with the liquidity of hedge funds, significantly de-risking the interests of LPs and simultaneously providing the best and most promising AI companies with a relevant amount of investment.

Deep Knowledge Analytics reports

Deep Knowledge Analytics, a subsidiary of Deep Knowledge Ventures, regularly produces comprehensive quarterly reports on multiple topics including DeepTech, AI, Longevity, and AI for Drug Discovery. Deep Knowledge Analytics, a subsidiary of Deep Knowledge Ventures, regularly produces comprehensive quarterly reports on multiple topics including DeepTech, AI, Longevity, and AI for Drug Discovery.

On April 12, 2019 Deep Knowledge Analytics published a new open-access quarterly report on the AI for Drug Discovery Industry. This 108 page report provides a comprehensive overview of the AI Pharma landscape through Q1 2019. This report features analysis of 350 investors, 50 corporations and 150 companies active in the sector, and features a list of 30 leading R&D centres that provide important research in this area. The report also covers the

most important events that took place in the industry in Q1 2019.

Deep Knowledge Analytics' 108 page open-access Q1 report on the AI for Drug Discovery Industry provides a comprehensive overview of the AI Pharma landscape through Q1 2019. This report features analysis of 350 investors, 50 corporations and 150 companies active in the sector, and features a list of 30 leading R&D centers that provide important research in this area. The report also covers the most important events that took place in the industry in Q1 2019.

“ALTHOUGH THERE IS NO CONSENSUS SO FAR AMONG ANALYSTS REGARDING THE EXPECTED VALUATION OF THE INDUSTRY, ESTIMATES RANGE FROM \$5 BILLION TO \$20 BILLION BY 2024”

Q1 2019 report highlights

- Investment in AI for Drug Discovery startups increased from \$200 million in 2015 to over \$700 million in 2018.
- The number of AI for Drug Discovery companies increased by 20 companies.
- The report shows 350 investors identified in Q1 2019, which is 30 more investors than Q4 2018.
- There are 350 investment funds investing in the sector including Google Ventures, Tencent, Wuxi, Andreessen Horowitz, Khosla Ventures, and Sequoia Ventures.
- Although there is no consensus so far among analysts regarding the expected valuation of the industry, estimates range from \$5 billion to \$20 billion by 2024.
- Cost of R&D per drug is growing exponentially, but sales per asset are definitely not increasing.
- An additional 10 new research centers were recorded since Q4 2018.
- Regional proportion remained almost the same, despite an increased number of entities and a growing interest from China.
- Declining R&D efficiency of Biopharma Companies remains a major concern among all parties in the industry with a continuous decline recorded during the last 8 years.

- Demand for AI technologies and AI talent is growing in the Pharma and healthcare industries and driving the formation of a new interdisciplinary field — data-driven drug discovery/healthcare.

Download the Q1 2019 report here: AI for Drug Discovery Landscape Overview Q1/2019 (ai-pharma.dka.global/quarter-1-2019)

To see a complete list of reports please visit: Deep Knowledge Analytics (ai-pharma.dka.global)

Deep Knowledge Ventures is an investment fund focused on DeepTech. Investment sectors include AI, Precision Medicine, Longevity, and Neurotech. Deep Knowledge Ventures led Insilico Medicine's seed funding round in 2014 and has remained a close advisor in the company's journey towards becoming a global leader in the application of advanced AI, particularly deep learning and GANs. Deep Knowledge Analytics, a subsidiary of Deep Knowledge Ventures, regularly produces comprehensive open access analytical reports on topics related to Deep-Tech including AI in Drug Discovery and AI in Healthcare. ■

Conflicts of interest

Deep Knowledge Ventures led Insilico Medicine's seed funding round in 2014 and has remained a close advisor in the company's journey towards becoming a global leader in the application of advanced AI, particularly deep learning and GANs.

KEY POINTS

- ✓ The pace of innovation in AI for Drug Discovery is unprecedented.
- ✓ Discovering new drugs using AI is one of the most challenging areas in biological sciences.
- ✓ AI-Pharma companies are 100 times as complex as FinTech companies. Methodologies used to assess them should be 100 times as rigorous.
- ✓ Companies in this sector are developing very advanced AI techniques that may enable them to produce the next blockbuster drugs, making them the new unicorns of the Pharma industry.



TOP TARGET TREATMENTS

KEY STATISTICS

Global personalised medicine market was valued at \$1,007.88 billion in 2014 and will reach 2,452.50 billion by 2022.

Source: <https://iii.hm/u3l>

Key drivers of growth include the development of next-generation sequencing, whole genome technology, companion diagnostics, and retail clinics.



28% of FDA approved drugs in 2015 were personalised medicines.

Source: <https://iii.hm/u3f>

35% of FDA approved drugs for cancer were personalised medicines.

TECHNOLOGIES NECESSARY FOR PERSONALISED MEDICINE

Big Data capture and storage Predictive analytics Collaborative tools Interoperability capabilities



Source: <https://iii.hm/u3j>

IMPLEMENTATION CHALLENGES

- Regulatory system
- Economic concerns
- Socioeconomic factors
- Privacy issues

Source: <https://iii.hm/u3m>

EXPECTED RESULTS

- Improved patient outcomes
- Improved treatments
- Reduction in toxicity due to adverse drug responses.

Source: <https://iii.hm/u3j>

WHY WE NEED PERSONALISED MEDICINE

- To identify the primary drivers of disease.
- To discover drugs that can target these specific drivers.
- To find new ways to combat drug resistance.
- To improve clinical trial designs to test new treatments more effectively.

Source: <https://iii.hm/u3g>



TOP TARGET TREATMENTS

Effective therapies

Based on specific tissues, gene mutations, and personal factors.

<https://iii.hm/u3m>



Fewer side effects

Examples include immunotherapies, vaccines, companion diagnostics, etc.

“It’s far more important to know what person the disease has than what disease the person has.”

Hippocrates

Source: <https://iii.hm/u3h>

AREAS OF FOCUS FOR PERSONALISED MEDICINE

- Oncology
- Cardiovascular Diseases
- Neurodegenerative Diseases
- Psychiatric Disorders
- Diabetes
- Obesity
- Arthritis
- Pain
- Alzheimer’s disease

Source: <https://iii.hm/u3j>

Secrets of innovation success

International transfer of successful lessons and strategies is essential for improving quality, accessibility and affordability of healthcare services.



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Innovators in both developed and developing nations have found ways to deliver healthcare at a significantly lower cost while increasing access and quality, but we need more established channels for transferring these valuable lessons and strategies to other markets. At McKinsey & Company, in collaboration with the World Economic Forum, we have studied successful models to not only find out what makes them successful but also to establish ways they can be spread to add value nationwide, or even internationally. In this article, we hone in on significant findings and discuss areas where progress is still needed.

Challenging healthcare delivery

Despite their differences, every country is trying to address a similar set of challenges around the triple aim in healthcare—improving the quality, accessibility

and affordability of healthcare services—whilst facing pressure on both the demand side (driven by an ageing population, increasingly unhealthy lifestyle, and patient expectations) and supply side. And, of course, they are trying to achieve all of this to the highest quality.

The World Economic Forum identified the triple aim issue framed above, but also challenged the world by expressing that examples must exist where this has already been addressed—that is to say, healthcare models must exist that simultaneously improve (or at least hold constant) quality, accessibility and affordability and do this in a step change manner.

The World Economic Forum, supported by McKinsey & Company, initiated a multi-year effort to identify and learn from these types of models, culminating in a research paper, "Unlocking productivity

through healthcare delivery innovations: Lessons from entrepreneurs around the world" (McKinsey & Company and World Economic Forum 2010). In this project, we analysed some of the most effective, novel innovations in healthcare delivery throughout the world—from emerging nations to developed countries. The innovations we studied spanned across the field, and we went on to analyse the business models behind 30 of them, thus uncovering a variety of strategies that successful ones used. We were able to discern what drove their success and what types of challenges or issues they solved. Finally, the work looked at some of the barriers to scaling or replicating successful healthcare delivery models.

“ THE LACK OF ENTRENCHED
WAYS OF DOING THINGS OPENS
THE DOOR TO NEW IDEAS AND
APPROACHES ”

Necessity breeds innovation

Ways to achieve the triple aim of healthcare can differ significantly between emerging markets and developed countries. The elements that make emerging and developed countries different include demographic dynamics (developed countries tend to have a large, older population) and starting point (developed systems tend to be more advanced with greater funding in absolute and relative terms). The flip-side of this last point is the resistance from legacy systems and ways of doing things—emerging markets tend to find it easier to innovate and adapt, and they face less resistance to change from legacy systems and ways of working.

Our study found that many of the most compelling innovations come from emerging markets. As such, an important finding is that necessity breeds innovation. The challenge in developing countries is three-fold: firstly, they have a lower GDP per capita and therefore overall budget to spend on healthcare; secondly, a lower proportion of GDP per capita tends to be spent on healthcare; and finally, population growth. All of this is what makes emerging markets ripe for innovation, and the need is growing exponentially, meaning there is almost no other choice but to innovate and transform the way that healthcare is being delivered. In addition, the lack of entrenched ways of doing things opens the door to new ideas and approaches to tackling healthcare challenges. This

finding challenges markets to extend their boundaries in their search for ideas and models.

Six secrets of success

Our findings were chiefly around two major themes. Firstly, we looked at different types of models that span different categories of care (eg long term conditions, acute care, planned care, etc) and stages of the care delivery value chain from prevention through to recovering and monitoring. Broadly, we found four different archetypes or “clusters of innovation” that address different needs in healthcare delivery. These models ranged from franchised approaches (akin to approaches in retail like Subway, Starbucks, etc), production specialisation models (more commonly known as focused factories, like hospitals that focus on a certain set of procedures, at scale, in a very lean manner), technology enabled models, and integrated care.

In addition, we looked at these models to identify a common set of success factors. Overall, we found six “secrets of success.” Successful healthcare entrepreneurs pull as many of these levers as they can—although some innovations more naturally leverage some elements more than others. Awareness of the six success factors that we have identified can enhance existing delivery models, inspire new innovations, and test the validity of early ideas. These “secrets of success” are: get close to the patient and follow their established behaviour patterns, reinvent the delivery model by using proven technologies disruptively, confront professional assumptions and right skill the workforce, standardise operating procedures wherever possible, borrow someone else’s assets (eg networks and infrastructure), and open up new revenue streams across sectors.

Transfer ideas across markets

We believe that each of the archetypes is relevant to some degree in emerging markets as well as in developed markets, and we can see applications for them. The franchise model lends itself to low-complexity, high-scale care models such as primary care, to drive consistency and efficiency; technology enabled networks lend themselves to enabling care across the continuum—from prevention to treatment; and production specialisation models could play a role in transforming acute care via focused, high volume approaches. In the round, we would say that the technology enabled solutions have the greatest potential to move the needle at scale. We are seeing that in

many developed countries already, and expect this to continue into the future.

Apply tech to new geographies

Our perspective is that the technology enabled network solutions offer the most valuable lessons. Many of these solutions are still successful today and tend to be the solutions which translate best across international borders. In fact, recent research by McKinsey Global Institute on Global Trade Flows demonstrates the fact that 70-80% of tech entrepreneurs tend to operate in more than one other country. These models are asset-light and scalable, often B2C solutions, which are easier to implement in new geographies.

“EVEN AT NATIONAL LEVELS, MORE COULD BE DONE TO ACCELERATE THE EXCHANGE OF PROVEN IDEAS TO DRIVE SCALE OF IMPACT”

Secure an opportunity with funding and vision

Identifying an opportunity is the first step towards seizing it through innovation and strategy, but an important element is that the prospect is adequately supported on various levels. The innovations that we found to be most successful solved real problems and met real need, and they did this by using solutions that were simple yet effective. Just as importantly, they all had a funding model that under-pinned them. Too often, innovation can solve issues but if it can't be absorbed by the existing payer and provider landscape, it can be challenging for it to get past a pilot – which is where many innovations struggle.

Accelerate the translation of ideas

With available funding, ideas can be transferred across markets and opportunities need to be increasingly recognised. Healthcare can be an isolated and local activity, with innovations not widely known across different systems or beyond sector boundaries. These innovations can—and should—be shared across these boundaries to help deliver higher value healthcare. Lessons and insights from innovations in developing markets are often transferred to more developed markets; for example, SalaUno in Mexico is based on Aravind Eye Care System in India. Many

countries have adopted other approaches and models from emerging markets, which we uncovered in our research. Although this does happen, the challenge, which some organisations are addressing, is that there aren't well established market places for exchanging and translating ideas, or funding pools to enable this.

Innovations in Healthcare, founded in 2011 by Duke University, the World Economic Forum and McKinsey & Company, is one organisation that has created a network of innovators who are exchanging ideas, translating best practice etc. Others do exist but, even at national levels, more could be done to accelerate the exchange of proven ideas to drive scale of impact.

Substantive research exists on the topic of understanding whether, and how, the lessons of innovators can be replicated in another market. For example, via forums like World Innovation Summit for Health (hosted by the Qatar Foundation), as well as via networks like Innovations in Healthcare. We will continue to endorse a free flowing transfer of ideas that will enrich healthcare on an international scale. Meanwhile, we continue to scan the world for ideas, both ourselves and via our partnership with Innovations in Healthcare (founded by Duke University, the World Economic Forum and McKinsey). The organisation has established a network of ~100 innovators globally and has a highly competitive process for identifying and selecting new innovators for the network. ■

KEY POINTS



- ✓ Examples that encompass the triple aim issue of improved quality, accessibility and affordability in healthcare delivery already exist in the global landscape, and we must learn from them
- ✓ Emerging markets face less resistance to change from legacy systems and ways of working, so they tend to find it easier to innovate, adapt and respond to necessity
- ✓ We found four different models to exist, incorporating six secrets to innovation success in healthcare delivery. These are relevant to developed and emerging markets
- ✓ We need more established market places for exchanging and translating ideas, and funding pools to enable this



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New hospital policies and procedures required for patient safety

Eighteen Actionable Patient Safety Solutions are the key to zero preventable patient deaths in our hospitals

What are the patient safety processes that every hospital administrator and healthcare professional should adopt today to avoid preventable patient harm and death in hospitals?

It's an unfortunate fact of the medical profession that we can't save everyone who enters the hospital for life-saving surgery, critical care for a serious illness, or emergency trauma. But we collectively draw on all our skills and technology to always do everything we can to give each patient the best chance of a successful outcome.

What's more, we continue to develop new techniques, medicines, procedures, and technologies to further improve a patient's chances of surviving and healing from any medical condition. Yet, when it comes to doing everything we can to prevent medical errors in a hospital setting, that same effort is often lacking.

Over my career, I've seen how a certain number of losses from medical errors have become accepted around the world, if not expected. In the U.S., that number is anywhere from 200,000 deaths per year to 400,000 plus deaths.

What if I told you that we know how to prevent most, if not all, of these deaths? That there are proven processes that have been developed and tested by teams of patient safety experts and have been made freely available to every hospital? What if I told you a major reason anyone still dies from medical error is a lack of awareness or willingness on the part of hospitals to adopt new policies and procedures and to do everything they can to implement a culture of patient safety?

Patient safety

Patient safety has been a primary preoccupation of mine for decades, mainly through my work to improve

the safety of administering anaesthesia, once a very serious source of patient safety risk.

I developed the Ramsay Sedation Scale, a measurement designed for interpreting the depth of sedation for patients in the critical care unit. This scale has been adopted around the world. Just as new methods and technologies were devised by experts over the years to improve the safety of anaesthesia, so too have methods and technologies been developed that address other patient safety challenges.

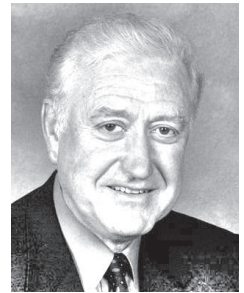
The Patient Safety Movement Foundation

Since 2012, the Patient Safety Movement Foundation (PSMF) and its partners have put tremendous effort into achieving its goal of ZERO preventable patient deaths by the year 2020.

I am proud to have been with them from day one and look forward to furthering the PSMF's mission, in collaboration with patient safety experts and advocates around the world, as the organisation's board chair starting in 2020.

One of the PSMF's greatest contributions to the advancement of patient safety is the development of 18 Actionable Patient Safety Solutions (APSS). The APSS are specific actions, researched, tested and proven to reduce harm and written up by teams of experts in their respective fields. Any medical facility can implement these APSS to prevent harm to a patient and reduce preventable deaths. These are "living documents" and improvements can be suggested by any provider or organisation as long as they can be proven to be effective.

As announced at the PSMF's 7th Annual World Patient Safety, Science & Technology Summit in January, more than 4,700 hospitals around the world have pledged to implement at least one of these APSS.



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These hospitals have demonstrated to independent audit that over 200,000 patient deaths have been prevented with this effort. But why stop there? If you were an administrator or patient safety officer at a medical facility, why wouldn't you do everything in your power to try to prevent any known source of patient risk? Implementing all of the APSS is certainly a great place to start.

Thankfully, as just announced at the 2019 Summit, four hospitals (three in the U.S. and one in Mexico) have committed to doing just that: CHOC Children's Hospital in Orange County, University of California Irvine Medical Centre, Parrish Medical Centre in Florida, and Hospital Español in Mexico City. They are not hoping for zero preventable deaths, they are planning for it.

An Overview of the 18 APSS

It's understandable that overcoming longstanding institutional cultures that are resistant to change is a tricky proposition. That's why the PSMF has gone to great lengths to provide detailed information and checklists to facilitate the implementation of its APSS. Complete overviews of the 18 APSS are available on the PSMF's website, along with instructions on how to make a commitment to implementing one or more of them. The APSS cover everything from education in patient safety to specific medical procedures, as the following summary shows.

APSS 1. Culture of safety

As outlined in the first APSS, creating a culture of safety within a healthcare organisation is critical and entails fostering a safe and reliable environment of transparency, safety, trust, and accountability. You need to emphasise teamwork, build trust and reject intimidating behavior that suppresses reporting. One approach explained is called CANDOR – Communication and Optimal Resolution.

APSS 2. Healthcare-associated infections

Healthcare-associated infections are serious and often times preventable if best practices to safely manage these infections are followed. This APSS has developed such practices in the following sub-APSS areas: 2A. Hand Hygiene, 2B. Catheter-Associated Urinary Tract Infections, 2C. Surgical Site Infections, 2D. Ventilator-Associated Pneumonia, 2E. Clostridium Difficile Infection, and 2F. Central Line-Associated Blood Stream Infections. Several hospitals have demonstrated that Zero HAIs are possible if the right processes are in place and adhered to.

APSS 3. Medication safety

A medication error leading to patient harm and/or death is another preventable event in any healthcare setting. This APSS classifies medication errors (3A) into five categories: 1) wrong drug, 2) wrong dose, 3) wrong route, 4) wrong frequency, and/or 5) wrong patient. It also lays out actionable steps in these additional challenge areas: 3B. Antimicrobial Stewardship, 3C. Severe Hypoglycaemia, 3D. Paediatric Adverse Drug Events, 3E. Standardise and Safeguard Medicine Administration, and 3F. Drug Shortages. This last one, Drug Shortages, was officially announced at the 2019 Summit, demonstrating that the PSMF is continuing to find solutions for clinical

“ OVER MY CAREER, I'VE SEEN HOW A CERTAIN NUMBER OF LOSSES FROM MEDICAL ERRORS HAVE BECOME ACCEPTED AROUND THE WORLD, IF NOT EXPECTED ”

challenges that threaten patient safety.

APSS 4. Monitoring for opioid-induced respiratory depression

We know that opioid-based medications can lead to respiratory depression that decreases the level of oxygen in the blood, which can cause irreversible brain damage in two to three minutes and death in five minutes. There are recommended doses for prescribing these medications, but the reality is that every person reacts differently to these drugs. What's safe for one person may be too much for another. Every patient receiving these powerful painkillers postoperatively should have the opportunity to be monitored continuously with modern technology that is unobtrusive but can alert a caregiver that adverse effects are developing.

When a patient dies because a complication was not recognised in a timely manner or treated properly, the death is preventable and is called "Failure to Rescue." One of the known adverse effects of opioid analgesics in post-surgical patients is respiratory depression, which must be monitored for and prevented. Failure to rescue patients should no longer occur in our hospitals. We have the technology to be alerted if a patient is at risk, just as we have in modern day vehicles.

APSS 5. Patient blood management

Red blood cell transfusions (RBC) are often administered to patients during active bleeding, chronic blood loss, or poor production in order to increase the body's oxygen-carrying capacity. Despite its perceived benefits, RBC transfusions are often deemed unnecessary resulting in risk or harm and defined as "overuse." Errors in the use of blood components are a significant cause of hospital patient morbidity and mortality. Effective solutions now exist and should be implemented.

APSS 6. Hand-off communications

The Agency for Healthcare Research and Quality reports that nearly half of hospital staff believe patient information is lost during transfers across hospital units or during shift changes. This APSS outlines the process for a successful hand-off of patient care and information through effective communications and check lists, thereby eliminating multiple risks of potential harm resulting from insufficient or incorrect information being transferred among hospital staff.

APSS 7. Neonatal safety

Two critical and common neonatal safety challenges are addressed by this APSS in order to protect one of the most vulnerable categories of hospital patients: newborns. The two challenge areas are 7A. Optimal Neonatal Oxygen Targeting and 7B. Failure to Detect Critical Congenital Heart Disease (CCHD) in Newborns. Congenital heart disease is one of the most common types of birth defects.

APSS 8. Airway safety

Airway safety refers to the management and monitoring of the respiratory tract (ie mouth, nose, lungs) to ensure air is properly transported to the lungs avoiding any complications that may arise, such as the need for intubation (placing a tube down the trachea) or an unplanned extubation (the tube being dislodged from the trachea before it is ready to be removed). Unplanned extubation is common and leads to 33,000 preventable deaths each year.

APSS 9. Early detection and treatment of sepsis

Sepsis occurs when the body reacts to an infection and releases chemicals that cause inflammation as well as organ failure. Early detection of sepsis, with the timely administration of appropriate fluids and antibiotics, is one of the most important factors in

reducing morbidity and mortality from sepsis. This APSS addresses the varying capacities and resources of hospitals around the world, separating actionable solutions under two categories: 9A. Early Detection and Treatment of Sepsis for High-Income Countries and 9B. Early Detection and Treatment of Sepsis for Low- and Middle-Income Countries.

APSS 10. Systematic prevention and resuscitation of in-hospital cardiac arrest

In-hospital cardiac arrest is a major preventable cause of patient harm and death, yet outcomes have been largely unchanged for decades. This APSS gives recommendations to improve care systems, including use of data to identify patients at risk of cardiac arrest, improving staff CPR capability, and integrating technology into clinical practice. Again "Failure to Rescue" must and can be eliminated.

APSS 11. Optimising obstetric safety

The goal of obstetric safety is to improve early recognition and the readiness and responsiveness of healthcare professionals in treating pregnant women. This APSS focuses on the following obstetric-related challenges: 11A. Postpartum Haemorrhage, 11B. Severe Hypertension in Pregnancy and Postpartum, and 11C. Reducing Unnecessary Caesarean Sections. Postpartum Haemorrhage is the most common problem in pregnancy and the leading cause of severe maternal morbidity.

APSS 12. Embolic events

The most common source of embolism is a blood clot (thrombus) from the periphery, usually from the leg veins. This mechanism of "Deep Venous Thrombosis," or "DVT," is the subject of APSS 12A. Another common embolic mechanism is the admission of air into the venous circulation. "Air Embolism" is the topic of APSS 12B. Other sub-APSS for future development may include fat, marrow, and amniotic fluid embolism.

APSS 13. Mental health

With more than 1,500 suicides taking place at in-patient psychiatry units in the United States each year, patient safety events in psychiatry units is a serious concern, requiring heightened levels of monitoring, early recognition of warning signs, and applying appropriate interventions. There is a lack of access to acute psychiatric beds which increases the rate of suicide. The sub-APSS, 13B. Collaborative Care Planning in Mental Health, draws on the combined efforts

of staff, patients, and their family caregivers to set and achieve health goals in the planning, delivery, and evaluation of care.

APSS 14. Falls and fall prevention

Every second an older adult in America falls. The Centers for Disease Control and Prevention estimates that approximately 2.8 million older adults are treated in emergency departments for fall injuries every year. Despite significant research over the last several decades to minimise harm and mortality due to falls, the topic still remains one of the great challenges facing hospitals today. The PSMF continues to work toward developing solutions to ensure preventable falls no longer occur and to minimise injury from falls that aren't preventable.

APSS 15. Nasogastric tube (NGT) placement and verification

A nasogastric or NG tube is a plastic tubing device that allows delivery of nutrition directly into the stomach (feeding), or removal of stomach contents (drainage). It is passed via the nose into the oropharynx and upper gastrointestinal tract. Many times, these tubes can be malpositioned, leading to significant harm and even death. The National Health Service Improvement (NHSI) in the United Kingdom has placed this type of incident on their "never events" list; never events are "errors in medical care that are identifiable, preventable, and serious in their consequences for patients, and that indicate a real problem in the safety and credibility of a health care facility."

APSS 16. Person and family engagement

Person and Family Engagement (PFE) is an under-used "natural resource" for improving the safety of care. Patients and their family members see and learn things that care providers and researchers miss. Their input should not only be heard, but encouraged, for the substantial role it can play in helping healthcare organisations prevent harm. The PSMF website also offers resources to patients and their families who are anticipating a medical procedure and hospital stay to enable them to be their own best advocate.

APSS 17. Patient Safety Curriculum

The 2019 World Patient Safety, Science and Technology Summit marked the official announcement of this much-anticipated APSS that provides for a sustainable model for creating a culture of patient safety in all health fields and environments. The goal of the patient safety curriculum is to close a critical gap in

student training around patient safety. It was designed by a team of experts to be adopted by education programs in all healthcare professions (nursing, pharmacy, behavioral health, medicine, etc).

APSS 18: Post-operative delirium in older adults

At the 2019 Summit, I moderated a panel on post-operative delirium. Delirium is a condition of acute cerebral dysfunction and maybe seen in the early post-operative period or in the ICU patient. Delirium occurs frequently in elderly patients following surgery. It is predictive of cognitive decline, longer time in the hospital, and increased mortality. Recent studies have demonstrated a signature of dementia on EEG that may open doors to early diagnosis, aetiology, treatment, and prevention.

Every APSS is needed in every hospital. To download all 18 APSS, please visit patientsafetymovement.org. Whatever your current role is, there is always something you can do to begin introducing these concepts and procedures at your organisation. If you aren't already actively involved in implementing the APSS, I encourage you to reach out to the Patient Safety Movement Foundation and we will guide you through the process. Join us. Zero preventable deaths in our hospitals are possible but it requires all of us to do our part. ■

KEY POINTS



- ✓ ZERO Preventable patient deaths in hospitals is possible.
- ✓ The PSMF has developed 18 Actionable Patient Safety Solutions (APSS) to address the main Patient Safety challenges hospitals face.
- ✓ Every hospital needs to implement every APSS today.
- ✓ If you want to implement all of the APSS but need help in getting started, you can contact the PSMF.

People Powered Health Movement for patients

The People Powered Health Movement is ignited by Accreditation Canada (AC) and the newly created Health Standards Organization (HSO) and has a bold ambition of achieving quality health services for all. This interview was conducted with Leslee J. Thompson during the International Patient Experience Symposium in Abu Dhabi.

Health Standards Organization (HSO) was created to spearhead a global movement designed to improve and save lives by using and implementing the best standards, applying innovative tools and capitalising on leading expertise from around the world. Accreditation Canada is an affiliate of HSO and aims to deliver objective, credible and outcome-oriented assessment programmes based on the best standards to empower providers to focus on what really matters. In simple words, both HSO and Accreditation Canada are on a quality improvement journey working with patients and their families, practitioners, and policy-makers.

Leslee J. Thompson is the CEO of Health Standards Organization (HSO) & Accreditation Canada and is also the driving force behind the People Powered Health Movement. The goal of this movement is to unleash the power and potential of people around the world who share their passion for achieving quality services for all. Leslee is a leader who is used to making things happen. She has 25 years of experience that spans multiple geographies and sectors including healthcare, medical technology, government, and retail. She has been Board Chair of the Canadian Foundation for Healthcare Improvement, Chair of Council of Academic Hospital Ontario, Assistant Professor at Queen's University and a member of Ontario Health Innovation Council. Other honours include being an Executive in Residence at Rotman School of Management, University of Toronto, Canada as well as being named one of Canada's Top 100 Most Powerful Women. Leslee shares her thoughts with HealthManagement.org about the People Powered Health Movement, the influence of hospital accreditation on

hospital management, and establishing an optimal patient experience.

Tell us something about the People Powered Health Movement. How would this impact patient experience?

The health care paradigm is shifting toward the design and delivery of people-centred care where patients and their families are valued, respected and acknowledged as equal members of health care teams and as key partners in their care. The most successful health systems that deliver high-quality care outcomes are ones that are co-designed with people at all levels of the system: front line staff, patients, families, providers, and decision-makers who work together to actively produce high-quality outcomes that are centred around the needs of the patient.

People are at the center of everything we do. People Powered Health is about the right people coming together to build better health systems around the world. When you make sure that all stakeholders involved in the health system listen and collaborate based on mutual understanding and a common purpose, patients have better health experiences, from improved quality, safer care, reduced hospital visits, better outcomes, and lower system costs.

How does hospital accreditation influence quality and hospital management? Are there any guidelines/policies governing the implementation of patient experience measurement tools for healthcare providers?

Ongoing quality improvement is at the core of our accreditation programme. Participating in



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accreditation helps to shine a light on how an organisation can maximise quality and patient safety. Accreditation Canada assists organisations through the accreditation process and helps them identify where they can improve both before their survey and throughout their accreditation cycle. The on-site survey itself provides peer-to-peer coaching and gives insight on what an organisation is doing well and where there might be room for improvement. Hospital management is directly influenced by this exercise as their organisation strives to meet the criteria outlined in the standards. The accreditation program also contains specific standards for leadership and governance that ensure leaders put in place the right policies and procedures for quality and safety.

“PEOPLE POWERED HEALTH IS ABOUT THE RIGHT PEOPLE COMING TOGETHER TO BUILD BETTER HEALTH SYSTEMS AROUND THE WORLD”

The standards used to evaluate organisations are based on best practices and are co-designed by committees who have expertise in the area covered by the standards with representation from key stakeholder groups, including the “lived experience experts” (ie patients, clients, residents, families, etc).

In our Qmentum International Standard on Leadership, for example, we require that organisations use the Hospital Survey on Patient Safety Culture Instrument, which monitors client safety culture to determine an organisation’s commitment to client safety and to push the needle forward on client-centred services. We also ensure that leaders develop and implement an integrated quality improvement plan, which helps organisations understand the system from the client’s experience. All of this comes back to normalising patient and family co-design for a better and safer patient experience.

What are some of the challenges in establishing an optimal patient experience across an organisation?

One challenge in establishing an optimal patient experience is the attitudinal shift and change behaviours needed to embrace patients and families

as “lived experts” who can contribute valuable insight about the gaps in services and care and to co-designing successful solutions. They see things that you might not when they’re sitting in the waiting chair. It just makes sense to ask the patient and/or family member what can change to improve the patient experience.

In terms of collaborating with patients and families, some of the challenges we have heard include patients feeling excluded because they don’t “speak the same language” as health professionals. It’s critical to ensure that patients feel like they belong at the table and that their lived experience can help organisations co-design better health care. Another challenge is ensuring the diversity of patient voices being heard. Engagement processes often require time and resources that not every patient can afford. In order to minimise barriers to full participation from patients in diverse demographics, we are currently working towards a policy to compensate patients and families on technical committees to encourage more participation and to appreciate their contributions.

What is the importance of establishing supportive structures and mechanisms for patient partnership?

If patient partners show up to a co-design meeting and are engaged with as you would with a researcher, caregiver or policymaker, there is a good chance you won’t all be “speaking the same language.” Most patients haven’t taken years of health education or worked in the industry. Consequently, patients might not feel comfortable engaging and sharing key insights that could give your team a deeper understanding of how to improve.

Establishing a supportive structure for onboarding and working with patients and families will result in deeper learning that you can use to improve quality and patient safety. We have worked with our patient partnership office to create purposeful roles for patients who work on our technical committees and on surveys, but simply establishing these structures isn’t enough. Once roles are (wherever possible) co-designed with patients and staff, it is important to monitor their experiences. Do patients feel supported? Are they contributing? What can we do to help? Continuous listening and evolving the patient role will benefit everyone involved. It’s not just one role where they can help; it’s about having a process where you can integrate the patient voice into your organisational practices. ■

Healthcare and industry partner for tech innovation

Implementing emerging technologies in healthcare: incentives, challenges and successes

How a healthcare hub can bring industry and healthcare together to foster tech exploration and development for better care.



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Technology opens up new opportunities, and we expect implementation. Use of the new possibilities is now taken for granted in most parts of society. Banking, media, retail and education are just a few sectors that have been transformed by digitalisation and where use of artificial intelligence (AI) is applied. Healthcare, however, lags behind. The needs of healthcare have driven science and we have the tools for personalised medicine (PM). To reap the benefits of digitalisation and lay the foundation for personalised

healthcare, now is the time to scale-up collaboration and enhance understanding of the different driving forces of industry, academia and healthcare.

Emerging technologies are those which are under rapid development and have the potential to dramatically change society. Examples of emerging technologies of today are AI, virtual reality (VR), augmented reality (AR) and Blockchain – technologies that are underway to change our society as we know it today and contribute to a sustainable development which also holds potential for

healthcare. To deliver care that is safe and personalised, we need to allow these new technologies to enter healthcare. In order to get the full potential out of improved algorithms, methods and solutions, we need to modify the implementation process in healthcare and collaborate with the providers of the new solutions. Patients and healthcare professionals are ready for change, infrastructure may not always be. This is the prerequisite for personalised medicine and individualised care to become the norm.

Sweden has a tech savvy population of early adopters. Eight out of ten Swedes use digital identification services and 93% of the total population have access to internet at home (Statistics Sweden 2018). Today, Stockholm has 127 health tech companies (SSCI 2018) working on solutions and platforms for patients and healthcare. Some 40 of those companies are based at the H2 Health Hub, a coworking space for digital health. Additionally, Sweden is number one on the European Innovation Scoreboard (EWI 2018). Here, I will focus why the leap is still taking time and discuss possible approaches for the way ahead.

“ EMERGING TECHNOLOGIES ARE THOSE WHICH ARE UNDER RAPID DEVELOPMENT AND HAVE THE POTENTIAL TO DRAMATICALLY CHANGE SOCIETY ”

Incentives

Stockholm is one of the fastest growing metropolitan regions in Europe. The growth rate poses great opportunities, but also imposes challenges, especially for health and medical services. A well-developed healthcare system and a strong life science region with 50% of Sweden's life science industry (SSCI 2017), make Stockholm region an ideal large-scale test bed for the development of the future's more efficient and individualised healthcare. With personal identification numbers and health records we have been able to follow up and focus on personalisation in healthcare. The Swedish collaboration climate is highlighted as a competitive advantage as is our history of cross-disciplinary R&D collaborations. This makes Sweden an attractive ground for global actors.

Challenges

Innovation in healthcare is a broad scope. Products and services supporting patients, relatives or healthcare professionals can all be innovated, refined and remodelled to promote health. Region Stockholm, the county council responsible for healthcare in Stockholm, has set an innovation strategy with the goal to use innovation as a strategic tool to develop, streamline and quality assure healthcare. A strategy to minimise the tendency for initiatives to fade out after the test bed or pilot stage and improve new solutions for reaching the patient.

There are two types of challenges; structural and value based. The structural challenges are rigid or outdated reimbursement or compensation models; underdeveloped procurement models for health innovation; and weak economic incentives when the result does not benefit the originator directly. Value-based challenges are different organisational languages and culture, lack of trust as well as respect for the terms and incentives of other collaborators. New global tech companies are making an entry to the healthcare and now have healthcare providers as customers. In this new situation, cultural differences often result in linguistic confusion that make collaborations difficult.

Successes

Stockholm has the ambition to become a leading site for development and implementation of emerging technologies in healthcare focusing on individualised care. A couple of examples from the region are listed here:

Infrastructure for artificial intelligence in healthcare: The Karolinska University Hospital and Region Stockholm are jointly building an infrastructure to facilitate management and implementation of AI for diagnostics. Initially, focus is on image and function diagnostics. An example is assessment of X-ray images – demanding and time-consuming work where the use of AI can simplify and standardise the work significantly.

VR-based technology to treat mental unhealth: In a collaborative effort, researchers, doctors, film developers and VR-technicians have studied how VR can be used to treatment social phobia and panic disorders as a complement to cognitive behavioural therapy in primary care. Preliminary results are encouraging.

Augmented reality and 3D-images to support surgeons: Doctors at Karolinska University Hospital have performed spinal surgery using AR and 3D navigation technology. This is made possible using technology creating a high-resolution 3D image of the patient's spine combined with a video of the site of surgery. This way the surgical procedure can be planned virtually with great precision and also allow for enhanced control of the surgical instruments.

VR experiences for children in hospital care: Karolinska University Hospital is exploring the possibility to give children in hospital the opportunity to explore virtual worlds. The effect is young patients with increased mobility and motivation. Results show that after a VR experience, patients experience pain relief and children with difficulties moving are physically activated. The result is strengthened physical and mental health and improved quality of life.

Blockchain for safer handling of health data: There is a growing interest in Blockchain technology in the public sector with, among other things, a focus on how citizens can use their own health data in various digital solutions. Karolinska University Hospital is investigating use of Blockchain for safer handling and sharing of personal health data in highly specialised care. Blockchain enables work with distributed data that is owned and controlled by the individual as opposed to servers which store bulk data for populations.

H2 Health Hub – a coworking space for health tech: This co-working space and meeting place connects large companies and small innovators in health tech. Here, start-ups fast-track their business through an environment gathering highly motivated business builders to leverage their work through connection, collaboration and co-creation.

Innovation partnerships: Karolinska University Hospital has set up innovation partnerships through which large global companies can develop

tomorrow's solutions for healthcare in a clinical environment, together with clinicians, patients and SMEs.

Looking ahead

In Stockholm, the region aims to further facilitate implementation of new technology in healthcare. Formation of a cohesive innovation system and more systematic implementation processes are examples of structures for that. An innovation hub with test beds at the university hospital is already in place as is the exploration of procurement of innovation.

The route to success is through collaboration, thus the most important step is to build trust in partnerships between industry – both global corporations and SMEs – and healthcare. The Karolinska University Hospital has ambitions to do that through the above-mentioned innovation partnerships. This is one way to initiate dialogue and to overcome cultural barriers between industry and healthcare and focus on the needs. Mutual visions and goals and an acceptance of actors different driving forces are the pillars of trust. With that in place, joint focus can be on delivery of equal, personalised healthcare. ■

KEY POINTS



- ✓ Banking, media, retail and education have been transformed by digitalisation but healthcare lags
- ✓ Challenges facing collaborators are structural and value based
- ✓ Stockholm is fostering trust between industry and healthcare to develop personalised healthcare
- ✓ The time is ripe to scale-up collaboration to develop personalised healthcare



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Nursing on the Move: cross border hiring

Addressing pitfalls and best practice examples for successful hiring

Is it possible and feasible to successfully hire and integrate nurses from abroad into a relatively conservative environment?



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As a follow up to my previous article in February 2019 “Nursing on the Move - Cross Border Hiring” with a focus on “Introduction and Background,” this article focuses on how to successfully implement cross border hiring in your own enterprise/institute.

Given the magnitude of the requirement for qualified staff, it’s obvious that the strategic option of recruiting from abroad cannot be the only solution, but merely a building block alongside many other measures.

First, the good news - the volume of cross border recruitment is increasing, so it can be assumed that, with the increase in experience, the opportunity to learn from others and to adopt the concept will be favourable.

The bad news is - it does not work in a straightforward manner. The non-reflected "copy-paste" of concepts of other institutions might lead to failure due to multidimensional complexity.

Why is it then, still worth reading this article? Alternatively, there are an almost confusing number of scientific publications which, although may offer support to gain additional knowledge, usually cannot

bring about an individual set of instructions. The information provided in their brochures and with their offers, by the rapidly growing number of recruitment firms is often a very superficial and simply presented programme. Of course, this is understandable, because they want to get into business with you and present their concept as the ultimate one!

I would like to take a different approach, asking you to find a course of action more suitable for yourself and your company with specifically formulated questions.

As a result, individual relevant aspects are highlighted under the triad of *human being, economy and processes*.

“FIND A RECRUITMENT COURSE OF ACTION MORE SUITABLE FOR YOURSELF AND YOUR COMPANY”

Human being

Organisations, according to the system theory of Parson and Luhmann, are living social systems with their own rules, sensations, and the process of self-creation and preservation of a system. Both patients and their relatives as well as employees in general, are living in such a lived-in social fabric (Luhmann 2017).

The same applies, of course, to the nursing staff to be recruited from their background location. Depending on the volume and the visible and/or perceived other differences, additional discrepancy may arise which considerably influence their integration. In simpler terms, integrating nurses from "distant lands" into a relatively traditional and migration inexperienced institutes on migration process

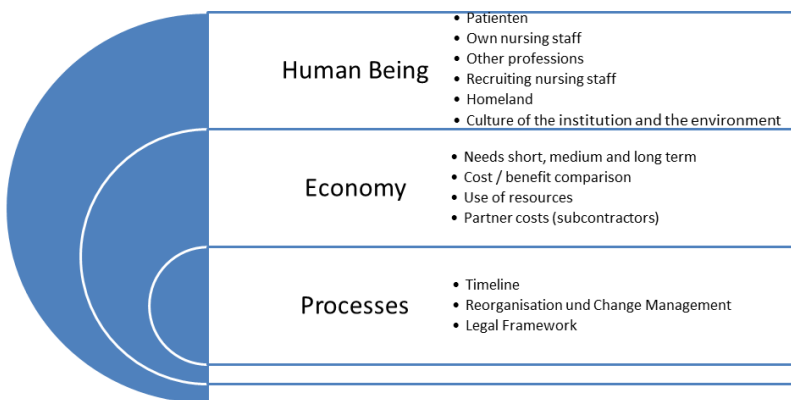


Figure 1. Triad recruiting planning (own illustration)

Year	2020			2021			2022			2023		
	Normal	Intensive	Total	Normal	Intensive	Total	Normal	Intensive	Total	Normal	Intensive	Total
Total jobs needed	700	250	950	720	300	1020	720	300	1020	720	300	1020
Actual filled jobs	650	220	870	625	208	833	608	197	805	587	187	774
Cover from own school	20	5	25	20	5	25	20	5	25	20	5	25
Inland applications	20	5	25	20	5	25	20	5	25	20	5	25
Turnover rate ~ 10%	65	22	87	63	21	84	61	20	81	59	19	78
Recruitment needs	75	42	117	118	103	221	133	113	246	152	121	273
Cross border hiring integrated	0	0	0	15	5	20	20	20	40	20	20	40
GAP	75	42	117	103	98	201	113	93	206	132	101	233
GAP without cross border hiring	75	42	117	118	103	221	133	113	246	152	121	273

Figure 2. Sample calculation of demand costing over four years including international recruitment (own illustration)

are far more complex than in large institutes with more experience internationally.

Compared to other professions, nursing interacts daily with patients and relatives in stressful situations in a very personal and sometimes intimate network of relationships (Braeseke et al. 2014). Therefore, it is essential to consider patients as stakeholders when selecting from which country the recruitment takes place in such a way as to be of optimum advantage, for example, if a high proportion of the patient-clientele is from "perceived" comparable countries. Another key factor to country selection is the consideration of WHO's "Code of Ethics" for recruiting professionals (WHO 2010).

Questions to be clarified by the institution:

- How do you rate the willingness of patients/relatives to allow physical and personal proximity and relationship of nurses originating from the recruitment country? How can you positively influence attitudes (for example, positive media presence, positive country information and qualifications)?
- To what extent do employees (especially your own nursing professionals) already have experience with the training and team integration of colleagues from abroad or how can the necessary skills be extended (preparatory workshop, participation in the recruitment and integration process in advance, training and information offers, adapted training concept, contact person for questions and unexplained situations, regular reflection discussions)?

Economy

Before deciding on which country and on which scale you would like to recruit nursing staff from abroad, as an institution, you need to have a clear idea of how high the actual requirements are and how it will evolve in the future (age of staff, turnover, maximum recruitment from your own training centre and within your own country, variation in requirements etc). Determine the gap - see rough example calculation over four years.

“ BOTH THE PATIENTS AND THEIR RELATIVES AS WELL AS THE EMPLOYEES IN GENERAL, ARE LIVING IN SUCH A LIVED-IN SOCIAL FABRIC ”

A necessary job creation was calculated for the year 2021, with constant inflow through your own school and other domestic recruitment as well as a structure of the foreign recruitment from initially 20 to 40 per year. The result clearly shows that international recruitment as a single additional measure is not enough but, at least, it helps to lessen the problem.

Include hidden costs (such as travel, negotiating contracts, meetings, preceptors, mentoring, etc), but bear in mind that additional cost-intensive measures for inland recruiting are only conditionally effective as the market diminishes.

Select a maximum of two recruiting firms and negotiate a suitable contract package for yourself. Good references, trust, fulfilment of contracts and

Module 1

Working Hours 41,81%

In this module, the language competence is in the foreground and concludes with a language test "language level B1"

The nurses get to know the fundamentals of nursing interventions and general working conditions in Germany

Module 2

Working Hours 50%

In this module, the language competence is in the foreground and concludes with a language test "language level B2"

The nurses are each assigned to a ward to gain practical experience - also in teamwork

Module 3

Working Hours 50%

Here the language competence is deepened, taking into account professionalism and the specific nursing orientation. The nurses deepen their expertise, taking into account the legal foundations in Germany (expert standards, criminal law, labour law etc.)

Module 4

Working Hours 100%

With official recognition as a "nurse" (RN), a longer training period begins in the respective wards. The expertise is individually supported by subject-related training offers.

Language Competence, Professional Competence and Social Competence as working time only, the professional competence is counted

Module 1

approx. 2 Months / 40 days
worktime 41,81%

Language Competence B1

40 x 5 Units @ 45 Minutes
Closing - B1 - Test

Professional Competence (Theory)

1 x 8 Units @ 45 Minutes
8 x 4 Units @ 45 Minutes

Social Competence

Offers for Leisure Activities

Module 2

approx. 3 Months / 60 days
worktime 50%

Language Competence B2

60 x 5 Units @ 45 Minutes
Closing - B2 - Test

Professional Competence (Theory)

2 x 8 Units @ 45 Minutes
12 x 4 UE @ 45 Minutes

Professional Competence (Practical)

36 x 5 clock hours
6 x 7,45 clock hours
Accompanied by mentors and preceptors

Social Competence

Offers for Leisure Activities

Module 3

approx. 1 Month / 20 Days
worktime 50%

Language Competence

20 x 5 Units @ 45 Minutes
Deepening from levels B1 and B2
and technical terminology

Professional Competence (Theory)

2 x 8 Units @ 45 Minutes
4 x 4 Units @ 45 Minutes

Professional Competence (Practical)

12 x 5 clock hours
4 x 7,45 clock hours
Accompanied by mentors and preceptors

Social Competence

Offers for Leisure Activities

Module 4

approx. 3 – 6 Months
worktime 100%

Language Competence

Self-directed learning with the support of textbooks, introductory concepts and online offers

Professional Competence (Theory)

Individual, subject-related training

Professional Competence (Practical)

Individual and department-specific training needs to be supported by mentors

Social Competence

Offers for Leisure Activities as well as integration into ward activities

flexibility in relation to your own needs are essential aspects and have priority over supposedly low prices.

The following packages of tasks are only a few examples and, of course, cannot cover the entire spectrum. Further supporting information for recruitment within Europe can be obtained from EURES (ec.europa.eu/eures/public/en/homepage).

Task packages to be clarified by the institution

Home country:

- Who assumes the responsibility, organisation and costs for the application process in the candidate's home country?
- Who, when and how is the job interview carried

out and in which language?

- Who and at what intervals the progress is supported and controlled in the areas of language, legal regulations, departure date, work conditions, work permits and the recognition process?
- What happens if there are unforeseen delays or cancellations of preparatory measures of the candidates?
- How do the candidates finance the language course and final test in their home country and ensure their livelihood during this time (N.B. repayment obligation/ loan dependence on the hiring agency)?
- Who pays the costs of travel, insurance cover

and the transitional period until the actual start of work?

Destination country/institution:

Who takes over the organisation, responsibility and costs including possible delays and varying volume of candidates for the following?

- Accommodation
- Advanced language costs
- Costs of receiving the candidates and the initial necessary requirements of authorities and information
- Living expenses and care during the first days/weeks?

Processes

In addition to recruiting and onboarding measures, the process also includes the involvement and training of employees regarding intercultural and diversity aspects. In addition to clear and transparent form of contract, promoting integration for all involved parties with the support of mentoring team, continuous strengthening of language, practical instruction, exchanges with colleagues/designated officials in the institution becomes key importance (Bertelsmann Stiftung 2015).

Practical example:

- After extensive analysis of requirements, the decision was taken to recruit approximately 20 nurses from abroad, twice a year, in addition to other measures
- Ukraine was chosen primarily as a recruiting country
- The collaboration has been carried out, so far, together with a specialised personnel recruiting agency and included language training in the Ukraine
- Accommodation is provided by the Personnel Recruiting Agency

- Long-term cooperation with a local language school in Hannover
- An integration officer and two preceptors were made available in my hospital

Overview of the individual modules as part of the integration

The objectives of the individual modules relate to three competences: language competence, professional competence and social competence. Alongside all the modules, offers are made for leisure activities in order to promote and support the individual social integration. ■

KEY POINTS



- ✓ There is a demand for qualified nurses
- ✓ There is no standard procedure for recruiting staff from abroad
- ✓ Recruiting and integrating nurses into an institute varies from country to country
- ✓ The recruitment process should include further training for employees regarding interculturality and diversity
- ✓ There are a number of hidden costs to be taken into consideration when recruiting staff from abroad



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DIANE BELL

HEALTHCARE EXPERT - PA CONSULTING, UK

TOP QUOTE FROM THE BLOG:

'Post-Brexit: should UK healthcare become more European?'

Even without Brexit, the NHS needs to think long and hard about how it can best meet the demands of an ageing population and a population that expects the service to fit round it. To address this, we should look beyond the current political rhetoric and be open to the positive lessons we can draw from our European neighbours.

See more at: <https://iii.hm/u9h>



CHRIS MCCAHAN

CHIEF INVESTMENT OFFICER AND GLOBAL SECTOR LEAD FOR HEALTHCARE SERVICES INTERNATIONAL FINANCE CORPORATION, U.S.

TOP QUOTE FROM THE BLOG 'Making ethics the business of healthcare':

"The more ethically responsible you act, the more patients you attract, the higher quality staff you retain, and consequently the better you perform as a business."

See more at: <https://iii.hm/u4l>



GREGORY A. GARRETT

HEAD OF U.S. & INTERNATIONAL CYBERSECURITY ADVISORY SERVICES, BDO, U.S.

TOP QUOTE FROM THE BLOG 'How to be one step ahead of health-care cyber hackers':

It is far easier to be a cyber-attacker to find one cyber vulnerability to gain access to valuable information, than to be the cyber security analyst (defender) and try to defend a large organisation. Healthcare needs to make real cyber security a top priority.

See more at: <https://iii.hm/u4m>



CHELSEA BEECHER

DIRECTOR OF DEVELOPMENT, AMERICAN HEART & STROKE ASSOCIATION, U.S.

TOP QUOTE FROM THE BLOG 'Innovator of the year':

"We're making an incredible impact by connecting young

women to mentors and engaging them in STEM activities outside the classroom, but we are also funding more heart and stroke research, community programmes, tools, and resources."

See more at: <https://iii.hm/u4n>

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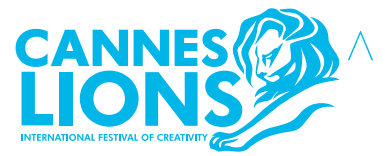
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