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Editorial

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Reset 2021

2020 was an eye-opener for most healthcare systems around the globe. Fighting against the pandemic required more than ever better management competencies and improved leadership. Our organization model showed flexibility towards covid-19, new supply chains were identified, skill mix was changed, and e-health moved from the trend to the mainstream. Nonetheless, despite all the efforts, too many non-covid-19 patients were left behind. The economic crisis follows the sanitarian one. Will we be able to assure universal health coverage or forget the new needs? Everything at every level, from global to the most local, has changed and will never be the same. It is the 'new normal'. As such, 2021 will be the year to prove whether we have learnt anything from this unprecedented experience and if we can implement our newly gained knowledge so that we thrive in the future.

In this issue, we talk about lessons learnt and the future emerging. What comes next? Which practices worked and which need to be changed? How do we improve leadership and management? Does the regulation reflect the realities? In other words, what worked, what did not, and what needs to change. Our contributors analyse different highlights and pitfalls and provide some suggestions on adjusting and improving.

We ask healthcare experts about the significant changes they think are necessary for healthcare in 2021. Prof Christian Lovis, Prof Simona Agger-Ganassi, Iris Meyenburg-Altwarg, Dr Rafael Vidal-Perez, John Nosta, and Sabine Torgler talk about the changes they expect and the improvements that should be made. They emphasise the need for change, and this change must be significant in their opinion.

In light of the vaccination programmes being rolled out across the world, a team of researchers led by Prof Dr Robert Vander Stichele stress the need for global monitoring of vaccine use as well as its safety and effectiveness.

Dr Kurt Holler talks about the dramatic shifts happening in the field of healthcare innovations in Europe. Prof Florencio Travieso provides an overview of the most promising trends and technologies meant to both disrupt and give a boost to healthcare in 2021.

Dr Shahar Alon talks about expansion technology and its role in treating complex diseases like cancer and Alzheimer's. Prof Ahmed Sarafi discusses the evolution of teleradiology and how it has become a critical healthcare tool today.

In the Management Matters section, Bari Berger, GeirArnhoff, and Iris Meyenburg-Altwarg investigate our understanding of the interaction between healthcare professionals' burnout, morale, and competence level and question some current practices of competence acquisition.

The Winning Practices section looks into several practical aspects of healthcare delivery in different countries. Prof David Caramella and Maurizio Mian share their experience of a charitable initiative that provided a high-end ultrasound system for critical care patients in Pisa, Italy. Patient advocates Maria Chacon and Peter Kapitein highlight the urgent need for upgrading cancer care in Latin America through a united effort.

Massimo De Vittorio discusses the DEEPER project, funded by the European Union, that puts together technologists, neuroscientists and clinical experts to explore effective treatments for neurological disorders. Prof Theresa Rohr-Kirchgraber and Kaela Miller discuss the need to develop an optimal breast cancer screening approach for transgender women.

We hope you will enjoy this issue and will gain inspiration from it. As always, your feedback is welcome.

Happy Reading!

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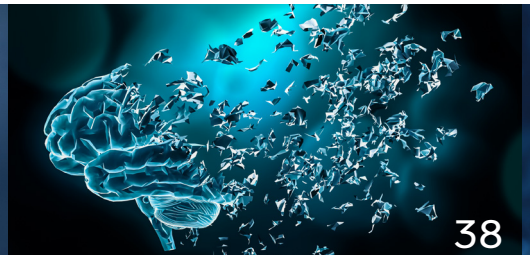

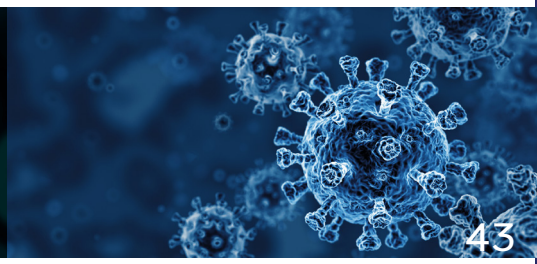

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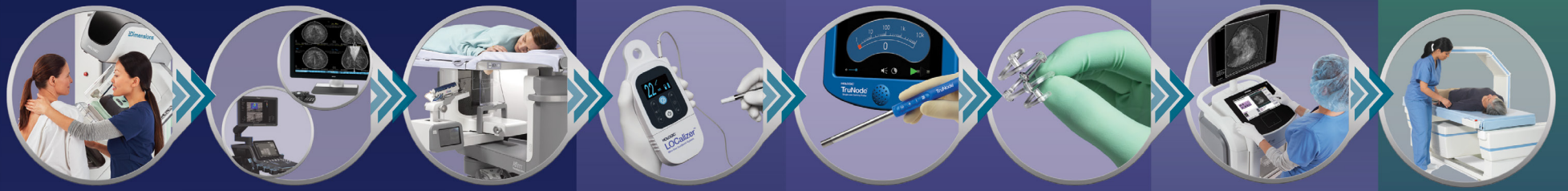

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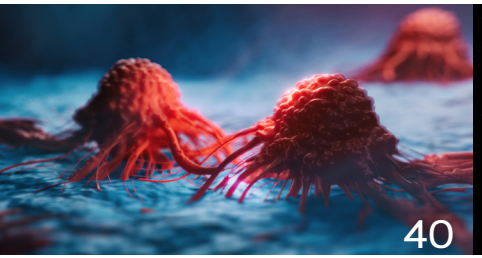

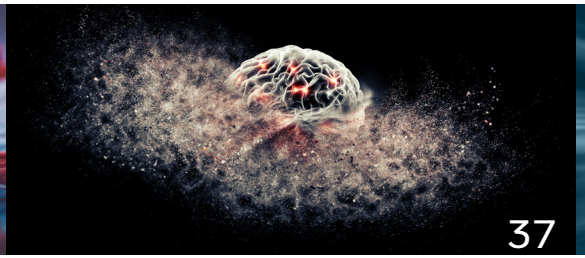

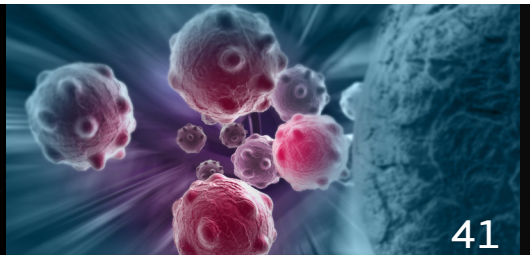

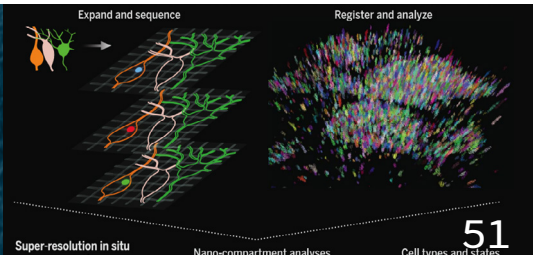

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Have your say. Engage!

2020 was an eye-opener for most healthcare systems around the globe. Key questions: What have we learned? What comes next? Which practices worked and which need to be changed? How do we scale up healthcare systems? How do we improve leadership and management? Which new regulations do we need and which do we need to amend? In other words, what worked and what did not? This issue provides an in-depth look into different highlights and pitfalls, and offers suggestions on how to adjust and improve.

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Shahar Alon is a neuroscientist in training and skilled at many domains of engineering, ranging from bioengineering to data science to genomics to optics. Over the last ten years, he has created new technologies and analysis methods to measure RNA complexity. In his lab at Bar-Ilan University, he studies the 3D location of RNA molecules inside cells and tissues.

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13 Competency: Is it the Wonder 'Drug'?

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For more than 20 years Bari worked in Paediatric and Adult Emergency Care, Med/Surg Nursing, Orthopaedics, etc. She was clinical director for multiple governing agency programmes in the U.S. and built education programmes in hospitals.

13 Competency: Is it the Wonder 'Drug'?

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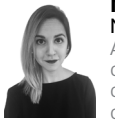

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A nutritionist and psychologist, Maria specialises in oncological nutrition and provides support to cancer patients. She is a strong advocate of reducing the risk of developing cancer and other diseases through lifestyle choices and eating habits.

40 Prevent or Treat in Latin America?

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30 Ensuring COVID-19 Vaccine Traceability

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30 Ensuring COVID-19 Vaccine Traceability

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30 Ensuring COVID-19 Vaccine Traceability

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13 Competency: Is it the Wonder 'Drug'?

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35 Teleradiology – Evolution and Use

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30 Ensuring COVID-19 Vaccine Traceability

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11/2020

Competency: Is It the Wonder 'Drug'?

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In the world of modern healthcare, especially since the start of the COVID-19 pandemic, the understanding of interaction between healthcare professionals' burnout, morale and competence level is key to improving the quality of care and decrease staff turnover. A team of experts investigate this complex area and question some current practices of competence acquisition.

Key Points

- How competency affect our frontline staff is the main question to be asked by any organisation.
- Burnout is a major problem among healthcare professionals.
- Competence acquisition needs to be balanced in terms of theory, mentoring and experience in line with the 70-20-10 model.
- Current inadequate models of competence acquisition lead to exhaustion, frustration and retention among nurses.
- Increased standardisation in competence and skill acquisition may help to improve quality of care.

Everyone has heard of 'competency'. But what exactly is it? Let us start with what it is not. It is not the typical skills checkoff, traditional e-learning, or what we like to call the 'great paper chase' that happens right before annual reviews happen. You know what we are talking about; the pages of 'competencies' staffers must complete before their annual review that they wait until the last minute to complete. We already know that a lack of competence leads to poor patient outcomes and poor-quality care. What we need to question is how does competency affect our frontline staff? Does competency create less stress, less burnout, or greater satisfaction for the staff? Does this lead to the ultimate question: Does it decrease turnover? These are the elements this article will be discussing based on a literature search.

To decide if competency does affect all of these things, we need to first start at the beginning by defining the key principles.

Burnout: Sources, Development and Consequences

There are several definitions of burnout. The term describes a state of illness. People with burnout are completely exhausted – physically, emotionally and mentally – and performance is significantly reduced. The description has given the disease its familiar name: burnout syndrome. It is also known as stress syndrome. According to the World Health Organization (WHO), burnout is not a disease, but a problem "related to lifestyle difficulties" (WHO 2019).

The term 'burnout' first appeared in the U.S. in the 1970s. The psychotherapist Herbert Freudenberger described the consequences of heavy stress in the so-called helping professions. According to this, doctors and nurses who sacrifice themselves for other people through their work are often 'burned out'. This manifests itself in exhaustion, excessive demands and listlessness (Institute for Quality and Efficiency in Health Care [IQWiG] 2020).

Workload	Control	Reward	Community	Fairness	Values
Excessive workload and demands, recovery cannot be achieved	Employees don't have sufficient control over the recources they need to fulfill their job	Lack of adequate reward (financially, socially and/or intrinsic)	Employees do not perceive a sense of positive connection with their colleagues and managers	A person perceiving unfairness at the workplace (inequity of workload and/or pay)	Employees feeling constrained by their job to act against their own values and aspirations or experience conflicts between the organisation's values

Figure 1. Six Dimensions of Work Based on Christina Maslach.

Burnout runs in a cycle with 12 stages (Freudenberger 1975) but individual stages can be skipped. The main component is the continuous deterioration until, in the end, it is hardly possible to distinguish it from severe depression. The first part of it is the Alarm Reaction and includes the compulsion to prove oneself (1), working harder (2), and neglecting their own needs (3) and displacement of conflicts and needs (4). The next part is the Resistance Phase and includes revision of values (5), denials of problems (6), withdrawal (7) and obvious behavioural changes (8). The final phase is the Exhaustion Phase which starts with depersonalisation (9), inner emptiness (10), depression (11) and finally the burnout syndrome (12).

Christina Maslach (Social Psychologist U.S.) theorised that burnout was a state that occured because of a prolonged mismatch between a person and at least one of six dimensions of work (Figure 1). In addition, there are more and more developments of burnout outside of normal work processes, especially in circumstances of associates who take care of people in need at home (Maslach and Leiter 2016).

The presence of burnout among healthcare professionals (HCP) is associated with worsening patient safety, the weakness of the healthcare system – including suffering of the individuals themselves – and increasing shortage of HCP (Figure 2).

Competency Acquisition in Healthcare

The interest about our knowledge, skills and competencies goes back to the ancient history of early philosophers. Still today, understanding the nature of competencies and its impact on outcome is and should be on top of any organisation's agenda. However, there has been huge progress on understanding the nature of competencies, knowledge on how we learn, and how competencies are transformed into high-quality outcomes.

In ancient times, the transfer of competencies was primarily done by learning from the masters. The one and only way to become a blacksmith was through an apprenticeship, learning by closely mentoring the tacit knowledge (Polanyi 1966) of the right temperature for iron to be shaped into essential tools for society.

This key principle is the same one we base all our residency programmes on today. While acknowledging that courses and theoretical knowledge do not make a competent HCP, it can take one to the level of 'advanced beginner' (Dreyfus 1986) by knowing the subject matter (Figure 3). But it lacks the situational contexts, holistic perspective such as the entire patient journey, and understanding of outcome.

Link Between Competency and Retention

More recently, the 70-20-10 model for learning and development has been suggested by Lombardo and Eichinger (1996) to explain that theoretical learning covers only 10% of the learning while the last 20% and 70% of the competence acquisition come from mentoring and experience over time, respectively. In the healthcare setting, the residency programme fills in the 20% of mentoring, oftentimes in a very structured manner. The latter 70% of the learning journey is what evolves over the course of becoming an experienced practitioner (Lombardo and Eichinger 1996).

Figure 2. Consequences of Burnout of HCP (West et al. 2018).

Skill Level	Components	Perspective	Decision	Commitment
1. Novice	Context-free	None	Analytical	Detached
2. Advanced beginner	Context-free and situational	None	Analytical	Detached
3. Competent	Context-free and situational	Chosen	Analytical	Detached understanding and deciding. Involved in outcome
4. Proficient	Context-free and situational	Experienced	Analytical	Involved understanding. Detached deciding
5. Expert	Context-free and situational	Experienced	Intuitive	Involved

Figure 3. Five Stages of Skill Acquisition (Dreyfus & Dreyfus 1986).

Nurse turnover and the retention of healthcare staff in general is a well-founded and global concern. According to a 2019 survey of 424,284 U.S. healthcare workers, the average nurse turnover calculated to 17.1% annually while as much as 89% of the total staff at an average hospital has shifted since 2015. These numbers are from prior to 2020 and do not include the impact of COVID-19. The same survey uncovered that more than 21% of all newly graduated nurses quit their jobs within the first year. We need to investigate the 5- to 10-year experience to lower the annual turnover rate to less than 15%.

Drawing the line back to the 70-20-10 learning and developing model indicates an interesting and well-spoken correlation: nurses as well as other healthcare workers need to learn swimming in deep water is unsuccessful. Literature (Polanyi,1966; Dreyfus 1986; Lombardo and Eichinger 1996) shows us there is no good reason to believe that our 'superheroes' are competent at this early stage of their careers. Clearly, the lack of competence causes frustration, disappointment and exhaustion, resulting in an unfortunate separation of employment.

Europe vs. U.S.: It is About Quality of Care

Competencies and skill acquisition in European healthcare specifically have been studied more closely by Patricia Benner (1984), building up on Dreyfus (1986) explaining nurse's competency through experience (learning 'how to') without the theoretical ('knowing that') knowledge being taught. While Benner has gained much attention in Europe, Donna Wright's Competency Assessment model (2005) is more widespread in the U.S. The competency model is supposed to form a more standardised approach to competence to ensure quality of care and draws the link from competencies at the point of care to patient outcome. It ties in with the increasing push for the value-based healthcare (VBH) model (Porter 2010) that has enforced the finance and reimbursement model by Medicare in the U.S. It is also suggested for Europe by Porter (2010) as a response to the strain on health budgets caused by an ageing population, more chronic conditions, and higher cost of care driven by more advanced treatments available.

With the tight link between competency and quality, is it likely to suggest that downplaying the need for competency development, particularly in early years of nursing careers, causes reduced quality of care and outcomes. Which, again, leads to exhausted staff, increased turnover, and negative impact on competencies as a closed loop.

So, what can we do about this? How do we handle stress and this dreaded burnout that looks like it is bound to happen across the world as our healthcare systems are overrun with sick people? In the next article, next month, we will discuss some tools to use to decrease burnout, increase staff morale, and decrease turnover.

Conflict of Interest

None. ■

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Enterprise Imaging and Personalised Care at Istituti Fisioterapici Ospitalieri

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Author: **Dr Francesco Ripa di Meana | Managing Director**

Author: **Dr Antonello Vidiri | Chief Radiologist**

An overview of how Enterprise Imaging supported the multidisciplinary needs of Istituti Fisioterapici Ospitalieri (IFO), an oncology hospital and research centre in Rome, Italy, and how it enhanced the productivity and efficiency of its radiology services.

Key Points

- Istituti Fisioterapici Ospitalieri (IFO) is a renowned scientific institute in Rome, Italy. IFO is a public hospital that specialises in oncology and dermatology.
- In June 2020, IFO went live with Agfa HealthCare's Enterprise Imaging solution, which includes the Enterprise Imaging for Radiology platform, the Elefante RIS and the XERO Universal Viewer.
- The platform has upgraded the radiologists' PACS function and has improved efficiency and productivity.
- Enterprise Imaging has automated the workflow and has resulted in the elimination of repetitive tasks.
- Since the implementation of the Enterprise Imaging solution, the number of CTs increased from 16,422 in 2019 to 18493 in 2020, and the number of MRIs increased from 5099 in 2019 to 5706 in 2020.

Introduction

Istituti Fisioterapici Ospitalieri (IFO) is a renowned scientific institute in Rome, Italy. IFO is a public hospital that specialises in oncology and dermatology. It comprises two scientific institutes: the Reginal Elena National Cancer Institute (IRE) and the Dermatological Institute S. Gallicano (ISG), both of which are scientific institutes for research, hospitalisation and care (IRCCS).

IFO handles about 10,000 inpatient admissions and 1,275,000 outpatient appointments each year. It also carries out 100,000 imaging exams each year. The hospital is well-known for its focus on research and high-quality patient care, and, in particular, its commitment to supporting patients and staff by using the most advanced technology. IFO follows rigorous protocols and is known for its collaboration with international institutions to ensure patients are supported throughout their care journey - from diagnosis to therapy - with a personalised, end-to-end care plan.

In June 2020, IFO went live with Agfa HealthCare's Enterprise Imaging solution. The goal was to implement an image management solution that could integrate advanced research technology and increase efficiency and productivity. So far, the research hospital has shown a successful increase in its productivity in radiology and fast, secure and easy imaging access for specialists and researchers.

Supporting a Smarter Hospital

At IFO, the goal is to bring the highest degree of digitisation and to ensure clinicians have access to the information they need and when they need it for accurate diagnosis, care and research, in a smart way. According to Guiseppe Navenateir, IT and Clinical Engineering Manager for IFO, the research hospital looks for new and improved image management technologies and applications every three years.

Advanced image management solutions are critical for IFO. That is why it was natural to transition to Agfa HealthCare's Enterprise Imaging solution, which includes the Enterprise Imaging for Radiology

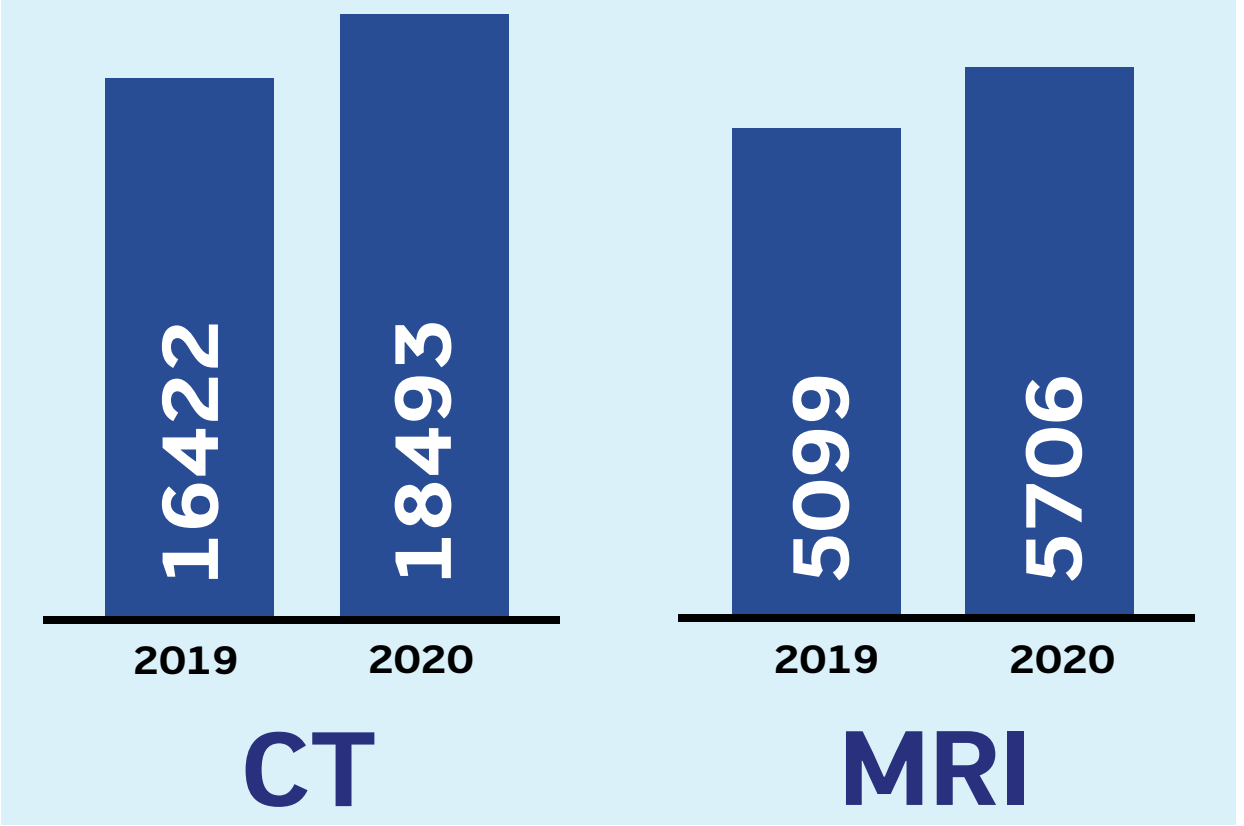

Figure 1. Increase in CT and MRI at IFO with Enterprise Imaging

platform, the Elefante RIS and the XERO Universal Viewer. This comprehensive solution offers radiologists access to advanced functionalities and specialised applications that can be embedded in one platform.

The Enterprise Imaging platform enables radiologists and specialists to access diagnostic information whether they are in or outside the hospital. Also, the flexible RIS interfaces with the appointment system of the regional government, which is important for IFO.

Successful Implementation and Results with Enterprise Imaging

With the successful implementation of the Enterprise Imaging solution, IFO has seen the following positive results:

- The platform provides easy access to images, anywhere, anytime, for every specialist. Clinicians can access imaging studies immediately and can view images from the EMR or any other computer or mobile device through the XERO Universal Viewer. In addition, the XERO Xtend offers advanced clinical applications and 3D processing.
- The platform has upgraded the radiologists' PACS function and has improved efficiency and productivity.
- Elefante RIS1 is integrated within the Enterprise Imaging platform and offers IFO the ability to customise it as per the specific needs of the hospital.
- Enterprise Imaging has automated the workflow and has resulted in the elimination of repetitive tasks.
- Since the implementation of the Enterprise Imaging solution, the number of CTs has increased from 16,422 in 2019 to 18493 in 2020, and the number of MRIs has increased from 5099 in 2019 to 5706 in 2020.
- The Business Intelligence feature with Enterprise Imaging helps the hospital monitor its radiology Key Performance Indicators so that the team can analyse areas for improvement and determine how to increase the quality and quantity of activities.
- The platform has increased the reach beyond the radiology department. Every case can be discussed between a number of specialists, and information can be exchanged easily and efficiently.
- The XERO Viewer allows patients to view their own images via the Patient Portal, also provided by Agfa HealthCare, and access their results from the comfort of their home. This feature also provides cost-savings to IFO as they no longer have to make CDs or DVDs. ■

At Agfa HealthCare, we support healthcare professionals across the globe to transform the delivery of care. Our focus is 100% on providing best-of-suite Imaging IT software solutions that enable secure, effective and sustainable imaging data management. From product development to implementation, our unified Enterprise Imaging Platform is purpose-built to reduce complexity, improve productivity and deliver clinical value. We use our proven track record as an innovator, our in-depth medical knowledge and our strategic guidance to help healthcare providers achieve their clinical, operational and business strategies.

SPOTLIGHT

"For EIT Health, that was a very important question: how much we could progress the clinical research and development that was not directly related to COVID-19", *page 21*

Major Changes in European Health Innovation

Author: Dr Kurt Höller | Director of Business Creation | EIT Health | Munich | Germany

Since the start of the COVID-19 pandemic, the healthcare sector has been changing at an unprecedented pace. Some innovative solutions, which seemed futuristic just recently, are becoming part of the routine and many others are in the pipeline. HealthManagement.org talks to Dr Kurt Höller of EIT Health about the dramatic shifts happening in the field of healthcare innovations in Europe and the priorities and challenges that will be defining the year of 2021 and beyond.

What major changes, both positive and negative, did you see in the European health and care landscape in 2020?

There can be so many answers to that. If you look from a birds-eye perspective, of course, we have all seen that healthcare in general has changed. Everyone had to focus on COVID-19, and it had an impact on routine care, which had been dramatically reduced, including people who could get access to face-to-face care but were hesitant to go to a hospital. That has transformed the whole healthcare landscape at a high level.

Looking at how EIT Health and our partners have been affected, in the first months of the pandemic we were facing some delays with advancing our projects. Clinicians have, rightly, concentrated on treating COVID-19 patients, and getting prepared for the emergency situation. Hospitals are very important partners in our work, but they were understandably dealing with the pressing pandemic situation and did not have the capacity for much else.

In turn, the necessity of doing additional research also got tiered, especially in areas related to COVID-19. There was an interesting situation when, on the one hand, the whole world was looking to see developments in the healthcare area and at the same time there were reductions in research spending. Even in the European Commission, the discussions on the recovery funds versus expenditures on research last autumn were quite intensive. That was one very important question: how much we could focus on clinical research that was not directly related to COVID-19. In the end, however, I think we found a good balance. Over the year, there were moments and months when hardly any collaboration with a medical hospital was possible, and then the overall attention to clinical research, the value of it and everyone on the front line got a major boost. In other words, the research aspect really went up and down, down and up.

The third aspect, especially important in my area where startups are involved, is about the investment that usually goes into new companies: it was not as freely available during the early stages of the pandemic. Many investors held their capital back for their portfolio companies because they expected those companies might struggle. Especially in the beginning, in March, we saw that there was an absence of large investments into new companies.

Seeing this, we launched the Start-up Rescue Instrument, an initiative for startups to receive up to €500,000 in co-investment from EIT Health, in return for options. With this, we were able to inject some investment into new companies, to give a push into those investment rounds by attracting additional capital. We first developed this concept at EIT Health and then the other eight EIT KICs (knowledge and innovation communities) – joined. Overall, the Commission invested a significant amount of money, €60 million, into the EIT crisis response.

The Rescue Instrument initiative covered two directions. One was the crisis support for startups to get additional investments in their current fundraising rounds. The other one focussed on the development of COVID-19-specific products and services. We got a lot of positive feedback from our investment network for this.

We focussed on promising companies with a value of at least €5 million, that were in the middle of a fundraising round they could not conclude due to the pandemic. We got about 300 interested companies – an unprecedented amount within such a short period of time – and 120 of those applied. Just imagine 120 companies working in the healthcare domain in Europe with a value of more than €5 million that were actively fundraising at that point of time! Eventually, 11 companies were selected, to which we will be contributing up to €500,000 each under the condition that other investors would remain on board and the companies could conclude their investment round. The launch of the instrument also spurred investment from others, one

which was concluded in early January, was €15 million. In the end, we decided to step away from this particular company so as not to crowd out the private investors and focus on others who were struggling.

In any case, it was interesting to see how through that trigger we could contribute to supporting innovation in healthcare even amid the crisis. The Commission is perhaps not widely perceived as being fast, but collectively we managed to get €60 million released within a couple of weeks. That was remarkable, I would say.

What were the most important technological advances in healthcare last year?

One aspect was certainly digital health, which made a huge leap in terms of technology but also recognition and adoption. Of course, it was always attractive – and we already had digital health and AI in healthcare as areas of focus within EIT Health, but their importance became abundantly clear to all stakeholders during the crisis. There are several reasons for this. Before the pandemic, the value of digital health was not always fully understood. As an example, digital health solutions such as telemedicine were considered valuable in specific circumstances such as providing access to care for people in rural areas. But we could have never imagined that the general population across Europe would not have access to face-to-face care because clinics were closed. In this new situation, where people have to stay at home and hospitals are open only to emergency care, digital health has gained a completely different dimension. We are seeing many new technologies focussing on digital health and AI activities, both in the crisis response initiative and our innovation projects.

Digital health is certainly here to stay. Interestingly, some countries benefitted from having launched digital health initiatives just before the pandemic. One of them is Germany, which rolled out its Digital Healthcare Act in spring 2020, at exactly the right moment, so, without knowing it upfront, they were very well-prepared.

The interest in companies with digital tools is supported by increasing willingness of investors to invest in digital health, it is being viewed as a growth area that is very resilient. Moreover, local reimbursement is being adapted in line with the needs of the pandemic which is leading to adoption at a much greater speed and without some of the red tape we have seen, which has impeded the speed of uptake of digital solutions. We can certainly see an emergence of a 'new normal' for digital health based on the experiences and progress we have made during the pandemic.

For EIT Health, that was a very important question: how much we could progress the clinical research and development that was not directly related to COVID-19

Would you say that regulation lags behind the technological developments in European healthcare?

When the GDPR was introduced, the positive effects for healthcare that could have been considered back then were not fully leveraged. We would have included some regulations on how clinical data can be shared and used, for example, to train algorithms – they have to be trained with a lot of data, which means we need to have those data available. This has not been implemented back then, but I think we will now move into that direction, even if that's an ongoing process. The importance of having the data regulation that is allowing to train digital health technologies is certainly big.

Let's look also at the Medical Device Regulation that is due to come into force this May, after being postponed for a year due to COVID-19. This delay was a very wise decision because even before COVID-19 it would have been difficult for all stakeholders to align within the timelines, and during the pandemic completely impossible. I have a feeling that even by May 2021 not all companies will be fully prepared.

Jumping to a related topic, I would certainly add reimbursement into this consideration.

The reimbursement landscape is totally different to regulation, even though they're so closely related. Reimbursement is extremely fragmented. Take, for example, a small startup in Belgium that has developed an algorithm to identify atrial fibrillation. They have programmed the algorithm, patented it, and even got a CE mark for it. But in order for their solution to actually be bought and used by healthcare providers, they need to apply for reimbursement in each country individually, sometimes it is fragmented even further than country by country, to region by region or hospital by hospital. The point is that there is no way of getting approval for reimbursement in the whole European (or just EU) region. That's a huge disadvantage compared, for example, to the U.S. where, once you get approval, you get reimbursement across all its regions. I think that's still the biggest problem Europe is facing and I hope we can begin work to solve it.

Does this mean that in the health innovation domain the EU is behind other big markets, such as the U.S. or China?

There are, of course, different strengths and weaknesses in every system. In the U.S. healthcare is extremely expensive and not affordable for many people there, but the revenue opportunities for the new companies are pretty good. Earning money in the U.S. seems easier, on the face of it. Again, China has its own specifics. It's very hard to get into the system but once you have access, you can scale immediately because everything is just replicated. I think Europe needs to focus on ensuring broad adoption and uptake of healthcare innovation once it is certified, and for this we need to address our problems with reimbursement.

Nevertheless, I would say that the creativity we have in Europe as well as the willingness to focus on health innovation is high. It's certainly not too easy to enter the market, but if you have the right partners and if you get to the right networks, then your chances for success are high. That's exactly what EIT Health does – making sure startups get access to the right knowledge and expertise, networks and partners.

How would you describe the current role of startups in the European healthcare sector?

They are key drivers of innovation.

This is one of the reasons EIT Health together with the European Investment Fund (EIF) has started its Venture Centre of Excellence (VCoE), a programme bringing together investors and other key stakeholders from the life sciences and healthcare ecosystems through a custom AI platform. Personally, I find this new instrument amazing and hope that corporates in Europe would look more into the European innovation landscape.

Our intention with VCoE is exactly that: we want to make sure that European corporates are watching the European innovation ecosystem driven by startups and entrepreneurs. The model is rather simple. EIF provides co-investments to the VCs, we at EIT Health identify corporates and their VC arms to partner up with private VCs that are supported by EIF, and we present a portfolio of vetted startups to these investors. As a first milestone, the European Commission has dedicated €150 million investment in the VCoE.

> It is impossible to apply once and get approval for reimbursement in the whole European (or even EU) region. That's a huge disadvantage

In January, EIT Health and the European Innovation Council (EIC) signed a Memorandum of Understanding. What are the expectations from this partnership?

At some point, we realised that about 25% of the companies that EIT had supported in one of its major programmes have also been supported by EIC, so there was a huge overlap in terms of having the same companies but providing different tools and instruments, not in terms of doing the same. EIC was supporting them with money and we were offering them education, funding and access to the network. The idea of a pilot emerged around 2019, first with three EIT KICs – EIT Energy, EIT Climate and EIT Digital, with EIT Health – and, eventually, the rest of the KICs – also joining.

It's a huge opportunity. We bring together the methodology of the KICs mainly focussing on networks, access to partners, education, and the funding that is available via both EIC and the EIT. There are three main interests that we want to address. First, we would like some companies that have been supported financially through EIC, to join our EIT Health programmes like Bridgehead or the EIT Health Catapult and vice versa, EIT Health-supported startups should have access to EIC programmes. EIC is extremely interested in this, and as soon as we have the confirmation of our proposal, which should happen shortly, the formal partnership can begin and we can take the first companies in.

We still have to address some challenges, like the GDPR, especially if we want to do this on a larger scale and to have joint databases.

Another aspect, which is very important, is to create a fast track between the two institutions. This would mean easier access for those companies that have already been vetted, to EIC resources and vice versa, without the need for them to start from scratch. This dimension is something that we need to build up. We need to bridge the processes in both institutions and to do that, we have to define a good mechanism that is compliant with the GDPR and quality expectations.

What are the priorities for EIT Health for 2021?

I would say the focus for business creation is on having fewer companies but with more tailored support. We want to go back and concentrate on defining a journey

for our companies and initiating more interaction with partners. Right now this interaction is happening at a programme level, but I would like to also see that at an organisation level.

From an innovation perspective, we want to give more attention to high value care (HVC). Until now we have been focussing on new innovation projects that involve technology and are mostly business-driven. With HVC we want to change the system and have an impact on the way healthcare is delivered, with a focus not only on the service but also on the outcome.

What changes do you expect to see in your area in 2021?

Circling back to the 'new normal', in 2020, we found out that we could still bring forward innovation, support startups and make things happen without travelling 3-4 times a week. Our organisation is built 100% on networking, exchange and trust. It was interesting to see that it also worked online, so we'll definitely be acting and behaving differently, focussing now on both personal and online interaction. Nevertheless, switching to online has worked out only because we have built that trust before, I am absolutely sure of that. Therefore, we will have to have a good balance, at some point being able to meet again but at the same time using online technologies more. That's certainly a huge change for our organisation.

What does it mean for innovation in general? I've heard about billions being paid for companies with the investors having never met any of those people in person. That is something that never could have been anticipated before. In spring 2020, when we first talked about having online investment conferences, many investors insisted that it was essential to meet people in person. So the basic principle is that there will be a long-term change in how we do business, and I believe this will be a positive change. It can make life easier for everyone, and speed things up.

Education, which is a key priority area for EIT Health, has also evolved dramatically, and will continue to do so. The online education that is now possible changes the way skills are provided. So far, for us it was somewhat fragmented, with summer schools and various programmes in the education pillar usually happening separately. However, our mindset is shifting to consider how we can reframe the delivery of education in light of the 'new normal'. It may be that we see a shift in education altogether to 'online first', that's not to say all education will be delivered online, but I think in-person education will become less of a pinnacle for education. This presents a huge benefit and means that access to education can be much broader – from anywhere in the world, across time zones, for example, and it could attract more talent that has previously struggled to access traditional education, such as women with young children.

Conflict of Interest

None. ■

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COVER STORIES

"The equilibrium between data privacy and market expansion will be key to improving the quality of patient care", *page 34*

2021: Reset or Not?

As we move into 2021, and as the second wave of COVID-19 continues to rage, HealthManagement.org asked healthcare experts what they anticipate as the most significant change this year and what they would like to see in the future. Read on for a snapshot on whether healthcare in 2021 needs a reset and what could be improved.

Prof Christian Lovis

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

There has been fast and impressive contribuitions of digitalisation in healthcare last year, and the development of vaccines against SARS-CoV-2 is one of them. But the struggle of sharing interoperable data, be it for the public health governance, for prediction, or just to improve understanding of the disease and its impact, has demonstrated important weaknesses. This is not to even mention the more than 10 'global international' research initiatives around COVID-19, each one building its own community of contributors and silo of data.

All actors, in all countries, have experienced the need for meaningful health information in 2020. Every aspect of the COVID-19 pandemic from surveillance to logistics to research have shown the need to have better interoperable and interpretable data landscape. Not just data. Usable data. 2021 will allow an important progress in the interoperability and interpretability of the health data landscape.

A new strategy for health data is needed, including a new societal contract. This would mean moving from the intention of 'we share data' to a distributed landscape of shareable data. And shareable means data are interpretable and usable, not open and unusable. Data generate costs, data generate value.

Building a new path towards shareable data that are semantically enriched, has value and is recognised for it. Moving towards a new societal contract to ease sharing, not only of data but also of profits. Building accountability towards all stakeholders, including handling potential discrimination, biases and consequences affecting individuals or organisations. All of it is needed. And all of it requires a serious mind shift.

Prof Arch Simona Agger Ganassi

Member of the Council of Health Care Without Harm – Europe (HCWH –EU) | Member of the Board, European Health Property Network (EuHPN) | Member of the National Council of SIAIS | Member of the International Federation of Healthcare Engineering | Italy

According to what I hear in professional, academic and also political speeches, the most urgent progress that healthcare should make is in the field of digitalisation and in a more extensive acquisition of Artificial Intelligence (AI).

Certainly these are important factors and I am not against the technological evolution in healthcare. I am, however, in agreement with Richard Heinberg, of the Post-Carbon Institute who, with regard to climate change explains why technology will not save us. This pandemic has shown the profound need of renovation that is necessary in healthcare and this cannot be achieved only by more technology.

In my point of view, the first need is that hospitals and related care infrastructures stop considering themselves as "islands apart" from the rest of the evolving world. New values should become the pillars and a new way of operating should be implemented. Synthetically I consider that we should focus on having:

- Healthcare respectful of our planet – climate change, air and water pollution, protection of natural environments and biodiversity, all fundamental for good global health conditions. Hospitals and health facilities can and have to reduce their "footprint" and increase the awareness of these problems.
- Healthcare for a different globalisation – In-depth studies have highlighted, in parallel with obvious positive aspects, the negative consequences for the global health conditions produced by this phenomenon as it has developed, and driven primarily by economic goals.
- Healthcare for social responsibility – social responsibility starts with the assumption that technical solutions should provide health support to people within a framework of social justice and inclusion.

I am deeply conscious of the transformative power that healthcare has, so I would like to see that the year 2021 produces a healthcare system that addresses this power toward actions oriented by the three principles highlighted above and move towards building a healthier planet, within the framework of different ways of "being global", and driven by more social justice.

Iris Meyenburg-Altwarg

Managing Director | Com-P-Tense Germany GmbH | Hannover | Germany **| President | European Nurse Directors Association (ENDA)**

2021 will not be a year of straight paths. The (healthy) handling of stress and changes is a life's task for each and every one of us. It is about making decisions and dealing with one's own and external expectations. Some people simply have high expectations that are not questioned further. Disappointments are thus inevitable. The danger with expectations like this is you get stuck on something. That clouds the view for opportunities and ends in a negative spiral. On the other hand, you can have a lasting effect on your success if you deal realistically with your expectations. In order to be able to deal with one's own expectations, ambiguity tolerance is immensely helpful. This is the degree to which someone can deal with conflicting expectations and contradictions. The higher this tolerance for ambiguity, the better one can cope with ambiguous and contradicting situations.

More specifically, I hope that in 2021 we will regret less the many lost things from 2020 and that we will deal, in a targeted manner, with the mistakes of the last year and with what we can learn from them for the future. That can be professional as well as very personal development.

My view is that a positive attitude allows us to penetrate into spheres that we could never reach in any other way and it is often our attitude that stands between who we are and what we want to be.

Dr Rafael Vidal-Perez

Cardiac Imaging Consultant | Cardiology Department | Hospital Clinico Universitario de A Coruña | A Coruña, Spain

For 2021 I would like to see in healthcare more advancement on the application of technology for this pandemic period. We are still learning the best way to deliver telemedicine. It was there for years and we embraced it extremely fast due to the situation. Maybe the technology that is available does not fully offer what we really need to be able to give the best service to our patients. For example, better tools for dealing with old patients that are not ready for digital services due to absence of prior use.

We also need better integration of these tools in our electronic health records. We need better apps to trace contacts that help us in the isolation of potential infected patients. I believe the next step is home centred systems that can detect the presence of infection and that would allow us to perform serial tests. But for me the most important change are the vaccines. It is the biggest challenge for 2021 – how to organise vaccine rollout, to make it fast and effective, maybe through artificial intelligence. AI could help us design the best strategies or the collective intelligence that seems to be missing during this crazy period of our lives. Stay safe in 2021. The end of this nightmare is nearly here.

John Nosta

President – NostaLab | Founding Member – Digital Health Roster of Experts, World Health Organization | Google Health Advisory Board, Google | USA

The year 2020 was certainly complex. Clinical uncertainty was met with the demands of rapid action and the results were both innovation and confusion. COVID-19 compressed years of science, pharmaceutical development, technological advances and clinical practice into just months. And then, layered moral imperative of action into this equation. The lessons learned from 2020 are vast. But, in many instances, it can come down to a single word: agility. It seemed that almost every day in 2020 provided new data, insights, and guidelines that helped informed clinical practice. Yet, this pushed clinicians away from the "clinical comfort zone" into more a "risk/reward" posture where conformation was either antidotal, pre-published, or driven by societal and political pressures. Consensus was commonly in the minority and COVID-19 admissions and hospital census resulted in logistical and emotional pressures that took a significant toll on both patient and practitioner.

It's this unpredictability of today's world that demands we embrace both functional and intellectual aspects of being agile. And it's critical to differentiate this from the conventional notion of "failing fast". Agility is "failing smart" with awareness of varied options – from technology to social – that afford clinicians the template of adaptive solutions that may have not been considered prior to the COVID-19 era. Learning and adopting tools like telemedicine, home monitoring, pulse oximeter and others can help place you ahead of the innovation curve rather than falling the victim to the "next" COVID curve.

Prof Dr Paul Timmers

CEO | iivii BV | Brussels | Belgium **| Chief Scientist Cyber.Cerides | European University Cyprus | Nicosia |** Cyprus **| Senior Advisor | EPC | Brussels |** Belgium

Health is a global common good. Dealing with the cyber-resilience of health systems must then also become a joint effort of countries and international organisations. I would like to see an international plan of action established in 2021 in the global common interest. We need to work together on cyber-capability building, information exchange about cyber incidents, and mutual assistance for cyber protection.

Sabine Torgler

Staff Nurse | University Hospital Bristol and Weston NHS Foundation Trust (UHBW) | Bristol | UK **| Director | English for Nurses Ltd | HealthManagement.org Columnist**

As a clinical-working registered nurse and a lecturer, I would love to see that all governments of this world consider nursing, midwifery, paramedic and care workers as well as medical staff as one of the most important work sectors in every society.

This pandemic has shown that if healthcare professionals wouldn't have worked as much and as hard as they did (and thousands of healthcare professionals got ill and many died in the duty of care) and still do, the death numbers would have been even higher.

I demand for my colleagues and, of course, for myself that governments equip their countries, their societies with functional healthcare systems, with enough hospital (primary and secondary) facilities, modern standards, PPE, and profound education which should be state-funded, and act for their societies to ensure people's protection.

We are currently seeing how 'lucky' we are in Europe, even with the incidence numbers for the UK still being high in comparison to other EU states. But if you look at the wider picture in healthcare and at other states and continents – how, in some way, forgotten they are – I still find it shocking.

I call for the international solidarity here amongst all healthcare professionals and all governments. Only with a stable, professional and modern healthcare system one can govern its people.

The politicians should stop thinking about – and certainly acting towards – making healthcare systems a profit market. They should stop reducing healthcare budgets – in the UK, where the NHS budget has been continuously cut for years now, we have seen and keep seeing in what kind of state we live, even with a high educated nursing workforce and colleagues. If one saves money at the wrong end, they will pay the price for it. And the price is here – lives of healthcare workers, which no government is willing to accept as their responsibility.

Dr Rafael Grossmann

Healthcare Futurist, Technology Innovator, Surgeon & Educator | USA

The role of AI in healthcare will continue to grow. Its applications are already many, and if we couple AI with big data analysis and collection from all sorts of wearables, there is no limit to what AI can be tasked with. It is going to have a tremendous impact on how we approach healthcare. But. We don't do 'healthcare', we do 'sickcare': we treat those who are sick instead of focussing on prevention. This is where digital health can have a real impact – turn our 'sickcare' into 'healthcare'. That's the main trend.

At the same time, the way virtual (VR), augmented (AR) and mixed (XR) reality is developing is really interesting. Head-mounted displays are becoming smaller, more powerful, connected, and can gather eye movements, motion and potentially other physiological data. This technology will change not only education and diagnostics but treatment of diseases as well, especially in the light of the mental health and well-being issues coming to the forefront during the pandemic. I think that these tools will become increasingly important in preventing or healing the mental health issues. The potential has been only barely tapped, so we'll be seeing more of these technologies.

Managing the Pandemic at Foch Hospital, France

Author: Floriane de Dadelsen | **Deputy Director | Foch Hospital | Suresnes,** France

Author: Pål Arne Wøien | **General Manager EMEA |** GE Healthcare Life Care Solutions

The COVID-19 pandemic has created havoc around the world. Foch Hospital in Suresnes, France had to implement a new and improved strategy to ensure effective patient care and staff safety during these challenging times. Here we review the changes that were implemented and their outcomes.

Key Points

- Foch Hospital in Suresnes, France is one of the largest private healthcare institutions of public utility in the Paris region.
- During the COVID-19 crisis, the hospital has adapted its medical strategy.
- The experience has highlighted the importance of team sharing for improved efficiency, mobilisation of support activities, managing limited resources and utilising all available healthcare staff.

How should we treat patients infected with a virus we know hardly anything about? This was the very first challenge that hospitals in Europe had to solve when COVID-19 patients started to flood in early March.

Foch Hospital in Suresnes, France – one of the largest private healthcare institutions of public utility in the Paris region – is no stranger to this challenge.

In the absence of scientific studies and reliable information about COVID-19, they had to improve at first, and as they learnt a little bit more about it, they adapted their medical strategy day after day, constantly sharing information between the various departments to ensure consistent and optimum care for patients.

"Every day was bringing new challenges," shares Dr Charles Cerf, Head of the Intensive Care department. "We connected with intensivist colleagues from other institutions to share experience". That is how for example they quickly decided to replace assisted ventilation with high-flow oxygen therapy. "This critically helped rationalise the use of resuscitation ventilators and to only use intubation if non-invasive therapy failed", he adds.

Even more than beds or intensive care materials, experienced nurses and doctors started lacking very quickly. The hospital had no choice but to redeploy staff from other departments to the intensive care: first anaesthesia teams, as well as surgical staff and recovery room staff, followed by nurses, doctors and care teams with little or no training to intensive care.

"This was a tremendous source of stress for the staff, who had to urgently acquire new skills and remain mobilised for an indefinite time", comments Floriane de Dadelsen, Deputy Director.

At the pick of the pandemic in early April, fatigue had already set in for several of them, without the slightest drop in the number of patients being treated. At the request of the Regional Health Agency (ARS), the hospital had already stopped all scheduled procedures in order to be able to accommodate as many COVID-19 patients as possible and to relieve emergencies for public hospitals.

The distribution of patients between public and private institutions managed by the ARS was shown to be quite effective; however the provision of heavy equipment and consumables to satisfy the high demand was often complicated.

"Accurately predicting the volume of materials when we had no idea of the exact number of patients we would have to accommodate, and building stocks as the ARS controls the delivery of equipment and medicines to ensure equal distribution among health institutions was just impossible", adds Ms. Dadelsen.

The biomedical team was on the front line in early May to manage a return to a somewhat normal: restore the hospital to what it was, treat diseases other than COVID-19 whilst prioritising the most urgent cases, enable nursing staff to go on holiday with the hope, in the meantime, that the number of patients would not rise again.

Several months after the first wave, the team reflected on the lessons learned from the management of the health crisis.

Numerous positive points made them proud: the sharing of teams which enabled an efficient level of care to be maintained; the faultless mobilisation of support activities for the hospital - biomedical team, logistics, pharmacists - who struggled to overcome the shortage of materials and medicines; the flexibility and reactivity of all staff who had to adapt day after day to a perpetually changing working environment; the cohesion of governing authorities and efficiency of management which enabled an unprecedented and stressful situation to be managed over time.

However, certain problems remained: the challenge to deploy telemetry and remote monitoring tools due to the ineffective Wi-Fi network; the lack of budgetary resources to renew its pool of heavy equipment; and for months mobilising all hospital resources for COVID-19, to the detriment of other diseases, and chronic diseases, in particular.

Though the hospital is now better prepared today for a massive influx of patients, this crisis has demonstrated the need to rethink certain aspects of healthcare crisis management: stronger collaboration between healthcare institutions, stock management of materials and consumables, partnerships with manufacturers to implement financing solutions to lease or renew equipment without putting a strain on the hospital's investment capacities.

So many logistical and financial challenges which require loser cooperation amongst all those involved - public authorities, care institutions and companies – and at all levels.

The management of the crisis in figures:

• An accommodation capacity multiplied by 3.4 in mid-April with 48 resuscitation beds as opposed to 14 in normal circumstances, 8 intensive care unit beds as opposed to 8 continuous care in normal circumstances and 113 hospital beds.

• €1.2 million mobilised in on-call staff and additional hours (according to Foch internal data). ■

Ensuring COVID-19 Vaccine Traceability

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Author: Christian Hay | Sr Consultant Healthcare | GS1 Global Office | ISO TC 215, WG 6 | Brussels | Belgium

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A recent paper (Vander Stichele et al. 2020) published in Vaccine highlighted the need for global monitoring of vaccine use (who was inoculated with which vaccine product, where and when) as well as its safety and effectiveness. HealthManagement.org asked the authors about the challenges of implementing such system in practice and possible measures to minimise the accompanying risks.

For a project of such scale, how to ensure the truly global monitoring? Is creating a new specialised body justified?

For the global monitoring of adverse events, we see no reason why a new specialised body should be justified.

Vigibase, the global source of adverse events data shared by the member states of the WHO programme for International Drug Monitoring, operated by UMC, has that role and should continue to do so, hoping that the remaining countries will adhere. Current coverage is 142 member states and 29 associated members, representing more than 75% of the world's countries and 90% of the total population which is hard to beat. Data in Vigibase are open to access for the members of the programme via the free of charge analytical tool, VigiLyze, tailored to the global data, but its major strengths include capacity to recalculate disproportionality based on any chosen country or region to compare and analyse the shared information. Vigibase does already contain adverse events data following immunisation to enable also global safety surveillance of vaccines from countries who have chosen to also share this information.

For the global monitoring of utilisation of COVID-19 vaccines, it can only be a concerted effort of agencies in jurisdictions, working with interoperable standards so that results can be brought together. In Europe, the European Centre for Disease Prevention and Control (ECDC) already coordinates antibiotic consumption surveillance. This could be extended to (COVID-19) vaccine monitoring. Some jurisdictions have national vaccination registries in place and we hope COVID-19 will provide incentive for others to do so too.

The implementation of the system would require much 'background' work, such as creating proper IT infrastructures, training and education, etc. Who should bear the cost of these? How to avoid this increase in costs being prohibitive for both states, vaccine recipients and companies?

There exist open-source solutions for national vaccine registries and supranational support to develop lean and mean national systems in those countries which do not have this yet, at reasonable prices. Organisations such as GAVI and COVAX, which strive for equitable distribution over countries, allow for some of their funds to be used for needed associated health systems strengthening (e.g. information systems for monitoring).

In addition, UMC provides a web-based system, VigiFlow for the management of individual case safety

report (ICSR) on national pharmacovigilance and vaccine surveillance processes available to the members of the WHO programme. This service is based on global standards to ensure interoperability and can be linked to reporting apps and to web-forms allowing direct input from health professionals and patients. As discussed below, COVID-19 is an opportunity for all countries to make progress in solving longstanding issues.

What possible technical challenges should be anticipated? How could these be addressed?

Drug utilisation monitoring is based in many countries on reimbursement claims. COVID-19 vaccines are distributed 'for free' and may not turn up in these administrative databases. Maybe a symbolic 100% reimbursement fee could solve the problem. In countries, which have systems in place to fight against medicinal product falsification, these systems may provide an additional outcome to better manage COVID-19 vaccines' supply chain. Interchangeable information for identifying the vaccine is crucial to exchange information in-between systems, requiring the name (ID) of subject of care, date, name (ID) of vaccine, batch or lot, name (ID) of vaccinator, and location (setting) of vaccination.

In your article you mention that there will be no mandatory 2D barcoding of the vaccines supplied to low- and middle-income countries via UNICEF or GAVI for some time. What could be the consequences of this gap for the vaccination programme at the global level?

The consequence will be that we lose track of who is vaccinated with what in many countries, and that we will not have reliable internationally verifiable information of the vaccination status of countries. Tolerating distribution of vaccines without proper identification with barcodes is not acceptable, because these products require capacity to analyse mid- to long-term effect of the different vaccines, at macro- and micro-economy levels.

Now that the most sophisticated vaccines have been developed in record time, we should not be penny wise and pound foolish when it comes to distribution and monitoring. Pharma could take the lead in this, to avoid that the most modern vaccines get into the healthcare system in a truly archaic way.

Another point you highlight is that "provisions for non-digital alternatives to tracking COVID-19 vaccines will be needed." Could you provide some examples/best practices? How can the results be efficiently incorporated into the global system?

Non-digital examples are never best practices. One has to recognise that manual capture of immunisation information is error prone; it may serve an individual need, but will not help the pragmatic, reliable retrieval of data on who received which vaccine, needed to conduct pharmaco-epidemiology studies efficiently. The U.S., the UK, the EU have written appointment cards with the date of the first vaccination and the expected date of the second vaccination (now contested). In Belgium at least, there is space to write (sic) the lot number (if that is available). See also our explanation of possible technical challenges.

Ideally, the whole path of a vaccine, from manufacturer down to individual patient, should be transparent. Here, blockchain technology is being deployed by some companies. What potential do you see here? What might be the obstacles?

For the supply chain from manufacturer through wholesaler to community pharmacist or immunisation centre, regulations in place (to fight against medicinal product falsification) should be used. These regulations require standardised product identification by using GS1 Datamatrix data carrier. Blockchain is a technology which could be used in addition, to secure information about supply chain and immunisation. That technology requires at least the same identifications as for the fight against medicinal product falsification: name (ID) of subject of care, date, name (ID) of vaccine, name (ID) of vaccinator, and location (setting) of vaccination.

The first vaccines are already being dispatched around the world – are the suggested recommendations being implemented? How could these early 'unmonitored' stages of vaccination be accounted for at a later stage, when the proposed system is in place?

In the first phase, there is only one vaccine and distribution is highly centralised, prioritised and supervised. Even in this clear situation, chaotic distribution of vaccine batches and leftovers is possible. Distribution will become even more complex in the near future, when multiple vaccines come to market, with extra cold, cold channels and normal fridge channels allowing multiple methods of distribution. Remediating an unmonitored stage is very difficult. There is no guarantee that things will go better at later stages.

Assuming that some countries might not be very cooperative in ensuring the transparency of their vaccine manufacturing and administration, what are the possible ways to address such cases to ensure global safety?

Equity in delivering vaccines to LMICs and in Europe should go hand in hand with requirements of transparent monitoring. These countries are more vulnerable to falsified medicines and racketeer sales of vaccines. Bad management in several countries keeps the world vulnerable to new outbreaks of the pandemic and gives variants of viruses the freeway to develop. Presumably public acceptance of vaccines in such countries may be lower. Some countries receiving vaccines from less stringent approvals may be willing to conduct post-introduction pharmacovigilance studies.

How do you assess the prospects of the COVID-19 pandemic eventually leading to a global standardisation of vaccine supply?

There are several initiatives to strengthen the vaccine supply chain, led by organisations such as UNICEF, GAVI, USAID and WHO, which are based on international standards. This crisis is an opportunity to expand these initiatives to the global community, which is a very much-desired outcome. Never waste a good crisis. We have a few months to go into warp speed to expand these standards for distribution, supply and monitoring of utilisation for COVID-19 and then, hopefully, learning from this crisis, for all vaccines.

Is there anything else you would like to add?

The first vaccine authorised in high-income countries have had very stringent and specific cold chain distribution characteristics. Their stringencies have kept various task forces in these countries all over the world very busy and doing their utmost best to initiate this gigantic operation with one vaccine, with specific distribution characteristics. The other vaccines in the pipeline will use more routine cold chain, or can even be distributed at room temperature, in smaller, prefilled packages. This will make the distribution challenge easier. However, it also increases the importance of correct labelling and provision of practical identifiers, readable with scanners, on the secondary and primary packages. It will allow that the distribution with correct documentation can be scaled up globally, including in low- and middle-income countries, regardless the distribution channels, the vaccines and the jurisdictions.

Tolerating distribution of vaccines without proper identification with barcodes is not acceptable

Conflict of Interest

CH is Sr Consultant for GS1 Global Office. No conflict of interest.

Other authors declare no conflict of interest. ■

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2021 in Healthcare: Snowballing into the Future

Author: Prof Florencio Travieso | Co-director of the MSc in Health Management & Data Intelligence, Law Professor | emlyon business school | Lyon | France | HealthManagement.org Columnist

Since the start of the COVID-19 pandemic, digitalisation in healthcare has become as important as probably never before. Its upgraded role spans across a multitude of areas, from blockchain applications and smart hospitals to patient data protection and vaccine logistics. An expert provides an overview of the most promising trends and technologies meant to both disrupt and give a boost to healthcare in 2021.

Key Points

- Without a doubt, development in healthcare and med-tech sector will continue to accelerate.
- The volume and application of data will keep expanding in parallel with the adoption of data protection frameworks. The two must be balanced to allow higher quality of patient care.
- Hospitals' operating models increasingly become outdated. The focus is shifting towards prevention and non-hospital settings. This will be accelerated by predictive AI.
- 2021 will be a breakthrough year for blockchain, which promises to become widespread and standard technology in healthcare.
- Telehealth, which received a major boost during the pandemic, will continue to grow, although the threat of 'Uberisation' persists. This may also change patients' perception of the value of their data.
- The vaccine rollout has been challenged in logistics and distribution, but created an opportunity to enter the field for non-healthcare companies

Where Do We Go from Here?

2020 has been quite a ride for the planet. But despite all the hopes we envision for 2021, this year is telling us that we might have to be a bit more patient. 2021 still tastes a little bit like 2020.

We don't need a crystal ball to see that last year's acceleration in the healthcare and med-tech sector will clearly continue to rapidly develop. Let us review a few of the areas that are worth paying attention to, and that will probably bring new and better solutions in the upcoming months.

Data Rocks!

Personal healthcare data will become the key to unlock healthcare's previous burdens. Data will not only continue to expand but also their legal protection will slowly become widespread. Spearhead regulation like the European Union's General Data Protection Regulation (GDPR) is driving many other legislations to follow suit. The GDPR (also known as 'HIPAA on steroids') and healthcare data have been put to the test multiple times in the last few months, especially with the application of contact tracing mobile applications, setting a trend for the market.

The equilibrium between data privacy and market expansion will be key to improving the quality of patient care. This new paradigm – collection, treatment, as well as an ethical and transparent exploitation of data – will help the sector reinforce some struggling national healthcare systems that have been underperforming or inefficient in the last few years.

Towards Smart Hospitals

Hospitals and their caregivers, on the front line since the beginning of this COVID-19 crisis, have been subject to continuous stress. It's clear that the future functioning of hospitals will have to be revised. There is an open market opportunity to guide, advise, treat and manage patients before they enter the hospital. This will be accelerated by predictive AI that will help with performing intelligence triage, optimisation, length of hospitalisation, setting priorities and smart scheduling functions depending on urgencies, availabilities and specialisations. Hospitals will probably expand with different peripheral services through existing intermediaries such as pharmacies, nurse offices, or telehealth hubs.

New Chains on the Block

Blockchain will make its grand entrance this year, by becoming a traditional and standard technology, differentiating itself from its 'estranged' cousin, Bitcoin. Blockchain will be used in clinical trials to make them more transparent, allowing faster and more efficient processes. E-prescriptions and secure and integrated transactions will continue to grow using this technology, and 'health passports' could also benefit from blockchain in the future months of COVID-19 management.

Telehealthier. Patient Care 4.0

Telehealth will represent more than half of consultations. Telehealth and digital consultation-linked activities will certainly boom this year. Patients have realised that distant consultations are no longer taboo, and that in COVID-19 times they have proven to be sufficient for a large part of consultations or follow-ups. The expansion of related applications to telehealth will also surface, in an intention to recreate a previously empty territory.

Generalised digitalisation of these services will also have an impact in the more traditional pharmaceutical sector, such as in pharmacies, primary care offices, dispensaries, or vaccine rooms. There is certainly a limit: the potential 'Uberisation of healthcare', which could lead to a degradation of basic services.

In the face of the pandemic (and the post-corona scenario) users might begin to perceive their health data differently. User data monetisation is not (yet) an alternative, but the realisation of data sharing capabilities is, including those sourced by connected devices, IoT and centralised electronic medical records by national authorities (e.g. France's 'Dossier Medical Partagé').

Last-mile Delivery & Logistics for Vaccines

The rollout of COVID-19 vaccines has been greeted with joy and hope. However, as we thought, the effective mass production and logistics has been confronted with the reality of actual distribution. At the same time, we've seen that Amazon has offered help to administer vaccines in their facilities. This proposal, coming from the e-commerce giant, could also be shared and replicated by other players like Walmart or Costco - in the U.S., but think of your national leader retail chain. This move will not only multiply the chances of faster and effective distribution, but also introduce a new way, in which users set up a relationship with these companies.

The equilibrium between data privacy and market expansion will be key to improving the quality of patient care

2021 had the potential to become an easy-going and hopeful year, but it seems that it will take a bit longer to experience that feeling. Nevertheless, we're sure that this year will bring surprises, good surprises. This year will also bring long-awaited advances on data interoperability, uniformisation of electronic medical records, AI-assisted drug discovery and more. So much to look forward to.

Conflict of Interest

None. ■

Teleradiology – Evolution and Use

Author: Prof Ahmed El Serafi | Founder | International Radiology Centre | Dubai, UAE | Professor of Radiology | Suez Canal University | Egypt

Ahmed Serafi is the founder of the International Radiology Centre, Dubai and Professor of Radiology, Suez Canal University, Egypt. He has been working in the field of telemedicine for more nearly two and a half decades. Prof Serafi spoke with HealthManagement.org to share some of his experience with telemedicine, how it has changed over the years, and why it's so crucial a tool today.

What are your general thoughts about telemedicine and where do you think telemedicine is going, in particular radiology and reading images, and how has it evolved?

My first experience with telemedicine was in 1996. At the time, I was a lecturer of radiology in Suez Canal University in Egypt. I had started a CT service in my hometown, Port Said, which is 200 kilometers from Cairo, where I lived. I only commuted two or three days a week, working remotely the rest. EpicCare, a company working with Kodak at the time, launched a product at RSNA called "Readwork" which enabled image transmission from one site to another using phone line fax modems.

So this was very high-tech at the time?

Well yes but I wondered if it was really possible, so I sat with them to hear about it. We got the very first system in the Middle East and Africa in 1996. This enabled us to report cases as they were being scanned. It was very slow transmission with brain CT taking up to half an hour to transmit 10 to 12 images. Still, it was progress and I know it saved lives.

How was it first received by those in the medical community?

I wrote a paper about it and the committee reviewing it was in agreement that it had no value in radiology and disqualified it. Like many things in medicine and academia, adoption and even acknowledgement can be slow.

What benefits does teleradiology provide?

One immediate benefit can be seen in something that's on everyone's minds lately – the pandemic. With staffing challenges, if it weren't for teleradiology and remote reporting, we would not be able to sustain our business under these conditions. It's a crucial part of our daily practice and it will continue to grow.

In a broader sense, for the radiologist, teleradiology will provide more work opportunities and flexibility both for the times of day they work and where they live. They're not tied to standard 9 to 5 hours or a proximity to a radiology facility. They could be at their home office, or group practice for teleradiology and reporting for several other facilities.

From the start though, the benefit I recognised was the ability to get diagnostic results as soon as possible to that patient 200 kilometres away because there was no one else doing that. We are still benefiting patients by saving time and travel, but we've also increased the quality of reporting available as well. Now, with the availability of experienced and subspecialised radiologists doing readings, you're offering that patient the best options for an accurate diagnosis by putting it in front of the needed specialist. It also is a benefit for me as a business owner. I can't afford to have all the different specialists at my facility waiting for a case to come in once or twice a week. But I can work with them through teleradiology.

So, we have general radiologists who are quite competent in handling almost everything. However, for the 20 or 30% that really need sub-specialisation, there's teleradiology. But even for the 70% our general radiologists handle, we utilise teleradiology. We have our radiologist do the reads and then we have a teleradiologist do a second read and then an in-house coordinator who's also a radiologist compares the reads. If they match, then he releases the report, but if they don't, he escalates and asks for a consultant's opinion on that discrepancy.

What are the economics of this?

Although peer reviews and second reads are not a requirement in our part of the world, we're doing second reads for 100% of our MRI and CT studies. We do this without breaking the bank because outsourcing teleradiology service, especially for general reads, is quite affordable. It only gets expensive when you're going for specialised reads or very specific body parts that need particular experts. But for general reads it's been economically feasible, and definitely gave us a good name and a good reputation.

How has teleradiology equipment, like workstations, evolved?

There have been some very smart innovators. For instance, EBM Technologies has come up with a system called Rad@ that uses iPad Pro as a diagnostic monitor which provides portability at a very low cost and offers exquisite resolution. The system has acquired FDA Class II clearance with iPad Pro displaying three-megapixel resolution for diagnosis, which is good enough for all our x-rays.

It is FDA approved in Japan to be compatible for reading mammography. For us, that was a breakthrough because all you need to ask of your radiologist is to have an iPad Pro that's configured by EBM through their app, the Rad@, or their UDE (Ubiquitous Diagnostic Environment) and they're able to read our studies. That made it possible to do our second reads, not only for MRI and CT, which were okay on standard computer monitors, but now we could do it for our x-rays and mammography as well.

During the pandemic, with staffing challenges, if it weren't for teleradiology and remote reporting, we would not be able to sustain our business

So this technology is currently deployed?

Yes. The UDE application allows images to also be stored on the iPad Pros, whereas Rad@ reads the images from servers. It's important to note that both are vendor neutral and work with all PACS. UDE is basically a server plus viewing diagnostic monitor solution all in one. For a radiologist who wants to be free, it is a dream come true. Think about it – the iPad then is your back server, your workstation and your diagnostic monitor. Now that is something I could not have imagined back when I was writing the paper that got rejected!

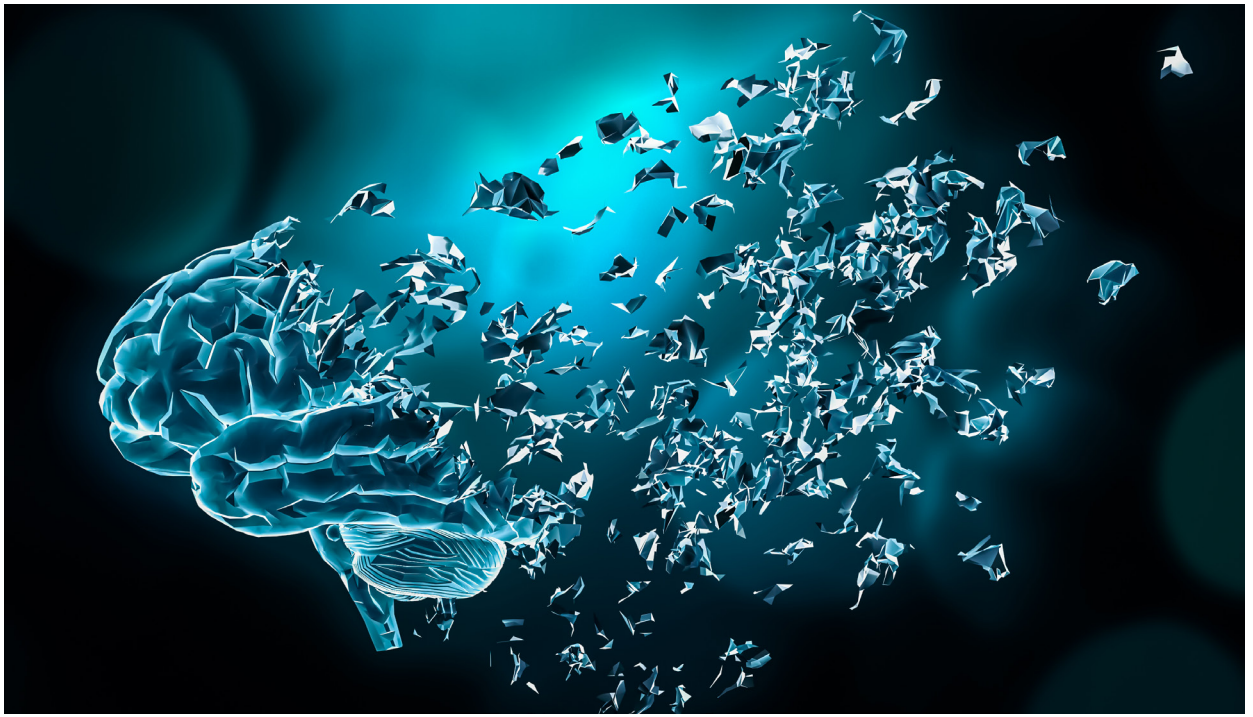
Conflict of Interest

None. ■

The DEEPER Project: Augmenting the Understanding of Brain Disorders

Author: Prof Massimo De Vittorio | **Director and Principal Investigator | Center for Biomolecular Nanotechnologies | Istituto Italiano di Tecnologia** | Lecce, Italy | **Professor | Università del Salento** | Lecce, Italy

The Deep Brain Photonic Tools for Cell-Type Specific Targeting of Neural Disease (DEEPER) is a unique and ambitious venture putting together technologists, neuroscientists, and clinical experts with hi-tech companies. DEEPER involves 12 partners in 8 countries and is funded by the European Union with about 5.7 million Euros for the next four years. HealthManagement.org spoke to Massimo De Vittorio, Coordinator of the IIT's Center for Biomolecular Nanotechnologies in Lecce, to learn a bit more about this project and the role it can play in understanding and treating brain disorders, such as Alzheimer's disease, addiction, chronic pain, depression, and schizophrenia.



Can you tell us something about the Deep Brain Photonic Tools for Cell-Type Specific Targeting of Neural Diseases (DEEPER) project? Why was it initiated, which primary diseases it targets and what are your primary goals?

The DEEPER project has been conceived because most of the molecular and cellular dysfunctions underlying the origin of several neurological and psychiatric disorders occur in deep brain regions, where current technologies are not very effective. Being not able to efficiently access those regions means that neuroscientists and clinicians cannot fully study neurological pathologies and their aetiology, and validate scientific hypothesis and therapies.

In the last few years, light and photonic tools are more and more employed for studying the brain because they give the possibility to both control and record neural activity with great accuracy and specificity. However, the brain is not transparent to light, and therefore access to its deepest regions with high precision is very challenging. DEEPER aims at producing a wide range of photonic tools to provide neuroscientists the best technologies to face this challenge. The clinical experts involved in the project will target both neurological disorders and psychiatric disorders. DEEPER aims at developing and applying new photonic technology for less invasive and more effective treatments for conditions with dramatic social impact such as addiction, chronic pain, Alzheimer's disease, depression, schizophrenia, and autism spectrum disorder.

The project is a large-scale European initiative that involves 12 partners in 8 countries. What will this collaboration entail, and what role will the different parties play?

The DEEPER project has been funded by the European Union through one of the most technologically ambitious financing systems, the Research and Innovation Action (RIA) on "Disruptive photonics technologies" (ICT-36-2020). The research consortium is coordinated by the Istituto Italiano di Tecnologia (IIT) and involves the University of Zurich (Switzerland), the University of Geneve (Switzerland), the University of Strathclyde (UK), the University of Freiburg (Germany), the University of Hamburg (Germany), the Institute of Scientific Instruments of the Czech Academy of Sciences (Czech Republic), the Sorbonne University (France), the Weizmann Institute of Science (Israel), the Institute for Bioengineering of Catalogna (Spain) and two companies, OptogeniX (Italy) and Atlas Neuroengineering (Belgium).

I am the DEEPER project coordinator, but in IIT two additional IIT principal investigators (PI) are also involved, Tommaso Fellin, Coordinator of IIT Neuroscience Area and Head of the Optical Approaches to Brain function Lab in Genova, and Ferruccio Pisanello, Head of the IIT's Multifunctional Neural Interfaces with deep-brain regions Lab in Lecce. In total, DEEPER sees the involvement of 17 principal investigators distributed among experts in developing molecular tools to make neurons responsive to light, experts in photonic and multifunctional probes for the deep brain, and experts in optical microendoscopy and microscopy. Clinical experts in the already mentioned brain pathologies will guide the technology development and validate it in animal models. This is a unique multidisciplinary team that will enable a study of neurological and psychiatric disorders from different perspectives in order to produce useful technologies for improving knowledge and find new therapies.

There is no doubt that brain disorders affect millions of people worldwide, and the burden of neurological disease is quite high. How will DEEPER help ease this burden?

The discovery of new therapies, treatments, and medical devices to cure and control brain disorders requires first a full understanding of the origin of the dysfunctions. This challenge demands large-scale initiatives such as DEEPER to face the disorders from both the technological, scientific, and clinical points of view, being ready to immediately transfer the results on the market.

DEEPER is a unique and ambitious venture putting together technologists, neuroscientists, and clinical experts with hi-tech companies. We all share the target of developing new, more effective photonic tools for the brain, and we are all aware that this will enable in the medium/long term effective treatments for multiple neurological pathologies.

How will DEEPER augment the understanding of brain disorders? How does it work exactly?

The possibility to interrogate and control deep brain neural circuits with sub-cellular resolution relies on the parallel development of high-efficiency molecular tools and high-performance hardware tools, i.e., implantable probes, microendoscopes, and microscopes. The molecular tools are being designed to make neurons sensitive to light and to produce light in response to a specific neural activity and neurotransmission. This allows a precise optical monitoring, control, and pharmacological reproduction of neurotransmitter transients in the living brain. The hardware tools, instead, deliver and collect light in the deep brain regions and, together with the molecular tools, allow both to acquire images of specific deep brain areas and to control brain electrical activity on selected portions of the central nervous system. The combination in DEEPER of state-of-the-art molecular tools, new minimally invasive probes, microendoscopes and microscopes represents a unique toolset that allows studying dysfunctions at the molecular and cellular level in a very controlled fashion.

If you were to list the key benefits of this project and the technologies that will be used, what would those be?

The key benefits are multiple, especially from the technological point of view. The most important benefits come from the applied methodology because we are facing the project targets from the scientific, technological, clinical, and market perspectives in parallel. Indeed, the consortium includes among the most expert scientists in their respective fields, and their involvement in a multidisciplinary project guarantees the development of cutting-edge technologies and that the research results will be properly validated. The involvement of companies in the project will make sure that any technology result will be immediately transferred to the market and made available to the scientific community. Last but not least, all the developed technologies will be useful not only for the pathologies we have mentioned but for any brain or body region where imaging and photonic tools can be applied.

The tools are believed to be minimally invasive but overall, how safe will these technologies be? How do you plan to test its safety and effectiveness, or if you already have, what are the initial results?

Safety and effectiveness are extremely important both in the short term when validating the technologies in acute and chronic in-vivo experiments and in perspective for their translation in clinical trials. This is the reason why we target hardware miniaturisation and why we are designing and developing different molecular tools whose safety profile will be definitely assessed. However, the DEEPER technology is also expected to be extremely useful in validating the effectiveness and safety of drugs and therapies in animal models, without the necessity of being directly applied in humans.

The project intends to transfer the technological results from laboratory to market. What would that entail? How close are you to doing that, and what does this process involve?

There are different levels for the transfer to market of the project results. The first relies on the presence of two companies, OptogeniX and Atlas Neuroengineering, producing minimally invasive brain probes and whose current customers are mostly the neuroscience labs. This will ensure that the DEEPER technologies on implantable probes will be made immediately available to the scientific community, with an exponential increase of the experiments and impact on several brain disorders. The targeting of the right deep brain circuits and the possibility of understanding the origin of specific dysfunction in brain disorders will enable, in the longer-term, more effective drugs, therapies, and medical devices.

What is your outlook about the technologies that are to be used and the overall goals of this project?

I think that the technology to be developed in DEEPER will have a strong impact also out of the project borders. I expect that all the demonstrated tools will enable a large number of experiments for multiple pathologies and that they will have a huge and lasting impact on the discovery of therapies and on the control of brain pathologies.

Conflict of Interest

None. ■

Prevent or Treat in Latin America?

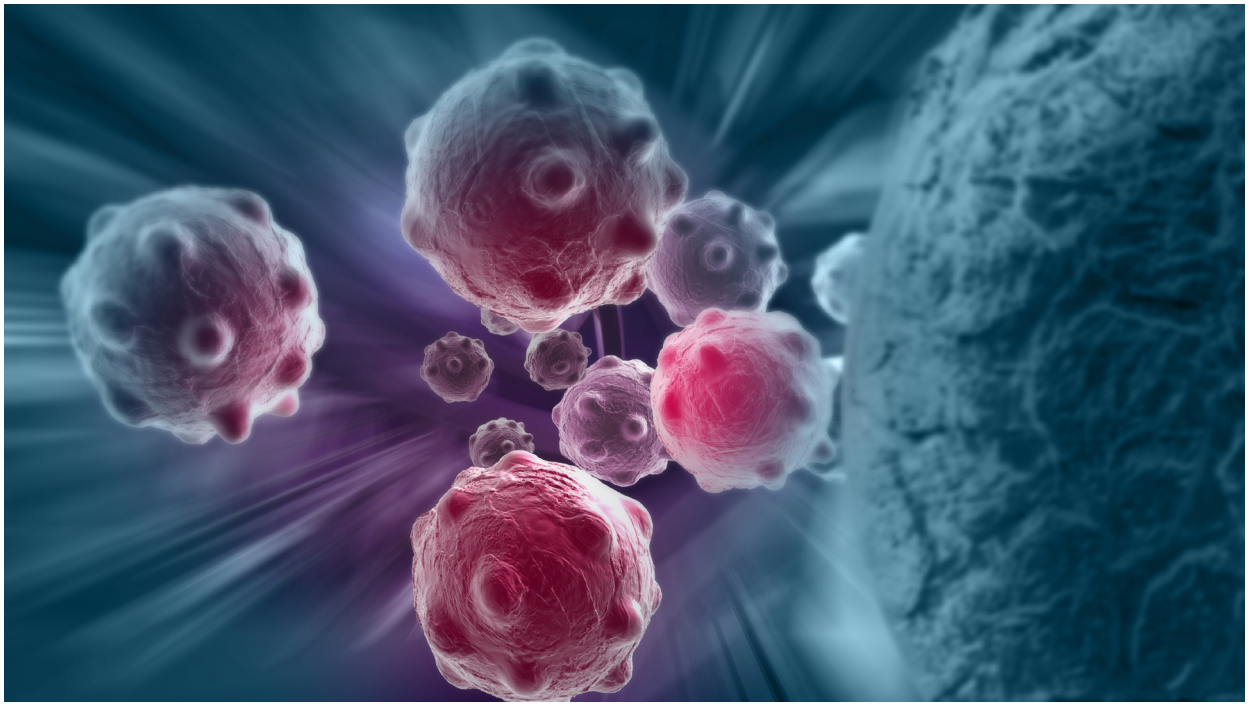
Author: Maria Chacon | **Patient advocate | Inspire2live | Rotterdam |** Netherlands

Author: Peter Kapitein | **Patient advocate | CEO | Inspire2Live | Amsterdam |** Netherlands

In Latin America there is a big need for prevention as many people do not have access to treatment due to high costs. Prevention not only in terms of becoming sick but also of not paying more than necessary. The situation varies across the continent, and in some countries there are good working examples. Still, the challenges of cancer in Latin America demand immediate action. By joining forces of the countries and learning from innovative discoveries, we can, without too much expense, help a lot of people.

Key Points

- Education is the basis of prevention.
- While screening becomes more important every year, in Latin America COVID-19 has negatively affected this practice.
- In low-resource countries, there are groups of patients who do not have access to health care. Inequality in Latin America affects prevention and early detection as well as palliative care, with high costs as a result.
- We need to reduce the impact of COVID-19 on inequality.
- It is important for low- and middle-income countries to cooperate and share the innovative discoveries on the basis of reciprocity.



What We Know

Cancer is a huge global health challenge. In Latin America cancer was the second leading cause of death in 2019 after cardiovascular diseases. The situation is quite serious. The most frequently diagnosed types of cancer in men are prostate (21.7%), lung (9.5%) and colorectal (8.0%); in women, the most frequent cancers are breast (25.2%), lung (8.5%) and colorectal (8.2%) (PAHO 2020).

Latin America comprises 20 countries with a total of 650 million inhabitants. Of those 20 countries, all have different health policies, different economies, and different budgets dedicated to health in general. In 2014, the countries of the region committed to investing at least 6% of their Gross Domestic Product in the health sector but very few have succeeded. Uruguay, Costa Rica and Cuba are the only countries in the region that comply with this agreement.

Oncological Challenges in Latin America

The position of the World Health Organization (WHO) is very clear: we should prevent! If we do this, the occurrence of cancer could be lowered without having to fight it. Prevention has been shown to be cost-effective for cancer care (Bray 2015). Education is the base of prevention and is necessary to achieve early diagnoses, develop friendly health systems that are receptive to the requirements of patients, and unite society.

Further to this, the states and the pharmaceutical industry should manage the rising price of treatments and make the treatment accessible to patients who need it. For example, in Latin America, cervical cancer remains one of the most common types of cancer in women and can be prevented with vaccination against the human papillomavirus (HPV), in addition to screening and treatment for precancerous lesions. Another example worth mentioning is the commitment of countries like Uruguay and Brazil to tobacco control, with measures such as designating public places and workspaces to be 100% smoke-free, printing strong messages on cigarette packs, and imposing heavy taxation of tobacco.

A big issue in Latin America is the lack of screening records that enable early detection. Screening is not appropriate for all types of cancer and, for some types, the cost makes it prohibitive in countries with lower economic development. Problems with programme structure, quality service, infrastructure, monitoring and integration with other health services prevent better use of screening (Kielstra 2017). In addition, most of the human resources and specialised equipment for cancer control continue to be concentrated in urban areas, therefore diagnosis is unlikely in rural areas. In addition, travel expenses are added to the effective cost of treatment for people living far away from the main cities.

It is necessary to mention that these issues around screening have worsened since the start of the COVID-19 pandemic. Social lockdowns and travel restrictions have had a negative impact on both screening and care for cancer patients. Screening interventions and visits were postponed from March to June 2020, leading to delayed diagnosis and late treatment of new cases. If this substantial decline in screening tests continues, there will be a related decrease in confirmed cancer cases, but only in the short term. There will, however, be an increase in cancer cases later, which will sadly entail the diagnosis of more advanced stage cancers. As a consequence, there will be an increase in cancer mortality and direct costs associated with treating patients at more advanced cancer stages (Slacom 2020)

The problem is worse for those who can neither afford private insurance nor get insurance provided by the social security system. Few countries, for example, Costa Rica, Brazil, Colombia and Uruguay, have what

could be described as universal coverage of health care. Other countries generally struggle to meet the needs of the uninsured. Some countries, such as Mexico, are creating specialised insurance; others, such as Paraguay and several Argentine provinces, offer free hospital care within their public systems.

It is even more important to emphasise prevention and education of the population in these situations. If tobacco use and other key risk factors are regulated, between 30% and 50% of cancers are potentially preventable and about 30% could be cured if diagnosed early and treated in a timely and effective manner. Failure to encourage effective care policies that improve public prevention and early detection has a detrimental effect on both cancer control, social welfare and economic growth.

This inequality in Latin America affects the prevention, early detection of tumours and the stage of palliative care. Government budgets for health in Latin America are low compared to those in developed countries. According to WHO, less than 30% of cancer patients in low-income countries have access to care and treatment compared with 90% in high-income countries. Furthermore, cancer has often been a low priority in distributing such limited funds. Most countries have insufficient resources to meet current cancer needs and even less for future needs because of these budget decisions. They cannot implement active plans for needs like palliative care. There is a need for more staff in oncology; to give an example, the number of specialised oncology nurses trained in Brazil would cover only half of São Paulo's current needs. Only Uruguay and Chile have enough radiotherapy equipment to treat all patients in the country (Goss et al. 2013).

As a result of the COVID-19 pandemic, planned operations were postponed, including chemotherapy, radiotherapy, and palliative treatment. Diagnosis at later stages will mean a significant increase in cancer care costs compared to pre-pandemic levels.

Until recently, Latin American countries had relatively few population-based cancer registries, providing information for designing effective cancer control and evaluating the impact of initiatives on cancer policies. In low-resource countries, there are groups of patients who do not have access to health care; there are people who do not get mammograms, get vaccinated, nor have access to screenings. This makes it difficult to collect proper, reliable, and unbiased data (Kielstra 2017).

What Needs to Be Done?

Urgent action should be taken to reduce the impact of the pandemic on poverty. Before the COVID-19 pandemic it was already important to establish a permanent dialogue and cooperation between healthcare systems and economy sectors, involving professionals not specialised in oncology or in the care for cancer patients. We can reduce the economic and well-being impact of cancer on patients through the effective use of communication resources, the development of care networks and the structuring of different levels of responsibility for clinical routes. A good example here is the 'M-Tiba' smartphone-based payment facility for health care in Kenya.

Another case is our work at Inspire2Live, a patient advocacy platform launched in the Netherlands and expanding worldwide through the development of hubs. We aim to establish a world campus with patients, researchers and clinicians working together to get cancer under control and live balanced lives in harmony with cancer.

An example of this collaboration is the 'Teddy Bear Project' run as part of our Latin American hub. The project is based on the promotion of photoprotection of patients with Xeroderma pigmentosum (XP). XP is an autosomal recessive disorder caused by a germinative mutation that impairs the DNA repair process. Patients with this condition are at high risk of developing skin cancer. The 'Teddy Bear Project' aims to provide UV-protective hats, full-face UV-protective visors, sunglasses, sunscreen and UV-protective shirts to XP patients because for them photoprotection directly leads to cancer prevention and improves the quality of life.

To be continued...

Conflict of Interest

None. ■

We would like to thank Barbara and Mark Moss, patient advocates from Inspire2Live, for their assistance.

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Charitable Institutions During the COVID-19 Pandemic: The Pisa Experience

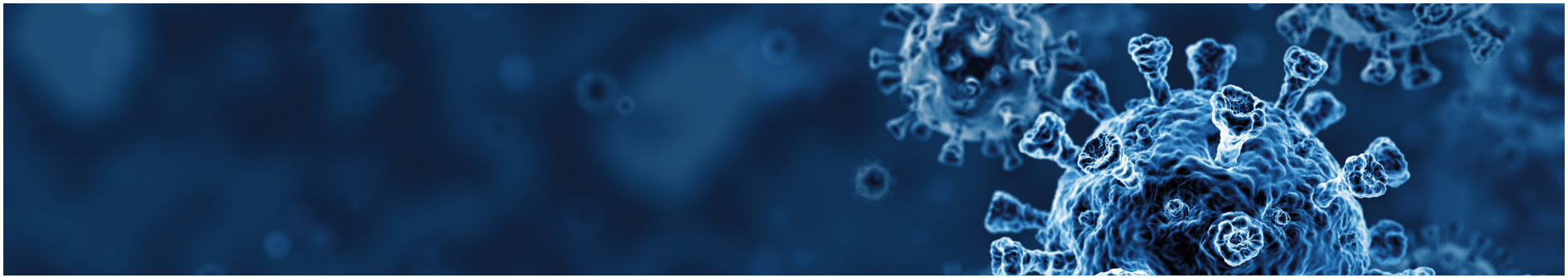
Author: Prof Davide Caramella | Chairman | Radiodiagnostica 1 | University Hospital of Pisa | Italy

Author: Maurizio Mian | Chairman | Fondazione Gioia | Pisa, Italy

During the COVID-19 pandemic, several charitable institutions in Pisa, Italy helped local health authorities cope with the crisis. One of these charitable initiatives led to the purchase of a high-end ultrasound system. This paper describes how this project was envisioned and implemented and what lessons were learned from this initiative.

Key Points

- Gioia Foundation is the charitable institution involved in the project.
- The goal of the project was to identify a support technology that could help first-line healthcare personnel in the critical wards where severely ill COVID-19 patients were treated.
- The aim of the project was to donate a high-end ultrasound system for diagnosis and follow-up of COVID-19 patients, reducing the need to move patients to the dedicated radiology unit.
- The Center for Instrumentation Sharing of the University of Pisa was selected for deployment in the ICU for immediate relief during the COVID-19 emergency as well as for reuse in other research applications.
- The installation of the ultrasound system in a clinical environment with research experience allowed to obtain measurable benefits not only in patient care but also in the production of scientific results.



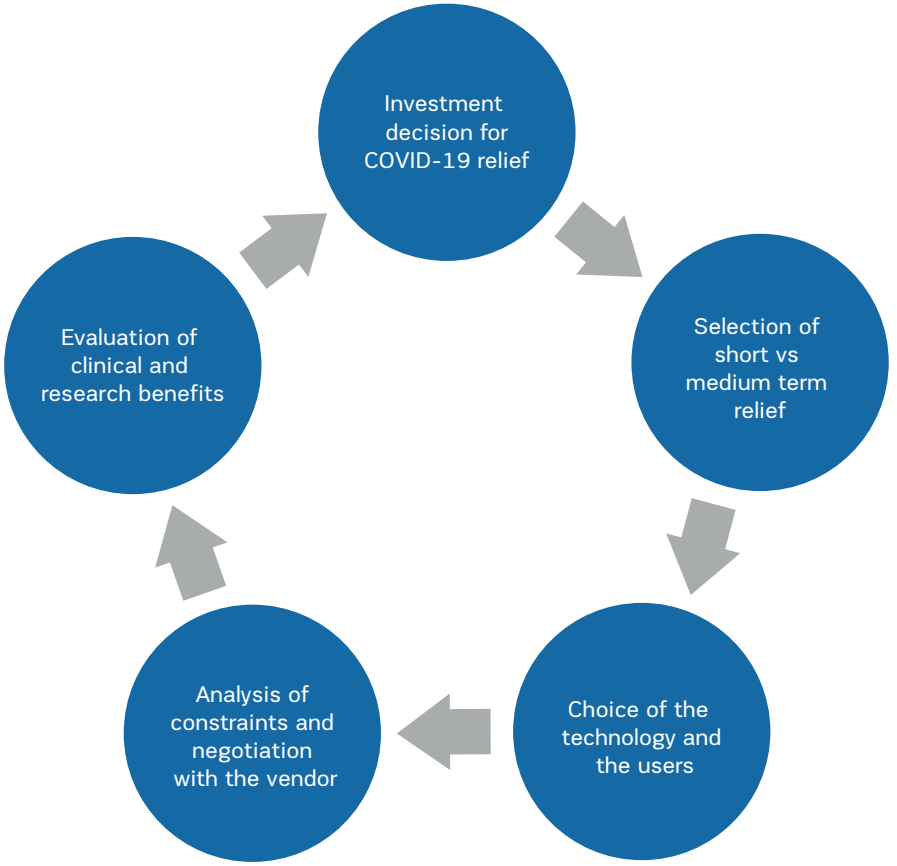
Pisa is a small Italian town of 90,000 inhabitants. It is world-renowned for its iconic leaning tower and for being the birthplace of Galileo Galilei, who taught at the local University and is considered the father of modern science. In recent times, the University of Pisa had two Italian presidents, five Italian prime ministers and three Nobel Laureates as students, faculty or staff affiliates.

Moreover, Pisa has a tradition as a leading Italian industrial site for pharmaceutical production, is in the forefront of gravitational waves research (one of the three interferometers in the world is located in Pisa), is the only Italian centre having a 7T MRI system operational since 2012, and has an outstanding reputation in transplant and robotic surgery.

In this unique historic cultural environment several charitable institutions were established in recent years. During the COVID-19 pandemic, they played a significant role in helping local health authorities cope with the emergency situation.

Most charitable initiatives were aimed at addressing the initial shortage of personal protective equipment (PPE), and at mitigating the suffering of gravely ill intensive care unit (ICU) patients that were unable to communicate with their loved ones. For the latter initiative, dedicated Wi-Fi networks were put in place and tablets were given to patients in order to enable them to be in touch with family members who were not allowed in the hospital for a visit (https://fondazionearpa.it/a-wifi-rainbow-over-the-hospital-walls/).

A different type of charitable initiative led to the purchase of a high-end ultrasound (US) system for the ICU physicians. In this paper we will briefly describe how this project was speedily envisioned and implemented and what were the lessons learned (Figure 1).



The Project

The charitable institution (Gioia Foundation) involved in the project is headed by Maurizio Mian, the last scion of a family counting some university professors in different medical disciplines and having a fruitful osmosis with a pharmaceutical company (Istituto Gentili) and its research division, whose director, Sergio Rosini, was responsible for the outstanding discovery of one molecule active in the treatment of osteoporosis.

The Gioia Foundation proposes itself as the ideal extension of the research activity of these prestigious forerunners and invests in charitable projects in the Pisa area.

When the pandemic started to rage in spring 2020, most investments and donations were aimed at mitigating immediate problems linked to the overflow of patients arriving to the hospital in severe conditions. On the contrary, the Gioia Foundation project was envisioned with the aim to answer a more strategic question: “Which support technology could make a difference in this healthcare crisis?” Such an approach was uncommon in the early days of the pandemic, and its merit was to analyse the new workflows forced by

COVID-19 and to identify a support technology that could be of help to the first-line healthcare personnel in the critical wards where severely ill COVID-19 patients were treated.

Which Technology?

The Pisa University hospital is spread over several buildings. During the initial months of the pandemic, one of the challenges was to move COVID-19 patients safely from some of these buildings to the Radiodiagnostica 1, which was the radiology unit dedicated to serve the highly contagious COVID-19 patients. In this context, it was noticed that one of the main ICU was staffed by superbly trained intensivists with good experience in the use of bedside US systems for the ultrasonographic evaluation of the lungs. The aim of the project was to donate to these first-line physicians a high-end US system able to assist them in the diagnosis and follow-up of COVID-19 patients, thus reducing the need to move patients to the dedicated radiology unit. In fact, pulmonary US was reported being able to document involvement of COVID-19 by demonstrating signs suggestive of interstitial-alveolar damage and by showing diffuse pleural line abnormalities, sub pleural consolidations, white lung areas and thick, irregular vertical artefacts (Buonsenso et al. 2020).

Which Vendor?

Once the technology was selected, the next issue was to assess which vendor was able to expeditiously deliver an US system with all the technical features needed for the required application, and possibly with a sufficiently complete set of functionalities to grant other advanced applications after the end of the COVID-19 emergency. Finally, price and delivery time were taken into consideration.

Several vendors were contacted and their offers were compared by using a quantitative method. The final choice was a US system meeting the high-end quality requirements for performing US examinations of the lung while retaining the potential for being re-used after the pandemic in research involving other clinical domains.

The instrument was directly purchased by the project in order to maximise the effectiveness of the negotiation. In fact, the project was able to obtain nearly 65% discount on the original price (60,000 Euro instead of 168,900 Euro, VAT excluded) and a delivery time of less than two weeks: the order was issued on March 27, and the installation of the US system took place on April 10, 2020.

Which User?

The choice where to install the new equipment was guided by the following requirements: presence of clinical experience of US examinations performed on critically ill patients and multidisciplinary integration of medical and technological competence. This led to the selection of the Unit of Anesthesia and Reanimation that had the experience needed to study the acute respiratory insufficiency US patterns due to SARS-COv-2 infection and to compare them to other pulmonary US patterns due to pulmonary oedema, cardiac insufficiency and sepsis-induced ARDS. This is particularly important since the US diagnosis based on the operators' visual analysis of the images can be implemented with an algorithmic analysis that has the potential to lead to early identification of SARS Cov-2 patients and to quantify the changes in lung involvement during follow-up.

Which Institution?

The main issue was to choose whether to donate the US system to the hospital or to the University. Two factors were taken into consideration: the regulatory constraints of the beneficiary institution and the flexibility in the deployment for allowing a possible reuse after the end of the pandemic. On the basis of such analysis, the Center for Instrumentation Sharing of the University of Pisa (CISUP) was selected because it guaranteed the immediate deployment in the ICU for immediate relief during the COVID-19 emergency as well as for later reuse in other research applications (https://www.facebook.com/CISUPofficial).

Lessons learned

Our experience shows that in an emergency situation, a strategic vision may help to address needs that are not apparent if only the immediate relief is taken into consideration. The ample degree of freedom granted to a charitable organisation helped to "think outside the box" and to overcome the constraints of a highly regulated environment such as the Italian one that usually prevents speedy relief investments. The installation of the US system in a clinical environment with research experience allowed to obtain measurable benefits not only in patient care but also in the production of scientific results. Indeed, two scientific papers were written in the months immediately following the donation describing novel clinical applications made possible by the donated US system (Corradi et al. 2020a; Corradi et al. 2020b).

Conflict of Interest

None. ■

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Breast Cancer Screening After Male-to-Female Transition in Transgender Women

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Author: Prof. Theresa M. Rohr-Kirchgraber | IU National Center of Excellence of Women's Health | Professor of Clinical Medicine and Pediatrics | Indianapolis | USA

Despite the lack of general consensus about the optimal breast cancer screening approach in transgender women, it is imperative that physicians remain vigilant and aware of each transgender individual's health risks based on their birth assigned sex and their particular mode of gender-affirming therapy.

Key Points

- Over the last decade, the number of transgender individuals seeking medical care has continued to increase.
- The transgender population has historically been more vulnerable to health disparities and structural discrimination leading to inadequate health care.
- Transgender women taking hormone therapy are at higher risk for breast cancer than natal males but lower risk compared to natal females.
- There is a lack of consensus among experts about the appropriate timing of breast cancer screening in transgender women. It is important to spread awareness among providers and transwomen about the uncommon but potential development of breast cancer following male to female transition.

Introduction

Over the last decade, the number of transgender individuals seeking medical care has continued to increase. It is estimated that currently 390 out of every 100,000 adults in the United States are transgender, which computes to almost one million Americans (Meerwijk and Sevelius 2017). Gender identity is defined as a person's internal sense of self while gender expression is the outward display of an individual's gender, including expression in the form of clothing, speech and mannerisms (UCSF Guidelines 2016). The definition of transgender is a person whose gender identity is different from the biological sex that was determined at birth. A transgender female is someone who was born biologically male and identifies as the female gender. A transgender male is someone who was born biologically female and identifies as the male gender (UCSF Guidelines 2016).

Compared to cisgender individuals, the transgender population has historically been more vulnerable to health disparities and structural discrimination leading to inadequate health care (Du Bois et al. 2018). In recent years, the options for gender affirming therapy have progressed and include cross-sex hormonal therapy, surgical breast augmentation and surgical reconstruction of genitalia (Hartley et al. 2018). Research has shown that these therapies not only alter physical appearance but also improve overall quality of life for transgender individuals (Nehlsen et al. 2020). Despite the advances being made in the management of this population, there are still many questions and grey areas remaining when it comes to optimal treatment strategies. One such challenge involves the question of breast cancer screening, specifically in transwomen who transition from male to female using cross-sex hormone therapy. Best practices are still

being discussed and debated, but overall it is of utmost importance for providers to remain vigilant and aware of each transgender individual's health risks based on their birth assigned sex and their particular mode of gender-affirming therapy.

Cross-Sex Hormone Therapy

Cross-sex hormone therapy for male-to-female transition typically consists of two components: anti-androgens to reduce testosterone levels and exogenous oestrogen to develop the desired female secondary sex characteristics (Unger 2016). Spironolactone and cyproterone acetate both have anti-androgenic properties and are used to decrease testosterone levels to the female range (<55 ng/dl). Other anti-androgens shown to be effective are GnRH agonists. Finasteride and progesterone are additional options but are less commonly used. Oestrogens can be administered orally, parenterally, or transdermally with the goal of maintaining oestradiol at the daily level of premenopausal women (100 – 200 pg/ml) (Hembree et al. 2009; Unger 2016).

Breast Development in Transgender Women

One of the main changes seen with hormone therapy in male-to-female transgender individuals is the development of breast tissue. Oestrogen therapy induces the growth and maturation of ducts, lobules and acini as seen in natal females (Sonnenblick et al. 2018). According to the Clinical Practice Guidelines of the Endocrine Society, development of breast tissue begins between 3-6 months following the onset of cross-sex hormone therapy with the maximum growth expected after 2-3 years of therapy (Hembree et al. 2009).

A prospective multicentre study done in the Netherlands followed 229 transwomen during their first year of hormone therapy to measure breast development. The study found that the most significant growth occurred in the first 6 months of therapy followed by smaller increments of growth in the succeeding 6 months. At the end of 1 year, only 10.7% gained a bra cup size greater than an A (de Blok et al. 2018). Another study done in Florence followed participants for 2 years and found that the majority was able to reach Tanner Stage 3 breast development after 24 months of hormone therapy (Fisher et al. 2016).

Although there is a modest increase in breast size for most individuals following hormone therapy, approximately 60-70% of patients pursue surgical breast augmentation options (Wierckx et al. 2014). The standard surgical methods used in the United States utilise saline or silicone implants to augment breast size (Sonnenblick et al. 2018). However, some patients may have had injections of free substances such as free liquid silicone for the purpose of augmentation, although this practice is illegal in the United States (Sonnenblick et al. 2018).

Breast Cancer Risk with Cross-Sex Hormone Therapy

As per the American Cancer Society, the estimated lifetime risk of males developing breast cancer is 1 in 833 while the average lifetime risk in females is 1 in 8 (American Cancer Society 2019). In the US in 2020, it is estimated that there will be 276,480 new cases of invasive breast cancer diagnosed in women and 2,620 cases diagnosed in men (American Cancer Society 2020). There are many risk factors that can contribute to development of breast cancer in both men and women, including ageing, obesity, alcohol use, liver disease, radiation exposure, family history and inherited gene mutations. Another risk factor to consider is oestrogen exposure, which is of particular concern in the transgender female population as long-term exogenous oestrogen exposure is part of typical gender-affirming medical therapy. While individuals undergoing male-to-female transition may be at lower risk than cisgender females due to less lifetime oestrogen exposure prior to therapy, there is concern that the high dose exogenous oestrogen used for sex reassignment therapy may increase the risk of breast cancer for these patients. However, the lack of longitudinal data regarding breast cancer incidence in this patient population makes it difficult to ascertain the degree to which cross-sex hormone therapy influences breast cancer risk in transgender women.

Despite the advances being made in the management of the transgender population, there are still many questions and grey areas remaining when it comes to optimal treatment strategies. One such challenge involves the question of breast cancer screening

A systematic review was completed in April 2018 to identify cases of breast cancer in transgender women. A total of 18 articles were included in the review spanning the United States, Netherlands and the United Kingdom and 22 cases of breast cancer were reported. Twenty of the 22 patients were taking hormone therapy but the length of treatment varied. The median age of diagnosis in this group was 51.5 years old and the majority presented initially with a palpable breast mass. Other presentations included peri-prosthetic seroma, dislocated implants, bloody nipple discharge and asymptomatic mammography screening. The majority of the identified cases were determined to be adenocarcinomas, 10 out of 19 tested were ER positive, 5 out of 14 tested were PR positive, and 2 of 8 tested were HER2 positive (Hartley et al. 2018). One of the studies included in the review described incidence of breast cancer transwomen. A cohort study done in 2013 by Gooren et al. identified 1 confirmed case and 1 unconfirmed case of breast cancer out of 2307 transgender female patients. The calculated incidence was determined to be 4.1 per 100,000 patient years (95% CHI 0.8-13.0), which is slightly higher than the expected incidence in natal males (1.2 per 100,000 patient years) and significantly lower than the expected incidence in natal females (170 per 100,000 patients years) (Gooren et al. 2013).

A large retrospective cohort study done in the Netherlands in 2019 measured the incidence and characteristics of breast cancer in transgender patients to evaluate breast cancer risk in transpatients on hormone therapy compared to the general Dutch population. The study population included 2260 transgender women who were seen at the same gender clinic in Amsterdam between 1972 and 2016. Of the 2260 transwomen, there were 15 cases of invasive breast cancer and 3 cases of noninvasive breast cancer diagnosed in 17 patients. These cases were diagnosed after a median of 18 years of hormone therapy and the median age of diagnosis was 50, which is a younger age of diagnosis compared to Dutch cisgender women. Ten of the 15 cases of invasive breast cancer were ductal in origin, 10 were ER positive, 8 were PR positive, and 1 was HER2 positive. When compared to the Dutch cisgender male population, transwomen were found to be at higher risk with a standardised incidence ratio of 46.7 (95% CI 27.2-75.4). However, transwomen were found to have a lower risk of breast cancer than the Dutch cisgender female population with a standardised incidence ratio of 0.3 (95% CI 0.2-0.4). Although the study did not include data regarding the prescribed hormone therapy such as route, dosing and frequency, median oestradiol and testosterone levels were found to be similar between the entire cohort of patients and those diagnosed with breast cancer (de Blok et al. 2019). The data collected in this Dutch study suggests that transgender women on cross-sex hormone therapy are at an increased risk of breast cancer compared to natal males but at a decreased risk compared to natal females.

Breast Cancer Screening Considerations in Transgender Women

Based on the studies that have been published thus far, it appears that transgender women taking hormone therapy are at higher risk for breast cancer than natal males but lower risk compared to natal females. The overall incidence appears to be low, but breast cancer does occur in this patient population and commonly presents at a younger age than in cisgender individuals. While universal breast cancer screening guidelines have not yet been published due to lack of transgender population data and longitudinal studies, several groups have proposed possible suggestions for screening.

Maglione et al. (2014) recommended screening for transwomen with additional risk factors such as BRCA2 mutation, family history, Klinefelter syndrome. For patients age 50-69 who have utilised hormone therapy, current Canadian Society Guidelines recommend mammography every two years. However, they do not recommend screening in patients who have not taken hormone therapy (Hartley et al. 2018). Clinical practice guidelines published in 2009 from The Endocrine Society in the United States suggest screening transgender women as biological women (Hembree et al. 2009). The Center of Excellence for Transgender Health at the University of California San Francisco published "Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People" in 2016. This group recommended screening mammography every 2 years after age 50 and after the patient has been on hormone therapy for at least

Breast cancer screening in transgender women can be done via mammography, ultrasound and MRI just as in cisgender women

5 years. Similar to cisgender women, breast exams are not recommended in the transgender population (UCSF Guidelines 2016).

Breast cancer screening in transgender women can be done via mammography, ultrasound and MRI just as in cisgender women (Sonnenblick et al. 2018). Selecting a method of imaging should be based on the form of breast development and augmentation. In patients with implants or hormonally developed breasts, mammography or ultrasound is suggested. However, in patients who chose free silicone for augmentation, breast MRI may be a more beneficial modality (Maglione et al. 2014). The challenges associated with surgically augmented breasts are the same between transgender and cisgender women. Breast tissue may be obscured and the radiodensity of the breast may be reduced if there is compression by the implant. The Eklund, or Pushback technique that is used for cisgender females with implants is also recommended in transgender patients with breast augmentation for more accurate viewing (Tang and Gui 2011).

Overall there is a lack of consensus among experts about the appropriate timing of breast cancer screening in transgender women. Therefore, it is more important to spread awareness among providers and transwomen about the uncommon but potential development of breast cancer following male to female transition. If patients change their legal sex, they may no longer be flagged and invited for population-based screenings, including screening mammography, so it is imperative that doctors and patients alike remain vigilant about preventative care (de Blok et al. 2019). A retrospective review done in 2015 at a urban health centre in Massachusetts found that transgender patients were less likely than cisgender patients to follow breast cancer screening guidelines with an odds ratio of 0.53 (95% CI 0.31-0.91), which further emphasises the need for better outreach and communication with sexual minorities (Bazzi et al. 2015). As with all areas of medicine, the decision about when to begin screening and how often to screen for breast cancer should be made after an in-depth discussion about the benefits and risk of radiologic imaging as well as the patient's individual risk factors.

Conclusion

Although there is not a large body of research about the risk of breast cancer in transgender women, the studies discussed here suggest that this patient population is at a lower risk of breast cancer than cisgender women but at higher risk than cisgender men. The suggested recommendations from various experts are not uniform, emphasising the need for further longitudinal research to determine the optimal screening guidelines. Because the breast cancer screening recommendations are still unclear, it is imperative that physicians facilitate individualised discussions with each transgender woman about breast cancer risk and screening as part of preventative health appointments.

Conflict of Interest

None. ■

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Treating Complex Diseases with Expansion Technology

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Expansion technology is a step forward in efforts to treat complex diseases and in cancer and Alzheimer's research. The technology has been developed by researchers from Bar-Ilan University, Harvard University and the Massachusetts Institute of Technology (MIT). HealthManagement.org spoke to Dr Shahar Alon, of Bar-Ilan University's Faculty of Engineering, Multidisciplinary Brain Research Center and Institute of Nanotechnology and Advanced Materials to learn more about this novel technology and the role it can play in future.

Can you explain the concept of expansion technology and its application in diagnosing and treating complex diseases like cancer and Alzheimer's?

The concept is simple – instead of extracting RNA molecules from tissues and then quantifying them, we quantify RNA molecules inside tissues. Therefore we obtain the location of RNA molecules within the tissue. This spatial information is known to be important for learning and memory in brain tissues, and likely to be important in diseases such as Alzheimer's and cancer.

Building this technology took years of work. The main difficulty was the fact that tissues are very dense, and therefore mapping RNA in their original location is a complicated task. We solve this difficulty by physically expanding the tissues. This creates room inside the tissues and allows us to reach RNA molecules deep inside them.

When you say this technology can map tissues with nanoscale resolution, what does that mean exactly?

It means that this technology allows to pinpoint RNA not only to individual cells inside tissues, but also into subcellular regions. One key example is the synapses that connects neurons in the brain. These synapses are very small and can be seen only with nanoscale resolution (only termed 'super-resolution'). With this new technology, we map RNA inside synapses.

Does this method target genes?

This method can work in two ways: untargeted - meaning that the users don't need to pick specific targets in advance, therefore allowing unexpected discoveries; and targeted, meaning that specific genes (usually between 50-300 genes) are targeted. The targeted method allows high detection yield – meaning that roughly 50% of individual RNA molecules within a cell are detected.

Molecules from a tissue of a healthy individual can be compared to that of a diseased one, possibly revealing the cause of disease. How accurate do you think that would be? What advantages does that offer over the diagnostic tools/strategies that are already available?

Regarding accuracy, we compared our technology to standard RNA sequencing technology and found it to be very accurate. Still, the main advantage is the ability to see aspects of the tissue that were not seen before, namely the 3D location of millions of individual RNA molecules. It remains to be seen how important this information is in studying disease.

Expansion technology has the potential to create complete molecular maps of tissues. How close are you to achieving that and do you think there are experts with the capability to read those maps?

The technology can create complete molecular maps of small tissues, say a small cancer biopsy. However, we are only in the beginning of building the capability to read those maps. This effort will require new computer vision, machine learning, and artificial intelligence tools.

Moving forward, how do you see expansion technology contributing towards cancer research and improved cancer treatment and management?

Expansion sequencing is one technology in the new field of spatial genomics – studying genes in their original location in space. I anticipate that this new field will allow new understanding in cancer research. Indeed, Nature Methods just declared this field as the technological breakthrough of the year.

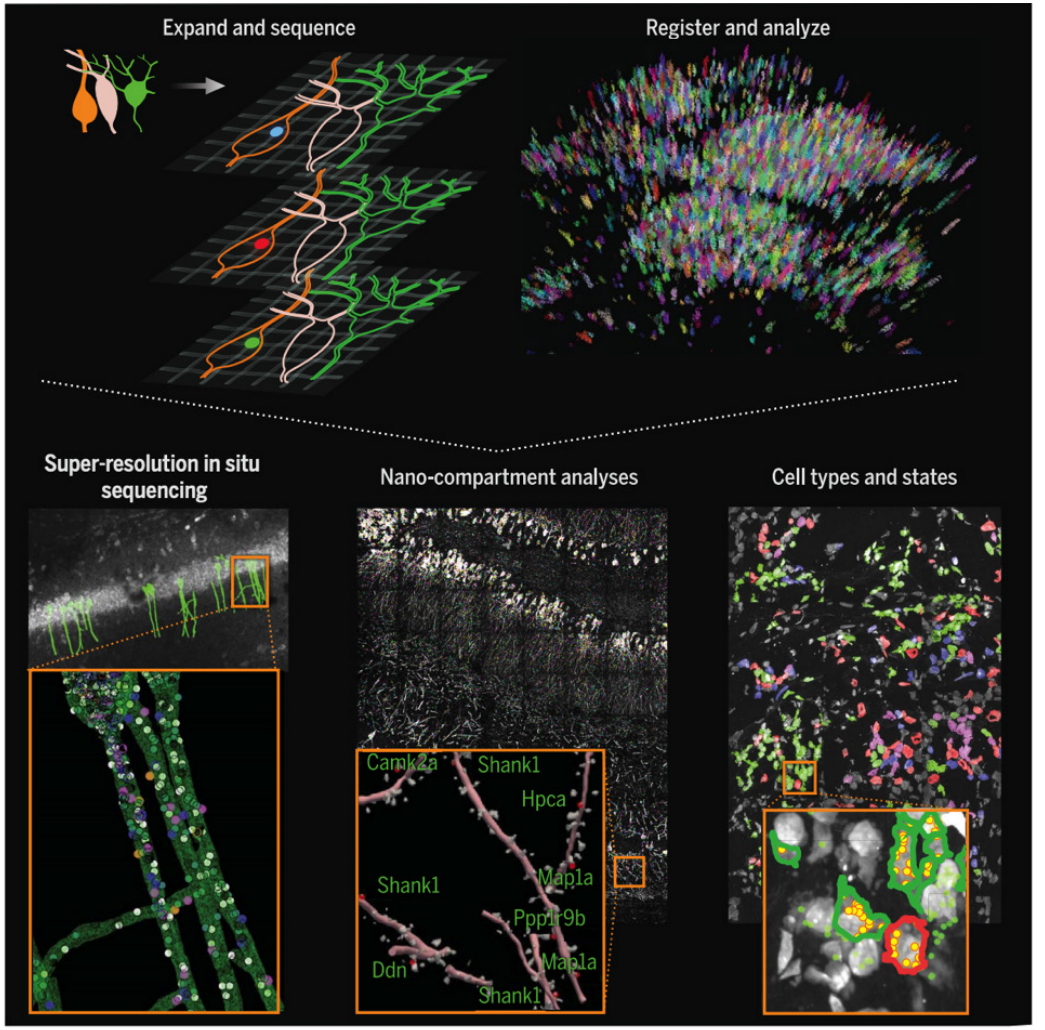
What is your outlook about expansion technology and the overall goals of this project?

These are exciting times for us. After years of developing this new technology we can finally utilise it in the study of complex diseases. In our lab in Bar-Ilan University we study eye diseases, Alzheimer's, and many other applications.

Building of this new technology required a large multidisciplinary effort. This includes researchers from MIT, Harvard and other centres around the world.

Conflict of Interest

None. ■



In situ sequencing of physically expanded specimens enables multiplexed mapping of RNAs at nanoscale, subcellular resolution throughout intact tissues. (Top) Schematics of physical expansion and in situ sequencing (left) and image analysis (right). (Bottom) Characterization of nanoscale transcriptomic compartmentalization in mouse hippocampal neuron dendrites and spines (left and middle) and maps of cell types and states in a metastatic human breast cancer biopsy (right).

Image credit: Alon et al., Science 371, 481 (2021)

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