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Banking on Bio

MARTIN CARKETT, BENEDICT MACON-COONEY, CALEB WATNEY AND ALEC STAPP

BACKGROUND

Crises are always great levelers. They reveal hard truths and shortcomings, where our strengths lie and where we are weakest. Covid-19 was no different. Nations that thought they were best prepared were often those found the most flat-footed, whereas our technological capabilities were shown to be far more flexible and profound than many assumed. The best sign of our abilities was the rapid development of mRNA vaccines.

For leaders around the world, the overarching question post-pandemic is: How do we replicate these successes and accelerate technological progress when not in crisis? For this to happen, our political class needs to up its ambition. Rather than get bogged down in limited or short-term questions, they need to harness the ongoing technological and biological revolutions. The prize is massive improvements to people's quality of life and longevity. Internet-era architecture and institutions will be critical to this, but if we want to fully realise the benefits of recent advancements in biotechnology, a core focus should also be on the development of global biotech infrastructure.

This should have been a fundamental question for leaders of G7 nations when they descended on the UK this summer. Yet despite some references to increasing our genomic surveillance capabilities, too little attention was paid to increasing our global biomedical facilities. Scaling technological solutions around the world, including via cloud-based infrastructure to collect critical biomedical data and increasing our sequencing capacity, should be a primary concern. As the US, the UK, and others commit to the "Build Back Better World (B3W) Partnership" and look to mobilise capital towards climate, health, and health security, so too should expanding the global network of core bio-infrastructure.¹ All countries should have the

means and capabilities to take part in the biotech revolution and reap the health and economic benefits that this will bring.

As discussed in our previous report, China is investing \$1 trillion in countries around the world to build infrastructure as part of its Belt and Road Initiative.²

It would be a mistake for liberal democracies to simply emulate China, especially given that many Western countries have little recent experience in building massive infrastructure projects (at least not without runaway costs). Instead, the G7 and its partners should leverage their own comparative advantages, including biotech, where the West remains dominant.³ Supporting the development of bio-infrastructure, particularly biobanking and biomanufacturing capacity, would be a smart target for the B3W Initiative, exploiting the West's primacy in this area and bringing significant benefits to both target nations and the rest of the world. We discuss the benefits and key challenges policymakers should take into account when promoting biotech investment.

ACCELERATING DISCOVERY AND DELIVERY

Biobanks are essential tools for driving biomedical research and personalised, precision medicine.⁴ Their concept is simple: biobanks are repositories and databases that house biological and clinical samples (biospecimens) and their associated data. UK Biobank, for example, holds blood and tissue samples (both healthy and diseased), alongside relevant patient information, for over half a million UK residents.⁵

Operating at scale, biobanks offer a deep range of samples that can be used in a wide variety of advanced biomedical research, including genomics, multi-omics (the study of other key biomolecules such as proteins and metabolites)

and precision medicine studies.⁶ Statistically powerful datasets can then be produced to help us better understand the molecular basis of diseases, and in different populations, the different genetic and environmental risk factors associated with them. For example, during the Covid-19 pandemic, biobanks played a critical role in collecting patient samples for clinical studies, helping identify those most at risk of serious illness or death and chart the population's immune response to the disease.⁷

At the other end of the spectrum, large bioreactors and other industrial equipment required for mass manufacturing biologics, represent another critical component of biomedical infrastructure. These specialised apparatus are optimised to grow and combine specific organisms or biomolecules for biomedical, pharmaceutical or industrial purposes, such as antibodies, proteins, mRNAs or viruses for use in vaccines. This can increasingly be done at scale and bioreactors have also been critical in responding to the pandemic by producing vital components of mRNA vaccines.⁸

There's been enormous (though insufficient) growth in the bioreactor industry over the past year, as nations have scrambled to build capacity to produce the vast quantities of vaccine needed globally. The market is expected to nearly double to \$2 billion by 2025 and the volumes at which bioreactors can operate has also grown considerably to meet the insatiable demand — the largest can now hold thousands of litres of growing cells, producing millions of doses of vaccines.⁹

Biobanks and bioreactors have become increasingly important components of biomedical research and clinical delivery — helping accelerate efforts to understand how

diseases work, uncover novel drug targets, identify patient-specific treatment approaches and produce vital pharmaceuticals at scale. This also means that the geographical distribution of these manufacturing and supply chain networks is becoming a critical question for both public health and global equity.

EXPANDING AND DIVERSIFYING OUR NETWORKS

Driven by increasingly affordable whole genome sequencing and the advent of multi-omic technologies, the global footprint of biobanks has expanded over recent decades. There are now more than 120 biobanks worldwide.¹⁰ However, many of these are small operations and there are still relatively few big enough to offer the large, deep sampling and datasets that researchers, clinicians and innovators need.

Geographical distribution and diversity is another issue. Of the current large-scale biobanks, most are situated in Northern Europe, North America or East Asia, with relatively few in Africa, South America or Oceania. This means there is limited local access to biospecimens to facilitate research in these parts of the world and secondly, without local repositories, populations from these regions will continue to be underrepresented in biological and clinical samples and subsequent biomedical research.¹¹

Diversity is an issue even within existing biobanks. More than 90% of the biospecimens at the UK Biobank are taken from individuals of ethnically white backgrounds.¹²

We are therefore likely to lack a complete understanding of the genetic and molecular basis of many diseases and, moreover, how subtle genetic variations or differences in local environmental factors may contribute to different

disease outcomes in various sub-populations. This in turn limits our abilities to design more personalised medicines and contributes to inequalities in health outcomes for minority groups.

Separately, bioreactors have also become increasingly important to pharmaceutical and other industries reliant on biological products in recent decades. The pandemic ruthlessly exposed a global shortage in biomanufacturing capacity, which limited the pace at which vaccines and therapeutics for Covid-19 could be produced and rolled out.¹³ This too has had a geographical dimension, with many low- and middle-income countries lacking the infrastructure needed to produce vaccines at scale, leaving them reliant on other nations for supply.

“There is a pressing need to build bio-infrastructure capacity at regional and global levels to ensure the world is collectively better prepared for the next pandemic.”

Pandemics are global by definition and one country's exposure to an infectious disease can rapidly spread across borders. There is a pressing need to build bio-infrastructure capacity at regional and global levels to ensure the world is collectively better prepared for the next pandemic. The large pharmaceutical companies are already beginning to recognise this issue with Pfizer and BioNtech recently announcing a new partnership with South Africa's BioVac Institute to support vaccine manufacture and distribution in Africa.¹⁴ But more will be required to meet the needs of Africa's 1.2 billion people, not to mention the needs of other populations in regions that

currently lack bio-manufacturing capacity.

Both biobanks and bioreactors have broader functions too. Biobanks are now increasingly being used to store biological specimens other than human samples, presenting a range of novel opportunities. During the pandemic, they were vital in collecting SARS-CoV-2 samples from patients, enabling the genomic surveillance that was crucial in identifying and characterising new variants of the virus. In the post-pandemic era, biobanks should be increasingly used towards this purpose, supporting centres for genomic surveillance and monitoring the prevalence of new infectious diseases. In many countries, biobanks are also being used as repositories for the agricultural industry: storing samples of commercial crops, the microbiomes of the environments they are grown in and the pathogens that target them. The Svalbard Global Seed Vault in Norway is a good example of how valuable these biobanks can be for agriculture, having already provided seeds for crops lost during the war in Syria.¹⁵

Meanwhile, bioreactors can also manufacture a range of other biological products beyond vaccines and pharmaceuticals that can have wider commercial or societal benefits. A great example can be seen again in the agri-food industry, where bioreactors are being used to produce cell cultures for commercially viable lab-grown meat substitutes, reducing reliance on traditional agriculture and lowering associated environmental impacts.

There is consequently both a strong scientific and social case for expanding the global network of large scale biobanks and bioreactors and the benefits this could bring to both local and global populations in advancing biomedical research, improving health outcomes, and reducing

inequalities are significant. Moreover, target countries would also stand to gain secondary long-term economic benefits through sustainable job creation and improved health outcomes.

BUILDING FUTURE INFRASTRUCTURE

Some challenges need to be overcome to realise these ambitions.

Raising sufficient finance will be the first of these. Building and maintaining bio-infrastructure is an expensive business: more than £100 million has already poured into UK Biobank, the world's largest publicly funded biobank, since its inception in 2006. Robust evidence to make the strategic, economic and commercial cases to both public and private investors will therefore be critical.¹⁶ Helpfully, thanks to advances in biotech such as mRNA vaccines, manufacturing capacity requirements can often be smaller and more affordable than with previous generations. As a recent techno-economic assessment concluded: "the RNA vaccine production process can be two to three orders of magnitude smaller than conventional vaccine production processes in terms of facility scale, and can be constructed in less than half the time with 1/20 to 1/35 of the upfront capital investment."¹⁷

Quality control and the standardisation of collecting, processing, and annotating samples and data will be another challenge. Partnerships across global networks will be necessary to ensure consistency and interoperability. Samples and data should also be openly available to both public and private research and healthcare communities.

Achieving strong, representative patient participation through assurances on privacy and data protection will be another challenge to overcome. While the need for foreign direct investment and international partnerships are

critical when it comes to advancing biotech in developing countries, these interventions must not come at the expense of local control and respect for human rights. Outside experts in life sciences can offer support and guidance, but final decision-making authority regarding data collection and experimentation must remain with local governments.

The history in this area is littered with abuses and disregard for oppressed groups. Informed consent is necessary so that researchers do not repeat the harms like those inflicted on Henrietta Lacks, whose cancer cells were used without her consent to create the first immortalised human cell line.¹⁸ Assurance around privacy and data protection is paramount, and policymakers need to address the complicated ethical, legal, and social challenges that biobanks present to overcome patient scepticism.¹⁹

For bioreactors, ensuring there are stable associated supply chains and wider infrastructure for culture reagents, preliminary small-scale bioreactors, and downstream distribution of biological materials such as vaccines will be critical for success. Without a steady revenue stream or market commitment, we run the risk of building up significant bio-infrastructure capacity that will not be sustainably managed over the long-run. One option would be financing through advance market commitments for yearly mRNA flu vaccines that are currently in development, as well as for future therapeutics for malaria, HIV, or any number of neglected diseases that disproportionately impact developing nations.²⁰

Finally, leaders will also need to consider where such facilities would have the most impact. There's of course a geopolitical angle to this, but policymakers will also need to think about this from practical viewpoints too – what populations

are most underrepresented in clinical studies and which locations offer the greatest diversity? Which countries already have relevant expertise or wider infrastructure to support large-scale biobanking or biomanufacturing? Or world-class research institutions that could best utilise local access to biological and clinical samples? Given the global relevance and importance of these projects, another key consideration is whether such infrastructure should exist within traditional state jurisdictions or whether an international model would be more appropriate or offer greater benefits. This question also pertains to data storage, as well as the legal barriers that can limit the flow of data across borders.

None of these questions are simple to answer. But none are insurmountable. With political will, the right expertise and strategic investment, these challenges can be overcome and the potential benefits that can be achieved by far outweigh the costs.

MEGAPROJECTS AND INNOVATION PRIZES TO PREVENT PANDEMICS

Governments also need to consider how they can drive innovation to maximise the potential of new infrastructure and the capacity it brings. Prizes, advance market commitments, and regulatory awards present powerful ways in which governments can incentivise the private sector to bring to bear its resources and creativity. According to a recent report from the Bipartisan Commission on Biodefense, there are a number of areas where new innovations could be of immediate and significant benefit:²¹

- Production of vaccines that don't require a "cold chain" for distribution²²
- Development of drugs and vaccines that can be self-administered and delivered without regular needles (such as intranasal, inhalable, or microneedle patches)²³

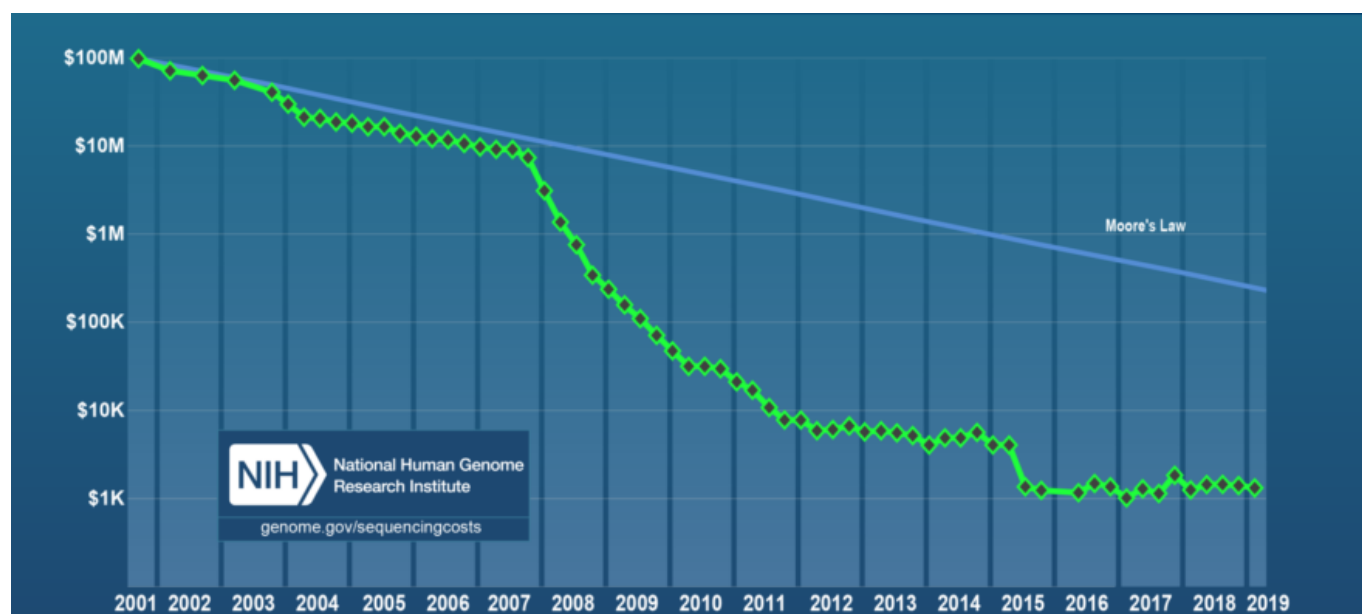
- R&D on microfluidics and on-chip sample preparation for hand-held genetic sequencers²⁴
- Non-invasive wearables for infection detection²⁵
- Multiplexed detection capabilities (pan-viral and pan-microbial tests)
- Rapid point-of-person diagnostics
- Methods to repurpose existing commercial plants for bio-manufacturing

All of these mobile and resilient innovations would greatly enhance the benefits that could be derived by investments in bio-infrastructure and would bring greater utility to countries with less mature public health systems.

In addition to innovation prizes, liberal democracies should also invest in new international scientific collaborations to drive progress. The Human Genome Project serves as a blueprint for what can be achieved in biotech. The project was a huge success that achieved its goal of decoding the entire human genome and kick-started industry to drive down marginal costs of the learning-by-doing curve. The original Human Genome Project cost \$2.3 billion, but individual genomes can now be sequenced for as little as \$1,000, making genomic sequencing a feasible part of personal healthcare.

There are already early efforts toward a Human Immunome Project (also known as the Human Vaccines Project), which would likely be much more computationally intensive than the Human Genome Project given that our immune systems are orders of magnitude more complex than our genomes.²⁶ But recent advances in machine learning are well-timed to help crack the complexity of the human immune system and unlock the full potential of mRNA vaccines and other therapeutics.²⁷

SEQUENCING COST PER HUMAN GENOME (LOGARITHMIC SCALE)



SOURCE: NATIONAL HUMAN GENOME RESEARCH INSTITUTE, [GENOME.GOV/SEQUENCINGCOSTS](https://genome.gov/sequencingcosts)

Many of these projects and funding mechanisms will be maximally effective if they receive buy-in from a coalition of government agencies and if we encourage cross-border scientific collaboration.

CONCLUSION

Covid-19 has killed more than 4 million people around the world and cost the global economy an estimated \$25 trillion.²⁸

One key lesson from this crisis is that in an ever-interconnected world, both developed and developing nations need to work together to harness the power of emerging technologies to deliver world class precision health for all. Building bio-infrastructure, particularly large-scale biobanking and bio-manufacturing capacity, in areas of the world where populations are underrepresented in clinical studies or lack the ability to produce vital medicines at scale, is a key piece of this puzzle.

Data at the personal and population level will play a central role in realising this vision and generating high quality data from broad, deep, and diversified pools of clinical samples is a key

first step in advancing this agenda. Supporting investment in an expanding global network of biobanks is critical to understanding how diseases manifest in different genetic and environmental contexts, enabling improvements in the prevention, diagnosis, and treatment of diseases.

At the other end of the spectrum, increasing bio-manufacturing capabilities is critical in turning the fruits of research into real-world clinical and health outcomes at scale and speed. This can't be the privilege of only the wealthiest countries, and as we have seen in the recent pandemic, the health of any one nation can impact the health of all nations.

Bio-infrastructure then represents a shrewd target for the G7's Build Back Better World Initiative. Beyond supporting strategic geopolitical and economic aims of building closer ties with developing economies, bio-infrastructure offers great opportunities to improve health outcomes both in local populations and around the world, and will leave us better prepared for future pandemics.

ABOUT THE AUTHORS

MARTIN CARKETT

Martin Carkett is the Policy Lead in the Science & Innovation Unit at the Tony Blair Institute for Global Change. Martin's work focuses on a broad range of areas across science and innovation including Health and Biotech, Structures of Science, and Innovations in Financial Markets. He has spent the past six years at Her Majesty's Treasury where he most recently headed the Innovative Financing team. Prior to this, Martin completed a PhD in Stem Cell and Developmental Biology at the Francis Crick Institute and University College London (UCL).

BENEDICT MACON-COONEY

Benedict Macon-Cooney is the Deputy Executive Director for Technology and Public Policy at the Tony Blair Institute for Global Change. Benedict works on accelerating science and innovation, with a particular focus on biotech, climate tech and the future of food. He started his career as an economist in Her Majesty's Treasury, later becoming a speechwriter in the ministry. He has also worked in the Office of the President in Rwanda and on development issues in other countries.

CALEB WATNEY

Caleb Watney was the director of innovation policy at PPI. His work focuses on the policy levers the US can use to increase long-term rates of innovation, including high-skill immigration, basic science funding, R&D incentives, and the development of emerging technologies like artificial intelligence.

ALEC STAPP

Alec Stapp was the director of technology policy at PPI. His work focuses on regulatory issues related to tech, including antitrust, privacy, and content moderation.

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Based in Washington, DC and part of the Progressive Policy Institute, the Innovation Frontier Project explores the role of public policy in science, technology, and innovation.

The future can be a better, more vibrant place, but we will need significant technological breakthroughs to get there. To solve climate change, cure diseases, prevent future pandemics, and improve living standards across the globe we need continued scientific advancement and technological improvements. The United States is particularly well-positioned to drive these advancements because we are on the frontier of knowledge ourselves. Even small changes to the way we govern and incentivize science and technology can have long-run consequences for the US and for the world.

To achieve the progressive goals we have for the future we need to fundamentally evaluate how policy impacts the rate of progress. The Innovation Frontier Project commissions research from talented academics and regulatory experts around the world to bring new ideas and ambitious policy proposals to these debates.

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