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Tech Solutions for Global Genomic Sequencing and Surveillance

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Idea in Brief

- The emergence of variants of concern (VOCs) of the SARS-CoV-2 virus may prevent us from ending the pandemic in a timely manner. New variants are more infectious and reduce immune protection and could potentially thwart current vaccine effectiveness or protection from prior infection.
- Despite calls for global cooperation on genomic sequencing and surveillance, limitations with technology solutions for uploading and analysing sequence data prevent full use of this data for combatting the pandemic.
- Having the right technology solutions in place, with appropriate governance and security, can address these problems to enable leaders to better fight the pandemic and VOCs. Critically, early recognition of variants adversely affecting vaccine effectiveness is vital to rapid vaccine redesign.
- This application of technology has utility beyond the current pandemic and can critically support data collection in a standardised and coordinated way to support surveillance for other diseases, including emerging infectious diseases.

POLICY RECOMMENDATIONS

- Identify the most promising technology solutions to strengthen cloud-based genomic sequence data analysis and storage for a range of pathogens, and facilitate global surveillance with appropriate tools and dashboards.
 - Fund, pilot and support development of promising solutions to ensure they are validated and have appropriate technical and security functionality.
 - Establish an international body, ideally convened by the World Health Organisation (WHO), to serve as the steward for a global technology solution; set, monitor and enforce standards for participation, data-sharing and reporting; design key incentives for data-sharing; and oversee scientific committees to set consensus on wild-type SARS-CoV-2 versus variant strains and identify phenotypic and epidemiological implications.
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Foreword: Introducing the Global Health Security Consortium

We will only defeat Covid-19 and prevent future global health security issues by working together. This ethos must sit at the heart of the global response to the pandemic. It is the ethos that sits behind the Global Health Security Consortium (GHSC).

We are a team made up of three organisations: the Tony Blair Institute for Global Change, the Ellison Institute for Transformative Medicine and scientists from the University of Oxford.

POLITICS. MEDICINE. SCIENCE.

These three components are essential to making progress, to defeating Covid-19 and to preventing future pandemics and health security issues. They must be grounded in evidence and insight, practical and politically possible, yet ambitious and far-reaching. To this end we are mobilising our efforts to complement and work with the many exceptional organisations and individuals in this space who share our ambition.

By drawing on our collective experience and global reach, we seek to offer ideas across a number of domains. Initial projects of the GHSC include the development of a feasible plan to revolutionise genomic sequencing and surveillance of the SARS-CoV-2 virus, set out in this paper, along with contributions on strategic global vaccine rollout, therapeutic development, diagnostics, the role of data and data-driven insights, and other critical topics to be developed over time.

We will always look to push the boundaries of what is politically and scientifically possible but also commit to presenting clear and actionable roadmaps that leaders can put to use. Our aim is to help turn ideas into reality that changes lives for the better.

We have seen that viruses do not respect borders. Our approach will always remain global, our agenda single-minded: to help leaders contain this pandemic as quickly as possible for all of humanity, and ensure nothing like it ever happens again. We have no choice.

Dr David Agus

Founding Director, Ellison Institute
for Transformative Medicine

Tony Blair

Executive Chairman, Tony Blair
Institute for Global Change



Executive Summary

WHY DOES THIS MATTER?

The emergence of variants of concern (VOCs) will prevent us from ending the Covid-19 pandemic in a timely manner. If VOCs achieve “viral escape” – when a virus can evade the immunity (T-cell and humoral) generated by a vaccine – new strains of SARS-CoV-2 could infect and kill at a global scale, even after we achieve mass vaccination. Genomic sequencing and surveillance at scale would allow the global community to identify VOCs and their spread earlier so that we can respond rapidly with appropriate vaccines (including boosters), treatments, and policy and public-health measures. Analytic tools, platforms and dashboards enable the viewing of sovereign data and global data to facilitate early public-health interventions, policy planning and decision-making. Genomic sequencing, surveillance and analytic capabilities play a similarly critical role for other infectious diseases, which should be carefully managed as part of emerging global health security priorities.

WHAT IS THE PROBLEM?

Despite calls for global cooperation on genomic sequencing and surveillance, three interrelated technology-related problems prevent global coordination on this topic.

1. **There is no turnkey, standardised processing and upload solution for sequencing labs to share data in a common database.** The number of sequences collected and shared to date is insufficient. As of the beginning of March, the largest database of SARS-CoV-2 genomic sequences had only amassed one-tenth of the total number of sequences recommended by the World Health Organisation (WHO). Standardised processing of sequence data is critical to enable sharing of data and collaborative research.

2. **Current platforms comparing sequences from multiple geographies to identify and track SARS-CoV-2 VOCs have made significant progress synthesising and visualising genomic evolution, and they have opportunities to further develop to translate this data into actionable research.** Additional solutions are needed to rapidly identify when viral evolution would cause a strain to be considered a VOC (i.e., it may result in viral escape) and to allow for transparent governance for data-sharing.
3. **Analytic tools, platforms and dashboards can go further to link genetic mutations and variants to changes in epidemiology, clinical outcomes and effectiveness of vaccines, therapeutics and diagnostics.** By linking genetic mutations to these phenotypic changes, genomic surveillance can inform decisions about public-health measures, clinical guidelines and vaccine, therapeutic and diagnostic R&D.

WHAT IS THE SOLUTION?

Having the right technology solutions in place, with appropriate governance, can address these problems and enable leaders to better fight the pandemic and VOCs. We need a **technology solution complemented by the right governance and incentives** that can:

1. **Enable existing and new sequencing labs to rapidly upload and share raw data using standardised processing approaches, including to databases such as GISAID, NCBI and EBI. This solution should protect the privacy of the patient's data, respect the rights of the lab and sovereignty of the nation whose lab generated the data, and keep the data secure from external threats.** Any global cloud-based repository capturing and processing this data should allow for rapid turnaround and return of the consensus genome for download by the user who uploaded the sequence. Nations should have sufficient access to each other's data to understand global spread of the virus without compromising the ability to control the details of what is shared.
2. **Analyse aggregated, annotated consensus sequences to make key inferences about the pathogen (e.g., emerging lineages or specific mutations) and major phenotypic changes resulting from these genetic mutations (including VOCs).**
3. **Translate data about genomic evolution into insights for policymakers about VOCs, specifically their impacts on epidemiology, clinical outcomes, and effectiveness of vaccines, therapeutics and diagnostics.** Analytic and dashboard tools should be pragmatic and rapid, with an emphasis on guiding decision-making for combatting the pandemic, including a “variants-to-vaccines and therapeutics” R&D pipeline.

These technology solutions are applicable to SARS-CoV-2, other established diseases and new pathogens. Analytic platforms need to be low-cost and not-for-profit so that they can be readily used around the world, with clear policies and standards (including common data elements). They should have transparent algorithms and processes for users to submit requests so that researchers and users can understand the methodology behind the analytics.

Of course, design and adoption of any technology solution would need to be complemented by appropriate governance, dedicated financing, scientific oversight and sufficient sequencing capacity. Specifically, to complement the technology solution described above, we propose the following **broader enablers**:

1. **Expanding on-the-ground genomic sequencing capabilities so there are fewer blind spots around the world, complemented by local capacity for clinical phenotyping.**
2. **Incentivising the use of common data standards for sharing genomic sequencing data.**
3. **Developing international governance for sharing data and designating a custodian for the platform. An international body, ideally convened by the WHO, could set the “rules of the road” for data-sharing and privacy, incentivise global data sharing, and monitor nations’ compliance and participation.**
4. **Establishing a scientific advisory committee, ideally convened and chaired by the WHO, to define what counts as wild-type SARS-CoV-2, variants and VOCs, and to determine implications for public-health decisions.**

Simplifying and scaling the ability to share genomic sequences of pathogens has broad applications beyond fighting the Covid-19 pandemic. Medical research and drug design depend heavily on the ability to share genomic (and other) data. While the Covid-19 pandemic presents the most immediate use case for truly global coordination of genomic data-sharing, building out this global capability would also unlock genomic data-sharing capabilities for other disease areas, including other infectious diseases, cancer, autoimmune disorders and rare diseases.



Why Does This Matter?

The emergence of variants of concern will prevent us from ending the Covid-19 pandemic.

Early on, in the first half of the pandemic, there was genetic variation in SARS-CoV-2, but no dominant variants with changed behaviour emerged. However, over time and more recently, consistent with how RNA viruses typically evolve, we have observed different dominant genetic variants arising, predominantly based on their increased binding affinity to the ACE2 receptor and leading to increased transmissibility and infectiousness. Although most variation in the genome has little effect, it can occasionally lead to increased transmission; other variation can lead to reduced immunity from previous infections, reductions in vaccine effectiveness and changes in the performance of diagnostic tests. These are major concerns for managing national and international public-health interventions to better control the pandemic.

Viruses mutate and strains emerge for several reasons. Viruses undergo general adaptation, such as mutations that increase transmissibility and infectiousness. They can also undergo immune-driven evolution. Under these circumstances, viruses evolve in response to the changing immunity of the population.

While many mutations have very little impact on the nature of the disease, certain variants can have significant public-health consequences.¹ They can be more highly transmissible, cause more severe health problems for patients and have more resistance to treatments. Most importantly, variants can achieve viral escape, whereby a virus can evade the antibodies and T-cells generated by a vaccine or prior exposure to the virus. Under such a scenario, new strains of SARS-CoV-2 could infect and kill at a global scale, even after we achieve mass vaccination. There are already reports of “breakthrough” infections, where previously vaccinated individuals become infected with SARS-CoV-2, although these infections do not necessarily indicate viral escape.²

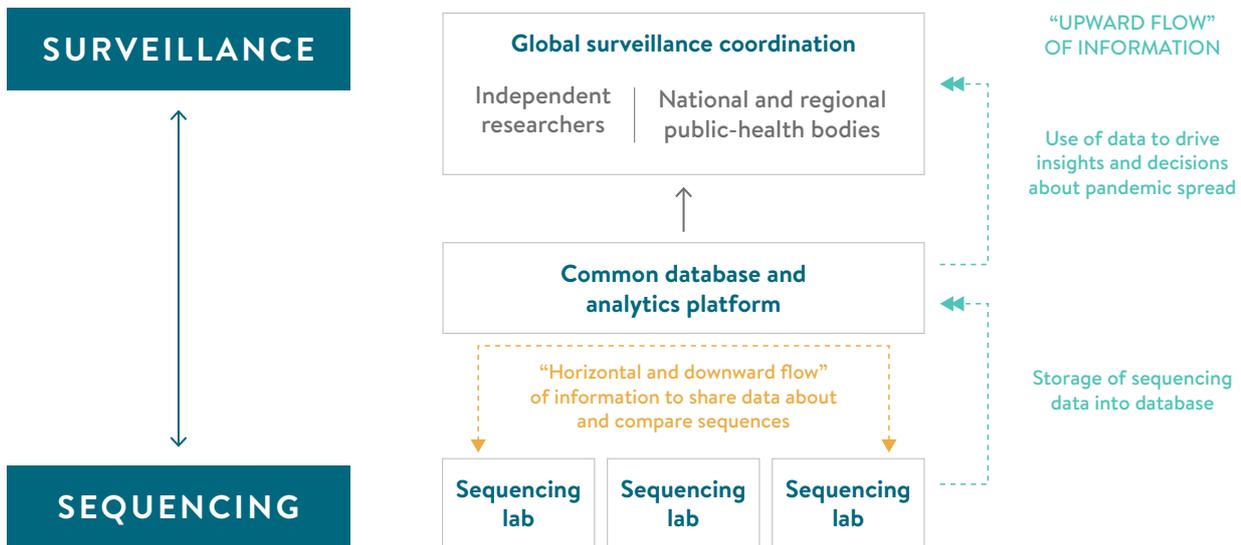
As of April 2021, there had been thousands of mutations in SARS-CoV-2,³ and the US Centres for Disease Control and Prevention (CDC) had identified five SARS-CoV-2 variants of concern and another three variants of interest.⁴ New variants have been identified all over the globe, and it is very possible that there are additional variants circulating that have not yet been identified or reported.

What Is the Problem?

Genomic sequencing and surveillance are critical for proactively identifying and tracking the emergence of new variants. This process involves an “upward flow” of information from sequencing to surveillance, as well as a “horizontal and downward” flow of information to compare sequences from different labs.

Figure 1

GENOMIC SEQUENCING AND SURVEILLANCE REQUIRE UPWARD, HORIZONTAL AND DOWNWARD FLOWS OF INFORMATION



Source: Author illustration

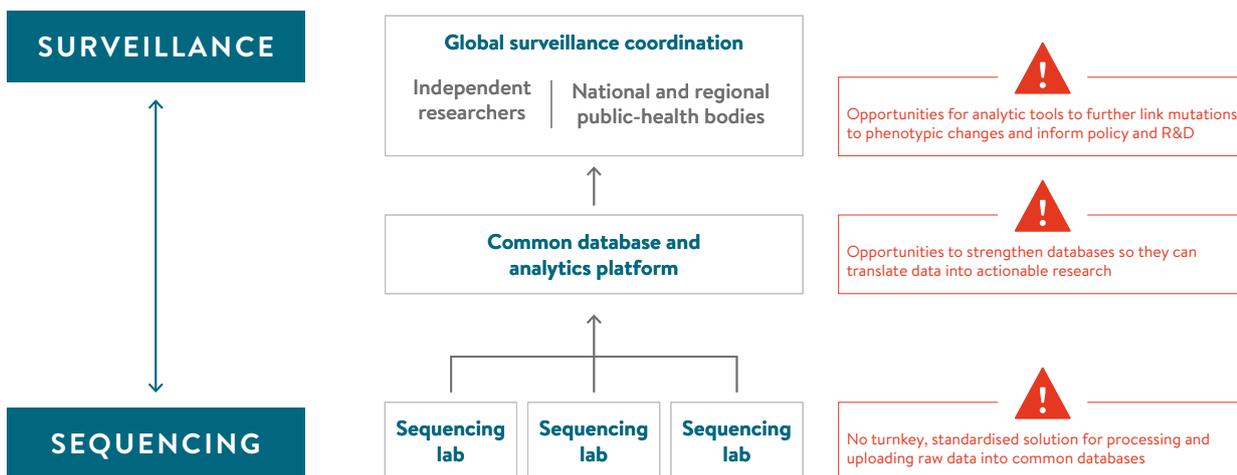
As shown in Figure 1, above, the “upward” flow of information moves data from individual sequencing labs into databases that allow them to be stored and used for diagnostic, clinical and public-health purposes. The “horizontal and downward” flow of information allows for comparison of sequences within and between sovereign sequencing facilities where it can be linked to patient-identifiable or sensitive data.

In a best-case scenario, these flows of information would be used to guide the global response to the pandemic. They would serve as an early-warning system for how the virus is evolving and how to combat it. As a global community, we cannot get ahead of the virus without this information.

However, in our current state, three interrelated technology problems prevent global coordination for this early warning system. See Figure 2, below, for a summary.

Figure 2

THREE RELATED CHALLENGES ARE PREVENTING LEADERS FROM USING GENOMIC SEQUENCING TO FIGHT THE PANDEMIC



Source: Author illustration

- 1. There is no turnkey, standardised sequence-processing and upload solution for sequencing labs to share data in a common database.** The number of sequences collected and shared to date is insufficient. As of the beginning of March, the largest database of SARS-CoV-2 genomic sequences had only amassed one-tenth of the total number of sequences recommended by the WHO. Further, standardised processing of sequence data is critical to enable collaborative research. Without rigorous quality control over processing of sequence data, it is difficult to compare data from different labs.
- 2. Current platforms comparing sequences from multiple geographies to identify and track SARS-CoV-2 VOCs have made significant progress synthesising and visualising genomic evolution, and they have opportunities to further develop to translate this data into actionable research.** Additional solutions are needed to identify when viral evolution would cause a strain to be considered a VOC (i.e., it may result in viral escape) and to allow for transparent governance for data-sharing. Existing global solutions have faced challenges with access to data and with transparency around rules for sharing data.⁵ As individual countries build out their genomic sequencing capabilities, they will need to be able to systematically track findings globally to track the spread of VOCs.
- 3. Analytic tools, platforms and dashboards can go further to link genetic mutations and variants to changes in epidemiology, clinical outcomes, and effectiveness of vaccines, therapeutics and diagnostics.** By linking genetic mutations to these phenotypic changes, genomic surveillance can inform decisions about public-health measures, clinical guidelines, and the vaccine, therapeutic and R&D pipeline. While certain tools, such as Nextstrain, have made progress on visualising the spread of strains, the primary use case for this tool is currently for research purposes. We see a gap in the field for dashboards, visualisations and analytics that can be used by decision-makers, including those without extensive scientific training, to understand the pragmatic implications of variant spread for public health. Further, a streamlined “variants-to-vaccines and therapeutics” pipeline would help ensure that R&D addresses the most recent genomic mutations.

Of course, this technology gap is not the only problem preventing the world from building out surveillance and sequencing. However, we see this technology limitation as a key bottleneck for achieving global, integrated sequencing and surveillance capacity at scale because without it sequence data (from existing or newly planned labs) will not achieve its full potential to inform the global response.

Other key issues that would also need to be addressed for a comprehensive global sequencing and surveillance platform include:

- **The lack of genomic sequencing lab capacity around the world:** Uploads of sequence data remain patchy around the world.⁶ In Africa, more than 70 per cent of genomic sequencing capacity is concentrated in only five countries, and the majority of this capacity sits outside of national public-health institutes.⁷ The United States has also had trouble scaling genomic surveillance capacity, although recently announced plans aim to address this challenge.^{8,9} Gaps in local sequencing capacity are effectively blind spots in our global view of what is going on with the spread of the disease.
 - **No clear governance, oversight or incentives for the sharing and use of data:** Like all health data, genomic sequencing data is very sensitive due to the private nature of information stored. At a global level, this data is also particularly sensitive because it can have implications for national security and the economy (i.e., if nations use it to block travel). Regulations pertaining to health and governing multiple countries can be notoriously difficult to implement, as evidenced by the mixed compliance of nations with the 2005 International Health Regulations.¹⁰ Without clear governance and standards for how data will be used or shared, or a custodian of this data trusted by governments, it will be impossible to centralise the necessary data to have a global snapshot of sequencing results. Sequencing labs, in particular those managed by public-health bodies that have a mandate to support disease control, need appropriate incentives for the sharing of data globally.
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What Is the Solution?

Having the right technology solutions in place, with appropriate governance, can address these problems to enable leaders to better fight the pandemic and VOCs. To that end, we need solutions that will support a global cloud-based repository for capturing and processing genomic sequencing, surveillance, analytics and dashboards. Cloud-based infrastructure is critical so that sequences can be rapidly compared across different labs and around the world. A global repository and processing service could mirror national and international repositories – for example, GISAID, the China National GeneBank (CNGB), the DNA Data Bank of Japan (DDBJ), the European Bioinformatics Institute (EBI) and the National Center for Biotechnology Information (NCBI) in the USA – while ensuring sovereignty and security of national data. At the same time, it is critical to ensure that the proper mechanisms are in place to enable interoperability, safety and integrity of data.

A technology solution to address the challenges described earlier would serve three key functions:

1. **Technology tools should enable existing and new sequencing labs to rapidly upload and share raw data using standardised processing techniques, while protecting the privacy of the patient’s data, respecting the rights of the lab and sovereignty of the nation whose lab generated the data, and securing the data from external threats.** Processing of genomic sequences through a pipeline would perform quality-assurance checks, standardise variant names and produce a “consensus genome” (i.e., what variant a specific sequence belongs to), annotated with variations in the sequences (i.e., genomic substitutions, insertions and deletions [“indels”]). Any global cloud-based processing service should allow for rapid turnaround and return of the consensus genome for download by the user who uploaded the sequence.

- 2. Analytic tools and platforms should allow for analysis of aggregated, annotated consensus sequences to make key inferences about the pathogen (e.g., emerging lineages or specific mutations) and major phenotypic changes resulting from these genetic mutations (including VOCs).** Phenotypic changes of variants would include increased transmissibility and infectiousness, increased clinical severity and mortality, viral escape from existing vaccines and changes in detection by diagnostic tests. It is critical to understand the links between changes in the viral genome and phenotypic changes because these phenotypic changes will ultimately guide the R&D, clinical and public-health priorities for responding to the pandemic. Drawing these links will require comparing genomic sequencing data with epidemiological data (i.e., positivity and mortality rates) to understand a variant's spread and clinical impact. Of course, linking genomic sequences to patient data introduces additional security concerns, and the technology solution must account for ways to understand clinical implications of genomic change without sacrificing patient privacy or national data protection.
- 3. Analytic tools, platforms and dashboards should translate data about genomic evolution and phenotypic changes into insights about VOCs and should be pragmatic and rapid, with an emphasis on guiding decision-making for combatting the pandemic.** As mentioned earlier, the first step in drawing meaningful insights will be to compare individual viral sequences to each other in order to determine which strain a specific sequence belongs to. That functionality could provide a dashboard about geospatial and temporal trends in global viral spread. Building on this, the dashboard should also present phenotypic and epidemiological implications of these trends, including potential for increased transmissibility and viral escape. The dashboard could ideally integrate independent research findings and real-world evidence. Intuitive user interfaces, visualisations and dashboards will be critical for managing both operational aspects of the pandemic response and policy changes as the pandemic evolves. These operational responses and decisions would include guidance on non-pharmaceutical interventions, priorities for surveillance capabilities, updated clinical guidance, and R&D for novel diagnostics, therapeutics and vaccines needed to combat new strains (i.e., a “variants-to-vaccines and therapeutics” pipeline).¹¹

The Common Data Standards Required for a Global Repository

The three main sets of standards required for interoperable and secure health informatics are **data capture** (what data is captured), **data mapping** (how is this data captured to make it interoperable) and **data access** (how people can access this data).¹² On-the-ground genomic sequencing capabilities will define the data capture components of this process, but platforms for processing the data need to be agnostic to sequencer used and method of preparing the nucleic acid for sequencing. The cloud-based technology solution to link these data must account for data-mapping and data-access standards.

For data mapping, it is critical to have common data elements and standards for metadata so that users of the data can investigate not only the sequence itself, but also the source of the data and how it is being used. Adequate standards will make information on the consensus sequence genuinely interoperable and shareable. Common data elements and harmonised metadata will support the identification of the consensus genome for a specific sample. This will help researchers track the spread of variants as samples are uploaded. Structuring the data appropriately will make it more usable for machine learning and artificial intelligence applications, enabling better and faster research going forwards. Standardised, automated and codable naming based on genomic variation (i.e., substitution or indel) will also be critical in order to ensure identification of unique variants and their phenotypic changes.

For data access, it is important to protect both the patient and the sovereign entity uploading the data. To protect the patient, the tool should only upload de-identified data that cannot be tracked to a specific individual, but which also has enough information to prevent duplication of records and other data-quality issues. To protect the sovereignty of the nation uploading the data, each sequence should have a “sovereign stripe” that marks who controls the data. As mentioned earlier, any global cloud-based repository could mirror national repositories, which would also ensure ease of use and data-sharing following agreed-to rules. All participating nations should agree to a common set of rules and principles about data-sharing, including the level of detail that they share and what their data can and cannot be used for.

It is important that nations see significant benefits from receiving data from others (i.e., the ability to surveil and understand global spread of VOCs) so that they feel sufficiently incentivised to upload their own data. Adequate security protocols and safeguards also need to be in place to protect the data from external threats, including hackers.

Protocols to ensure quality of the data – including data cleaning, quality-assurance checks on data uploaded, validation of algorithms on “control” sequences to ensure that they produce equivalent results and proficiency testing for users – will be also be critical.

These technology solutions and analytics platforms need to be managed on a not-for-profit basis so that they can be readily used around the world, with clear policies and standards (including common data elements). They should have transparent algorithms and processes for users to submit requests so that researchers and users can understand the methodology behind the analytics.

Of course, design and adoption of any technology solution would need to be complemented by appropriate governance, dedicated financing, scientific oversight and sufficient sequencing capacity. Specifically, to complement the technology solution described above, we propose:

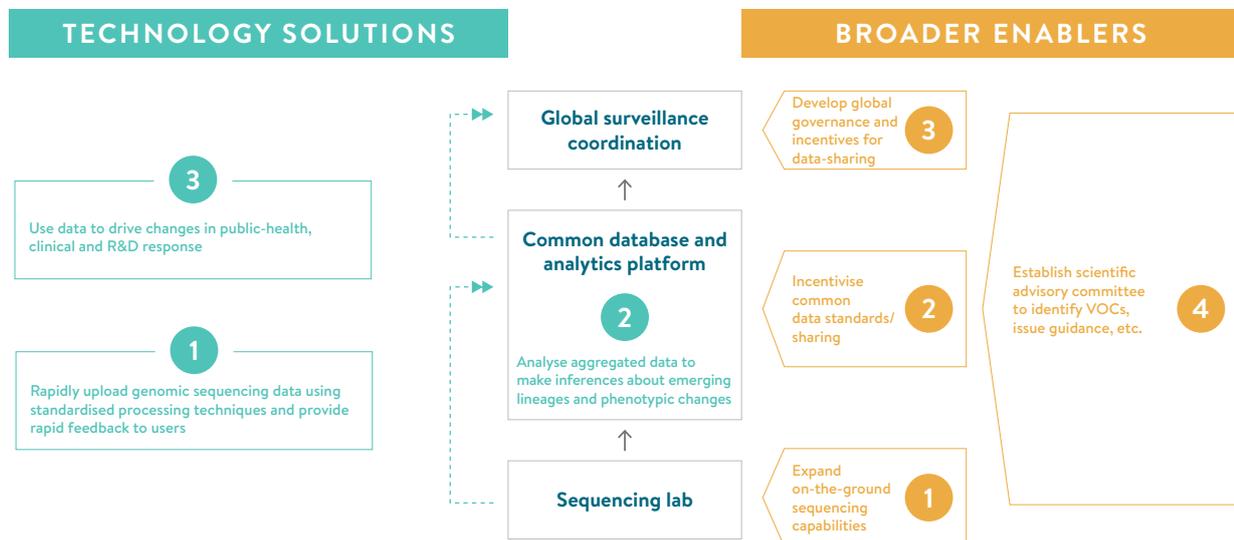
1. **Expanding on-the-ground genomic sequencing capabilities.** Doing so requires adequate coverage of sequencing capabilities around the world so that there are no blind spots, and adequate staff, sequencing machines and resources to conduct sequencing work. These sequencing capabilities should be complemented by local capacity for clinical phenotyping to evaluate new variants.
2. **Incentivising the use of common data standards for sharing genomic sequencing data.** In this case, even if different labs use different platforms for uploading and storing sequence data, key data will be interoperable for use in shared analytics.
3. **Developing international governance for sharing data and designating a custodian for the platform.** An international body, ideally convened by the WHO, could set the “rules of the road” for data-sharing and privacy, incentivise data-sharing, and monitor nations’ participation and compliance with these rules. Incentives for data-sharing are particularly critical since shared data is a global public good for combatting the pandemic, and sharing data will be done on a voluntary basis by nations.

At the very least, nations need guarantees about how other countries, researchers and the private sector will use the data to diminish any disincentives for data-sharing (e.g., imposing overly burdensome travel restrictions or not getting access to novel R&D innovations based on data shared).

4. **Establishing a scientific advisory committee, ideally convened and chaired by the WHO, to define what counts as wild-type SARS-CoV-2, variants and VOCs.** This body, in collaboration with regional and national centres for disease control, could also issue normative guidance about public-health measures, R&D priorities and vaccination/treatment guidelines in response to emerging VOCs.

Figure 3

TECHNOLOGY SOLUTIONS, COMPLEMENTED BY BROADER ENABLERS, ARE CRITICAL FOR GLOBAL SEQUENCING/SURVEILLANCE



Source: Author illustration

Simplifying and scaling the ability to share genomic sequences of pathogens has broad applications beyond fighting the Covid-19 pandemic. Molecular surveillance, outbreak management and surveillance, biomedical research, drug design, and drug safety and efficacy monitoring depends heavily on the ability to share genomic (and other) data. While the Covid-19 pandemic presents the most immediate use case for truly global coordination of genomic data-sharing, building out this global capability would also unlock genomic data-sharing capabilities for other disease areas, including other infectious diseases, cancer, autoimmune disorders and rare diseases. For example, the Africa Centres for Disease Control and Prevention recently published a range of genomic sequencing use cases beyond SARS-CoV-2 that would improve public health across the continent, including for (re-)emerging infections, HIV, TB and neglected tropical diseases.¹³ Genomic sequencing of tumours is also critical for accurately diagnosing and treating cancers, as well as designing novel therapeutics for oncology.¹⁴ With the increasing global burden of cancer, expanding genomic sequencing and surveillance capabilities can help us get ahead of this and other emerging health threats.¹⁵

Policy Recommendations

To address this urgent and global problem, policymakers should:

1. Identify the most promising technology solutions to strengthen cloud-based genomic sequence repositories and processing solutions, and facilitate global surveillance with appropriate tools and dashboards.
 2. Fund, pilot and support development of promising solutions to ensure they have appropriate technical and security functionality.
 3. Establish an international body, ideally convened by the WHO, to serve as the steward of a global technology solution; set, monitor and enforce standards for participation, data-sharing and reporting; design key incentives for data-sharing; and oversee scientific committees to set consensus on wild-type SARS-CoV-2 versus variant strains and identify phenotypic and epidemiological implications.
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Endnotes

1 <https://www.bbc.com/news/science-environment-55404988>

2 <https://www.washingtonpost.com/health/2021/04/09/do-people-get-covid-after-being-vaccinated/>

3 <https://www.bbc.com/news/science-environment-55404988>

4 The US CDC defines “variants of concern” as “a variant for which there is evidence of an increase in transmissibility, more severe disease (increased hospitalizations or deaths), significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures.” They define a “variant of interest” as “a variant with specific genetic markers that have been associated with changes to receptor binding, reduced neutralization by antibodies generated against previous infection or vaccination, reduced efficacy of treatments, potential diagnostic impact, or predicted increase in transmissibility or disease severity.” They also include a third category, “variants of high consequence”, defined as having “clear evidence that prevention measures or medical countermeasures (MCMs) have significantly reduced effectiveness relative to previously circulating variants.” As of the beginning of April 2021, the CDC had identified no variants of high consequence. Source: <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html>

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13 [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30939-7/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30939-7/fulltext)

14 <https://www.nature.com/articles/d41586-020-00845-4>

15 <https://canceratlas.cancer.org/the-burden/the-burden-of-cancer/#:~:text=In%202040%2C%20an%20estimated%2029.4,rates%20in%202018%20remain%20unchanged>





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