

# Navigating the Next Frontier of Precision Medicine Oncology

## Challenges and Opportunities amid Covid-19 and Beyond

The covid-19 pandemic has exposed the vulnerabilities and inequities of the global healthcare system, but it could also catalyse long-overdue transformative change. As the virus began circulating widely in many countries, demand for hospital beds and other resources strained health systems worldwide—and the consequences were quickly felt by patient populations struggling with other serious challenges, including cancer. Fifty-five percent of countries experienced partial or severe disruptions to cancer diagnosis and screening services, according to an August survey conducted by the World Health Organisation (WHO).<sup>1</sup>

With so many resources diverted to fight the novel coronavirus, the entire spectrum

of cancer care was impacted.<sup>2</sup> Treatments were delayed and many clinical trials were halted. Covid-19's impact on provision of services for cancer patients raises important questions about the ability of health systems to deliver timely and effective treatments. It also underscores how far we remain from achieving the promise of precision medicine, which has long focused on cancer care. Critical challenges hindering the development of precision medicine oncology predate covid-19, but with the pandemic highlighting the urgent need for accelerated development of cancer care technologies and greater international co-operation on common health threats, some obstacles could become easier to overcome in a post-covid world.

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<sup>&</sup>lt;sup>1</sup> WHO, "Pulse survey on continuity of essential health services during the COVID-19 pandemic". August, 2020.

<sup>&</sup>lt;sup>2</sup> Nature Cancer, "The impact of the COVID-19 pandemic on cancer care". May, 2020.

### Challenges

The key barriers to maximising precision medicine's potential lie in the realms of policy and governance, not science and technology. That's the consensus among the World Economic Forum's Global Precision Medicine Council, composed of experts from across the international healthcare landscape.<sup>3</sup> This year it identified five major challenges facing the development of diagnostic, therapeutic and preventive precision tools to fight cancer and other diseases.

Responding to the covid-19 pandemic requires thought leaders working at the intersection of public health and medicine to collectively enhance public awareness and appreciation of precision medicine, while delineating the challenges that complicate its broader adoption. Clinicians, researchers, industry executives, patient advocates and payers each play a role in explaining precision medicine's benefits to both policymakers and the general public, especially with regards to addressing the needs of patients with cancer and other diseases for which precision medicine is transforming the standard of care.

Edward Abrahams, PhD President, Personalized Medicine Coalition The first is data sharing and interoperability. Tools offering treatments geared to a patient's genetic profile can only emerge on a population-level scale if data sets are standardised and shared among all key stakeholders globally—providers, payers, academic researchers and national health programmes, for example. The big data challenge has only grown with the increasing ease of sequencing DNA from tumours and the falling cost of sequencing entire genomes.4 More data are being generated than ever before, but its usefulness hinges entirely on its dissemination—a process which is severely lacking at present. Data sharing is happening among stakeholders, but initiatives often lack interoperability and therefore scalability, stymieing valuable innovations.5 The Australian Genomics Health Alliance's partnership with Genomics England is a promising cross-border exception.

A truly global database compiling health, environmental and genomic information is impossible without patients' trust and engagement. This is the second challenge: ensuring genetic privacy and preventing genetic discrimination to accelerate data gathering. Part of this necessarily involves increasing the general public's awareness of and comfort with genomics. People want to know who has access to their genetic data and who benefits from its use—and they deserve clear and honest answers.

<sup>&</sup>lt;sup>3</sup> World Economic Forum, "Why precision medicine won't transform healthcare – but governance could", May, 2020. <sup>4</sup> Genetics in Medicine, "The complete costs of genome sequencing: a microcosting study in cancer and rare diseases from a single center in the United Kingdom," July 2019. 5 World Economic Forum, "Precision Medicine Vision Statement: Governance Gap 1: Data sharing and interoperability", May 2020.



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The covid-19 pandemic has not only led to alarming reductions in cancer diagnosis, but also to a substantial decline in biomarker testing, which is often pivotal to determining the most effective course of therapy for many common cancers. In times of extraordinary need, it is more critical than ever to ensure broader, more equitable access to precision medicines and associated biomarker testing for every patient who stands to benefit. This requires greater cooperation and collaboration from organisations working across the full spectrum of oncology care.

Seth Feldman, Head of US Oncology Precision Medicine & Nurse Education, AstraZeneca

Following on from this, the third challenge involves the ethical use of oncology-related precision medicine technologies. The potential benefits of genomic tests for inherited cancer risks, for example, are vast. But if such tests fail to be implemented consistently in clinical practice, the distribution of benefits will be unjust and health disparities could widen.6 Other ethical issues of concern involve informed consent. Research participants must understand the implications and risks of the trials in which they take part, and inclusiveness of study populations must be ensured so the value of treatments is not limited. As of last year, about 80% of participants in genomic studies have had European ancestry.7 The All of Us research programme being run by the US National Institutes of Health (NIH) aims to address this problem.8 Launched in 2018, the programme's purpose is to gather genetic data and other health information from 1m people to build a racially and ethnically diverse database. As of last year, more than

80% of participants were from groups that have consistently been under-represented in biomedical research.<sup>9</sup>

Accessibility of treatments presents the fourth challenge and is, of course, directly related to pricing—which is in turn related to perceived value and reimbursements. In the absence of overwhelming evidence of effectiveness, few private insurance companies or government payers currently reimburse broad-based genomic testing and analysis which slows their entry into clinical practice.<sup>10</sup> Improved global standards for diagnostics pricing models—and a more general shift towards value-based pricing and reimbursement models<sup>11</sup>—could enhance the value of precision medicine oncology. The decision made earlier this year by the US Department of Health and Human Services to expand coverage of Next Generation Sequencing (NGS) diagnostic tests for Medicare patients with inherited breast or ovarian cancer bodes well.12

<sup>&</sup>lt;sup>6</sup> PMC, "Implementing Precision Medicine: The Ethical Challenges", January 2018. <sup>7</sup> Nature Human Behaviour, "Whose genomics?", May 2019. <sup>8</sup> National Institute of Health, "All of Us Research Program", September 2020. <sup>9</sup> The New England Journal of Medicine, "The All of Us Research Program", August 2019. <sup>10</sup> PMC, "The growing role of precision and personalized medicine for cancer treatment", January 2019. <sup>11</sup> World Economic Forum, "Precision Medicine Vision Statement: Governance Gap 1: Data sharing and interoperability", May 2020. <sup>12</sup> Centers for Medicare & Medicaid Services, "CMS Expands Coverage of Next Generation Sequencing as a Diagnostic Tool for Patients with Breast and Ovarian Cancer", January 2020.

This segues into the final major challenge facing this area of cancer treatment innovation: the need for more responsive regulatory systems. Some regulatory bodies, such as the US Food and Drug Administration, have evolved over the past decade to meet the unique nature of pharmacogenomics.<sup>13</sup> But overall, the regulatory landscape governing complex precision medicine products and services remains convoluted. Tensions persist between traditional safety and efficacy frameworks involving large portions of the patient population and precision medicine drugs targeting relatively small groups of patients with particular biomarkers.<sup>14</sup>

programmes and greater patient trust and engagement.

Two other aspects of the current crisis could also help unlock precision medicine's potential: the essential need for cross-border co-operation among diverse healthcare stakeholders and the broad recognition that covid-19 amplifies inequality. This moment could marshal support for a truly global database supporting the development of precision medicine oncology—and more equitable access to and distribution of benefits as the field comes of age.

### **Opportunities**

Broadly speaking, the covid-19 pandemic threatens to undo much of the global health progress made over the past decade, as the WHO has noted.<sup>15</sup> But in important ways, the global crisis could also help us to overcome obstacles in the field of precision medicine oncology and accelerate innovation. The dramatically different effects of covid-19 on individuals, even in the absence of underlying conditions, is an opportunity to prove the value of precision diagnostic tests that could identify those most at risk.16 The NIH's expansion of data gathering in the All of Us programme to better understand covid-19's spread and impact may do just that.<sup>17</sup> The race against the virus could ultimately prove precision medicine's power to target infectious diseases and cancers, crystallising public support for (and regulatory responsiveness to) precision approaches. That would bode well for both research and development (R&D)

#### Conclusion

As a disease indiscriminate in its spread but discriminant in its impact on already-vulnerable populations fighting other illnesses like cancer, covid-19 has served as a wake-up call for the need to embrace interdisciplinary solutions to complex problems. Involving a broad range of stakeholders—from policymakers and healthcare professionals to researchers, payers and patient advocacy groups—will be critical to discern mutual values, develop strategies to address shared challenges, promote common goals and to achieve desired precision oncology outcomes.

It is precisely in moments of crisis that silver linings can present themselves and new opportunities can be seized. In light of this, what fundamental lessons can be taken from the covid-19 pandemic to ensure that cancer care services continue to improve, innovative cancer treatments continue to be developed and the resilience of health systems continues to grow?

<sup>&</sup>lt;sup>13</sup> PMC<sup>,</sup> "The growing role of precision and personalized medicine for cancer treatment: Table 6", January 2019. <sup>14</sup> Pharmaceutical Technology "Precision medicine: what barriers remain?", March 2020. <sup>15</sup> PWHO<sup>,</sup> "World Health Statistics 2020: Monitoring health for the SDGs", May 2020. <sup>16</sup> The Journal of Precision Medicine, "Personalized Medicine in the Aftermath of COVID-19", March 2020. <sup>17</sup> National Institutes of Health, "All of Us Research Program launches COVID-19 research initiatives", June 2020. <sup>18</sup> Washington State University, "COVID-19 Amplifies Inequality; We Must Do Better", July 2020.

To learn more, register today for our virtual roundtable on October 13th, co-hosted by The Economist Group and AstraZeneca. In the panel, a number of leading industry experts will discuss interdisciplinary approaches and innovative strategies to effectively deliver valuable precision medicine oncology outcomes: https://events.economist.com/events-conferences/americas/targeting-cancer/