



Considerations for developing a national genomic surveillance strategy or action plan for pathogens with pandemic and epidemic potential



Considerations for developing a national genomic surveillance strategy or action plan for pathogens with pandemic and epidemic potential

Considerations for developing a national genomic surveillance strategy or action plan for pathogens with pandemic and epidemic potential

ISBN 978-92-4-007656-3 (electronic version)

ISBN 978-92-4-007657-0 (print version)

© **World Health Organization 2023**

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: “This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition”.

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization (<http://www.wipo.int/amc/en/mediation/rules/>).

Suggested citation. Considerations for developing a national genomic surveillance strategy or action plan for pathogens with pandemic and epidemic potential. Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <https://www.who.int/publications/book-orders>. To submit requests for commercial use and queries on rights and licensing, see <https://www.who.int/copyright>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Design by Antonio Perez.



Contents

Acknowledgements	ii
Acronyms and abbreviations	iv
1. Introduction	1
Reading guide	4
2. Key considerations in developing a national genomic surveillance strategy for pathogens with pandemic and epidemic potential	5
2.1 Ensure strong national leadership, financial commitment and governance framework	5
2.2 Focus on public health decision-making	5
2.3 Target all relevant pathogens with priority pathogen use cases	6
2.4 Strengthen data management	7
2.5 Promote data sharing and collaboration	8
3. Stepwise approach to developing a national genomic surveillance strategy for pathogens with pandemic and epidemic potential	9
3.1 Strengthen coordination, collaboration and governance	9
3.2 Conduct a situation analysis	10
3.3 Identify a goal, objectives and strategic actions	11
3.4 Define the approach to strategy implementation	12
3.5 Establish a framework for Monitoring and Evaluation	13
3.6 Develop an overall costed implementation plan	14
3.7 Identify and mobilize resources for implementation	14
4. WHO support	15
5. Methodology for developing the strategy support tool and identifying key considerations	16
6. Additional tools	16
References	17



Acknowledgements

WHO would like to thank the collaborative efforts of all those involved in developing this strategy support tool.

WHO contributors

Technical concept, writing and review: Oluwatosin Wuraola Akande (Epidemic and Pandemic Preparedness and Prevention, World Health Organization, Geneva, Switzerland), Lisa Carter (Country Readiness Strengthening, World Health Organization Lyon Office, Lyon, France), Camille Péneau (Emergency Preparedness and Response, World Health Organization Regional Office for Africa, Brazzaville, Republic of the Congo), Gina Samaan (Epidemic and Pandemic Preparedness and Prevention, World Health Organization, Geneva, Switzerland).

Scoping and review: Mustafa Abdelaziz Aboualy (Infectious Hazard Prevention and Preparedness, World Health Organization Regional Office for the Eastern Mediterranean, Cairo, Egypt), Rachel Achilla (Emergency Preparedness and Response, World Health Organization Regional Office for Africa, Brazzaville, Republic of Congo), Amal Barakat (Infectious Hazard Prevention and Preparedness, World Health Organization Regional Office for the Eastern Mediterranean, Cairo, Egypt), Céline Barnadas (Country Readiness Strengthening, World Health Organization Lyon Office, Lyon, France), Sylvie Briand (Epidemic and Pandemic Preparedness and Prevention, World Health Organization, Geneva, Switzerland), Sebastien Bruno Cognat (Country Readiness Strengthening, World Health Organization Lyon Office, Lyon, France), Jane Cunningham (Epidemic and Pandemic Preparedness and Prevention, World Health Organization, Geneva, Switzerland), Nicky Gumede (Emergency Preparedness and Response, World Health Organization Regional Office for Africa, Brazzaville, Republic of Congo), Alina Guseinova (Infectious Hazard Management, World Health Organization Regional Office for Europe, Copenhagen, Denmark), Francis Yesurajan Inbanathan (WHO Health Emergencies, Regional Office for South-East Asia, New Delhi, India), Alexandr Jaguparov (WHO Health Emergencies Programme, World Health Organization Country Office, Astana, Kazakhstan), Masaya Kato (WHO Health Emergencies, Regional Office for South-East Asia, New Delhi, India), Etien Luc Koua (Emergency Preparedness and Response, World Health Organization Regional Office for Africa, Brazzaville, Republic of Congo), Juliana Leite (PAHO Health Emergencies, Pan American Health Organization, Washington DC, United States),

Baïdy Lo (Dakar Emergency Preparedness and Response Hub, World Health Organization Regional Office for Africa, Dakar, Republic of Senegal), Marco Marklewitz (Infectious Hazard Management, World Health Organization Regional Office for Europe, Copenhagen, Denmark), Tamano Matsui (WHO Health Emergencies, Regional Office for Western Pacific, Manila, Philippines), Jairo Andres Mendez Rico (PAHO Health Emergencies, Pan American Health Organization, Washington DC, United States), Luke William Meredith (Infectious Hazard Prevention and Preparedness, World Health Organization Regional Office for the Eastern Mediterranean, Cairo, Egypt), Chavely Gwladys Monamele (Emergency Preparedness and Response, World Health Organization Regional Office for Africa, Brazzaville, Republic of Congo), Karen Nahapetyan (Infectious Hazard Management, World Health Organization Regional Office for Europe, Copenhagen, Denmark), Dhamari Naidoo (WHO Health Emergencies, Regional Office for South-East Asia, New Delhi, India), Mehmet Ozel (Infectious Hazard Prevention and Preparedness, World Health Organization Regional Office for the Eastern Mediterranean, Cairo, Egypt), Dmitriy I. Pereyaslov (Epidemic and Pandemic Preparedness and Prevention, World Health Organization, Geneva, Switzerland), Karl Schenkel (Surveillance Systems, World Health Organization, Geneva, Switzerland), Maria Van Kerkhove (Epidemic and Pandemic Preparedness and Prevention, World Health Organization, Geneva, Switzerland), Andrea Vicari (PAHO Health Emergencies, Pan American Health Organization, Washington DC, United States), Taylor Warren (Disaster Risk Management and Resilience, World Health Organization, Geneva, Switzerland), Pushpa Ranjan Wijesinghe (WHO Health Emergencies, Regional Office for South-East Asia, New Delhi, India), Joanna Zwetyenga (Infectious Hazard Management, World Health Organization Regional Office for Europe, Copenhagen, Denmark).

External contributors

Review: Afreenish Amir (National Institute of Health, Pakistan), Natsuko Imai (Wellcome Trust, United Kingdom of Great Britain and Northern Ireland), Leena Inamdar (United Kingdom Health Security Agency, United Kingdom of Great Britain and Northern Ireland), Abebe Aseffa Negeri (Ethiopian Public Health Institute, Ethiopia), Paul Michael Pronyk (Duke-NUS Centre for Outbreak Preparedness, Singapore), Anita Suresh (FIND, Switzerland), Cristina Tato (Chan Zuckerberg Biohub, United States of America), Toni Whistler (The Global Fund, Switzerland).

Acronyms and abbreviations

AAR	after-action review
AMR	antimicrobial resistance
COVID-19	coronavirus disease 2019
GSD	genetic sequence data
IAR	intra-action review
IHR	International Health Regulations
JEE	joint external evaluation
M&E	monitoring and evaluation
PCR	polymerase chain reaction
SOP	standard operating procedure
SPAR	States Parties self-assessment annual reporting
SWOT	strengths, weaknesses, opportunities and threats
TB	tuberculosis

1. Introduction

Pathogen genomic surveillance has become a priority for public health systems in recent years. Genomic sequencing is increasingly being used to characterize pathogens and monitor important public health priorities (e.g. poliovirus, influenza virus, *Mycobacterium tuberculosis* and *Vibrio cholerae*, antimicrobial resistance (AMR)). The decrease in cost and time of sequencing and the exponential development of bioinformatic pipelines have played a critical role in integrating pathogen genomics into routine public health surveillance. The coronavirus disease 2019 (COVID-19) pandemic has highlighted the role that sequencing plays in the surveillance of infectious diseases. Sequencing facilitates earlier detection, more accurate investigation of outbreaks, closer real-time monitoring of pathogen evolution and tailored development and evaluation of interventions to inform local to global public health decision-making and action. However, there remains a need to coordinate efforts, leverage and link existing surveillance and laboratory networks and capabilities, and systematically integrate genetic sequence data (GSD) with clinical and epidemiological data to strengthen its utility.



Genomic surveillance contributes to multiple aims, including:

- Rapidly detecting and characterizing circulating pathogens;
- monitoring pathogen transmission;
- developing adapted diagnostic assays, medicines and vaccines;
- and tracking the genetic evolution of pathogens to determine its impact on the transmissibility and severity of disease, on public health and social measures, and on the effectiveness of existing diagnostics, vaccines and therapeutics.

In its first meeting in January 2020, the International Health Regulations (IHR) 2005 Emergency Committee for COVID-19 highlighted the importance of genomic sequencing. In its sixth meeting one year later, the Committee specifically stressed the need to strengthen the use of sequencing in surveillance systems while advocating for timely data sharing (1, 2). This need was further emphasized in the report of the Independent Panel for Pandemic Preparedness and Response and culminated in May 2021 with the 74th World Health Assembly resolution 74.7 on strengthening WHO's preparedness and response to health emergencies (3, 4). Resolution 74.7 urges WHO Member States to increase their capacity to detect emerging threats, including through laboratory techniques such as genomic sequencing.

Sequencing has thus become a key element of IHR 2005 laboratory core capacities that Member States can employ to detect, investigate and respond to public health emergencies (5). These capacities are directly assessed by an indicator in the IHR States Parties self-assessment annual reporting (SPAR) tool (indicator C4.4) and the IHR joint external evaluation (JEE) tool (indicator D1.3), which specifies under

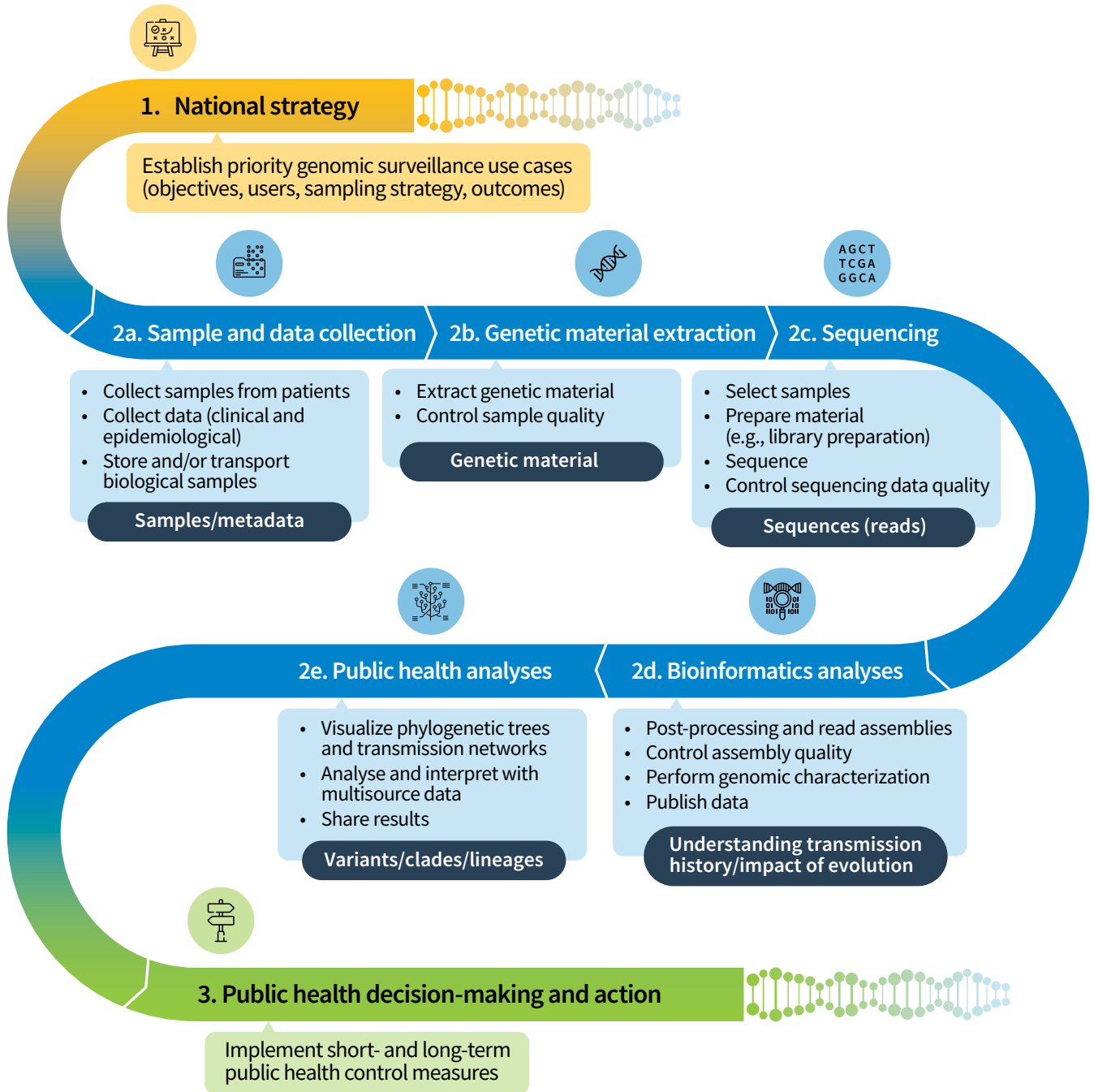
level 5 that “the laboratory system ... has access to whole genome sequencing identification of unknown and high-consequence pathogens” (6, 7).

In March 2022 WHO launched a 10-year global genomic surveillance strategy for pathogens with pandemic and epidemic potential (8). The goal of this strategy is to strengthen and scale up genomic surveillance to ensure quality, timely and appropriate public health action within local to global surveillance systems. The global strategy is designed to support countries in their efforts to expand capacity and adopt harmonized, pathogen-agnostic approaches to genomic surveillance. In addition, WHO developed 13 foundational principles to encourage global sharing of pathogen genome data for public health use (9).

Genomic surveillance presents considerable challenges and opportunities in terms of laboratory and surveillance infrastructure, capacity and capability requirements, and harmonization across systems to effectively analyse and use data and prevent duplication of effort. These challenges and opportunities depend on the national context. Developing an adequately resourced national genomic surveillance strategy, or an action plan that underpins a strategy, will enable countries to set goals, objectives and priority strategic actions, as well as targets tailored to their context to be achieved in the short and long term, in alignment with the global strategy (8).

This strategy support tool outlines key considerations and a proposed stepwise approach for countries to develop a national genomic surveillance strategy or action plan for pathogens with pandemic and epidemic potential. A national strategy should reflect all stages of the genomic surveillance value chain (Fig. 1), considering both existing public health priority pathogen use cases and readiness for the emergence of novel pathogens. Depending on the context, pathogen genomic surveillance could leverage capacities and resources for other pathogens outside of the health emergency context (e.g. malaria genomics) or outside of pathogen sequencing (e.g. cancer genomics). This document is intended for use by all stakeholders at the national and subnational level relevant to the development and implementation of the strategy, including health authorities, One Health partners, donors, public health officers, academia, the private sector and laboratory specialists.

Fig. 1. Overview of the genomic surveillance value chain with corresponding activities and outputs



Reading guide



- Based on strong **national leadership**
- Aimed at **public health decision-making**
- Defined **priority pathogen use cases**
- Focused on strengthening **data management**
- Promoting **data sharing and collaboration**

SEE SECTION 2 FOR THE **KEY CONSIDERATIONS** TO DEVELOP A STRATEGY

1 Prepare



Engage policymakers and partners in the genomic surveillance investment case, identify stakeholders, create a multisectoral strategy working group for coordination

2 Analyse situation



Describe the national context and identify priority risks, collect baseline information, identify use cases for genomic surveillance

3 Set scope of strategy



Define scope (multipathogens, interoperability, multisource data approach, specific time frame); identify goals, objectives and strategic actions

4 Outline activities for implementation



Identify and prioritize activities, choose implementation approach, develop a data management protocol

5 Design a monitoring and evaluation framework



Identify the process and output/outcome measures for monitoring the successful implementation of the national strategy

6 Cost activities



Elaborate costs and human resource needs, verify their consistency in the national budgetary context and time frame, validate with subnational/national authorities and stakeholders

7 Mobilize resources



Map existing funding sources, funding gaps and potential funders; advocate to secure national long-term commitments from national authorities

SEE SECTION 3 FOR THE **STEPWISE APPROACH** TO DEVELOP A STRATEGY

2. Key considerations in developing a national genomic surveillance strategy for pathogens with pandemic and epidemic potential

A national strategy aims to set each country's goal and objectives for genomic surveillance over a specified time frame and to describe the approach to implementation. This can include operational elements such as cost, monitoring and roles and responsibilities of stakeholders. The following considerations can inform strategy development.

2.1 Ensure strong national leadership, financial commitment and governance framework



As a result of efforts made during the COVID-19 pandemic, more than two-thirds of countries now have sequencing capacity. But much work needs to be done to stabilize the newly developed capabilities, ensure their sustainability over a longer period of time and integrate them with existing capabilities for other pathogens.

Advocacy and awareness raising for policymakers are therefore required, with the aim of funding and integrating pathogen genomics into routine national disease control strategies. Strong commitment and ownership by governments will ensure sustainability, help to define clear objectives and strategic actions adapted to the national context and promote rapid data sharing and international collaboration. The strategy should be integrated into existing national plans or other country-level mechanisms for action planning on public health.

2.2 Focus on public health decision-making



To ensure that GSD is used to inform decision-making effectively and efficiently for both short- and long-term public health control measures, countries should consider the following principles in developing a national genomic surveillance strategy or action plan:

- **Multisource data:** GSD is one element that should be integrated into a multisource data approach, through close linkages with clinical and laboratory data, epidemiological data, One Health data, phenotypic characterization and any other relevant contextual data. This approach can be greatly facilitated by integrating pathogen genomics into national infectious disease surveillance and laboratory systems for human, animal and environmental health.
- **Representativeness:** Include a sampling strategy at the national and/or subnational level to ensure geographical and temporal representation for every

disease epidemiology. This strategy should be based on the national capacity landscape and the country's needs. Context-specific sampling in humans, animals and the environment should be conducted using a One Health approach. Note that use of samples stored in biobanks could be considered if associated with a methodology to adjust for the nonrepresentativeness of these previously collected samples.

- **Quick turnaround time:** Ensure that the generation, analysis, interpretation and sharing of pathogen GSD occur in as close to real time as possible. This is essential for making informed decisions as part of public health monitoring, infection prevention and control through clinical implementation, and preparedness and response to epidemics and pandemics. A trade-off should be considered, however, between the priority of quick turnaround and protecting the rights of submitters of high-quality data, which may be compromised by release before publication.

2.3 Target all relevant pathogens with priority pathogen use cases



The national genomic surveillance strategy should not focus on one pathogen or a specific public health threat. A unified network with a clear coordination structure should be established for routine surveillance to monitor trends and identify any new pathogens. The scope of an existing national forum may also be extended to perform these functions. The strategy should be widely accessible to sequence any sample in a One Health approach to detect any potential biological threat that could cause a local outbreak or a global epidemic, including bacteria, viruses, fungi and other infectious organisms.

Nevertheless, priority pathogen use cases can be defined based on the national pathogen prioritization exercise or risk assessment and programmatic priorities. To ensure the interoperability of surveillance networks and build a unified integrated genomic surveillance system, countries should identify relevant use cases in their specific context. Doing so will help to determine where genomic surveillance provides significant added value over existing surveillance mechanisms.

For each identified disease or public health priority, the role and use of genomic surveillance should be described and analysed. More precisely, the following information should be articulated:

- genomic surveillance objectives (e.g. track pathogen evolution and spread, inform and update countermeasures);
- data users (e.g. national health authorities, WHO, emergency operations centres and response agencies, clinicians, disease modellers, researchers and manufacturers of countermeasures);

- use/analysis of data by users (e.g. identification of increased transmissibility or disease severity, development of countermeasures or public health and social measures, monitoring programme effectiveness, research); and
- outcomes (e.g. disease elimination, reduced incidence, maximized prevention and effective countermeasures, precise and timely identification of outbreaks, prevention of epidemics or pandemics).

2.4 Strengthen data management



All sequencing technologies, and in particular the high-throughput techniques that have been developed in the last two decades, generate large amounts of data and require complex resource-intensive bioinformatic analyses. Integrating GSD into surveillance databases may overwhelm existing infrastructure and approaches for managing data that lie at the intersect between molecular biology, bioinformatics and public health. Data management is therefore a key element to be strengthened for implementing genomic surveillance and must be based on standardized procedures. This policy should not focus solely on GSD but should consider all data relevant to surveillance systems to ensure interoperability.

The parameters to be considered comprise the following areas:

- Data storage to ensure easy access to data for short- and long-term analysis and archiving. Data storage policy should be defined based on the available hardware and software infrastructure, and connectivity. Data should be backed up in one or two different locations depending on the criticality of the data, but storage requirements should be sized according to the retention strategy chosen (raw data, filtered data, processed data). These requirements may be reduced by compressing data after analysis and for long-term archiving. Also, cloud storage may be used in addition to local storage if mechanisms are in place to maintain connections and relationships between data sets.
- Data quality and consistency to ensure high quality, harmonization and comparability between data sets. Detailed specific standard operating procedures (SOPs) should be established for data quality control, and regular internal and external quality assessment programmes should be implemented for genomics and analytics. Data quality and internal consistency must be given priority over the amount of data generated to ensure confidence in the overall system. The completeness and quality of metadata should also be verified and aligned with regional and global emerging best practices on metadata standards.
- Data analysis and interpretation to ensure accurate and adapted use of data sets to inform decision-making. Many tools are now publicly available online, and their use requires no or little programming knowledge. Nevertheless, collaborations with academia, the private sector and international networks, as well as communities of practices across disciplines (laboratory science,

bioinformatics, epidemiology, public health and policymakers), should be promoted to build local capacity and develop a sustainable national workforce.

- Data privacy/security to ensure data privacy and security before sharing. While developing data management policies and procedures, it is important to be familiar with and take into account the existing national legislative and regulatory documents regarding data confidentiality, protection, storage and sharing. As an example, several options can be considered to ensure the confidentiality of sequencing data and associated metadata, such as de-identification or encryption. Data security must be ensured for both local and cloud storage. It is advisable to consult legal and privacy experts to define agreements that ensure all aspects of data privacy and protection. Developing or updating regulatory documents may be necessary to fully implement GSD data management for the benefit of public health.
- Data reporting for public health to ensure that GSD of significance to public health generated by public and private agencies, including academia/research institutions, is reported to ministries of health and employed for public health action. Information should be reported or communicated to different stakeholders accordingly by public health actors.

2.5 Promote data sharing and collaboration



Data sharing is essential to inform risk assessment and trigger decisions that protect public health at the local, national, regional and global level. Whatever form it takes, successful and sustainable data sharing must be in place at every level to minimize potential harm to individuals and communities. A national pathogen genome data-sharing policy should be defined and implemented based on the 13 guiding principles developed by WHO which focus on public health use, in line with the global strategy (8, 9).

Indeed, timely data sharing is a key element for streamlining local to global public health decision-making and action. A national database (monitored by a national coordinating centre) can be set up to centralize information (sequencing data and metadata) and facilitate integration with publicly accessible genomic sequence databases.

Countries should encourage close collaborations among surveillance networks and laboratories, including One Health partners, at the subnational, national and international level to increase the timeliness, quality, comparability and representativeness of data, to facilitate achievement of public health outcomes and to ensure a holistic readiness posture for emergencies. Integrating analysed and interpreted GSD in national surveillance bulletins and interactive dashboards can help to inform stakeholders, policymakers and the general population.

3. Stepwise approach to developing a national genomic surveillance strategy for pathogens with pandemic and epidemic potential

In developing a national genomic surveillance strategy for pathogens with pandemic and epidemic potential, countries can follow the seven key steps outlined below, with proposed actions that can be directly implemented. The duration and chronology of these steps can be adapted to national contexts.

3.1 Strengthen coordination, collaboration and governance



The first step in developing the strategy is to establish a working group to facilitate coordination or to expand the remit of an existing forum involving all identified stakeholders, assigned with clear roles and responsibilities, to maintain a coherent integrated approach for developing and implementing the national genomic surveillance strategy. This step ensures strong leadership, multilevel and multisectoral government, and nongovernmental engagement. This coordination/working group will then be responsible for oversight, implementation and monitoring progress of implementation.

Stakeholders involved in this step should include policymakers; human, animal and environmental health authorities; partners; donors; public health officers; academia; the private sector; laboratory specialists; and information system specialists. To ensure alignment of the national strategy with the One Health framework, collaborations with One Health partners should be specifically targeted to add GSD in a comprehensive, integrated surveillance network.



Proposed actions:

- Raise awareness among national authorities and relevant partners on the value of genomic surveillance using a One Health approach
- Map and consult relevant stakeholders
- Establish terms of reference for the coordinating structure, identify its members and their roles and responsibilities
- Obtain approval of national authorities as needed to ensure leadership
- Organize a briefing workshop for members of the coordination/working group.

3.2 Conduct a situation analysis



The objective of the situation analysis is to review the current country situation to understand the country-specific context, provide baseline information and ensure that prioritized strategic actions are evidence-based, considering relevant existing national policies/strategies, WHO guidance and global best practices. Situation analysis is a necessary step in determining the scope and key content of the strategy or action plan. The analysis should provide background information on the country (e.g. demographics, health context, public health strategies), and detail national surveillance, clinical and laboratory systems and the coordination between these systems within the broader public health architecture. Analysis of past and current data and collection of additional data should focus on assessing national capacities for detecting and monitoring pathogens in relation to the genomic surveillance value chain. This should include a review of all national pathogen-specific strategies and programme initiatives, underlying use cases with a genomic surveillance component (e.g. influenza, COVID-19, tuberculosis (TB), HIV infections, measles, AMR, food safety). A pathogen prioritization exercise or risk assessment of the emergence and re-emergence of pathogens with epidemic and pandemic potential can also be performed on a regular basis. For example, using the decision-trees to support evidence-based priority pathogen mapping (Pronyk PM, de Alwis RA, Rockett R, et al. Advancing pathogen genomics in resource limited settings. Asia Pathogen Genomics Initiative, unpublished data, 2023) or the *Strategic toolkit for assessing risks* to better define national priorities in terms of surveillance and to future proof the strategy (10).

All relevant country documentation should be collected, including national health policies, surveillance strategies and associated operational plans, regulations and standards implemented for surveillance systems, laboratory networks, and related to priority pathogen disease burden/prevalence, data management, evaluation reports on surveillance or laboratory networks, IHR evaluation reports (SPAR, JEE, intra-action reviews (IARs) or after-action reviews (AARs)). Reviewing reports from IAR/AAR and simulation exercises, and consolidating lessons learned, can help countries gain a clearer picture of their national capabilities to deal with future epidemics.

A SWOT analysis can be conducted by stakeholders to identify the strengths, weaknesses, opportunities and threats at different levels of implementation. Strengths and weaknesses describe internal factors in the genomic surveillance value chain, while opportunities and threats refer to external factors that can have a significant influence on implementation. The following elements may be considered: leadership commitment, stakeholder engagement and coordination, financial resources, infrastructural capacity (including IT and computing needs), data management, technical capacity (human resources), documents for implementation (policies, plans, regulations), implementation of activities, supply chain and logistics, and monitoring and evaluation (M&E).



Proposed actions:

- Collect key country documentation;
- Conduct a situation analysis, including a pathogen prioritization exercise;
- Do a SWOT analysis;
- Convene stakeholders to review the outcome of the situation analysis.

3.3 Identify a goal, objectives and strategic actions



To define the scope of the strategy, the multisectoral coordinating structure can rely on the situation analysis and the priority pathogen use cases identified in the pathogen prioritization exercise. Moreover, the strategy should be defined for a specified time frame, costed and integrated into existing sectoral planning and budget cycles. It should be reviewed and updated periodically by the main stakeholders and adapted to the current national and global context, including progress in terms of scientific knowledge and sequencing technologies.

The goals and objectives identified by countries may reflect those of the global genomic surveillance strategy for pathogens with pandemic and epidemic potential (8). They should be adapted to each national context based on the findings of the situation analysis and the defined scope, with specific elements added or removed as appropriate. Though focused on genomic surveillance, the strategy should be linked to other surveillance networks and vertical disease control programmes. The objectives should align with national pathogen-specific strategies and programme initiatives that include a genomic surveillance component.

More precisely, to help countries identify national strategic lines of action, the following five elements are recommended at the country level:

1. A genomic surveillance and laboratory network (based on national capacities or international collaborations) consisting of a core facility that independently supports all programmes and sentinel sites, with a clear leadership and coordination structure and well-defined accountabilities.
2. Sustainable technical capacity in laboratories for sample and data management, regularly evaluated to ensure workforce development, regular provision of reagents and supplies, equipment maintenance and national and international accreditation.
3. Harmonized SOPs and external assessment programmes for quality and biosafety.

4. Agreements for data sharing and participation in local, regional and global collaborations (including to promote research and innovation) and timely feedback mechanisms to ensure links to public health action as appropriate.
5. Readiness exercises (IARs or AARs, simulation exercises) highlighting best practices and lessons learned from relevant public health emergencies.



Proposed actions:

- Define the scope of the strategy;
- Analyse the global strategy in the national context based on the situation analysis and defined scope;
- Identify the national goal and objectives;
- Determine strategic actions for each objective.

3.4 Define the approach to strategy implementation



To implement the strategic actions identified, prioritize activities based on the situation analysis, resources available, anticipated impact and feasibility.

The prioritization process should be an inclusive consultative process with all stakeholders. A prioritization matrix using a multidisciplinary approach can be used to assess each activity, its level of priority for stakeholders, impact of/on genomic surveillance, imminent risk if not undertaken and feasibility based on the existing human, technical and financial capacities. The time frame for implementation should also be considered, in particular for interdependent activities. To ensure sustainable implementation, it is essential to prioritize activities that leverage the strengths and capacities of existing laboratory and surveillance systems (e.g. influenza, TB, polio, AMR). To be efficient, genomic surveillance should be fully integrated into the national surveillance and laboratory networks through all steps of the value chain.

An important consideration for strategy implementation is the choice of a centralized or decentralized approach for each step of this genomic surveillance value chain. The choice will depend on the specifics of each country according to the following elements: resources available, quantity of samples to routinely process, national capacities in sequencing and bioinformatics, procurement system for reagents and consumables, distance between sampling sites and sequencing facilities, transportation and biobanking infrastructure, and protocols and infrastructure for data management (data storage, analyses, reporting and sharing).

In particular, it may not be feasible or optimal for all countries to have in-country sequencing capability. However, these countries should have access to timely genomic sequencing through an established international referral mechanism.¹ Details of the international referral mechanism and other parts of the value chain should be built into the national genomic surveillance strategy, which goes beyond the technological capability for sequencing. Sample-sharing agreements, material transfer agreements, transportation and logistics, and expected turnaround times should also be included.

Countries should develop a national data management protocol to ensure the highest standards of data quality and data sharing. It is generally worthwhile to centralize all or part of data management to optimize human and material resources and to facilitate harmonization, quality and data sharing.



Proposed actions:

- Define activities for each strategic action;
- Define the priority activities within the time frame for implementation;
- Determine the strategy implementation approach for each step (centralized/decentralized);
- Develop a national data management protocol that includes considerations for sharing data.

3.5 Establish a framework for Monitoring and Evaluation



Monitoring and Evaluation (M&E) is a key element in assessing progress towards and driving achievement of the strategy's hierarchy of results. An M&E framework (using quantitative and qualitative process and output/outcome measures) monitors implementation, measures effectiveness, facilitates transparency and accountability for all stakeholders and serves as a tool for sharing lessons learned.

Each country should define its key measure of success. For example, the global strategy's key measure of success is that "by 2032, all 194 Member States have, or have access to, timely genomic sequencing for pathogens with pandemic and epidemic potential" (8). The aim is to achieve the highest level of capacity as defined in the IHR indicators of the SPAR and JEE tools (6, 7). However, to closely follow implementation, key indicators can be detailed for each objective of the national strategy in the M&E framework. Note that indicators for genomic surveillance should be monitored even for "routine" pathogen use cases, as functional capacities underpin readiness for pandemics and epidemics.

¹ Access to genomic sequencing may be through international collaboration with a national, regional or partner institution with sequencing capability. "Timely" is defined as triggering genomic sequencing within 7 days of event or pathogen detection.



Proposed actions:

- Establish a subgroup of stakeholders to develop M&E components;
- Identify activities requiring close monitoring;
- Identify and define indicators for objectives;
- Review elements required per indicator e.g. purpose/rationale, definition of key terms, measurement i.e. numerator, denominator and disaggregation (where relevant), geographical scope, baseline, target, data source, time frame and reporting frequency.

3.6 Develop an overall costed implementation plan



Implementation should be consistent with the strategic objectives and the M&E plan, and include all prioritized activities within a specific time frame. Each activity should be detailed with the following elements: related sub-activities, responsible entity, implementation level (subnational/national), timeline, monitoring indicators and cost.

To maximize efficiency and public health impact, genomic surveillance activities should be synergized with other relevant national plans and programmes. This should be considered when estimating the cost of genomic surveillance activities. Countries are encouraged to develop integration mechanisms to pool surveillance, laboratory and bioinformatics costs across different national pathogen-specific strategies and programmes that have a genomic surveillance component.



Proposed actions:

- Detail each prioritized activity to establish the action plan;
- Verify that costs are consistent for activities shared with other national plans or disease control programmes containing a genomic surveillance component;
- Validate the action plan with subnational and national authorities and other relevant stakeholders involved.

3.7 Identify and mobilize resources for implementation



Genomic surveillance technologies currently rely on relatively costly techniques that require significant financial and human resource investment. Countries are encouraged to aim towards sustainable financing through domestic resource mobilization and identification of new funding sources with multisectoral engagement to leverage these resources effectively.

Stakeholder mapping (e.g. government and intergovernmental entities, development partners, donors, the private sector) can identify stakeholders that are already funding genomic surveillance activities, stakeholders that are funding related activities within other national plans and programmes (e.g. influenza, HIV, TB, polio, AMR, foodborne diseases) or stakeholders that have an interest and could potentially fund these activities.

In addition to government and development partners, stakeholders for genomic surveillance could include nontraditional public health partners across the academic and private sectors. This can especially help build the technical know-how over time. Advocacy directed at national authorities and policymakers is needed to ensure dedicated budgets and national funding commitments and human resource allocation to operate the national genomic surveillance network.



Proposed actions:

- Map existing funding and human resources;
- Identify funding gaps and potential funders for unfunded activities;
- Discuss with potential funders;
- Advocate to secure national long-term funding commitments and human resource allocation from national authorities.

4. WHO support

WHO has been and will continue to work closely with countries to support development of national genomic surveillance strategies; to advocate for engagement, resourcing, and implementation among partners; and to monitor and evaluate progress. Based on situation analysis and the objectives and strategic actions to be implemented, countries and partners should coordinate to identify their priority needs for collaboration with WHO. During implementation, WHO will provide technical assistance and guidance to countries, and where appropriate empower national agencies that will retain primary ownership and responsibility for genomic surveillance. To advocate the need for having and investing in a readiness posture and to ensure global coherence, WHO will support countries in incorporating lessons learned from the COVID-19 pandemic and recommendations from the IHR capacity assessments (IARs/AARs, SPAR, JEE) in national genomic surveillance strategies and action plans. In addition, WHO will encourage and support countries' efforts to regularly use pathogen GSD for decision-making; to promote international collaboration, innovation and research; and to protect global public health by strengthening prevention, detection and response to epidemics and pandemics at the national and international level.

5. Methodology for developing the strategy support tool and identifying key considerations

This strategy support tool was developed using a two-step process. The first step was a desk review of the literature, including existing normative guidance and reviews (8, 9, 11–14). The second step was a consultative process with representatives from ministries of health from different countries, international agencies supporting genomic surveillance strengthening and WHO collaborating centres engaged in genomics for pathogens with pandemic and epidemic potential. Key considerations were assessed based on existing WHO guidance and the experience of WHO teams at headquarters, and at regional and country offices, who work across the genomic surveillance value chain. Specific actions have been identified for each consideration to provide countries with concrete steps that can be taken to move forward in developing their national genomic surveillance strategy.

6. Additional tools

To develop a national genomic surveillance strategy or action plan, additional tools and resources are available from WHO and partners, including specific use cases (15–18).

Other resources being developed by WHO and partners that will be published in 2023 include a costing tool and pathogen prioritization decision-trees that can support national planning for genomic surveillance.

References

1. Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV) [website]. In: WHO/News. Geneva: World Health Organization; 2020 ([https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-\(2019-ncov\)](https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov))), accessed 5 May 2023).
2. Statement on the sixth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic [website]. In: WHO/News. Geneva: World Health Organization; 2021 ([https://www.who.int/news/item/15-01-2021-statement-on-the-sixth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/15-01-2021-statement-on-the-sixth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic)), accessed 5 May 2023).
3. COVID-19: make it the last pandemic. Geneva: Independent Panel for Pandemic Preparedness & Response; 2021 (https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf), accessed 12 May 2021).
4. Resolution WHA 74.7. Strengthening WHO preparedness for and response to health emergencies. In: Seventy-fourth World Health Assembly, Geneva, 31 May 2021. Agenda item 17.3. Geneva: World Health Organization; 2021 (https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R7-en.pdf), accessed 6 May 2023).
5. International health regulations (2005), 3rd edition. Geneva: World Health Organization; 2016 (<https://apps.who.int/iris/handle/10665/246107>), accessed 15 May 2023).
6. International Health Regulations (2005): state party self-assessment annual reporting tool, 2nd edition. Geneva: World Health Organization; 2021 (<https://apps.who.int/iris/handle/10665/350218>), accessed 15 March 2023).
7. Joint external evaluation tool: International Health Regulations (2005) – third edition. Geneva: World Health Organization; 2022 (<https://www.who.int/publications-detail-redirect/9789240051980>), accessed 15 March 2023).
8. Global genomic surveillance strategy for pathogens with pandemic and epidemic potential 2022–2032. Geneva: World Health Organization; 2022 (<https://apps.who.int/iris/handle/10665/352580>), accessed 5 May 2023).
9. WHO guiding principles for pathogen genome data sharing. Geneva: World Health Organization; 2022 (<https://apps.who.int/iris/handle/10665/364222>), accessed 11 April 2023).
10. Strategic toolkit for assessing risks: a comprehensive toolkit for all-hazards health emergency risk assessment. Geneva: World Health Organization; 2021 (<https://apps.who.int/iris/handle/10665/348763>), accessed 12 April 2023).
11. Guidelines for developing a national immunization strategy (NIS). Geneva: World Health Organization; 2021 (https://cdn.who.int/media/docs/default-source/immunization/mi4a/ia2030_nis_faqs.pdf?sfvrsn=c4c47664_5), accessed 12 April 2023).

-
12. Essential steps for developing or updating a national pandemic influenza preparedness plan. Geneva: World Health Organization; 2018 (<https://apps.who.int/iris/handle/10665/272253>, accessed 12 April 2023).
 13. Guidance for national strategic planning for tuberculosis. Geneva: World Health Organization; 2022 (<https://apps.who.int/iris/handle/10665/361418>, accessed 12 April 2023).
 14. NAPHS for all: a 3 step strategic framework for national action plan for health security. Geneva: World Health Organization; 2018 (<https://www.who.int/publications/i/item/naphs-for-all-a-3-step-strategic-framework-for-national-action-plan-for-health-security>, accessed 12 April 2023).
 15. Genomic sequencing of SARS-CoV-2: a guide to implementation for maximum impact on public health. Geneva: World Health Organization; 2021 (<https://www.who.int/publications/i/item/9789240018440>, accessed 31 May 2023).
 16. Interim operational guidance on SARS-CoV-2 genomic surveillance in Africa: An updated guide. Addis Ababa: Africa Centres for Disease Control and Prevention; 2021 (<https://africacdc.org/download/interim-operational-guidance-on-sars-cov-2-genomic-surveillance-in-africa-an-updated-guide/>, accessed 31 May 2023)
 17. Guidance for representative and targeted genomic SARS-CoV-2 monitoring. Stockholm: European Centre for Disease Prevention and Control; 2021 (<https://www.ecdc.europa.eu/en/publications-data/guidance-representative-and-targeted-genomic-sars-cov-2-monitoring>, accessed 31 May 2023)
 18. GLASS whole-genome sequencing for surveillance of antimicrobial resistance. Geneva: World Health Organization; 2022 (<https://www.who.int/publications-detail-redirect/9789240011007>, accessed 31 May 2023)

For additional information, please contact:

Department of Epidemic and Pandemic Preparedness and Prevention
World Health Organization
20, avenue Appia
1211 Geneva 27
Switzerland

Email: pathogenomics@who.int

Website: www.who.int/initiatives/genomic-surveillance-strategy

