CAMBRIDGE
DESIGN
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The Future of Diagnostics

Digital Health Monitoring

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In a world where vast amounts of personal data are constantly being collected via apps, genetic sequencing and innovative cloud-based devices, healthcare diagnostics is rapidly moving towards a highly-personalised patient-focused service. It is yet to be seen how this will evolve. How will the healthcare professional be affected when devices and data analytics could potentially offer earlier and more accurate diagnoses? Does this empower the patient, or leave them at risk of unexpected consequences? We explore this highly topical and complex subject.

”The future of diagnostics and digital health monitoring will be centred firmly around the patient.”

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...and your phone says you had 2.4 hours of 'high quality' sleep and it's time to take your weekly blood sample; while making breakfast you remember to attach the blood sampling device and wait for the colour change – all done. You slot the sample (a thin cartridge) into your 'Home Hub' – a device that resembles something between a coffee maker and a toaster, but this is no kitchen appliance – this is the latest technology in digital health monitoring. It's plumbed into your life, looking for tell-tale biomarkers in urine, saliva and blood samples you feed it. Sleep data and information about last night's run are logged and heading somewhere to be 'processed'. The only set-up this system required was a single saliva sample sent in the post – the insurance company needed it to assess your 'risk factors' – something about 'genetic sequencing' which was necessary to qualify for lower premiums.

You've been using this service for two years now, and each month you get notified of the results on your phone. These are usually all green - normal, but today one shows an abnormality. You look closer and your urine samples show elevated protein, which has been rising slowly for the last six months. Seconds later a message comes though with details about a personalised treatment plan.

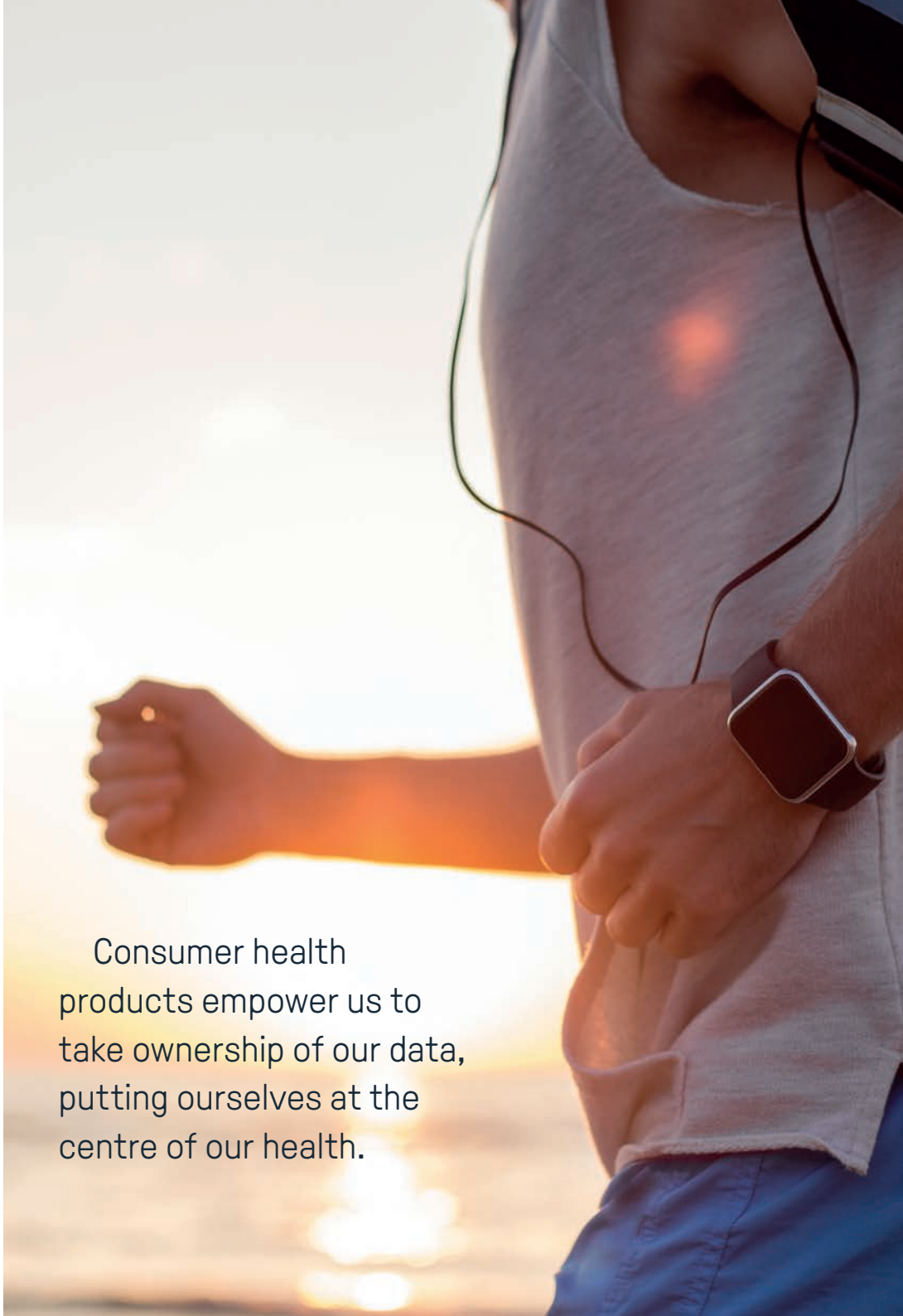
To many people, this view of health monitoring is probably unsettling and quite scary; an automated system collecting and analysing your highly personal information and telling you whether you are unwell or not. But elements of this are already here. Health apps are commonplace; from those that track sleep, to how much fat you've burned and what food you're eating. There are even predictive cardiovascular tests used to score your 'heart age' based on a simple set of questions [1]. Although they may not be overly accurate, these consumer products empower us to take ownership of our health and our data.

Next Generation Sequencing (NGS) has the potential to provide enormous detail about your genome, enabling us to determine what genetic disorders you might be at risk from, to how your body will respond to certain medicines. Deciphering the vast amount of information remains a massive challenge, and today scientists can only interpret a fraction of what it all means, but advances are being made all the time to gradually unlock more and more clinical value.

Data gathering

Today's consumer health apps and genetic sequencing are capable of harvesting vast quantities of data about you, but on their own they may not provide enough information to make informed clinical decisions. Combined with medical records, lab and point-of-care tests and compared with data sets derived from other similar patient populations, the predictive value could be huge.

But who or what is able to make sense of it all? Doctors do not want uncertain information to sift through and they do not have any spare capacity to review non-urgent test results with their current workload. In often underfunded and over-burdened healthcare systems they just want objective, clinically relevant information to make accurate treatment decisions. Instead it's the Googles and Amazons of the world, utilising data analytics, machine learning and Artificial Intelligence (AI) that know how to uncover correlations from observations and measurements about you.



Consumer health products empower us to take ownership of our data, putting ourselves at the centre of our health.

Evolving structure

The potential for algorithm-based healthcare tools is enormous, and deployment is happening at a rapid pace. For instance, in the UK, the NHS has started trialling AI based software tools to support doctors identify patients at risk of cancer. Diagnosing cancer is extremely difficult as each type has its own signs, symptoms and risk factors. The NHS believes the app called 'C the Signs' which is linked to the National Institute of Health and Care Excellence (NICE) guidelines, will help diagnose multiple different types of cancer much earlier to speed up decision-making and improve the chances of survival [2].

Currently this service is only available to a limited number of GPs, but it may only be a matter of time before platforms similar to this will be available to patients themselves. Moving towards this is what the team at Amazon's Alexa is doing: Public Health England launched the 'Breastfeeding Friend' on Amazon's Alexa [3]. Using evidence-based advice, it claims to provide 24/7 on-demand advice to support anxious parents.

Qualitative apps and software tools are all very well, but they are only as good as the symptoms which the user provides, as these can be subjective and may indicate a range of potential conditions. More clinical based tests are being launched, such as the FDA approved software application on the Apple Watch, used to measure ECG and signs of arrhythmias. Wearable glucose monitoring devices that measure optical and electrical properties of the skin rather than using finger prick blood are also showing promise. These examples of non-invasive, personal devices are certainly disrupting our traditional understanding of what a 'medical device' is. But valuable biomarkers hide in our blood, saliva and urine, so what's next for in vitro diagnostics (IVDs)?

De-centralised in vitro diagnostics

IVD tests start with sample collection. If you've done an 'ancestry' test you will know that home saliva collection is quite simple and standard. Urine is also fairly easy and the UK is sending free chlamydia test kits through the post for 16 - 24 year olds, offering a discrete service for home urine collection and on-line results reporting [4]. However, home blood collection is much harder due to its invasive nature. LabCorp in the US offers 'Lab-in-an-Envelope' using dried blood specimens from finger prick blood [5], but much larger blood volumes are needed for many tests and diagnostic systems. Several new devices are on the horizon and capable of collecting up to 0.3ml - enough blood for meaningful tests such as a lipid panel for cardiovascular disease, but they are still limited to capillary blood. Many in-vitro diagnostic systems need much larger volumes or specialist skill to be done properly.

Maintenance of specimen validity between the patient and test centre also remains a challenge; so maybe self-collection is not the future, maybe a mobile or automated phlebotomist is more appropriate, integrated with existing door to door specimen collection services?

Changing patient behaviour

In this evolving healthcare system, personalised health apps, non-invasive consumer-level diagnostic services and home IVD testing have the potential to change patient behaviours and habits. This is particularly important for the management of chronic conditions because healthcare costs associated with lifestyle related illnesses are set to increase at an alarming rate. Worldwide obesity rates have almost tripled since 1975 [6] and in the UK, the NHS estimates it spent £6.1 billion on overweight and obesity related illness in 2015. This is projected to rise to £9.7 billion by 2050 [7].

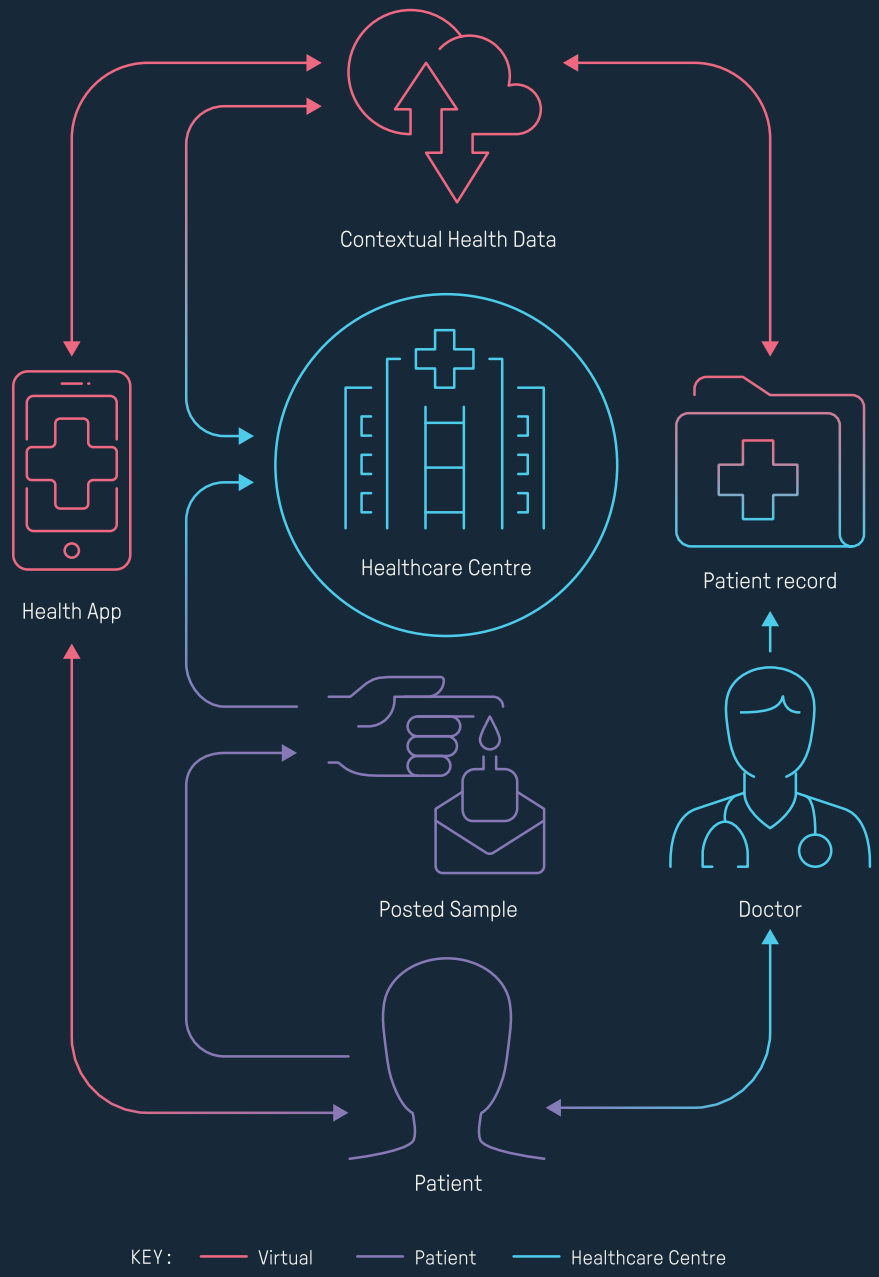
Historically programmes to fight lifestyle illnesses have not been very successful as poor design, inconvenient and infrequent access has resulted in low adherence. Today, new and innovative programmes involving smartphone apps and virtual coaches are being piloted to tackle this challenge, such as the personalised weight loss service by OurPath in partnership with Roche Diabetes [8]. These tap into patient's everyday lives to empower the consumer with their own real-time health information.

Sharing data

How can this help your health? All this data collected from apps, devices and services could grow to provide overseeing 'Contextual Health Data'; data that is processed in context of your own personal health records. Data analytics will churn away making sense of it as a whole, rather than as individual test data points.

For this to happen Electronic Health Record (EHR) interoperability is critical so that different devices and software applications can easily share information. A common language and communication standards will allow information to flow between hospital labs, mobile clinics, and pharmacies. These 'open' health records mean the right user can access test results at the right time, enabling more effective partnering and collaboration between specialists to further improve patient care.

The patient could review their health information too - just like internet banking, where everything is there to see – next check-up due, previous examinations, physio treatment, x-ray images – the works. Your health data is no longer shrouded in secrecy, but there for you to understand and to influence your behaviour!



Data security

But it is personal information that could be used against your interests. A recent survey found that 30% of patients would change healthcare provider if their protected data was compromised [9]. Data security is paramount to instil trust in the system and security breaches are commercially devastating – which is why companies like ClearDATA have developed secure and compliant interfaces to cloud-based systems. Roche's Navify product uses data stored in the cloud that is hosted by Amazon Web Service (AWS) and provides digital decision support to oncologists. This cloud-based system is designed to streamline and standardise oncology workflows by collating patient data from medical history records, biomarkers, radiology images, etc. that have previously been a labour intensive and time-consuming process [10].

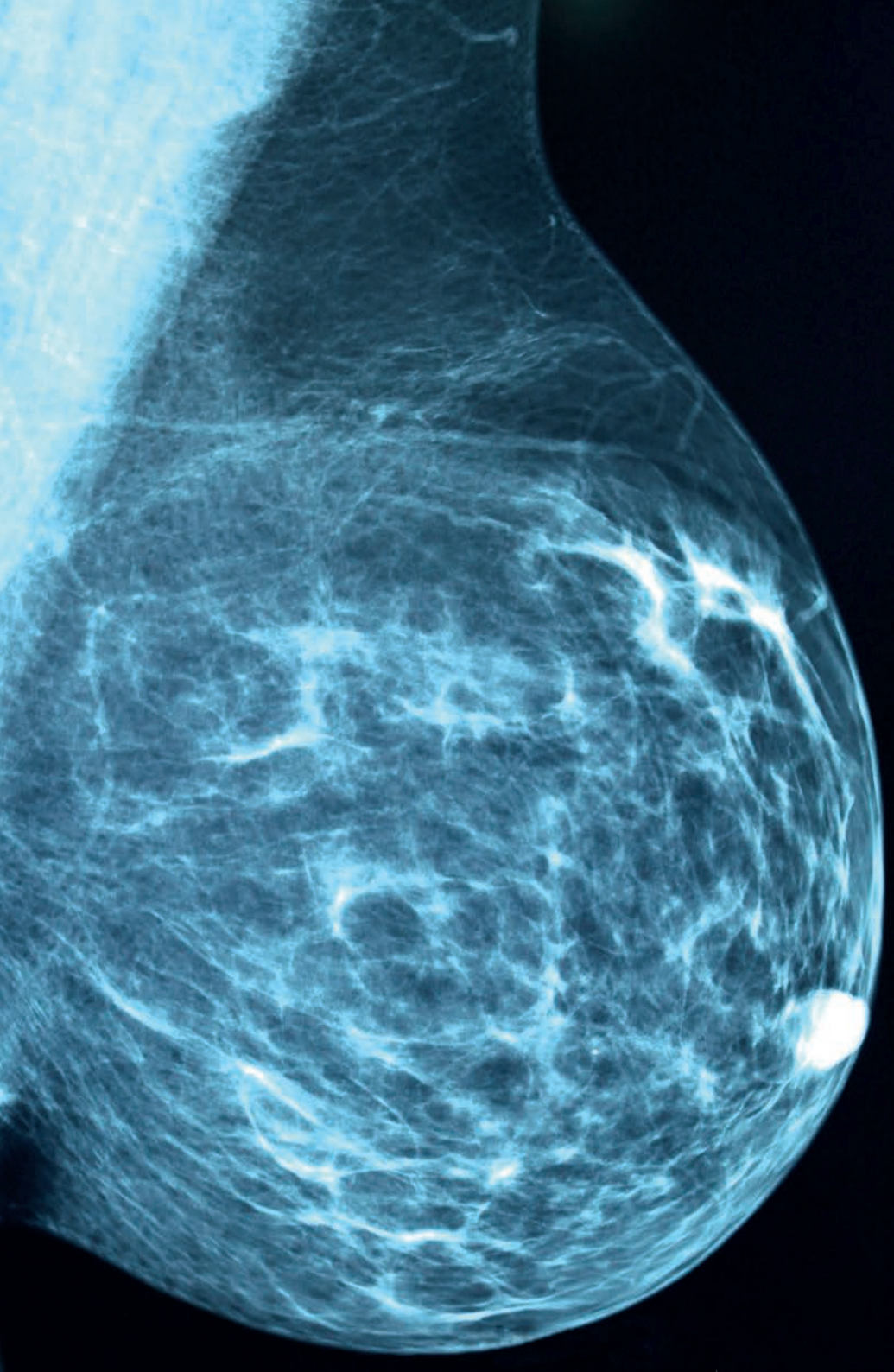
Data regulation has moved fast to support the interests and needs of patients: all electronic data related to an individual's health is considered 'Protected Health Information' (PHI) and is governed by standards such as HIPAA in the US and GDPR in the EU – legally enforceable requirements which have real teeth to ensure compliance. The UK government has also recently released an "initial code of conduct for data-driven health and care technology". Although currently voluntary, it wants data-driven technologies to be harnessed in a safe, evidenced and transparent way [11].

Data ownership

Who will really own our data? You are empowered by being able to review it, the clinician has access as they always have done, but it's the big corporations that are starting to make sense of it all. They have developed and own the algorithms, and they generate the reports. It appears we are prepared to allow companies to have our data in return for sharing their insights derived from it. But just like the recent Facebook issues [12], maybe we are unaware that our data is a highly valuable asset? Used appropriately, it could provide insights into populations to identify new product opportunities, tailored for highly specific and real user needs. However, in the wrong hands, there are more sinister implications; insurance providers and even governments may use it to incentivise and control how people should live their lives.

Data quality and the need to regulate

As algorithms get more accurate, perfected over decades of learning, will we even need the clinician in the decision-making process? Babylon claims their AI scores are better than doctor's decision making in certain cases, but this is highly disputed by doctors [13]. Ultimately, will the algorithms make the decisions or inform the decisions? If it's the former, what if the clinician disagrees, and chooses to follow a different pathway? Who is liable if the patient is mistreated?



Some algorithms might use high quality data sets, but others could be plagued with errors and use incomplete data derived from dubious sources. False positive results not only cause distress and risk unnecessary treatment but they can also cost the healthcare provider more than is saved by early diagnosis. Sophisticated algorithms by their very nature will be complex to understand, even opaque to most people, aptly named “black box” models. And what if the algorithm is not fixed? AI and machine learning techniques allow algorithms to dynamically improve as they are used, continuously updating and evolving as they access more and more data. These may pose significant problems when it comes to validating their output to ensure they are safe and effective. The regulatory bodies such as the FDA and MHRA which regulate medical devices (software algorithms included) currently see this as problematic and it is unclear how they can be validated using current methods. This is a hot topic right now, and one that will be fiercely debated.

Who (or what) decides?

Used appropriately, it is easy to see how “black box models” can automate tasks, improve the information available and reduce costs. Kheiron Medical is one such company that uses deep learning software to support radiologists screen for breast cancer. The team has trained their algorithms to process mammographic images and provide results within seconds with performance better than the average human radiologist [14].

This tool is designed to be a ‘second reader’ in the decision-making process, but as with all great things, there is a risk of becoming over-reliant on its use before the technology is fully developed; it would be very tempting to make increasing efficiencies in cash-strapped healthcare systems without ensuring the necessary rigour and check are met. The unintended consequences particularly concern the role of the clinician in the decision-making process: traditionally doctors have been in charge, able to make life and death decisions using their expert knowledge and years of training. The thought of being seen by an untrained ‘carer’ who blindly follows orders from a machine is beyond most people’s comfort zone.

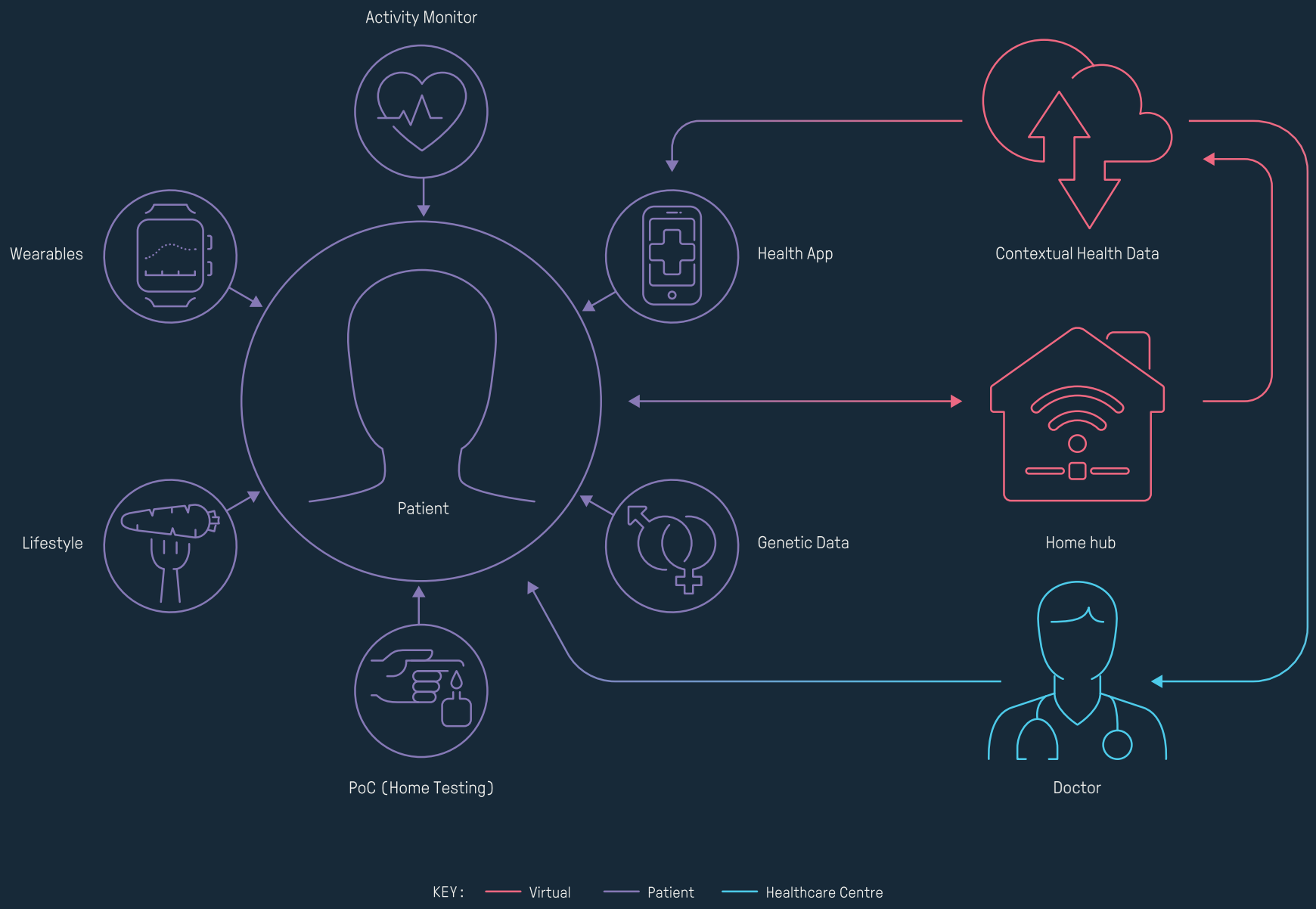
The future of patient empowerment

The future of diagnostics and digital health monitoring will be centred firmly around the patient. A variety of different biosensors and discrete IVD tests will be working away in the background, continuously streaming data to open access health records in a secure cloud for processing. This information will be blended with other data to enhance the predictive value and abnormalities will be picked-up sooner than ever before - even before the patient feels unwell.

These highly interoperative systems will alleviate tremendous pressure from front line medical staff as well as enabling workflow efficiencies; patients will be empowered to own their 'health status' and automatically advised when to see a doctor based on measured evidence. These efficiencies will enable limited healthcare funds and resources to be deployed fully to treat those who are actually unwell, allowing the patient greater access to better healthcare when they really need it. In return for this, patients will consent to their data to be anonymised and shared, allowing access by organisations interested in drug discovery, targeted therapeutics and large population studies for better predictive monitoring.

However, medicine is not an exact science and even the best diagnostic devices, digital health apps, and data analytics will not replace the human doctor any time soon; complex medical histories and life-critical cases will still require human interpretation and intervention.

Highly connected consumer based, point-of-care devices will revolutionise the way we access and manage our health, but this is an immensely complex area involving patient behaviour, doctors, regulators, payers, device developers and vast healthcare system infrastructures. We are only just touching the surface of this enormous topic, but one thing is for sure; the opportunity is game changing, and this is going to be a very exciting time in health and wellness.


Activity Monitor
Wearables
Health App
Contextual Health Data
Patient
Lifestyle
Genetic Data
Home hub
PoC (Home Testing)
Doctor
KEY:
Virtual
Patient
Healthcare Centre

[1] https://www.nhs.uk/oneyou/be-healthier/check-your-health/heart-age-test

[2] https://www.england.nhs.uk/cancer/case-studies/c-the-signs-how-artificial-intelligence-ai-is-supporting-referrals/

[3] https://www.nhs.uk/start4life/baby/breastfeeding/breastfeeding-friend-alexa/

[4] https://www.dontpassiton.co.uk/

[5] https://www.labcorp.com/provider-services/other-services/home-healthcare#h2-lab-in-an-envelope

[6] https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight

[7] https://www.gov.uk/government/publications/health-matters-obesity-and-the-food-environment/health-matters-obesity-and-the-food-environment--2

[8] https://www.ourpath.co.uk/

[9] https://slideblast.com/avoidable-collateral-damage-from-corporate-data-_595d9c831723dd1d865cb471.html

[10] https://www.roche.com/media/releases/med-cor-2017-10-03.htm

[11] https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology

[12] https://www.nytimes.com/2018/04/11/technology/facebook-privacy-hearings.html

[13] https://www.cnbc.com/2018/06/28/babylon-claims-its-ai-can-diagnose-patients-better-than-doctors.html

[14] https://www.kheironmed.com/

About the author

Dan Haworth has 15 years of experience in product development and R&D management for healthcare. With a master's degree in mechanical engineering and experience in molecular diagnostics, he bridges the gap between engineering and life-sciences. Dan's work has included the development of Alere's next generation point of care platform and the launch of the world first isothermal molecular system. Dan develops innovative devices that navigate the complex trade-offs between the assay, users and device architectures.

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