The evolving reality of digital health

Nana Bit-Avragim[1], Jean Bousquet[2,3], Stefano Cantù[4], Stefano Omboni[5,6], Elisabetta Ravot[7] and Paul Tunnah[8]

Abstract

Myriad digital health interventions, applications, devices and technologies have, and are, being developed to help refine and personalise medicine from the patient, healthcare professional (HCP), healthcare system and industry perspectives. At a gathering of leaders in digital health, discussion included the current landscape of such digital health tools (DHTs), with specific examples from cardiology and respiratory medicine, and both the benefits and sometime downfalls of such tools. While DHTs can help patients and HCPs detect and monitor health conditions, the experts discussed how adoption of DHTs may be hampered by issues such as access to technology; data privacy and security concerns; technology integration into current healthcare systems; cost and reimbursement; and lack of guidelines and regulatory hurdles. The experts suggested solutions to such issues, including wider availability of healthcare 'booths' local to a patient; easy to understand and use phone applications; patient and HCP incentives to use DHTs and clear paths to adoption within a healthcare system. These should help with integration of DHTs into the healthcare system to aid shared decision-making and, ultimately, streamline and personalise healthcare for all.

Introduction

Digital health tools (DHTs) include interventions, applications, devices and technologies involved in areas such as telehealth, personalised medicine, health information, wearable devices and mobile health. Use of such DHTs should help personalise medicine for patients, reduce costs and inefficiencies, and increase healthcare access and quality.[1,2]

To highlight some of the innovations and challenges regarding DHTs, prior to their participation in the Frontiers Health Global Conference in Rome, Italy, 8–10 November 2023, in a session titled 'HEALTHINKERS: Designing the future of healthcare', four leading experts gathered in an independent meeting to present their work, with a focus on cardiology and respiratory medicine, and discuss issues for both development and implementation of such. Dr Paul Tunnah, an independent consultant, served at the time as Chief Content Officer and Managing Director at Healthware Group, now part of EVERSANA INTOUCH®. Physician-scientist Dr Nana Bit-Avragim is

a digital health expert, healthcare strategist, mentor and startups advisor at EIT Health. Professor Stefano Omboni is the Director of the Italian Institute of Telemedicine and a Professor of Cardiology at the Sechenov First Moscow State Medical University. Professor Jean Bousquet holds a chair at Charité Universitätsmedizin, is editor of

[1]EIT Health, Munich, Germany
[2]Institute of Allergology, Charité Universitétsmedizin, Berlin, Germany
[3]ARIA, Montpellier, France
[4]Independent Consultant, Milan, Italy
[5]Italian Institute of Telemedicine, Solbiate Arno (Varese), Italy
[6]Department of Cardiology, Sechenov First Moscow State Medical University, Moscow, Russian Federation
[7]EVERSANA® INTOUCH Healthware, Milan, Italy
[8]Independent Consultant, Ascot, UK

Corresponding author:
Jean Bousquet. Institue of Allergology, Charité Universitätsmedizin, Berlin, Germany.
Email: jean.bousquet@orange.fr

Clinical and Translational Allergy and chaired the Global Initiative for Asthma. The session was moderated by Dr Elisabetta Ravot from EVERSANA INTOUCH® and Stefano Cantù, an independent consultant who was with the Healthware group at the time of the session (now part of EVERSANA INTOUCH®).

Differences in the digital health landscape in Europe

While the digital health ecosystem is evolving in Europe, it is currently fragmented. For example, in 2023, digital medical devices (DMDs) were defined and had a path to certification and/or validation in Germany, France, the UK and Belgium, but had no formal classification in Italy, the Netherlands, Catalonia in Spain, Luxembourg, Estonia and the Nordic countries.[3]

Where DMD and DHT definitions have occurred, gains have been made. For instance, in Germany, evaluation and reimbursement of Digital Health Applications (as Digitalen Gesundheitsanwendungen [DiGA]) was outlined in the 2019 Digital Healthcare Act. Evolving factors in this system include tying results from DHA to electronic health records and integrating DHA into care pathways.[3,4] In France 'Early access to reimbursement for digital devices' (Prise en charge anticipée numérique [PECAN]) was introduced in 2023. This is similar to DiGA legislation and enables existing and new DHTs to be scalable and reimbursed by health insurance companies.[5,6] In England and Wales, there is an Office for Digital Health with strategic aims including improving digital health approval and reimbursement systems, identifying tools that can improve health and wellbeing, and establishing data and evidence standards.[7]

An example of DHTs in cardiology

In cardiology, Omboni discussed, DHTs include remote home patient monitoring or telemonitoring (typically of blood pressure and electrocardiogram [ECG] output), remote monitoring of implantable devices, drug surveillance to assess adherence, telemedicine for rehabilitation, remote medical image acquisition and telerobotic surgery. 'Education is also crucial, particularly for prevention of cardiovascular disease' he said, citing diet and lifestyle websites and online discussion groups.

The certified web-based telemedicine platform Tholomeus® (Telemedicine and HOme teLemOnitoring for MEdical sUrveillance of chronic diSeases) was developed in 2007 by a group including Omboni.[8,9] The software, with both patient and healthcare professional (HCP) interfaces, amalgamates diagnostic tests from professional and home-based services, algorithms, medical reports and ongoing monitoring (e.g., blood pressure telemonitoring, cardiovascular telediagnosis

and pneumological telediagnosis including cardiorespiratory polysomnography).[8,9] 'In the last 10 years', Omboni reported, 'we have monitored more than 320,000 patients and have about 2000 HCPs'. However, he discussed, Tholomeus® is currently not reimbursed so uptake is smaller than it could be.

Tholomeus® can be used for research, as was carried out as part of the TEleMonitoring of blood Pressure in Local phARmacies (TEMPLAR) project registry that utilised Tholomeus® to collect and analyse 24 h ambulatory blood pressure monitoring data. A first analysis based on 20,773 patients (54% female) visiting community pharmacies revealed that almost half of the patients had sustained hypertension, including younger males with low cardiovascular risk and patients receiving antihypertensive medications, and that white-coat hypertension was more common in females.[10] These findings support tailored management of hypertension and are examples of where a single blood pressure reading in a general practitioner's (GP's) surgery or a pharmacy are not enough to provide a holistic view of a patient. The registry, Omboni discussed, 'currently contains ambulatory blood pressure data from almost 80,000 patients. 'Future analyses', he continued, 'will help better define the usefulness of telemonitoring to improve hypertension management in the community'.

An example of DHTs in respiratory medicine

Bousquet and colleagues developed and validated the free diary app MASK-air® (Mobile Airways Sentinel Network) for people with allergic rhinitis. The app includes four questions for patients to rate each day how much their allergic symptoms are bothering them overall, then individually, how much nose, eyes and asthma symptoms are bothering them. Patients also add medications and whether allergy symptoms affect work or study productivity. The app is currently available in at least 35 countries and in over 20 languages.[11–13] There are now over 58,000 users and 600,000 days of data.[14] MASK-air® includes daily electronic combined symptom-medication scores for rhinitis[15] and asthma (e-DASTHMA).[16]

One study utilising European MASK-air® app data from 13,122 users found that, contrary to recommendations, patients most often used medication to control, rather than prevent, symptoms, that they self-medicated with over-the-counter treatments and that they often combined treatments. For many, these measures did not lead to symptom control. This, the authors discussed, 'reinforced the conclusion that patients do not follow physician's prescriptions and attempt to control their disease by increasing medications'. This knowledge can be used by HCPs to help guide patients to adhere to their treatment plan to maximise drug therapy efficiency.[17]

Adoption of DHTs

DHTs, said Bit-Avragim, 'are becoming the mainstream of everyday lives and are enabling communication between

patients, HCPs and other players in the market such as insurance companies and digital health providers'. Access to telemedicine, Bit-Avragim suggested, should be offered via a variety of routes, such as a phone app or web-based system, and these systems should be regularly checked and improved for usability. Such systems should also be easily integrated with in-person care to ensure continuity.

Innovation in the digital health realm, said Bit-Avragim, needs to address a number of aspects, including easy and improved access to care, communication and education; technology integration; patient advisory boards; partnerships with HCPs toward predictive care and preventive medicine (a bottom-up approach); and decentralised health data exchange and storage. However, there are a number of needs and barriers surrounding adoption of DHTs, outlined by the experts in Table 1.

Table 1. Needs and barriers regarding adoption of digital health tools.

Needs	Barriers
Investment in health information technology	Health inequities
Promotion of patient education	Resistance to change
Enhancement of patient and provider/HCP communication	Lack of patient/HCP trust in digital solutions
Shared decision-making support	Data interoperability issues
Increase in transparency and data ownership	Regulatory hurdles
Data privacy and security	Privacy concerns
Patient-centric culture	Costs and complexity problems
HCP education	Digital divide
Incentives to use	Easy and open access to digital products
Clear guidelines	Lack of guidelines
Reimbursement	Lack of reimbursement
Evidence of safety and efficacy (clinical validation)	Generation/availability of evidence regarding safety and efficacy of digital health tools

Note. HCP: healthcare professional.

For Tunnah, the focus for DHTs 'is those that can really have an impact on the patient, whether it's better diagnosis or better treatment'. The way forwards for DHTs, he said, starts with investment and development alongside defining DHT access pathways, then includes clear reimbursement criteria and systemic adoption. This necessitates pressure from investors and key opinion leaders, as well as from patients, HCPs and patient advocates.
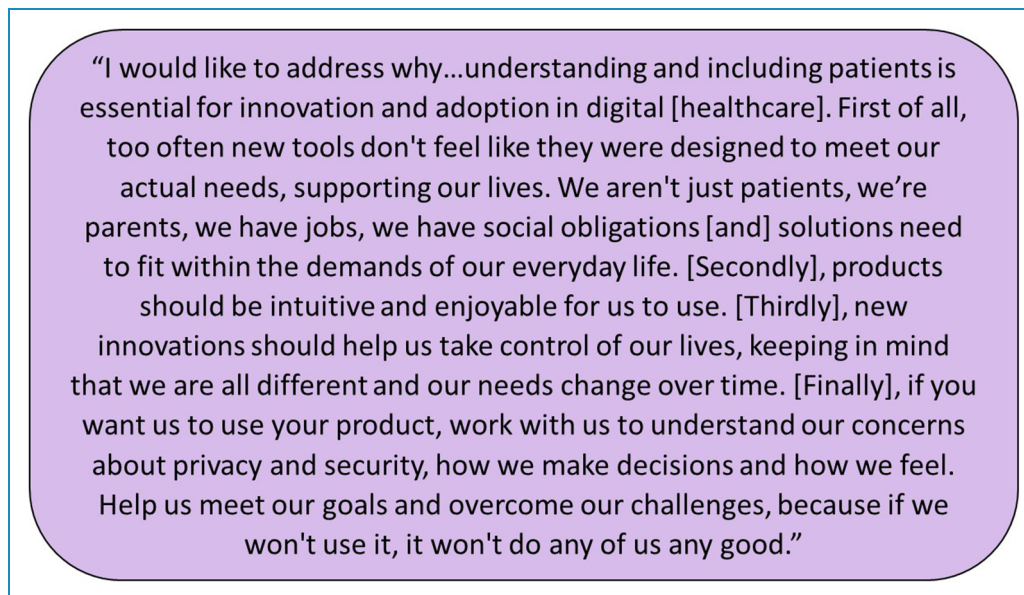
Another aspect of healthcare that DHTs may help with, said Bousquet, is targeting more precisely patients who need an expensive therapy. For example, there may be patients who have been prescribed a biologic for asthma control where use of the MASK-air® app shows that they are not benefitting, so the drug can be discontinued. The same technology may reveal patients that would be eligible for a biologic, such as those uncontrolled on their current asthma medication, that aren't receiving it.

Patient involvement in digital health

'The healthcare system', said Bit-Avragim, 'is a continuously learning ecosystem of patient-centricity…we're learning from the patient, we're giving back to patients'. In a time driven by technology, along with geopolitical, social and climate changes, patient centricity is key, she stressed, and must be a driving and foundational part of digital health. 'Patients are very good leverage to the doctor to implement DHT solutions', agreed Omboni. 'For instance … we developed a very simple app where the patient can measure their data and feedback and get in touch with their doctors. This was good leverage to increase their doctor's awareness'. Further, he explained, if the doctor is registered with the app, they can monitor the patient and get in touch if the patient's data points to such a need. To help illustrate patient needs, Bit-Avragim presented a testimony from Dimitri Katz, a researcher, designer and digital health consultant who lives with Type I diabetes (Figure 1).

Reflecting this testimony, Bousquet agreed that, when discussing phone apps in particular, 'the patient needs to understand what the app does and shouldn't need to have training to use the app and gain benefit from it'. However, he continued 'most [digital health] solutions have poor usability and most devices are not user friendly, affordable or scalable, so are refused by the patient and doctors'. Accordingly, said Omboni, we also need to improve the technology, increase connectivity and infrastructures, and educate and raise awareness among patients, because they still do not trust these kind of solutions. As patients are not always keen to continue to use these solutions, there is also the problem of sustained use. When I treat hypertensive patients, they are very enthusiastic at the beginning, they start getting the drugs, their blood pressure is good, then they stop taking the drugs, they do not show up and so on. The same for telemedicine.

'Usability tests and interaction over user interface/user experience design are also very important', explained Bit-Avragim. 'Startups and digital health companies

"I would like to address why…understanding and including patients is essential for innovation and adoption in digital [healthcare]. First of all, too often new tools don't feel like they were designed to meet our actual needs, supporting our lives. We aren't just patients, we're parents, we have jobs, we have social obligations [and] solutions need to fit within the demands of our everyday life. [Secondly], products should be intuitive and enjoyable for us to use. [Thirdly], new innovations should help us take control of our lives, keeping in mind that we are all different and our needs change over time. [Finally], if you want us to use your product, work with us to understand our concerns about privacy and security, how we make decisions and how we feel. Help us meet our goals and overcome our challenges, because if we won't use it, it won't do any of us any good."

Figure 1. Patient testimony.

sometimes neglect the very important part of testing their solutions, inviting and integrating patients and building the patient as experts in testing'. On the other hand, Bit-Avragim reported that several large pharmaceutical companies now have patient advisory boards. Within these, she discussed how 'initial design is tested and used by professional patient advocates who give feedback that they can share directly with the designers and providers of these digital solutions'. With these points in mind, using an illustration of stakeholder roles in digital health initiatives (Figure 2), Tunnah stressed the importance of, from initial DHT development, patient involvement in identification of unmet needs and development of solutions.

Bit-Avragim described how 'patient groups, expert groups and communities are building their own social media [so they can] participate and share specific, synchronised, anonymous data with research centres or other institutions'. 'This means', she continued, 'that when an initiative is launched, patients are very much open to share this information because they know it will contribute to future research of, for instance, groups of patients with rare diseases or severe symptoms'.

One example of a revolutionary company in the patient realm is PatientsLikeMe. This website and forum was initially started to connect people with amyotrophic lateral sclerosis, a condition experience by the brother of the website's founders.[18] 'They organised themselves as a community and shared knowledge', explained Bit-Avragim, with initiatives such as this leading to development of the term 'expert patient' or 'patient advocate'. 'Normally', she said, we know the top down approach where the HCP spends time educating patients, but from our experience we've seen that patients don't use the apps, they're not interested or they forget about taking medications. This

becomes totally different when they hear the stories of someone who has the same condition as them.

PatientsLikeMe, which are now also a clinical research organisation, 'work intensively with pharmaceutical company, HCPs and insurance companies' to ensure that their voices, their experience and management of the healthcare system will be implemented'.[19] However, Tunnah highlighted how we need to recognise that the patients that come forward, and who will give their input, is a particular group. They tend to be very empowered and more health literate. How do we ensure when we are co-creating and simplifying solutions that we're doing so for the benefit of all patients and not just this subgroup?

Patient organisations may be another powerful way to promote digital health initiatives, suggested Bousquet. 'You have one physician for 10 pharmacists and nurses, 100 social workers and 1000 patients. So if you work with patient groups, you are working with far more people'. He explained, for example, how if a patient organisation promotes a particular DHT available at a pharmacy, many more patients may request it from the pharmacist and it's more likely to be adopted by them than if one HCP requested it. Another patient-utilising initiative is regarding drug repurposing. 'Here', Bit-Avragim explained 'the patient community plays an important role sharing information and usability of a medication that is already on the market then reused for different purposes'.

The challenges of digital health for HCPs

For HCPs, discussed Omboni, DHTs allow constant patient monitoring, hospital-like quality tests and medical reports, decentralisation of screening and the possibility of
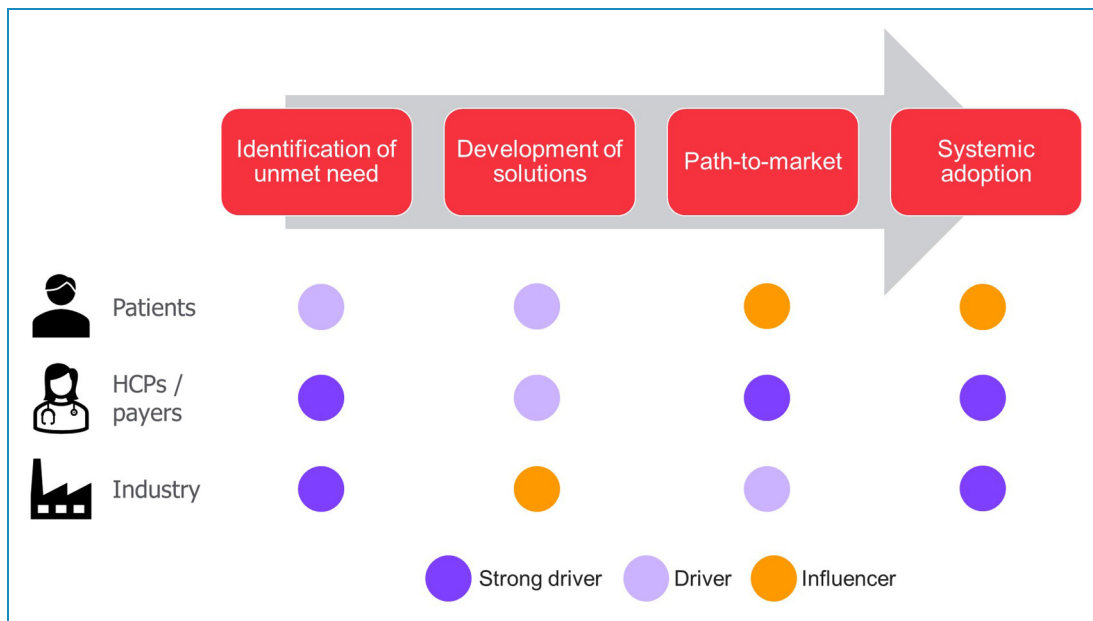
Figure 2. The roles of stakeholders in digital health initiatives. Dark purple: strong driver; light purple: driver; orange: influences the driver HCPs, healthcare professionals.

managing distant patients. This should 'increase the ability of managing more patients, more efficiently and increase the possibility to create networks with different specialists, not only doctors'. However, HCP uptake of DHTs is key. With DiGA in the German market, Bit-Avragim explained,

> we have this influential legislation and fantastic opportunities. HCPs just need to prescribe the app and then the patient will use it, which will help, but when I speak to my colleagues, they've never heard about it. The HCPs should be trained to know about these solutions and its valuable outcomes so as to be motivated to offer this to their patients. If we go to the patient as the end user, we are losing something along the way in the system. HCPs and patients need simple education, simple training and simple access to information.

With such large HCP involvement, Tunnah discussed how, when providing a DHT

> HCPs are right at the forefront, they can see where the unmet need is and where the problems are. They're the key drivers of what we should be developing. HCPs, key opinion leaders in particular, along with policymakers, are the ones with the payers that can really build the market and systemic adoption. (Figure 2)

HCP-centricity needs to be considered, he continued,

> in how we design these things and get them to scale. There's a risk that if we don't take account of what the HCP wants and keep them on board, we're pushing patients into a system and they're going to hit HCP resistance. If you

put power in the hands of the patient, how do we make sure that's not putting extra burden on the HCP?

As an example, he described how, in diagnosis, there's 'a plethora of DHTs coming through that are saying' 'you might have this or that'. It's typically not a formal diagnosis, because the guidelines in certain disease areas define diagnosis, but it's starting to feed people in for that formal diagnosis. That's good in some ways but it's bad in others because you start to clog up the system. For example, in the UK right now I keep seeing adverts on TV for remote ECG. I suspect that it's not actually that popular with cardiologists because you get a bunch of people going,

> 'that's really cool, I'll do that, oh, there's something not right, I'm going to my doctor' and cardiologists are potentially flooded with all these people and then have to send them for a proper ECG to see what's going on. So how do we take both sides with us on this journey in a useful way?'

Barriers to adoption of DHTs

Tunnah warned that

> it's quite a tough time for digital health right now. The investment environment is not what it was 2 years ago and there's real pressure on health systems with whatever they are using – drugs, devices, digital health – to show they're generating short-term value within the system.

One issue with DHTs, said Omboni, is that 'quality of care 'may be' perceived as poorer compared to traditional care, but

this is not true if these solutions are certified and submitted to a thorough validation process that ensures safety for the patient'. For example, studies Omboni carried out during the COVID-19 pandemic lockdowns showed that certified home tests can be performed with a good degree of accuracy.[20] This is of importance, because, he reported, some hospitals still refuse telemedicine facilities in the community and some patients are reluctant to rely on this kind of test.

> "Integration 'of DHTs' with existing healthcare systems is also very important," discussed Omboni, "training and education is fundamental, as is infrastructure and technology implementation and reimbursement.[21] If you do not have policies," he explained, "you have heterogeneity where everyone is using a 'different' solution, the solutions do not talk to each other and the patient is not managed in the proper way. In Italy, the national platform of telemedicine is planning to provide solutions for public health hospitals because 'currently they' are spending a lot of money to buy solutions from different companies and this is not good for interoperability. The main aim is to make public hospitals ready to provide these solutions, this will also allow private providers to get in touch with this platform and to provide these solutions. Scalability is also very important because we need solutions that can easily adapt to patients"**2**.To be sorted out in layout I presume, some quotations have "", some have '', some are in blue boxes with or without quotation marks and some aren't. These need to be formulated one way..

Access and use equity were particular aspects of DHT adoption the experts discussed. According to Omboni, 'demolition of cultural and social barriers is needed to ensure equity. We need to reach everyone, not only people that are able to use a computer, but also elderly people, fragile people, people living in rural sites'. He discussed how 'telemedicine is very important because some countries or areas within countries don't have hospitals and qualified doctors available everywhere so it's important to think about specific solutions'. In some areas though, access to technology may include very simple barriers such as a lack of batteries to power digital health-linked devices. To address this within cardiology, one solution was to develop a solar-powered blood pressure monitor.[22] As an example of another barrier, Bousquet provided his experience when carrying out a study in Portugal where many older people did not have a smartphone through which they could access an app needed for the study. The very simple solution, he suggested, was to provide that smartphone.

Bit-Avragim also highlighted the need to 'bring DHTs to a location where it's comfortable, where everyone can stop by'. Indeed, discussed Omboni, in many department stores and pharmacies in the USA, for example, there are kiosks where patients can test their blood pressure then either take their data home or, via the kiosk, get in touch with an HCP. A benefit of such kiosks is that, unlike smartphones, they can't

be stolen or sold. For Tunnah, this sparked the idea that apps could be turned into simpler telehealth measures.

> If you think about the MASK-air® app and take it into a lower tech environment, is there a version that still works? The four asthma questions could be four text messages or it could be four things asked in a kiosk. These are really good questions to ask when you think about scaling these solutions.

Solutions do not need to be as permanent as kiosks in stores. Ravot described an initiative recently deployed in Italy by the Heart Care Foundation and the National Association of Hospital Cardiology Physicians named 'Banca del Cuore' ('The Bank of the Heart').[23] This includes a large truck where, she explained, 'you get registered, you receive comprehensive cardiovascular screening and your data is kept safe and accessible for your future'. In places where this was set up, Ravot reported how 'there was a long line of people, motivated by the opportunity to access a medical checkup easily and cost-free. They saw other people waiting for their turn and this was a catalysing factor'.

Use of DHTs may also be in issue for certain HCPs such as pharmacists. Omboni discussed how, with regard to cardiovascular issues in Italy, after the COVID-19 pandemic, 'there are huge waiting lists and a huge increase in the number of tests performed in pharmacies'. However, he described that even with pharmacist training, it can be very difficult to obtain tests in some areas 'because, for the pharmacist, it's something that's a secondary activity'.

Using incentives and shared decision-making to increase DHTs use

'What are the incentives for HCPs, families and patients to use or not use these kind of solutions?' asked Bit-Avragim. 'There are two important aspects that can be useful', said Omboni, 'one is rewarding and the other is gaming'. For example, in the MASK-air® app, the incentive to use it every day is provision of pollen counts and pollution data.[13] 'In Dundee, Scotland', reported Tunnah, the use of an incentive has pretty much eradicated hepatitis.

> Attendees at major drug rehabilitation centres were told 'we're going to give you a food voucher if you get tested and if you get your friends to get tested, we'll give you more food vouchers.' So they got a cascade and got all these people tested and treated and pretty much wiped hepatitis out with a very simple incentive programme.

Bit-Avragim commented how 'communication and collaboration between the HCP, the caregiver and the patient is essential to build trust. Once trust is there, then the solutions will be adopted and the treatment will become more

successful'. 'Many adherence problems stem from a lack of shared decision making' agreed Tunnah, 'if it's not there at the beginning, you can do everything you like to say "take your drug", but it won't work'. 'An app can bring major help for shared decision making', said Bousquet. For example, for a patient using the MASK-air app[®],

> if they are not well and you show them (via their app use) that they have 17% of errors this helps them to understand, without an education system, that asthma control is easy. Additionally, the physician has a better assessment of the daily evolution of the patient.

Of note though, he continued,

> in the future, there may be reimbursement according to data on apps. Payers will need to have some proof that the expensive drugs they're making are being used correctly. When I see biologics used in hospital, 50% of patients are not adherent. We're working on a mathematical model to assess whether adherence with the app can be associated with adherence to treatment and if we can have some insight after 1 week.

Safety, privacy and liability with DHTs

Another important point to consider with DHTs coming to the market, highlighted Bit-Avragim, is patient privacy and security, as well as consideration around visibility and adoption.

> Negative scenarios experienced in some DHT solutions include telehealth platforms that ignore patient feedback regarding security, privacy or usability, thus eroding a patient's trust in the system, and overly aggressive data collection, leading patients to suspect their privacy is being violated. As such, General Data Protection Regulation is at the very heart of any digital solution that is coming to the market.

Also of need for consideration, said Bousquet, 'is liability for the physician because if a physician uses an app and there is an exacerbation and the app doesn't see the exacerbation, then there may be liability'. Tunnah agreed, describing how 'many years ago, I did social media pharmacovigilance training at one of the big pharmaceutical companies and their view at the time was, 'we don't want to monitor because we might see things''.

There is also the issue of anonymising data, explained Bousquet, 'because you can only do pseudonymisation and using many tricks you can eventually get some names'. 'Another problem I've heard', added Tunnah 'is patients deanonymising trials because of sharing on social media what's going on, so you have to have some guardrails around that as well'.

One need shown in Table 1 is that of evidence and clinical validation of safety and efficacy of DHTs. This is a mandatory requirement according to European Union law for all medical devices, including software and digital tools for managing patients.[24] However, it has been noted that such testing may be overlooked in the rush to supply the latest DHT, especially when it can be rapidly produced and disseminated.[25]

Funding for and development of DHTs

Bousquet discussed how he raised funding for running his app, which currently costs around €200,000 a year. 'My problem in the beginning was not to make money, but to make science. I wanted to know if I could learn something with an app. I had no knowledge about informatics and I wanted simplicity'. He described how, following studies using the four MASK-air® questions, he partnered with a pharmaceutical company who wanted to understand how their rhinitis drug could be used better. Based on the results of these studies, he received new grants to continued use and development of the MASK-air® app.

'What you describe', said Tunnah,

> is the way the best entrepreneurs do things. They get obsessed with the problem and focus everything they can around the solution to that problem. That to some degree has been the curse of digital health in the last few years, there's been so much money and so much activity, there's too many solutions trying to find a problem, rather than, 'let's start with the problem and think about what the solution is'. If we look at broader digital health.'

Tunnah continued,

> we tend to focus on the application, the thing we're trying to build for the patient and HCP, and we also know there's value in the data. But what if we flip that thinking and thought, actually, the most valuable thing here is the data. If we start with, 'this is the data we need' and then think about what's the right way to get that rather than starting with the application, that's when you get the highest quality data at scale and there's incredible value.

Moving forward with digital healthcare solutions

'Everyone who has access to the internet and owns a mobile device is consuming lots of information in their daily lives,' said Bit-Avragim; therefore, 'consumerisation of healthcare is not the future, it is reality. I hope, thanks to digitisation, access to healthcare will eventually become fully integrated into "traditional" channels of provider-patient communication'. There is also, described Tunnah, 'a hotbed of companion devices that sit alongside traditional medicine that help the patient take a treatment in the right way, monitor adherence and collect data'. These can be used, he said, 'to understand where a treatment is working, where it's not, and where we

need to optimise'. 'We also have to look at the role of big technology companies in providing those solutions', said Bit-Avragim. Indeed, Tunnah described using Figure 2 how 'industry also has a lot of expertise around different disease areas, they can see where the unmet need is and what's needed alongside the medicine'.

'We need to change to a semi-industrial solutions, otherwise DHT gains will be lost', remarked Bousquet.

> In Bonn we are going into artificial intelligence (AI) so our new guidelines in rhinitis will be digital enabled, AI assisted, person-centred care. I want to add AI to guidelines for many things, number one is to do an algorithm so that in 2 minutes or less, you get all the information from the computer in any language. We also recently found that AI can inform guideline developers of questions that were not raised by experts. I want to do something with app data analysis so that when a patient gets some symptoms, the AI-generated app feedback goes first to them and if the symptoms continue, there is a link with the physician.

As Bousquet mentioned, another arena for digital healthcare opportunities and challenges is in the realm of AI where a computer model that has learnt from *a priori* information is used to make decisions. This has been used, for example, to help analyse ECGs[26] and to provide a prognostic model for predicting pneumonia outcomes.[27] Of note though, there is a need to understand biases that can occur using AI algorithms based on unequal health data.[28]

Conclusion

Cantù concluded by saying that

> at the end of the day we are introducing something new that requires a new behaviour from all the actors. HCPs and hospitals need to rethink how HCPs are working today because otherwise we are expecting them to spend a lot of time looking at data and running analyses and not visiting patients or on telehealth. They need to think how to introduce telehealth within their current routine so that they have a certain amount of time they can devote to that activity. Otherwise, it would be only something on top.' Limitations to this discussion include that the authors are speaking predominantly from a European standpoint and that the issues under discussion were limited by time and by personal experience and knowledge. Further discussion could include a broader range of input from global specialists representing other continents and experiences.

References

1. Digital Therapeutics Alliance. Digital therapeutics: reducing rural health inequalities. https://dtxalliance.org/wp-content/uploads/2021/01/DTA_Rural-Health_r13_110220.pdf (2020, accessed 10 July 2024).
2. U.S. Food & Drug Administration. What is digital health?. https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health (2020, accessed 10 July 2024).
3. Healthware Group (now part of EVERSANA INTOUCH®) and Digital Therapeutics Alliance and Healthware. DTx policy pathways: The evolving scenario in Europe. https://3783108.fs1.hubspotusercontent-na1.net/hubfs/3783108/DTxPolicyReport/DTA-HW_DTxPolicyPathways_June23.pdf (2023, accessed 10 July 2024).
4. Vereinigungen K. Digital health applications (DIGA). https://www.kbv.de/html/diga.php (2023, accessed 10 July 2024).
5. République Française. Decree No. 2023-232 of March 30, 2023. Relating to the anticipated coverage of digital medical devices for therapeutic purposes and medical remote monitoring activities by health insurance under article L. 162-1-23 of the code social security. https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000047377863 (2023, accessed 10 July 2024).
6. Ministry of Health and Prevention. Prise en charge anticipée numérique (PECAN). https://gnius.esante.gouv.fr/fr/financements/fiches-remboursement/prise-en-charge-anticipee-numerique-pecan#:~:text=Le%20dispositif%20cible%20les%20dispositifs,un%20remboursement%20de%20droit%20commun (2023, accessed 10 July 2024).
7. National Institute for Health and Care Excellence. Office for Digital Health 2023. https://www.nice.org.uk/about/what-we-do/digital-health/office-for-digital-health (accessed 10 July 2024).
8. Biotechmed. What is Tholomeus®. https://www.tholomeus.net/Default.aspx (2023, accessed 15 February 2024).
9. Omboni S, Campolo L and Panzeri E. Telehealth in chronic disease management and the role of the Internet-of-Medical-Things: the

Tholomeus® experience. *Expert Rev Med Devices* 2020; 17: 659–670.

10. Omboni S, Mancinelli A, Rizzi F, et al. Telemonitoring of 24-hour blood pressure in local pharmacies and blood pressure control in the community: the Templar Project. *Am J Hypertens* 2019; 32: 629–639.

11. Sousa-Pinto B, Eklund P, Pfaar O, et al. Validity, reliability, and responsiveness of daily monitoring visual analog scales in MASK-air®. *Clin Transl Allergy* 2021; 11: e12062.

12. Sastre J, Del Cuvillo A, Colás C, et al. Validation of the MASK-air app for assessment of allergic rhinitis. *Allergy* 2020; 75: 2958–2961.

13. MASK-air. https://www.mask-air.com/ (accessed 10 July 2024).

14. Bousquet J, Anto JM, Sousa-Pinto B, et al. Digitally-enabled, patient-centred care in rhinitis and asthma multimorbidity: the ARIA-MASK-air(®) approach. *Clin Transl Allergy* 2023; 13: e12215.

15. Sousa-Pinto B, Azevedo LF, Jutel M, et al. Development and validation of combined symptom-medication scores for allergic rhinitis. *Allergy* 2022; 77: 2147–2162.

16. Sousa-Pinto B, Jácome C, Pereira AM, et al. Development and validation of an electronic daily control score for asthma (e-DASTHMA): a real-world direct patient data study. *Lancet Digit Health* 2023; 5: e227–e238.

17. Sousa-Pinto B, Sá-Sousa A, Vieira RJ, et al. Behavioural patterns in allergic rhinitis medication in Europe: a study using MASK-air(®) real-world data. *Allergy* 2022; 77: 2699–2711.

18. PatientsLikeMe. Patients Like Me. https://www.patientslikeme.com/?format=html (2024, accessed 10 July 2024).

19. PatientsLikeMe. Research manuscripts bibliography. https://patientslikeme-bibliography.s3.amazonaws.com/ PLM%20Research%20Manuscripts%20Bibliography.pdf (2019, accessed 15 February 2024).

20. Omboni S, Ballatore T, Rizzi F, et al. Telehealth at scale can improve chronic disease management in the community during a pandemic: an experience at the time of COVID-19. *PLoS One* 2021; 16: e0258015.

21. Omboni S, Padwal RS, Alessa T, et al. The worldwide impact of telemedicine during COVID-19: current evidence and recommendations for the future. *Connected Health And Telemedicine* 2022; 1: 7–35.

22. Parati G, Kilama MO, Faini A, et al. A new solar-powered blood pressure measuring device for low-resource settings. *Hypertension* 2010; 56: 1047–1053.

23. Foundation HC. Banca del Cuore. https://www.bancadelcuore.it/ (2024, accessed 10 July 2024).

24. EUR-Lex. Regulation (EU) 2017/745 of the European parliament and of the council of 5 April 2017 on medical devices. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745 (2017, accessed 10 July 2024).

25. Mathews SC, McShea MJ, Hanley CL, et al. Digital health: a path to validation. *Digital Med* 2019; 2: 38.

26. Somani S, Russak AJ, Richter F, et al. Deep learning and the electrocardiogram: review of the current state-of-the-art. *Europace* 2021; 23: 1179–1191.

27. Shin HJ, Lee EH, Han K, et al. Development of a new prognostic model to predict pneumonia outcome using artificial intelligence-based chest radiograph results. *Sci Rep* 2024; 14: 14415.

28. Kocak B, Ponsiglione A, Stanzione A, et al. Bias in artificial intelligence for medical imaging: fundamentals, detection, avoidance, mitigation, challenges, ethics, and prospects. *Diagn Interv Radiol* 2024, online ahead of print.