Viewing health through data

Data is the next frontier of healthcare opening enormous rewards yet also creating new risks.

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In 1951, African-American woman Henrietta Lacks visited the John Hopkins Hospital seeking treatment for vaginal bleeding. She was found to have cervical cancer and later died, but not before a cell sample was taken which would show a remarkable ability to survive and reproduce.

Today that sample is the foundation of a crucial cell line called HeLa that has been used globally in multiple medical discoveries. But it is also a symbol of consent -- neither Lacks, nor her family were ever asked if a sample could be taken and then propagated forever after, and none of them were asked whether genome or other highly personal data could be published publicly.

Consent is at the heart of health data. Who owns it? Who is allowed to make money from it? What is 'good' data?

"Ostensibly with data, many people can access it at any given time. So it's about who has appropriate consented access at any given time. How are we making sure that it's good actors, the patients themselves, their care partners, their clinical partners, and any research entities they have allowed to access that data," said Jennifer Goldsack, Digital Medicine Society CEO, at HLTH 2021.

She says 'good' data is consented, protected, trustworthy, and appropriately accessible.

But others say the question is not whether data is good or bad, but whether it's fit for purpose -- a Fitbit can tell you if a person is bed-ridden, but can't tell you what their blood pressure is doing.

Who owns the data -- be it the person providing it (the patient), their doctor, the company which stores it, or the company which uses it for another purpose -- and therefore who can monetise it, is a battle yet to be fought. Some experts' ideal is of a marketplace which values rarer data at a higher price, that is powered by a little bit of cash and a lot of altruism. The risk is that adding money to the mix may incentivise people to put their health at risk.

Consent is but one new challenge in the brave new world of health data, where information can be ingested into software and used for noble causes such as research, or for saving money, or for catching illnesses before biology tells us something is wrong.

What we do know is that data potential is one of the most exciting frontiers in healthcare today.

Free the data!

Doctor's typed notes do not translate well to an algorithm. One hospital's electronic health record (EHR) will probably be structured entirely differently to that of every other hospital. Sensor data, collated at home, arrives in a ZIP file via email and carries no hint as to how or when or under what circumstances it was taken.

Yet all of this needs to be shared within a system that is interoperable.

Interoperability is the promised land for health data devotees, where each part of the system can talk to each other and easily -- and securely -- share patient data. Fast Healthcare Interoperability Resources (FHIR) is how we get there. It was invented by Australian Grahame Grieve, who published the framework on his blog in 2011 and adopted by Health Level Seven International (HL7) a month later.

In Australia, the plethora of clinical systems and the need to make them FHIR-proof poses a challenge to data sharing and is a huge task.

Grieve said in 2020 at an InterSystems roundtable that Australia is falling behind in FHIR implementation, starting with a lack of government support for mandating standards and notwithstanding the Australia Digital Health Agency's (ADHA) My Health Record, the widely criticised attempt to create a national electronic health record.

The US has its 25-year-old Health Insurance Portability and Accountability Act (HIPAA), which is transforming from a patient right of access to a gateway for third parties, with patients able to direct health data holders to recipients of their choice. Despite the longevity of the scheme, experts say a request for medical records often still equates to a 2000-page print out -- which is not usable data for anyone.

But as more patients get used to digital access, healthcare providers are being put on notice, says DataRobot executive Sally Embrey.

Transparency and data sharing mandates in the US are coming from the Federal level. For example, from the end of 2022 all EHRs are required to have a FHIR-based API, while the 2016 Cures Act requires a wide range of health professionals to share data with other authorised parties -- but this time it's letting the market figure out how to standardise the data rather than prescribing how that should be done.

Embrey says industry push back is allowing tech companies to step in, such as those running price comparison websites ranking different hospitals which are attracting startup cash, or hers which offers cloud AI systems.

Google director Aashima Gupta says the conversation has moved on from 'why do we need to do this?' to 'how do we do this', although minimum viable compliance with new rules rather than embracing them as they were intended is still a major problem.

The open API approach to health is not only throwing the doors open to non-health companies but opening the way to new use cases such as remote patient monitoring, which is only possible with seamlessly shareable data.

How data is changing clinical trials and drug development

Some of the most exciting uses of health data is real world data (RWD) for clinical trials, and machine learning models to speed up drug discovery.

RWD is taken from sources outside the clinical setting such as EHRs, or the Australian Medicare Benefits Scheme, or insurers in the US, and may include gender, ethnicity, patient-generated biometrics such as sleep patterns, drug regimens and so on.

Carolyn Magill, CEO of real-world evidence software company Aetion, said at HLTH 2021 (tongue only half in cheek) that four years ago mentioning RWD in a pitch deck would almost certainly secure investment, whereas today the conversation has become about the purpose of data and how it's used.

For example, when does wearable data help make better decisions? Or what is the impact of including unstructured data in a trial?

Decentralised clinical trials, where much of the data is collected in a real-world setting became a real possibility after the pandemic forced all patients and trials out of the clinic and into the home. But it remains used largely in Phase 1 and 2 studies, rather than Phase 3.

"Imagine you are running a study and someone only comes in once a month to give the information. You would never manage diabetes with once a month blood sugar reading and yet we have billion dollar studies that are just collecting little bits of data," says Andy Coravos, CEO and co-founder HumanFirst, a company building the frameworks and software to enable completely decentralised trials.

The FDA is becoming more familiar with the use of real world evidence -- the insights that come from RWD -- after offering further guidance in September and October 2020 on how companies can use it in their applications. But there is a long way to go before a drug or device can clear the entire FDA runway using solely real-world evidence.

All of which is too slow for Matthew Roe, CMO of device company Verana Health.

"Why not go back in time and say how can we develop drugs better, using real-world data from inception, and not relying on biological mechanisms of cell-based assays," he said at HLTH 2021.

"Why don't we understand the disease better that we're trying to target drugs for, by connecting clinician generated real-world data with person generated real-world data, developing very rich natural history studies that we can then use to write much better protocols.

"Then we can use the real-world data to plan and operationalise these protocols to find the patients where they are, find the best sites which have the most patients, and help those sites recruit patients."

Drug discovery and AI

Today, scientists can use AI to look at large data sets and generate new hypotheses about drugs very quickly, a factor that has been used regularly during the pandemic to confirm and test ideas about how COVID-19 works.

But it's also one of the most hyped sectors as well, with views ranging from the skeptical to the magical as people hope AI-led drug discovery can be a silver bullet for the costly drug development industry.

The real power of AI is in pattern recognition and being able to analyse vast volumes of data quickly, to answer specific questions. This makes it possible to identify possible drug options, and later to optimise molecules for certain characteristics.

Novartis chief data and AI officer Shahram Ebadollahi says they cut the drug development process down to a year through its Nerve Life software, which pulls in data from different sources, cleans it, and analyses it. It allows for forecasting around staff needed, best locations for a study to take place, and trial costs, among a number of other outcomes.

Novartis is hardly the only company engaged with using AI models to speed up drug discovery, with several Australian companies already offering software in this space.

Software as a drug

Digital therapeutics (DTx) is one of the next big things in healthcare, but it needs data to get paid.

Investor Ankita Jha from Temasek International says it is a given that DTx solutions need to have hard clinical data showing it works to get FDA approval and reimbursement from insurers or public health bodies.

There is a better pathway on how to put a DTx application through the FDA, after Pear Therapeutics led the way in 2020 with its chronic insomnia treatment, but more clarity is needed before we know what the FDA considers a gold standard DTx product.

However, the next stage for DTx is real-world data that proves the treatment not only works the way a company says it does, but also that they save money. Investors expect DTx companies will soon also be able to charge based on longitudinal data proving they are ultimately cost savers.

DTx are digital therapies that might be delivered through an app or a video game and deliver medical interventions using evidence-based, clinically evaluated software with or without a sensor or hardware component. Examples of treatment include mental health diagnostics and treatments, or asthma monitoring.

But one aspect of the uniqueness of DTx is yet to be tapped: their ability to passively monitor patients and alter the therapy based on new data, and the simplicity of sending out a software update as opposed to tinkering with the fundamentals of a drug. Biologics drug companies must gain a new FDA clearance to do that -- and in fairness this is a rubicon the FDA and other medical regulators are yet to cross with DTx too.

That built-in intelligence to make dosing and treatment modifications, and ease of improvement, could mean DTx treatments could one day be better than standard drugs.

Even researchers are jumping on board now. Akili Interactive CEO Eddie Martucci says they reached out to Cornell University to run a clinical trial on COVID-19 to test whether its cognitive function video game could help with brain fog. The researchers said yes and had a trial running within months -- a stark change from before the pandemic when no one wanted to touch device- or DTx-based technologies.

Martucci says data need to adapt in real time so each patient is getting a slightly different treatment experience that suits them.

Getting personal

Health data is playing a huge role in personalising health. Consumers want seamless health experiences, like the proverbial Amazon purchase, and personalisation is a key factor here.

It is also key to solving some of the bigger challenges around health equity.

A particularly optimistic Dr Mansoor Khan, from population health management platform Persivia, suggested data from sources such as credit agencies could be used, not at the beginning of an appointment to discover whether a patient can pay, but at the end to uncover whether they have regular housing, food or access to transport, and thereby ensure the right resources go to the right people.

The digital front door is one example of how data can feed personalisation and create the kind of 'delighted' customer healthcare wants to import from the retail space.

The digital front door is a concept where a patient can go in through an app or a website and then be triaged and access all the usual services they would by speaking to the receptionist at a clinic.

At the core of this concept is engagement -- the whole object of having an open front door is to make your patient-customers more sticky -- and data liquidity.

"Engagement happens when you have a great experience," said Dedalus Group digital GM Vishnu Saxena at HLTH 2021. "Experiences are shaped and defined by data."

For example, if a patient calls a contact centre and the person they speak to doesn't have the right data about the person at their fingertips, they won't provide the kind of experience or care that patient is hoping for.

Which is where data liquidity comes in, or the ability of data to flow throughout the healthcare system easily and securely, and available to the clinicians who need it.

"We all are bringing our experiences of when we shop, when we bank, when we travel, to healthcare. We expect the same level of experience, on demand, from healthcare," he says. "There is an expectation chasm."

In the US, where the idea of the patient-consumer is becoming stronger, word of mouth is spreading news about centres with good digital experiences. Saxena says the point of collecting patient data and making it shareable isn't just to avoid mistakes and prevent ill health, but also to create an experience that results in a 'delighted' customer.

Problems

Bias, the loss of competitive advantages, expectation chasms…the rise of health data has either created or highlighted some serious problems healthcare has not (but arguably should have) dealt with before or which are completely new.

When it comes to AI, repeated problems arise when researchers take a thin sliver of data and try to extrapolate the conclusion to a larger population. This has arguably been happening throughout medical history, as women became small men or non-White ethnicities are treated using data derived from White populations.

Examples of this include the checklist tool created for VBAC (vaginal birth after caesarean), which has a built-in bias that means African American women are significantly less likely to attempt a VBAC.

Pulse oximeters have different measurements for light and dark skin, but the instruments are designed for light skin. This was identified in the 1990s but was not fixed, and during COVID-19 it meant African American patients were not being flagged for low oxygen and were not being taken to hospital when needed.

An equally historical problem is collecting data in ways that confounders are inextricably intertwined with biology, and researchers forget to account for them. For example, comparing data collected from one hospital with a particular representation of patients for one condition with data collected from a second with a different patient population.

But the key problem is lack of data.

In the US the Centers for Disease Control and Prevention (CDC) took months to report on COVID-19 disparities within different racial groups because of not having sufficient data.

Bias

Bias is possibly the biggest risk with health data, as predictive machine learning engines take a bigger place within all aspects of the new digital health sector.

Ensuring AI systems, via the data they receive, are for all and don't just apply to a narrow slice of populations is critical. And healthcare is riddled with data that by its very nature only comes from a narrow slice of the world -- hospital data only captures when a person chooses or is forced to go to a hospital, it can't predict anything outside that realm to create a more holistic view.

But the positive is the awareness that AI can become biased is forcing healthcare across the board to consider bias.

"What is very exciting is that AI has shone a light on the idea of bias. If you look at our healthcare practice overall we all know how biased it is," said Bayesian Health founder Suchi Saria at HLTH 2021.

"There has been article after article over the last year and a half on existing practices like something as simple as pulse oximetry, and how baselines were initially developed a long time ago on White populations and as a result it is not calibrated well for Black patients, and it often misses hypoxemia in black people, but that's been around for decades."

She says the chassis from which to build any health data-backed solution requires deep thinking.

"Doing well [in combating bias] means deep knowledge of the domain, the use cases, the messiness of data, and the technology itself, and marrying it all together to build solutions where you have adequate level of measuring and monitoring all the way from the get-go.

"This is so you understand what a potential source of bias is. Are you adequately measuring and monitoring for it, have you put strategies in place to correct for it, and are you continuously offering new ways to tune as new sources of bias arise."

Only by taking serious steps can safeguards against obvious bias be created.

Supply chains: from Excel to…

Before COVID-19 medical supply chains were controlled through Excel spreadsheets.

When hospitals and others began stockpiling drugs and PPE, it wasn't only the ability to access enough products that came under intense pressure, but how to get them from A to B.

The pandemic highlighted an awareness that medical suppliers need to operate in a different way, and that means embracing data transparency in the hyper competitive sector, said Sandoz US president Keren Haruvi at HLTH 2021.

Hospitals will order from one supplier but switch to another at a moment's notice for a cheaper price, leading to stock being tossed and an entrenched inability to plan far ahead.

Data sharing on price or inventory available in the supply chain might lead to competitive problems, but some hospitals, says Massachusetts General Hospital chief pharmacy officer Christopher Fortier, would be interested in contracts structured to incentivise data sharing.

"Hospitals don't manage drug inventory well. There are no dashboards to show what drugs are where and how much. It's a lot of manual work," he said at HLTH 2021.

They are trying to work with suppliers on better inventory management, but the ultimate dream is to create their own single front door with a variety of drug companies with whom they can contract large volumes of products in exchange for more open data on price.

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