Documenting the dramatic evolution of personalised medicine

- Personalised medicine is changing the face of healthcare.
- It features new and exciting approaches but also significant challenges.
- Science writer Dr Priya Hays covers these in her book *Advancing Healthcare Through Personalized Medicine Second Edition*.
- It is aimed at the scientific community, academics, laypersons, and policymakers and includes a focus on how personalised medicine is tackling cancer.

Humans aren't cars. That's an obvious statement, but worth reiterating when talking about medicine. When something 'goes wrong' with a human, there's no predetermined fix per its model. Each human is unique – a wondrously complex interplay of genetic history, current natural state and the myriad external factors making their mark. Properly fixing humans when they 'go wrong' should therefore require a unique intervention that considers and addresses this entangled interplay. That may sound like wishful thinking, but it's a burgeoning reality.

Dr Priya Hays is an experienced writer with an eye for the remarkable narratives unfolding within science. Of particular interest to her is how technology is changing healthcare. Usually, technological advances are like building blocks, adding to our evolving understanding of healthcare; every now and then, there's a seismic shift. But dramatic leaps in previously considered unconnected technology are now converging to overturn the historical fundamentals of healthcare. Hays can see this and has compiled an authoritative and highly detailed account in her book *Advancing Healthcare Through Personalized Medicine*. Aimed at the scientific community, academics, laypersons, and policymakers, the most recent edition includes significant developments since the first edition was published in 2017 – only five years ago. As Hays says, the second edition has 'benefitted appreciably' from these advances.

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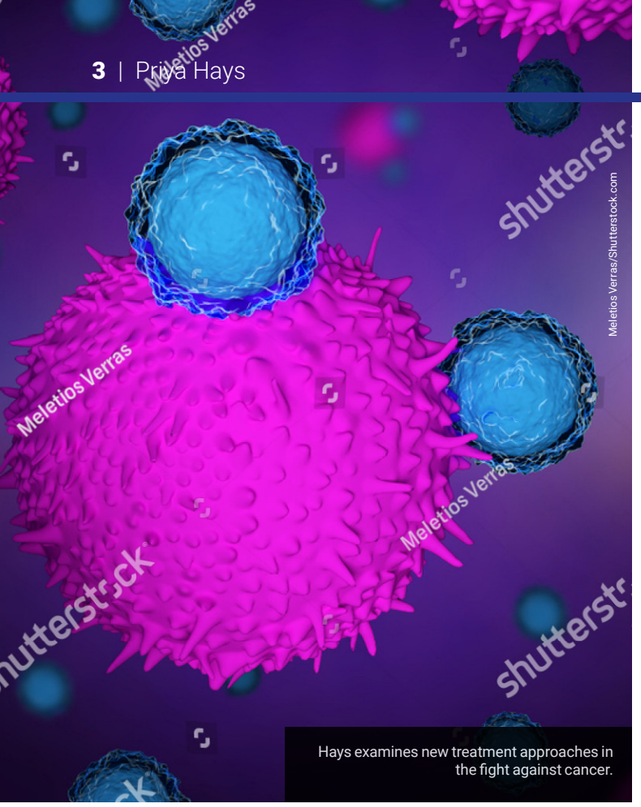
Data, and lots of it

Healthcare is now at the heart of a rapidly expanding realm of sectors beyond those traditionally associated with medicine. To give you an idea about the scope of this book, don't imagine a typical clinical setting; think data – and lots of it. Consider connected devices, big-tech companies corralling information, biotech pioneers unlocking mysteries within genomic data sets, and ethicists and regulators scrambling to keep up. Tumbling out of this highly energised melee are the exciting opportunities in personalised medicine previously considered only within the province of science fiction. Trying to keep track of it must be challenging, but Hays is committed – the latest edition is over 700 pages long.

Such depth is essential. Personalised medicine is not a monogrammed pill; it's a complete rethink of how to treat patients, and if there's a trigger point, it's The Human Genome Project. Codifying the human body by genomic sequencing not only unlocked new avenues for targeted therapies; it brought new players into the game. In her book, Hays sets the scene created by the tentative spread of genomics into various sectors within healthcare, such as pharmacogenomics and oncology, before focusing on how big data and artificial intelligence broke open the frontiers and steered the focus beyond standard frameworks. This expanded playing field has demanded new alliances between knowledge structures and the digitisation of precision health. If there's a poster boy for personalised medicine, it's a patient's watch, not a doctor's stethoscope.

Promises and challenges

It would be tempting to focus on the tech, but a large part of this book's heft lies in its detail. Hays goes into depth around how personalised medicine is tackling a disease that has hitherto largely



Hays examines new treatment approaches in the fight against cancer.

defied our most concerted efforts: cancer. The book examines the new fronts in the fight, such as personalised and precision oncology, immunotherapy, and molecular diagnostics. Instead of carpet bombing the body with chemicals, doctors can now target the specific genetic signalling pathways that lead to erratic cell growth. Hays shows how such tactics are plenteous and unrelenting, and amidst the detail and data on the pages is a real sense of hope. The book also highlights how personalised medicine is breaking new ground in other diseases, such as Alzheimer's, Parkinson's, diabetes, arthritis, multiple sclerosis, cardiac disease and HIV, and crippling psychiatric conditions such as schizophrenia and bipolar disorder.

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Of course, not all discoveries are cures, and new frontiers harbour all manner of complications. Hays points out some of the biggest challenges in advancing healthcare through personalised medicine, and they are largely attitudinal, not technical. Data is a double-edged sword in medicine. As much as it opens us up to whole genome and whole exome sequencing, it must be shared between providers, researchers, and patients to do so: enter the role of established regulators and other authorities claiming to speak on behalf of patients, and the new regulators and authorities forming around novel technologies. According to Hays, they encourage us to confront uncomfortable questions and consider unsettling scenarios: what are the ethics of epigenetics, where are the limits of your privacy, who owns your data, and what happens if it ends up in a courtroom as part of a patent dispute?

Beyond those calling for circumspection about personalised medicine are healthcare professionals and patients eager for progress. They see its promise and witness its benefits every day. Hays devotes due space to their stories and, in the process, provides a more personal touch. We are reminded not to be distracted by technology; the patient must remain centre stage.

The days when medicine was akin to a car owner's manual and had a pill for all people with the belief that it should work for most, definitely for some, are now past. Healthcare providers can now tailor treatment and prevention strategies to people's unique characteristics, including their genome sequence, microbiome composition, health history, lifestyle, and diet. As such, *Advancing Healthcare Through Personalized Medicine* is an honest, detailed appraisal of how the future of healthcare is already here.

Personal response

What do you see as the most exciting development in personalised medicine?

The data emerging from next-generation sequencing will require the development of big data solutions that store, process, and generate information for clinical use. These solutions would consist of new data analysis and data science streams to ensure that this information is portable and secure for patients. One example would be the use of Software as a Service and other cloud services, enabling the development of personalised medicine apps that would allow for easy transmission of clinical data between providers and other healthcare stakeholders. Unstructured data platforms such as social media will, and already have, allowed for the emergence of advocacy and communication platforms for patients taking targeted therapies and immunotherapies.

What do you see as its biggest challenge?

The biggest challenge of personalised medicine is to demonstrate its cost-effectiveness and robust health economics. In addition to efficacy and safety profiles, precision medicine therapies should lead to increases in quality-of-life years or QALY for patients. Drug manufacturers are making the transition from the niche blockbuster drugs to targeted therapies, and health economists are continuously making assessments of the economic value of these relatively expensive drugs and finding vibrant markets for them. These issues came to fore with the development of chimeric antigen T-cell therapies, or CAR T cell therapies. These therapies received Food and Drug Administration approval as Breakthrough Therapies for urgent medical need, but the cost remains approximately $1M USD per year. These costs must be factored in determining the cost-effectiveness of precision medicine therapies and technologies.

In embracing the technology of personalised medicine, how can we keep the patient centre stage?

To keep patients centre stage, access to clinical trials in cancer immunotherapies and targeted therapies for all demographics must be ensured and these drugs must be made affordable. Topics such as health disparities and health equity emerged when it was elucidated that certain populations were underrepresented in clinical trials. The oncology community in particular, who direct many of these clinical trials and determine patient eligibility, have been increasingly vocal in addressing the need for adequate representation of minority populations in clinical trials.

What are the more significant ethical conundrums facing personalised medicine?

Issues in data privacy and data sharing have been associated with personalised medicine as soon as it emerged as a viable paradigm for basic research and clinical care. There has always existed the dilemma that the participant's data be kept private and not be shared without informed consent, and the need for the investigator to advance their research goals and objectives for social good. Direct-to-consumer companies may share the data they receive from their consumer DNA kits with other stakeholders, thus potentially hindering data privacy.

How do you keep track of such a rapidly evolving field in medicine?

I keep abreast of the latest clinical trials in oncology and latest cutting-edge technologies in machine learning, artificial intelligence, and spatial omics.

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Bio

Priya Hays, PhD is an accomplished science writer, having written and published four books as well as having authored over twenty publications in journals as varied as the *Bulletin of Science, Technology and Society, L'Esprit Createur, Interdisciplinary Literary Studies, Genetics in Medicine, Journal of Clinical Investigation and Studies,* and *Preventive Medicine, Epidemiology and Public Health*. The publication of the first edition of *Advancing Healthcare Through Personalized Medicine* brought Dr Hays much prominence and credibility in the personalised and genomic medicine field. She was elected to three prestigious medical societies (as Allied Physician/Doctoral Scientist of the *American Society of Clinical Oncology;* as Affiliate Member of the *American College of Medical Genetics and Genomics*; and as Member of the *Society for Immunotherapy of Cancer*). She has also served as Editor for an edited collection on cancer immunotherapies.

References

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