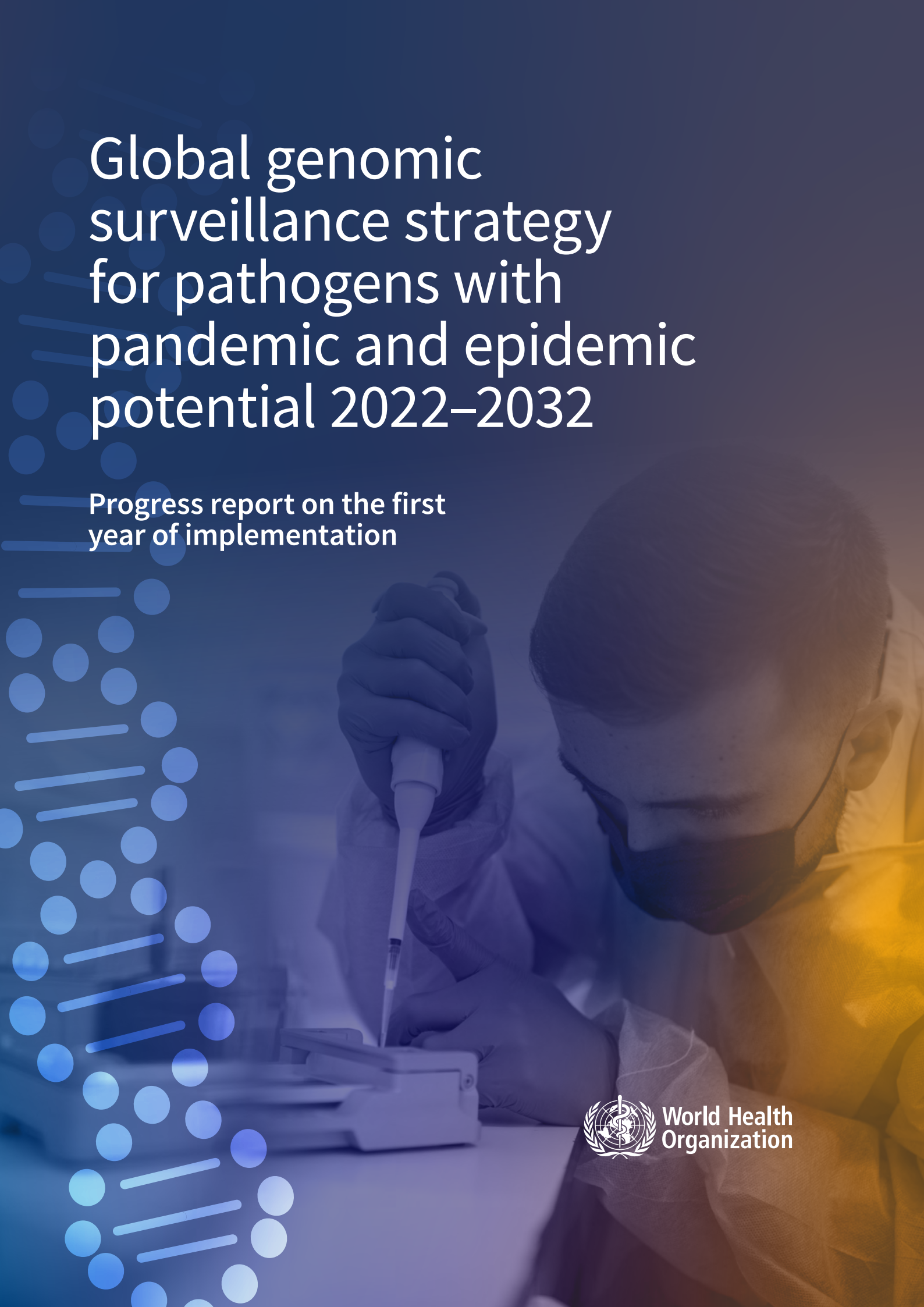
Global genomic surveillance strategy for pathogens with pandemic and epidemic potential 2022–2032

Progress report on the first year of implementation



World Health Organization

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Contents

Acronyms and abbreviations

Africa CDC	Africa Centres for Disease Control and Prevention
AMR	antimicrobial resistance
APHL	Association of Public Health Laboratories
CDC	United States Centers for Disease Control and Prevention
CoP	community of practice
COVID-19	coronavirus disease 2019
COVIGEN	COVID -19 Genomic Surveillance Regional Network
DNA	deoxyribonucleic acid
EGASP	Enhanced Gonococcal Antimicrobial Surveillance Programme
EQA	external quality assessment
GISRS	Global Influenza Surveillance and Response System
GPS	Global Pneumococcal Sequencing
GSD	genetic sequence data
IHR	International Health Regulations
IPSN	International Pathogen Surveillance Network
JEE	Joint External Evaluation
LMIC	Low- and middle-income countries
M & E	monitoring and evaluation
MPOXV	monkeypox virus
NGS	next generation sequencing
NICD	National Institute for Communicable Diseases
NVAP	New Variant Assessment Platform
PAHO	Pan American Health Organization
PCG	partners coordination group
PCR	polymerase chain reaction
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SPAR	States Party Self-assessment Annual Reporting
TB	tuberculosis
UKHSA	UK Health Security Agency
VOC	variants of concern
VOI	variants of interest
WGS	whole genome sequencing

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Executive summary

The COVID-19 pandemic has led to an increase in genomic sequencing capability globally. Between February 2021 and December 2022, there was a 58% increase in the proportion of Member States with access to timely genomic sequencing for SARS-CoV-2 (from 103 to 163 of 194 WHO Member States). Within the same timeframe, there was a 50% increase in the proportion of Member States that shared SARS-CoV-2 genetic sequence data at least once on a publicly accessible database (from 119 to 179 of 194 Member States).

There is global momentum and political impetus for strengthening genomic surveillance, including global recommendations provided through reports of the International Health Regulations (IHR) Emergency Committee *(1,2)*, the report of the Independent Panel for Pandemic Preparedness and Response *(3)*, and the World Health Assembly Resolution 74.7 *(4)*. Spurred by this, the World Health Organization (WHO) launched the Global genomic surveillance strategy for pathogens with pandemic and epidemic potential 2022-2032 in March 2022 (the 'Strategy').

The Strategy provides a high-level unifying framework to strengthen genomic surveillance capacities so that there is quality, timely and appropriate public health actions within local-to-global surveillance systems. WHO works with countries through its global and regional footprint and presence in over 150 countries, as well as partners to implement the Strategy and monitor gains against the Strategy's key measure of success –"By 2032, all 194 WHO Member States have, or have access to, timely genomic sequencing for pathogens with pandemic and epidemic potential".

This report presents the achievements and impact of the work undertaken by countries, partners and WHO across the objectives and strategic actions of the Strategy. As highlighted in the 'Progress on the Strategy's goal' in Section 1, and in more detail throughout the report, significant progress has been made at the national, regional and global levels. Leveraging on the capabilities and capacities gained during the COVID-19 pandemic, 97% of WHO Member States have, or have access to, timely[1] genomic sequencing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Yet, the stability of the gains made during the pandemic cannot be guaranteed. Further work is needed to sustain and expand the genomic surveillance capabilities and capacities for the detection, prevention and response to other pandemic and epidemic threats. This report also highlights planned activities and opportunities to sustain and strengthen these gains, for maximal country impact.

1 Access to genomic sequencing may be through international collaboration. Timely is defined as triggering genomic sequencing within 7 days of event or pathogen detection

1. Introduction

The COVID-19 pandemic has demonstrated the importance of global resilience and health emergency preparedness. The cornerstone of this preparedness is strong, broad and adaptable pathogen surveillance systems. The pandemic catalysed development of new tools and technologies, including rapid improvements in sequencing technology. The emergence of variants of SARS-CoV-2 has underscored the value of genomic sequencing data in rapidly detecting and characterizing circulating pathogens, assessing risk and monitoring pathogen evolution to inform strategic decision-making and public health actions.

Since the beginning of the COVID-19 pandemic, global recommendations *(1–4)* have advocated that countries strengthen genomic surveillance capacities and capabilities. The *Global genomic surveillance strategy for pathogens with pandemic and epidemic potential 2022–2032* aims to address the challenges (e.g. access to tools and equity, technical fragmentation, connectivity, information sharing, scalability and sustainability) in this landscape *(5)*.

This 10-year strategy seeks to link and embed genomic surveillance for pathogens within the broader surveillance and public health architecture, identify opportunities to strengthen and establish capacities and capabilities, and bring partners and stakeholders together to work on a common goal. The goal of the strategy is that "genomic surveillance for pathogens with pandemic and epidemic potential is strengthened and scaled for quality, timely and appropriate public health actions within local to global surveillance systems". The strategy identifies five objectives which will support achievement of this goal, alongside specific strategic actions (Fig. 1).

Countries are at the heart of the Strategy implementation. For maximal impact and contribution to public health, a collaborative approach across governments, networks, programmes, and partners is being used to drive the implementation of the strategy.

Fig. 1: Strategy results hierarchy including goal, objectives, and strategic actions

1.1 Progress on the Strategy's goal

Goal

Genomic surveillance is strengthened and scaled for quality, timely and appropriate public health actions within local to global surveillance systems

1.2 Access to timely sequencing

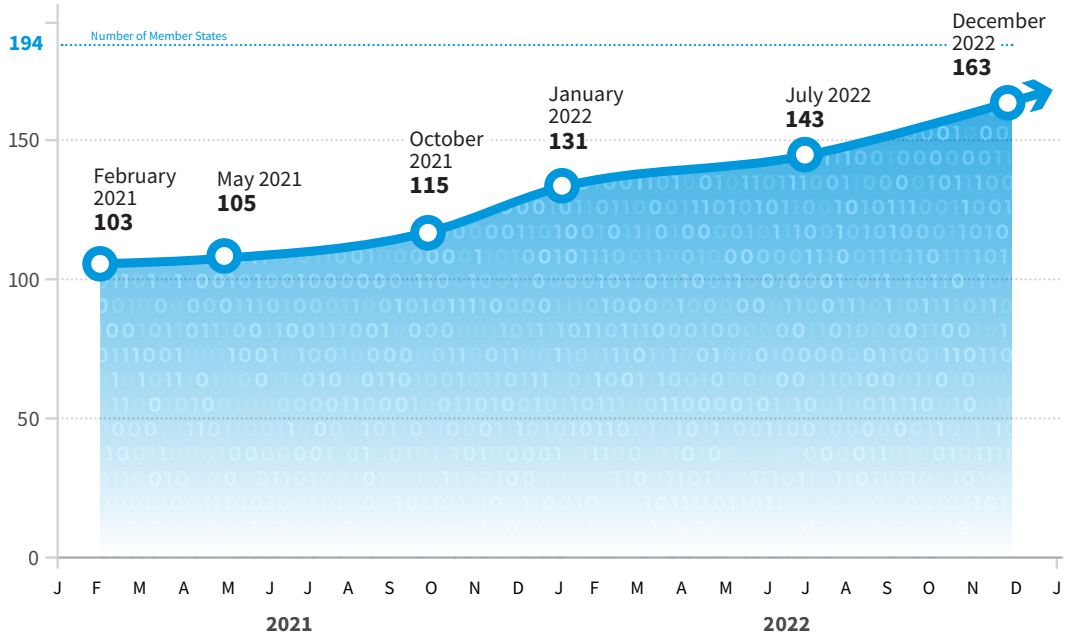
Timely access to genomic sequencing is critical to early detection and prompt public health action. As defined by the Strategy's key measure of success, timely access is defined as triggering genomic sequencing within seven days of event or pathogen detection, either in-country or through an established international referral mechanism. The capacity for genetic sequencing is an element of the IHR laboratory core capacities, and it is assessed by an indicator in the IHR States Party self-assessment annual reporting (SPAR) tool (indicator C4.4) and the IHR Joint External Evaluation (JEE) tool (indicator D1.3) *(6,7)*. It was also one of the indicators measured in the Monitoring and Evaluation (M & E) Framework of the *COVID-19 Strategic Preparedness and Response Plan 2022* (SPRP, indicator 2.4)*(8)*.

As of December 2022, 84% (163 of 194) of WHO Member States have sequencing capability for SARS-CoV-2. This represents a 58% increase (from 103 to 163) in the proportion of Member States with sequencing capability between February 2021 and December 2022 (Fig. 2). Notably, almost all (160, 98%) the Member States with in-country sequencing capability have at least one laboratory that serve public health surveillance function[2] (Fig. 3). As of December 2022, 13% of the Member States (n = 26) have access to timely genomic sequencing through an established international referral mechanism, and 3% (n = 5) have no in-country sequencing capability, or access to timely sequencing through an established international referral mechanism, or have an unknown sequencing capability.

However, the stability of these gains is yet to be seen, and thus, our efforts to embed genomic surveillance into routine systems is not yet done.

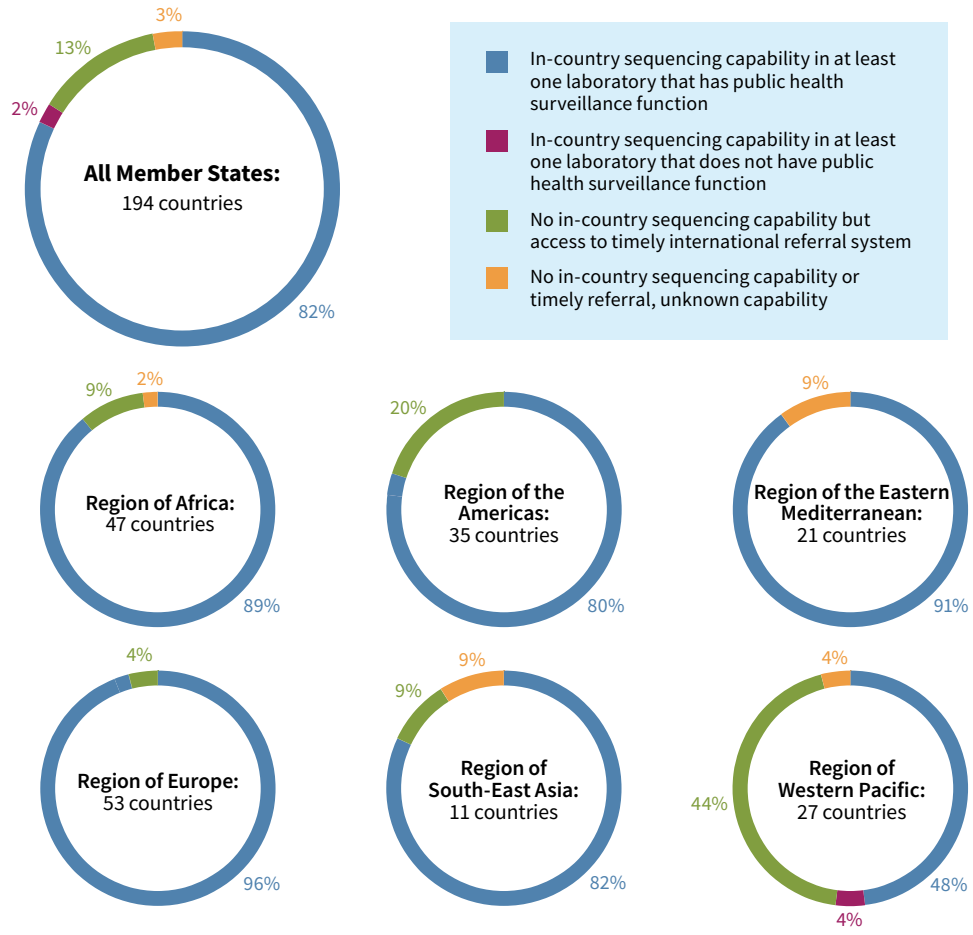
2 Laboratory providing public health surveillance function: laboratories which are responsible for providing timely and reliable results for the purpose of routine and acute disease surveillance, detection, response, control and prevention. These laboratories provide the data required to detect, confirm, monitor and respond to epidemic and pandemic events

Fig. 2: A 56% increase in WHO Member States with timely in-country access to SARS-CoV-2 genetic sequencing capability



Data source: World Health Organization Regional Offices, as of 31 December 2022

Fig. 3: Level of SARS-CoV-2 sequencing capability in WHO Member States



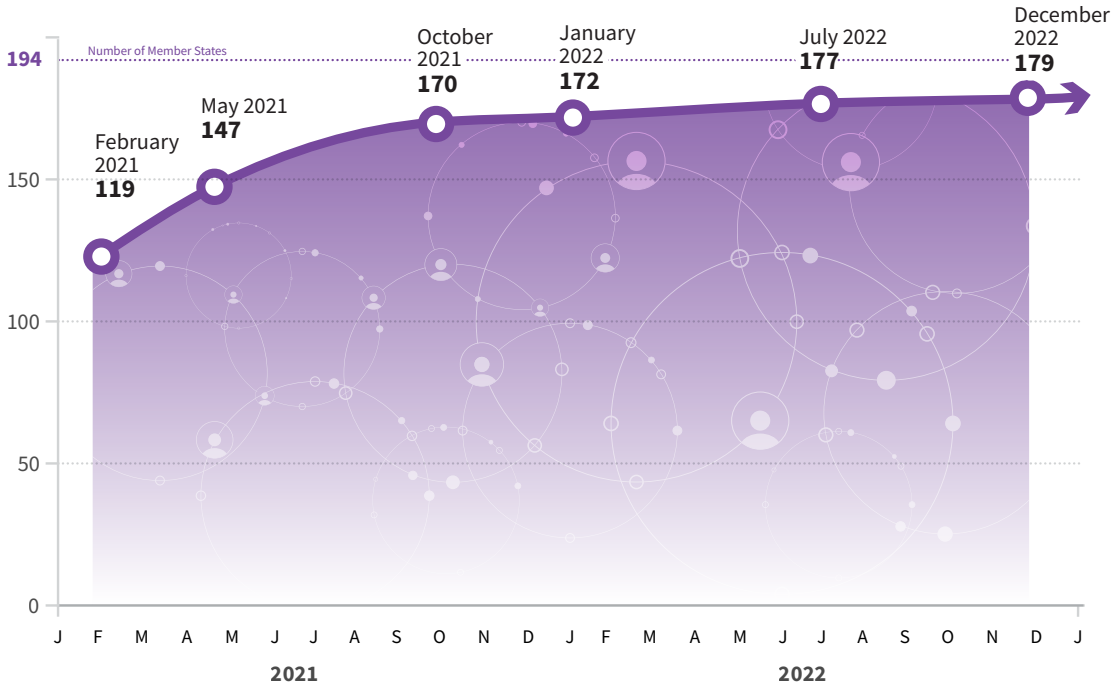
Data source: World Health Organization Regional Offices, as of 31 December 2022

1.3 Sharing of pathogen genetic sequence data on a publicly accessible database

In addition to supporting countries in building and strengthening capabilities for genomic surveillance, WHO encourages countries to share genetic sequence data (GSD) in a publicly accessible database. Generation and sharing of geographically representative GSD in as close to real time as possible will enable better strategic decision-making, which is key to strengthening collective global health security.

Between February 2021 and December 2022, the proportion of Member States sharing SARS-CoV-2 GSD at least once on a publicly accessible database increased by 50% (from 119 to 179 of 194 Member States; Fig. 4).

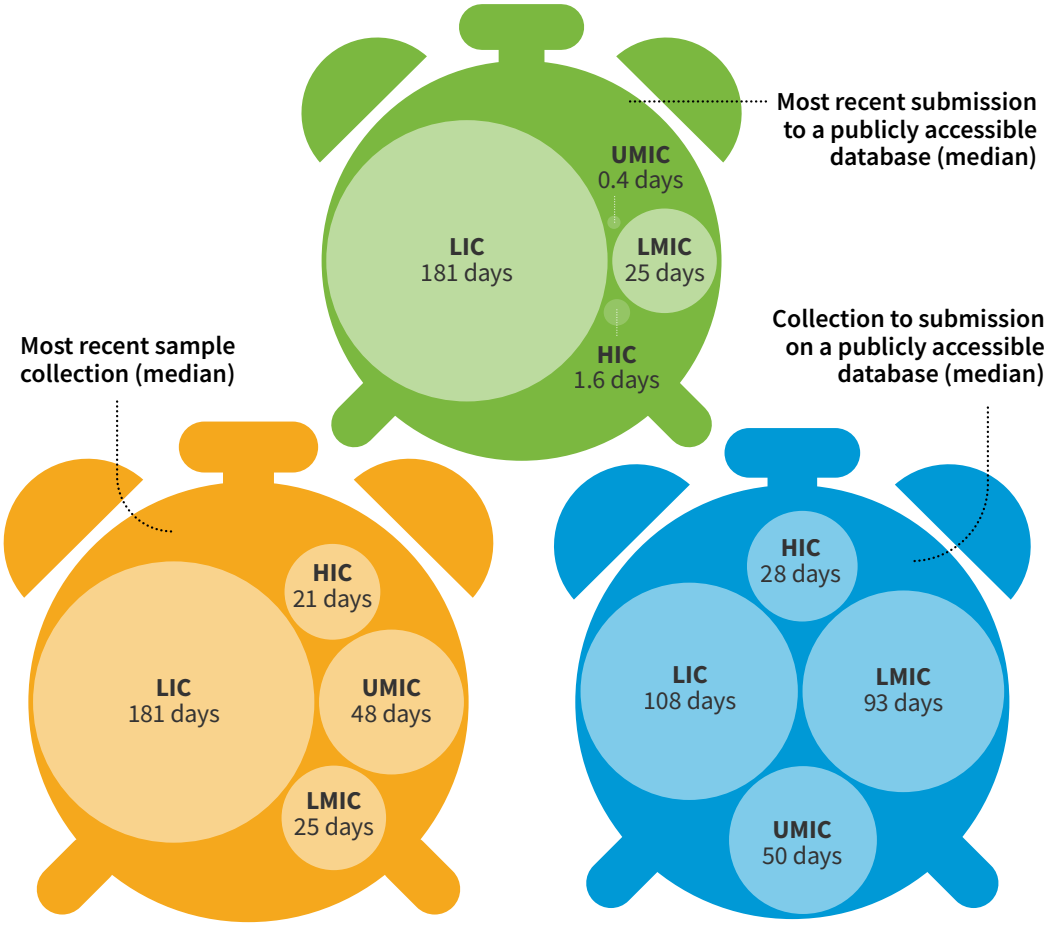
Fig. 4. A 50% increase in WHO Member States sharing SARS-CoV-2 genetic sequence data on a publicly accessible database



Data Source: GISAID EpiCoV database, as of December 2022

As the world transitions from the acute phase of the COVID-19 pandemic, work is now needed to stabilize and strengthen the capacities and capabilities gained by countries and the international community to prevent, prepare, detect and respond to SARS-CoV-2 and other pathogens with pandemic and epidemic potential. As Fig.5 shows, there is a longer time lag in SARS-CoV-2 data sharing from lower income countries. Barriers for timely surveillance and reporting need to be addressed to ensure representative data are available for analysis and public health decision-making.

Fig. 5. Submission of SARS-CoV-2 genetic sequence data among WHO Member States, from 10 January 2020 to 15 March 2023 (analysis contains 191 WHO Member States according to the World Bank Income Classification)



HIC: High income countries (*n* = 57)
UMIC: Upper middle income countries (*n* = 53)
LMIC: Lower middle income countries (*n* = 54)
LIC: Low income countries (*n* = 27)

Data Source: GISAID EpiCoV Database

2. Coordinated action

2.1 Global networks and initiatives

Global efforts are underway to strengthen the use of genomic sequencing as part of surveillance systems for pathogens with pandemic and epidemic potential. Highlights from various networks and initiatives are presented below.

2.1.1 GISRS: end-to-end integration of SARS-CoV-2 and influenza sentinel surveillance

The Global Influenza Surveillance and Response System (GISRS) is a worldwide network comprising 149 public health laboratories (national influenza centres), WHO H5 reference laboratories, WHO essential regulatory laboratories and WHO collaborating centres across 125 countries. GISRS functions to rapidly detect, monitor and respond to seasonal epidemics, zoonotic outbreaks and future influenza pandemics. During the COVID-19 pandemic, WHO supported GISRS to leverage its capacity to monitor trends in SARS-CoV-2 transmission. As part of integrated sentinel surveillance, WHO encourages GISRS to sequence samples positive for influenza and SARS-CoV-2 systematically collected from patients seeking care at sentinel health facilities, including primary care providers, emergency rooms, outpatient clinics, hospital wards and intensive care units in a timely manner and to share GSD with accompanying metadata through publicly accessible databases.

Recognizing the need for GISRS to monitor the relative co-circulation of the two viruses in the community, in January 2022 WHO published guidance recommending end-to-end integration of influenza and SARS-CoV-2 into all the phases of the surveillance process, from the sentinel site to the eventual sharing of GSD. This end-to-end integration is guided by four principles, namely quality, representativeness, sustainability and country ownership. It emphasizes the importance of connecting surveillance systems to guide policymaking and to adapt the country's public health response to influenza epidemics and the COVID-19 pandemic.

To strengthen the workforce for genomic surveillance, GISRS in partnership with WHO regional offices, the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) is supporting a training course on international influenza and SARS-CoV-2 genomic sequencing (Fig. 6). This course aims to enhance laboratory sequencing capacity using the Oxford Nanopore Technologies platform in countries implementing end-to-end integration of SARS-CoV-2 into their influenza surveillance schemes. As of April 2023, laboratory personnel from 35 countries from the WHO South-East Asia, Western Pacific and African Regions have been trained. Similar training workshops have been planned for the WHO Americas and European Regions and the Francophone countries of Africa. Furthermore, an OpenWHO six-module

course on sequencing and bioinformatics is under development and scheduled to be available online in mid-2023. These efforts will build and strengthen national, regional and GISRS genomic surveillance capacity and capability by enhancing genetic surveillance, data sharing and analysis.

Fig. 6. International influenza and SARS-CoV-2 genomic sequencing course, 22–25 August 2022, Nonthaburi, Thailand

Source: WHO/Dmitriy Pereyaslov

2.1.2 Application of whole genome sequencing to monitor antimicrobial resistance patterns

The increasing occurrence of antimicrobial resistance (AMR) poses a danger to global health. It is estimated that by 2030 AMR infections resulting in increased morbidity, disability, premature death and reduced effective labour will become a significant threat to the global economy. Thus, it is critical to strengthen systems to detect and monitor the occurrence of AMR-related infections.

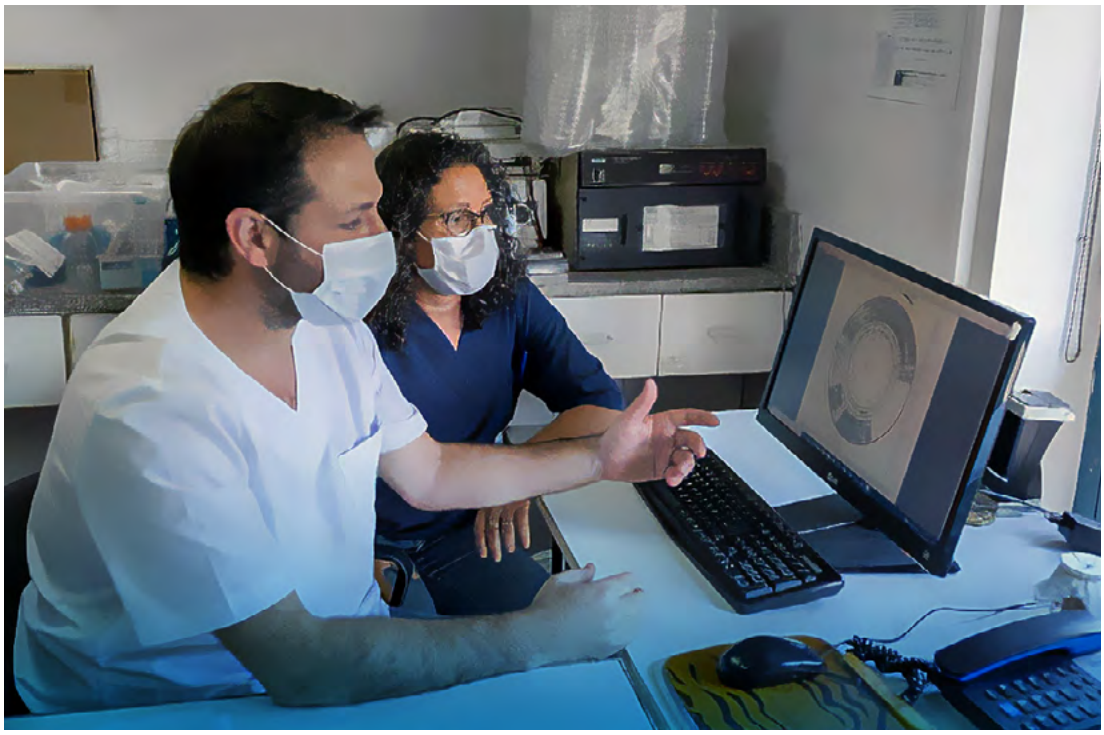
Bacterial and fungal whole-genome sequencing can provide new insights into disease transmission dynamics, enhance surveillance capacity *(9)*, facilitate identification and tracking of outbreaks and improve comprehensive detection of AMR determinants, including previously uncharacterized variants that might help identify new targets for drug development and diagnostic tests (Fig. 7).

EXAMPLE

The Enhanced Gonococcal Antimicrobial Surveillance Programme (EGASP) is a partnership between WHO, the CDC and WHO collaborating centres working in key countries across regions where scaling up gonococcal AMR surveillance is needed *(10)*. EGASP partners are developing a genomic sequencing and surveillance component to enhance understanding of the distribution of antimicrobial-resistant Neisseria gonorrhoeae strains in different risk groups nationally, regionally and globally. For instance, in 2022 the EGASP team in Cambodia referred several isolates with high alert values to the WHO collaborating centre in Australia for whole-genome sequencing. When placed within a global context of previously reported strains, the genomic analysis allowed detection of ongoing genetic exchange and the emergence of new strains (report in progress).

> *"Next-generation sequencing … is revolutionizing our understanding of the emergence, evolution, fitness, and geographical and temporal spread of AMR.*
>
> Magnus Unemo, Director, WHO Collaborating Centre for Gonorrhoea and Other Sexually Transmitted Infections, Sweden *(11)*

Fig. 7. Analysis of results from a whole-genome-sequenced bacteria sample in the genetics laboratory at Malbrán Institute in Buenos Aires, Argentina



Source: WHO/Sarah Pabst

2.1.3 WHO guiding principles for pathogen genome data sharing

Good public health responses depend on timely, high-quality and geographically representative sharing of pathogen genome data in as close to real time as possible. Sharing of GSD is key to preventing, detecting and responding to epidemics and pandemics at the country and global level. In addition, consistently generating and sharing GSD is vital to inform strategic decision-making with regard to endemic diseases and AMR.

WHO advocates sharing pathogen genetic information to safeguard global health. Following extensive consultation, the *WHO guiding principles for pathogen genome data sharing were launched in November 2022 (12)*. The principles and policies guiding sharing of this information prioritize ethics, fairness, efficiency and effectiveness (Fig. 8). These core principles emphasize public health applications and the most pressing research needs.

Capacities and capabilities for pathogen genomics around the world have advanced at unprecedented speed. The speed, scale and affordability of sequencing are all increasing at astonishing rates, allowing more sequencing data to be generated globally. However, inequities in access to new technologies leave blind spots in global surveillance that threaten global health security. A commitment to equity and support for capacity development must therefore be the overriding principle of the international system for sharing pathogen data.

> *Capacities for pathogen genomics around the world are advancing rapidly. The speed, scale and affordability of sequencing are all increasing at astonishing rates. The commitment to equity and support for capacity development must therefore be the overriding principle of the international system for sharing of pathogen data.*
>
> Dr Tedros Adhanom Ghebreyesus, Director-General, WHO

Fig. 8. Thirteen WHO guiding principles for pathogen genome data sharing

2.1.4 Application of genomic surveillance in recent outbreaks: mpox

Mpox (monkeypox) was announced as a public health emergency of international concern on 23 July 2022 *(13, 14)*. Capacities and capabilities gained in genomic sequencing and bioinformatics during the COVID-19 pandemic have been leveraged to enable pathogen characterization throughout the mpox outbreak. Accordingly, as of January 2023 over 5000 sequences had been shared by more than 50 countries to at least one publicly accessible genetic sequence database *(15)*.

The monkeypox virus (MPXV) possesses a large orthopoxvirus deoxyribonucleic acid (DNA) genome divided into clades I and II, with the latter further subdivided into clades IIa and IIb. The current extensive multicountry outbreak of mpox is due to clade IIb. Clade IIb further divides into lineages and sublineages, notably lineages A and B. All outbreak strains sequenced so far during this outbreak appear to cluster together (B.1 lineage), suggesting a single origin *(15)* (Fig. 9).

Fig. 9. Distribution of clade IIb lineages across the world

Data Source: WHO analysis of publicly available genomic data from the 2022 multicountry outbreak (15).

As a large DNA virus, MPXV is not predicted to undergo large mutational shifts. However, phylogenetic analysis of sequences from the ongoing outbreak reveal the presence of many more mutations than expected. The mutation rate is approximately 20-fold greater than estimated in the animal reservoir of the virus. Furthermore, a specific mutational pattern can be observed. This pattern is not seen in sequences prior to 2017, leading to a hypothesis that the current epidemic arose from an animal to human jump prior to 2017 (15). The animal reservoir of MPXV, and of clade IIb in particular, requires further investigation.

The mpox outbreak raises concerns about the (re)emergence of a human-adapted orthopoxvirus related to variola virus, the causative agent of smallpox. Unlike variola virus, other orthopoxviruses (including MPXV) have wildlife reservoirs with the potential to spill over into humans. Moreover, orthopoxvirsues characteristically feature host adaptations that occur more rapidly than through progressive mutation, as in the case of SARS-CoV-2. Circulating MPXV strains could undergo further adaptation to human hosts, creating a variola virus-like public health event (16).

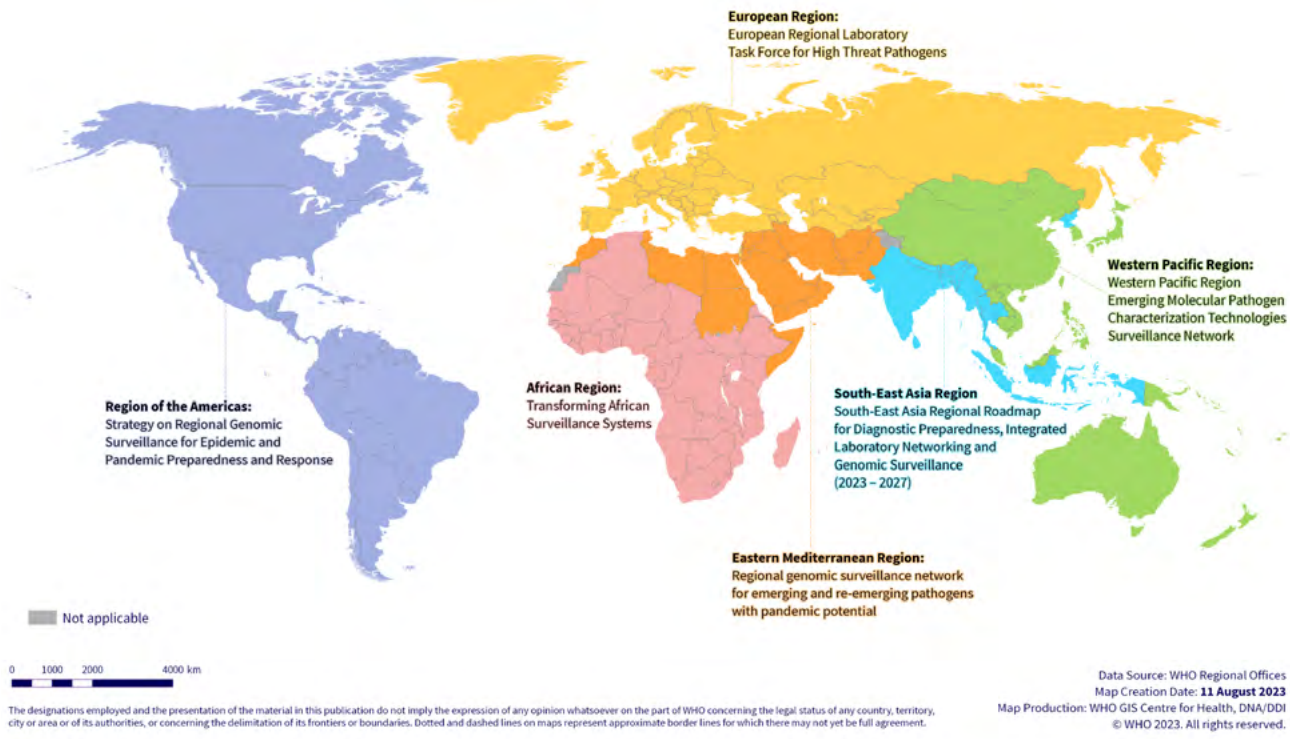
Genomic surveillance in human cases, and known and potential reservoirs, will be critical to closely monitor ongoing evolution and detect spillover events. Genetic information can also be used to detect large genomic shifts that may impact diagnostics and therapeutics. In addition, the capabilities and capacities gained from the genomic surveillance of mpox can be leveraged for other pathogens with pandemic and epidemic potential.

2.2 Regional initiatives and country implementation

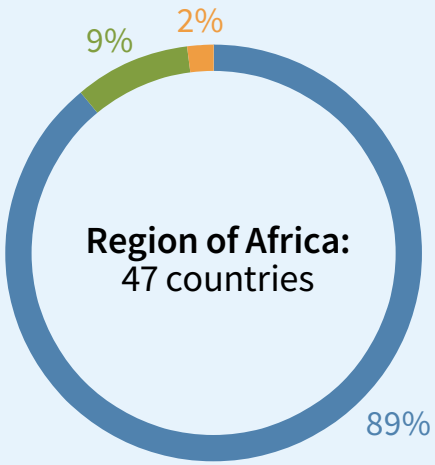
Following the significant progress recorded in the genomic surveillance landscape since the COVID-19 pandemic, it is imperative that countries strengthen and sustain these gains, and expand their genomic surveillance capabilities and capacities for detecting, preventing and responding to other pandemic and epidemic threats. WHO provides global leadership, coordination, advocacy and technical guidance to facilitate the strategy's implementation.

Recognizing the contextual diversity across countries, such as epidemiological dynamics, health system capacity and country priorities, the strategy is being implemented in regionally contextualized ways for maximal country impact (Fig. 10). At the regional level, genomic surveillance initiatives have been tailored to address these contextualities. Furthermore, WHO (at the headquarters, regional and country level) provides direct support to countries in developing a national strategy or action plan, and supports the implementation of planned activities in line with a country's needs.

Fig. 10. WHO's regional initiatives to strengthen genomic surveillance



2.2.1 African Region



Number of Member States: 47

- In-country sequencing capability: 42 (89%)
- Access to timely international referral system: 4 (9%)
- No capability/unknown: 1 (2%)

The first case of COVID-19 in the African Region was reported in February 2020. At the beginning of this pandemic, only four countries in the Region (Kenya, Nigeria, Senegal and South Africa) had the capability to sequence SARS-CoV-2. Recognizing this, in September 2020 WHO's Regional Office and the Africa Centres for Disease Control and Prevention (Africa CDC) jointly established a genome-sequencing laboratory network for COVID-19 and other emerging pathogens.

This work leveraged existing initiatives, including the capacities of the Africa CDC Pathogen Genomics Initiative launched in November 2020. Early in the pandemic, the incidence of COVID-19 was relatively high in southern African countries. Thus, initially, the network prioritized these countries for developing genomic sequencing capacities, eventually expanding to support the entire Region.

To establish closer working ties with the countries, the Regional Office decentralized its genomic surveillance activities, establishing three subregional hubs, including the South Africa-based Regional Centre of Excellence for Genomic Surveillance and Bioinformatics, which operates in partnership with the South African National Bioinformatics Institute to support 14 southern countries (Fig. 11).

Fig. 11 WHO Regional Office for Africa's supportive visit to the National Reference Laboratory, Nigeria. Source: WHO Regional Office for Africa.

As of December 2022, 42 countries had in-country genomic sequencing capability (roughly a 10-fold increase over 3 years). To capitalize on the infrastructure gains from the COVID-19 pandemic, the Regional Office launched the Transforming African Surveillance Systems programme in 2022 to help countries strengthen their laboratory and surveillance systems to enable rapid detection and public health response *(17)* (Fig. 11). This flagship programme brings political attention to genomic surveillance and advocates its use in the Region. The programme also spearheads a multisectoral approach to strengthening broader surveillance systems for emergency preparedness and response.

2.2.2 Reflecting on the implementation of genomic surveillance for COVID-19 and beyond in the African Region

To highlight the lessons learned and to discuss initiatives aimed at improving the quality and effectiveness of COVID-19 surveillance, including genomic surveillance, the Regional Office convened a meeting of COVID-19 epidemiology focal points from the ministries of health of selected high-risk countries in Brazzaville (Republic of the Congo) on 10–13 August 2022.

A selection of highlights from stories shared by countries at the meeting follows.

Ethiopia: Genomic sequencing capabilities were established in Ethiopia during the pandemic, and the data generated continues to support public health decision-making for COVID-19 and other priority diseases. The country is still working to address the shortage of laboratory supplies, lack of bioinformatics analytical capacity and the small number of sequencing laboratories.

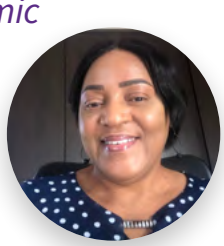
Democratic Republic of the Congo: The country has leveraged genomic sequencing capacities built during the Ebola virus disease outbreak in 2018 to

rapidly sequence SARS-CoV-2 after the first case was reported. The country's regional reference laboratory conducts sequencing by referral for four countries (Chad, Cameroon, Central African Republic and Republic of the Congo) with support from WHO and other partners. These genomic sequencing capacities are now being extended further to support other national priority diseases, such as mpox, polio, measles, malaria, cholera and yersinia pestis.

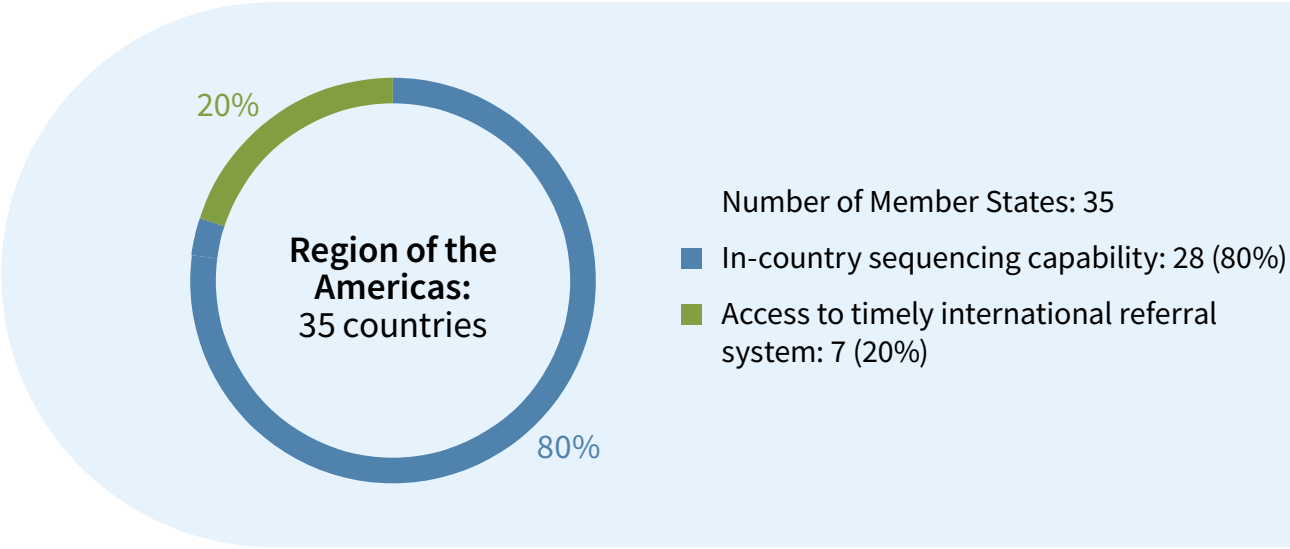
Nigeria: Genomic sequencing capacities in Nigeria span public health institutes and academic centres and have resulted in sharing over 7000 sequences. These capacities will be further leveraged to strengthen broader pathogen surveillance capabilities alongside coordination and building of a trained workforce.

South Africa: South Africa established the Network for Genomic Surveillance in May 2020, two months after the first COVID-19 case was reported. The country is committed to mobilizing domestic resources to strengthen the workforce and enhance access to tools for pathogen sequencing in the country and other African countries. So far, more than 51 113 SARS-CoV-2 samples have been sequenced and shared to a publicly accessible database, representing all regions and age groups and integrated genomic surveillance into the larger public health surveillance system.

> *"Currently, 42 out of the 47 Member States (89%) in the African Region have in-country capabilities for genomic sequencing and 46 Member States (98%) are sharing their genetic sequence data through a publicly accessible database. The Region has established a coordinated mechanism to sustain and strengthen these gains and has set up three centres of excellence for genomic surveillance, developed standardized guidance documents, offered capacity building for ministries of health personnel and set up laboratory infrastructure for routine pathogen genomic surveillance, including wastewater surveillance.*
>
> Nicksy Gumede-Moeletsi, Regional Virologist,
> WHO Regional Office for Africa



2.2.3 Region of the Americas



Recognizing the critical need for regional sequence data generation and timely sharing to a publicly accessible database, in March 2020 the Pan American Health Organization (PAHO) launched the regional COVID-19 Genomic Surveillance Regional Network (COVIGEN). This collaborative sequencing network brings together three types of laboratories: those that conduct in-country genomic sequencing, those that need to ship samples to regional reference sequencing laboratories and those that serve as regional reference sequencing laboratories. COVIGEN currently includes 33 laboratories from 30 countries and territories in the Region of the Americas.

Countries with in-country sequencing capability are being supported to strengthen and sustain existing capability. Countries lacking this capability are being provided support for timely shipping of samples for sequencing in one of the regional reference laboratories.

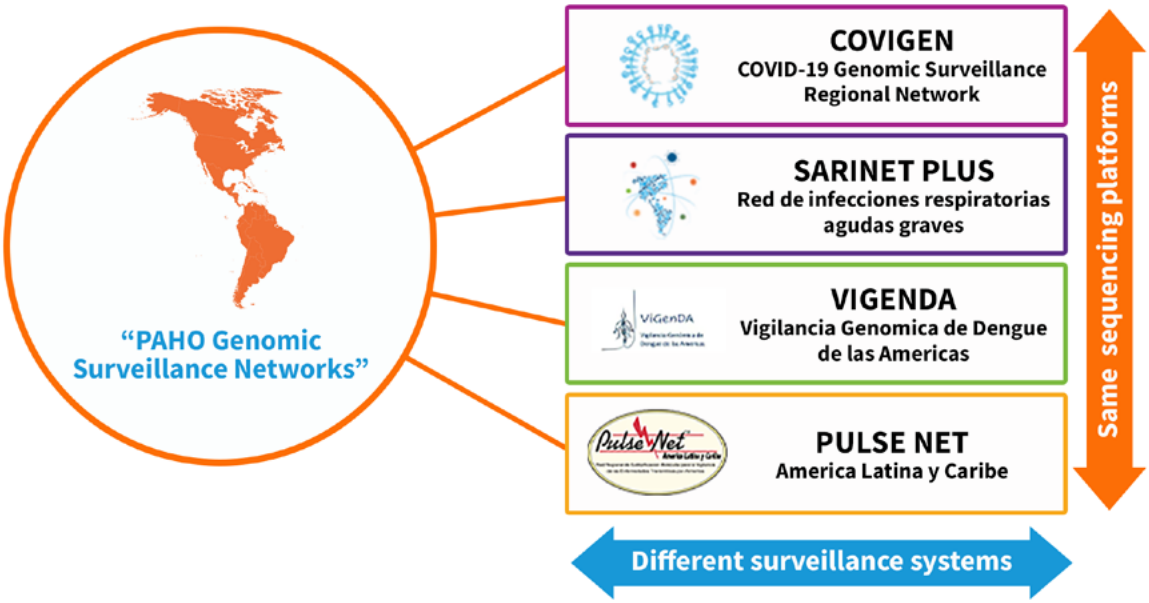
Additionally, PAHO has collaborated with countries to build and enhance sequencing capacities by providing standardized protocols, developing sample selection and sequencing strategies, assisting with critical equipment and reagent procurement and conducting several in-country and regional training courses on genomic sequencing and bioinformatics. As a result, the primary impact has been to strengthen and expand in-country SARS-CoV-2 sequencing and genomic surveillance capacities in the Region.

With the purpose of leveraging the genomic surveillance capabilities that were established in response to SARS-CoV-2 for responding to other emergencies, PAHO launched the Strategy on regional genomic surveillance for epidemic and pandemic preparedness and response, which was approved at the Pan American Sanitary Conference in September 2022. The strategy encourages all Member States to expand genomic surveillance tools to other pathogens prone to epidemics and pandemics, proposing a “network of networks” model to promote and strengthen collaboration across already existing disease-specific genomic surveillance networks. These networks include COVIGEN (COVID-19),

Severe Acute Respiratory Infections network (influenza), Vigenda (dengue and other arboviruses) and PulseNet (food-borne diseases), under the framework of the "PAHO Genomic Surveillance Networks" (Fig. 12). PAHO's regional genomic surveillance strategy provides the framework to facilitate sustainability and promote integration into existing disease-specific surveillance systems.

Currently, PAHO genomic surveillance networks support regional and country-level training in sequencing and bioinformatics, provides critical material and equipment, generates sample selection and sequencing strategies and fosters the integration of genomic sequencing into the broader surveillance programmes.

Fig. 12. Linkage between the genomic surveillance networks and other disease-specific surveillance systems in the Region of the Americas



2.2.4 Enhancing genomic surveillance in Brazil: building capacity in border laboratories

Country borders are one of the most critical areas for introducing and identifying non-autochthonous infections. Brazil has more than 16 000 kilometres of dry borders, which poses an enormous challenge to pathogen surveillance. The implementation of molecular epidemiology and building of sequencing capacity at border laboratories enable early detection of diverse pathogens, not only in Brazil but also in bordering countries.

Starting in 2018, the Brazilian Ministry of Health, through its General Coordination of Public Health Laboratories, has expanded the sequencing capacity to the state level, providing infrastructure to the 27 state public health laboratories. Nevertheless, the emergency response to COVID-19 challenged the sustainability of the support and significatively impacted the process.

As the first step in building sequencing capacity in bordering areas, molecular diagnosis platforms were implemented in five border laboratories during the second half of 2022 (October–December): Oiapoque (Amapá State, bordering French Guiana), Brasiléia (Acre, bordering Bolivia), Guajará-Mirim (Rondônia, bordering Bolivia), Cáceres (Mato Grosso, bordering Bolivia) and Corumbá (Mato Grosso do Sul, bordering Bolivia). These laboratories were provided with infrastructure, reagents and consumables. Relevant personnel were trained to use sequencing technologies. Furthermore, between November and December 2022, sequencing capacity was expanded to three additional laboratories with already existing capacity for molecular diagnosis: Tabatinga (Amazonas, bordering Colombia and Peru), Foz do Iguaçu (Paraná, bordering Argentina and Paraguay) and Uruguaiana (Rio Grande do Sul, bordering Uruguay).

In 2022 in the context of collaboration with COVIGEN, and the framework of the genomic surveillance regional strategy, PAHO worked together with the Brazilian Ministry of Health to strengthen the national network of genetic sequencing, focusing on three major objectives:

- strengthening SARS-CoV-2 and arbovirus genomic sequencing at the state level at the state public health laboratories;
- implementing a metagenomics pilot project in selected state public health laboratories; and
- strengthening molecular diagnosis and implementing genomic sequencing in selected country border laboratories.

Several activities have been conducted to achieve those objectives, including training in sequencing SARS-CoV-2 and arboviruses (with a focus on dengue, zika and chikungunya viruses) using positive samples from the relevant disease surveillance programmes. In addition to building capacities and capabilities, the training exercises have led to timely public health action in response to pathogens circulating in Brazilian territory.

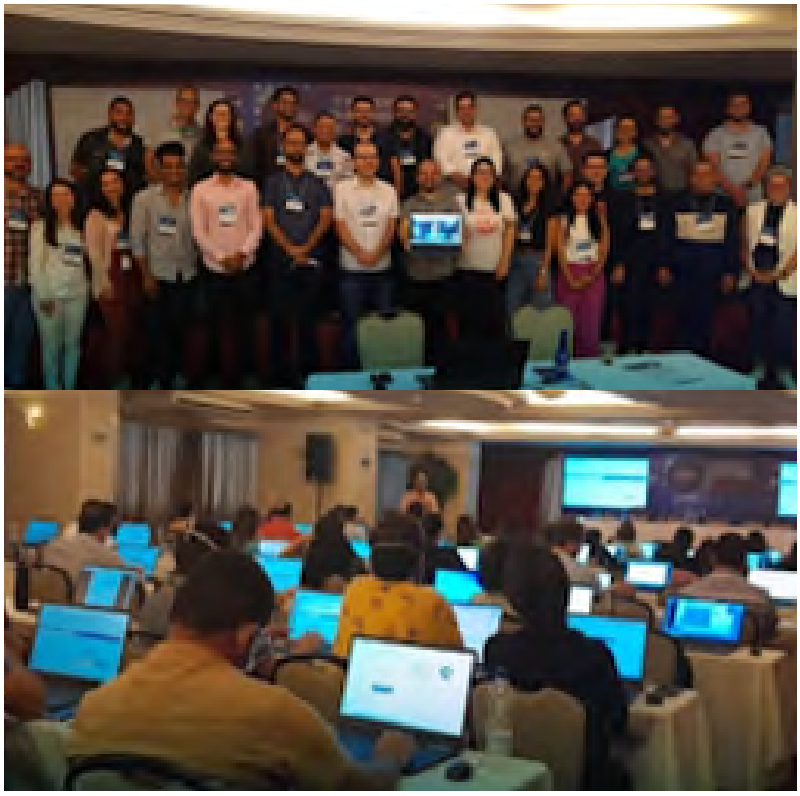
Specifically, two key activities had been conducted by the end of 2022:

- First training in genomic analyses offered by the national network of genetic sequencing (Brasilia, November 2022): over 50 technicians were trained, with at least two technicians from each state public health laboratory in attendance (Fig. 13).
- Training on SARS-CoV-2 genomic library preparation at the Laboratory of Respiratory Viruses and Measles, Instituto Oswaldo Cruz/Fiocruz (Rio de Janeiro, November–December 2022): staff responsible for sequencing in each of the 27 state public health laboratories were trained in an adapted COVIDSeq Illumina Test protocol (Fig. 14).

Fig 13. Training on genetic sequencing using minION technology at LAFRONS in Tabatinga-AM and Uruguaiana-RS

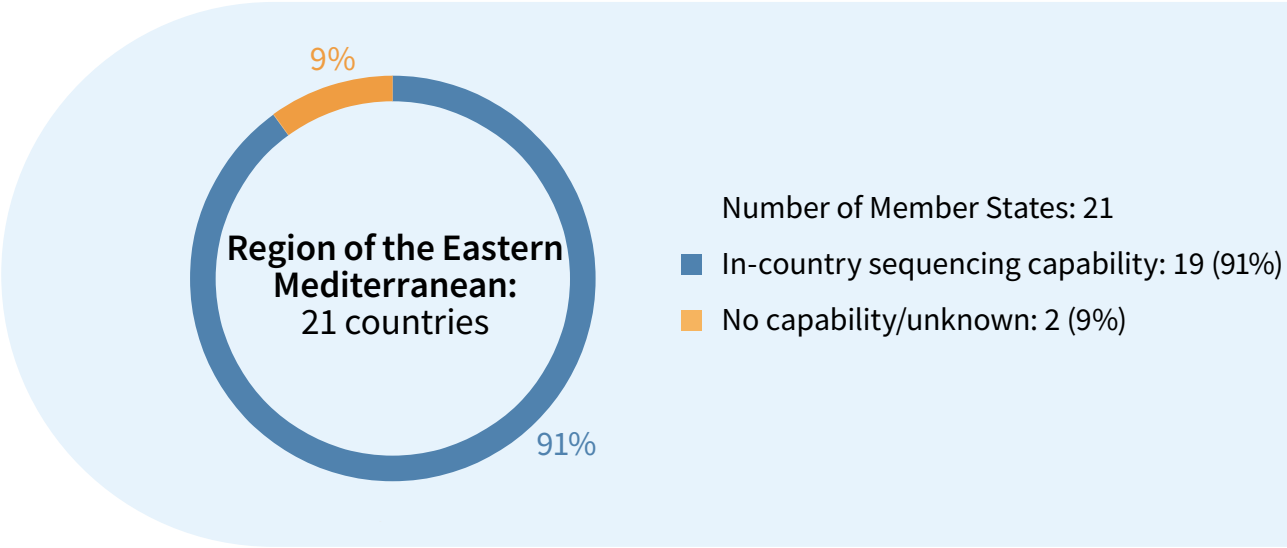
Source: WHO Regional Office for the Americas

Fig 14. Participants at the First Training of the National Gene Sequencing Network



Source: WHO Regional Office for the Americas

2.2.5 Eastern Mediterranean Region



The WHO Eastern Mediterranean Region comprises 21 countries with diverse cultures, socioeconomic conditions and demographic characteristics. Against a backdrop of fragile health systems, acute and protracted humanitarian emergencies, poverty and political challenges, this Region experienced a complex emergency situation during the COVID-19 pandemic.

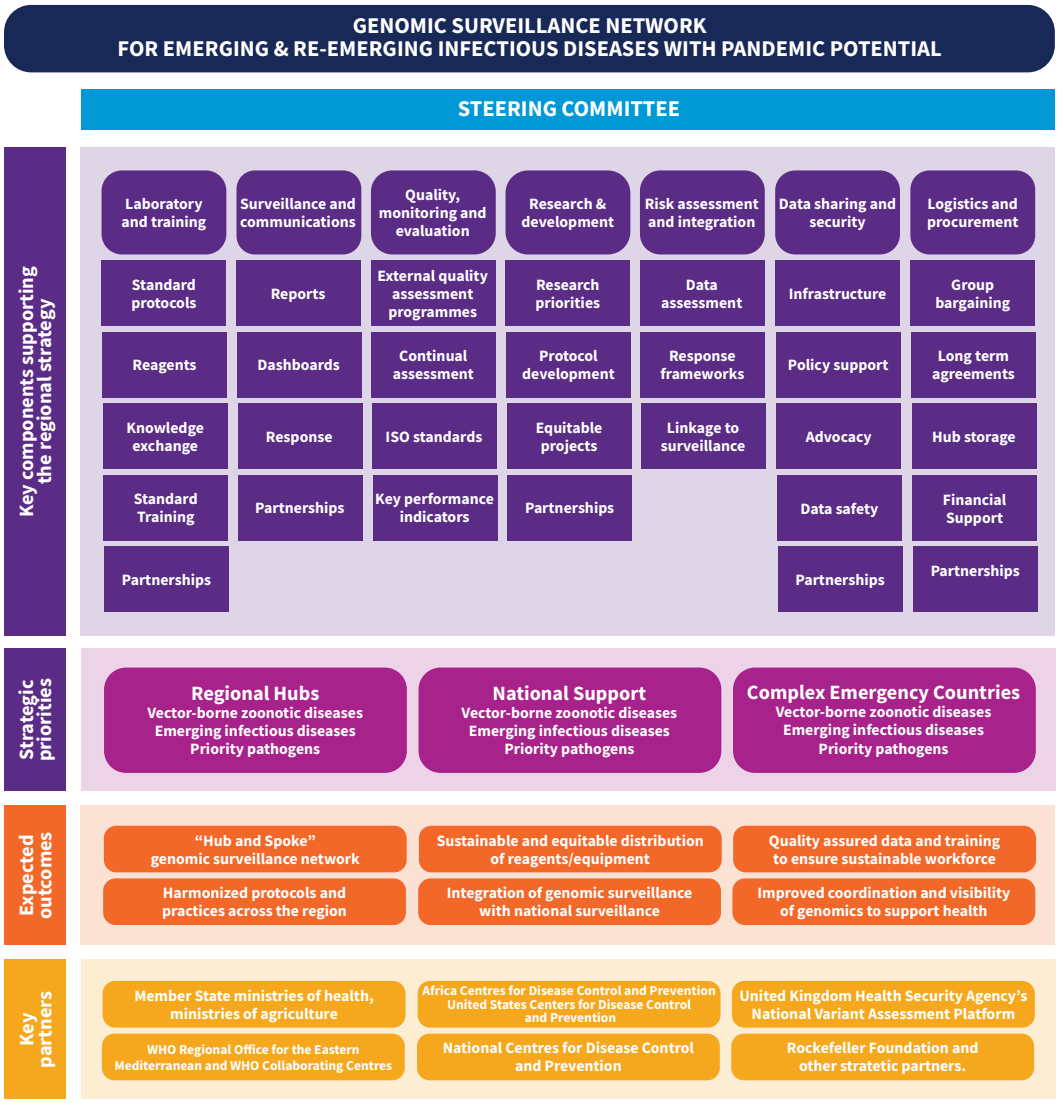
Though genomic surveillance was prioritized during the COVID-19 response, the Region faced significant challenges in implementing the technology at various levels. In 2020, for example, 15 countries had the capacity to sequence other pathogens such as influenza but lacked the required sequencing reagents, bioinformatics infrastructure and training needed to sequence SARS-CoV-2. Other countries lacked basic sequencing infrastructure and required support to build capacity and capability for genomic surveillance from scratch. In addition, many countries that were in complex emergency situations faced cold chain and logistical challenges in sample collection and transportation to regional hubs for sequencing.

To build sequencing capacity and capability for SARS-CoV-2, the Region leveraged GISRS with pre-existing expertise in genomic surveillance. Needed technical and logistical support and bioinformatics infrastructure were provided to build three regional reference hubs in Oman, Morocco and the United Arab Emirates. Furthermore, to enhance genomic surveillance capacity at the national level, the Regional Office supported the expansion of capacity at national influenza centres by integrating SARS-CoV-2 and influenza virus sequencing.

By the end of 2021, 15 countries (71%) had SARS-CoV-2 in-country sequencing capability. The Regional Office continued to provide support to the other seven countries (29%) without in-country capability, providing sequencing equipment (Oxford Nanopore Technology), reagents, bioinformatics support and training in these countries. By 31 December 2022, 20 (95%) of the 21 countries in the Region had in-country sequencing capability and 86% of countries in the Region had submitted GSD to a publicly accessible database at least once.

As part of its effort to strengthen and sustain genomic surveillance capacity in the Region, the Regional Office is leading establishment of a regional genomic surveillance network for emerging and re-emerging pathogens with pandemic potential (Fig. 15). To this end, the Regional Office proposes to convene a steering committee. This steering committee will be supported by multisectoral and multinational technical working groups with the goal of expanding capacity in regional hubs and national networks and supporting countries susceptible/experiencing complex emergencies in implementing genomic surveillance. This initiative is supported by national and international collaborators in the Region and will be finalized following further consultation and ratification by Member States. In addition, a regional genomic surveillance strategy with the goal of improving outbreak response and preparedness to prevent outbreaks from becoming pandemics is being developed and will be published in the second half of 2023.

Fig. 15. Structure of the Genomic Surveillance Network for Emerging and Re-emerging Infectious Diseases with Pandemic Potential in WHO's Eastern Mediterranean Region



2.2.6 The Eastern Mediterranean Region reflects on genomic sequencing and its future in integrated surveillance of respiratory viruses

On 8–9 June 2022, the Regional Office convened a meeting in Egypt with partner organizations, stakeholders and Member States to discuss a framework for integrating respiratory pathogen surveillance, including establishing the role of genomic surveillance. The meeting focused on shared challenges and how they were overcome, along with key success stories, with the goal of facilitating a regional genomic surveillance network to provide actionable public health interventions.

Highlights from stories shared by countries in the meeting follow.

Morocco: Building on increased molecular diagnostic capacity for SARS CoV-2, Morocco's Ministry of Health developed in-country sequencing capacity by establishing a national consortium of public and private laboratories to cover the country. This consortium makes it possible to rapidly address genomic surveillance needs by merging national capacity – such as the Laboratoire de Virologie and the Institut National d'Hygiène, with the capacity and capabilities of the private sector, such as the Institut Pasteur – that actively contributes genomic data to publicly accessible databases and bolsters national surveillance by sharing capacity and expertise.

Oman: In Oman, the Central Public Health Laboratory of the Ministry of Health collaborates with national and local academic partners to strengthen human resource capacity, improve coverage of genomic surveillance and enhance sampling strategies to provide actionable public health data from genomics. Multisectoral collaboration will be the cornerstone of any regional network moving forward.

Saudi Arabia: As a result of extensive efforts in Saudi Arabia, genomic surveillance was expanded from the national to the subnational level, enabling coverage for the entire country and improving the geographic representativeness of selected samples (Fig. 16). More than 60 000 SARS-CoV-2 samples have been sequenced in-country using national and subnational capacity and expertise. The country plans to utilize and build upon these expanded capacities to support broader pathogen surveillance and health emergency preparedness, focusing on priority diseases to prevent outbreaks becoming pandemics in the longer term.

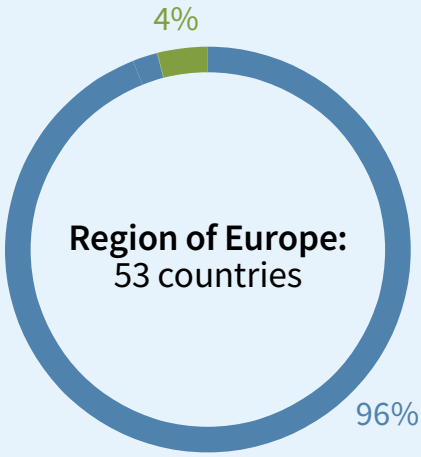
In line with WHO's recently launched Global genomic surveillance strategy for pathogens with pandemic and epidemic potential 2022–2032, the Regional Office is working with countries in the Eastern Mediterranean Region, as well as other regions, to capitalize on the gains made and to solidify the role of genomics in future public health practice.

> *Currently, 21 out of the 22 countries in the Eastern Mediterranean Region have genomic sequencing capabilities. A regional network has been established to enable all countries to have access to sequencing, and to strengthen their capacities coherently and collaboratively to be able to detect, investigate and respond to COVID-19 and other emerging and re-emerging infectious diseases with epidemic and pandemic potential.*
>
> Amal Barakat, Regional Laboratory Focal Point, WHO

Fig. 16. Staff from Saudi Arabia's National Influenza Centre in action

Source: Public Health Authority, Saudi Arabia

2.2.7 European Region



Number of Member States: 53

- In-country sequencing capability: 51 (96%)
- Access to timely international referral system: 2 (4%)

The WHO Regional Office for Europe has worked through multiple pathways to strengthen genomic surveillance capability in the European Region. Genomic surveillance is addressed in the workplan for the Region's high-threat pathogens Laboratory Task Force, and it is a major focus of the regional laboratory workplan *(18)*. A strong regional reference laboratory network provides sequencing services and technical support to countries.

The Regional Office convenes a bimonthly *COVID-19 variants and mutations updates call* for the Region's ministries of health to share and discuss genomic surveillance data. Additionally, the SARS-CoV-2 Virus Characterization working group, jointly with European Centre for Disease Prevention and Control, meets monthly to monitor genetic and antigenic evolution of COVID-19.

A subregional focus has been supporting development of a genomic sequencing hub at the Institute of Public Health of North Macedonia in collaboration with the UK Health Security Agency's New Variant Assessment Platform (NVAP). Within the framework of this collaboration, two online sequencing and bioinformatics training exercises have been conducted. Furthermore, an on-site train-the-trainers workshop on genomic sequencing, analysis and reporting for SARS-CoV-2 (on the Illumina platform) was held in Skopje, North Macedonia, from 13 to 17 February 2023.

In addition, the Regional Office in collaboration with the WHO Country Office in Türkiye has been supporting countries in the Caucasus and Central Asia to develop national genomic surveillance strategies through a series of consultations. A training programme in next-generation sequencing (NGS), bioinformatics and molecular epidemiology was developed by the Country Office in consultation with experts from all six WHO regions. This training programme was delivered in October 2022 to countries in Central Asia. On-site technical training, procurement of reagents and supplies (for the Illumina and MinION platforms) and support in developing a national genomic surveillance strategy are being provided to various countries.

The Region continues to hold technical meetings with key stakeholders to build and strengthen regional genomic surveillance capacities. Some of the meetings held since 2022 include:

- lessons learnt from national laboratory responses to COVID-19, 25–26 October 2022 (Paris, France);
- a workshop on developing a national sequencing strategy for Uzbekistan, 28–29 November 2022 and 23 December 2022 (Tashkent, Uzbekistan); and
- 9th Joint WHO Regional Office for Europe & European Centre for Disease Prevention and Control Annual European Influenza and COVID-19 Surveillance Meeting 2023, Copenhagen, Denmark, 31 May–2 June 2023.

2.2.8 Building next generation sequencing capacity for SARS-CoV-2 through workforce strengthening in Kyrgyzstan

Prior to the COVID-19 pandemic, NGS was being used for tuberculosis (TB) surveillance at the National TB Reference Laboratory, National TB Center, Bishkek City. This capability was leveraged in response to the COVID-19 pandemic with the support of the WHO Regional Office for Europe and the German Epidemic Preparedness Team of the Deutsche Gesellschaft für Internationale Zusammenarbeit. In addition, a multisectoral contingency plan was implemented to strengthen the country's laboratory capacity for COVID-19. In 2021, in collaboration with the Ministry of Health and Department of Disease Prevention and State Sanitary and Epidemiological Surveillance, laboratory specialists from the National TB Center commenced sequencing for SARS-CoV-2. The National TB Reference Laboratory serves as a learning hub for laboratory specialists from the National Influenza Center and other laboratories to increase country capacity on genomic sequencing. However, one major implementation challenge was a lack of experts in bioinformatics. Recognizing the need to build an adequate workforce to accelerate and sustain capability for genomic surveillance, Kyrgyzstan prioritized specialized training for NGS and bioinformatics.

With the support of the Regional Office, training on bioinformatics for the molecular epidemiology of SARS-CoV-2 was conducted for laboratory specialists involved in SARS-CoV-2 diagnostics in April 2022 (Fig. 17). The training aimed to strengthen NGS and bioinformatics capacity for SARS-CoV-2 surveillance and its application to other emerging and re-emerging pathogens of epidemic and pandemic potential. In June 2022, beneficiaries of the training in the National Tuberculosis Reference Laboratory shared SARS-CoV-2 GSD to a publicly accessible database. As of August 2022, over 300 SARS-CoV-2 sequences had been generated and shared, largely by national experts in Kyrgyzstan.

Kyrgyzstan is committed to scaling up genomic sequencing and bioinformatics for public health at the national level. One of the objectives of the *Global genomic surveillance strategy for pathogens with pandemic and epidemic potential 2022–2032* is to "strengthen the workforce to deliver at speed, scale and quality" (*8*). This can be achieved through implementation of training packages in genomic

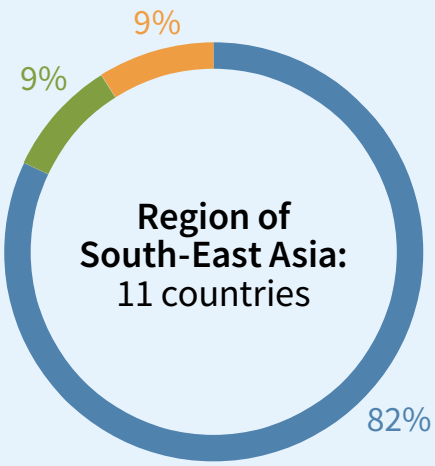
sequencing and bioinformatics. Outputs from workforce strengthening for genomic surveillance will enable the country to prepare and respond effectively to the COVID-19 pandemic and other pathogens with pandemic and epidemic potential.

> *"With the aim of supporting the use of genomic epidemiology in decision-making for public health, and openly and rapidly sharing the genomic sequence data in the collective effort of public health surveillance, Kyrgyzstan is committed to scaling up its genomics capabilities by bridging the workforce gap (laboratory specialists, public health practitioners and policy experts) and providing adequate infrastructure.*
>
> Aigul Djumakanova, Head, Department of Disease Prevention and State Sanitary and Epidemiological Surveillance Laboratory Service, Kyrgyzstan

Fig. 17. Participants at the training exercise in bioinformatics for the molecular epidemiology of SARS-CoV-2 at the National Reference Laboratory, National Tuberculosis Center, Bishkek City, Kyrgyzstan

Source: WHO Regional Office for Europe

2.2.9 South-East Asia Region



Number of Member States: 11

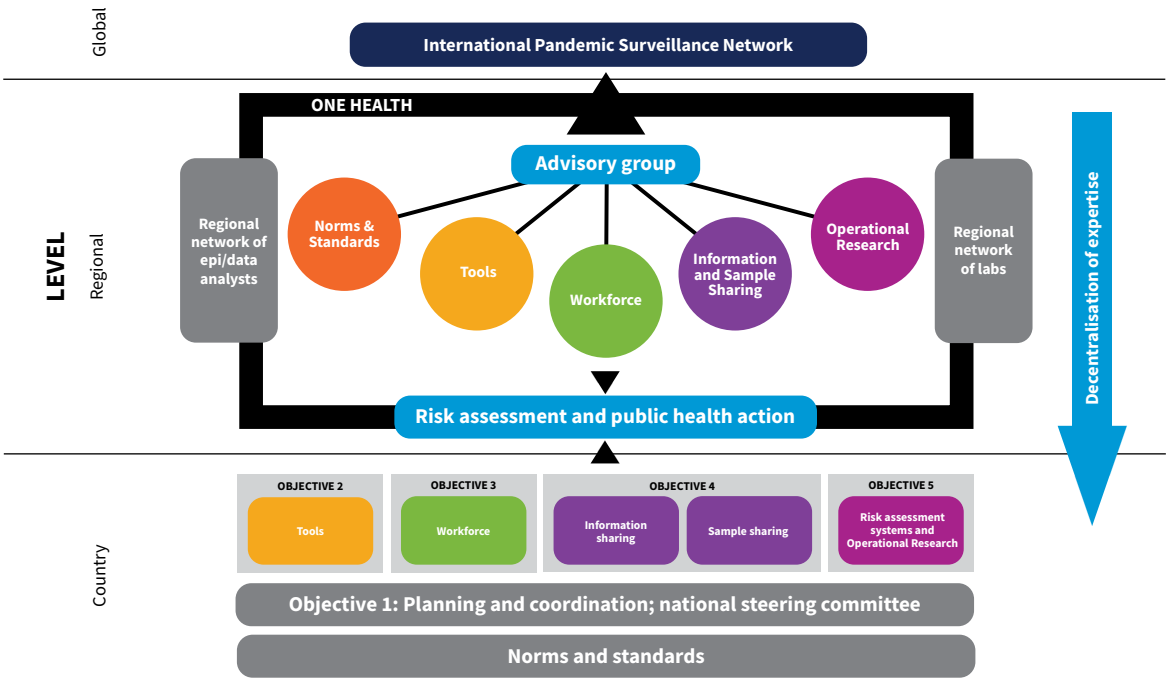
- In-country sequencing capability: 9 (82%)
- Access to timely international referral system: 1 (9%)
- No capability/unknown: 1 (9%)

The COVID-19 pandemic has resulted in rapid inclusion of genomic sequencing as an important response tool and highlighted its contribution to laboratory-based services for surveillance, clinical management, primary research and other purposes. With 11 countries containing one-quarter of the world's population, WHO's South-East Asia Regional Office has focused on short-term activities to strengthen genomic surveillance in response to the COVID-19 pandemic. Simultaneously, the Regional Office has been developing a long-term vision to support countries in integrating these activities into broader public health systems in a sustainable way.

This action plan builds on the global genomic surveillance strategy, incorporating a regional consortium to establish a trust architecture for data and sample sharing while ensuring coordinated efforts by WHO, Member States, donors and partners to include genomic sequencing within the broader public health disease surveillance framework.

A regional strategy document endorsed by the Regional Committee in 2022 – the *South-East Asia regional roadmap for diagnostic preparedness, integrated laboratory networking and genomic surveillance (2023–2027)* – considers establishing a regional genomic surveillance consortium to be a key component of the strategy (Fig. 18). The consortium is envisioned as a country-led mechanism, decentralizing capacities and tools to the national and subnational level in the Region through multisectoral collaboration. The vision is to develop an architecture founded on trust for rapid sharing of data to support informed public health decision-making. The strategy also aims to strengthen linkages between surveillance and laboratory systems.

Fig. 18. Structure of the consortium to implement the South-East Asia Regional Committee's roadmap for diagnostic preparedness, integrated laboratory networking and genomic surveillance



2.2.10 A focus on Thailand: reflections from Pilailuk Akkapaiboon Okada, Medical Technologist (Senior Professional Level), National Institute of Health, Thailand

What do you use genomic surveillance for in your country?

The National Institute of Health in Thailand is a reference laboratory in the South-East Asia Region, and it was accredited as a polio sequencing reference laboratory by WHO in 2012. The laboratory has capacity and capability for Sanger sequencing and NGS. Currently, genomic surveillance is used to sequence many pathogens with pandemic and epidemic potential, such as influenza, SARS-CoV-2, polio and antimicrobial resistant pathogens. Furthermore, Thailand shares its GSD on publicly accessible databases, for the global public health good.

What information does genomic surveillance contribute to disease control efforts?

The information from genomic surveillance is used to provide guidance and information to support the influenza vaccination programme, compare circulating variants with vaccine strains and monitor the evolution and spread of dominant variants of pathogens.

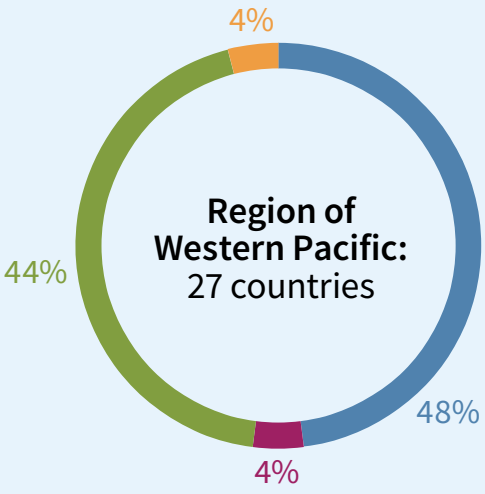
What are you doing in your country to strengthen genomic surveillance?

To strengthen genomic surveillance in Thailand, it is being integrated into the existing routine surveillance systems. With proactive efforts from the government, the national laboratory has been given the mandate and is being supported to continue monitoring SARS-CoV-2 variants and other pathogens with pandemic and epidemic potential. To expand capacity beyond SARS-CoV-2, the country has identified the need to strengthen its workforce (training in wet lab and bioinformatics) and to participate in external quality assessment programmes.

How does the global strategy on genomic surveillance help your efforts at the country level?

The global strategy provides guidance and information which has been translated and adapted at the country level to the national action plan and policy for public health preparedness and response.

2.2.11 Western Pacific Region



Number of Member States: 27

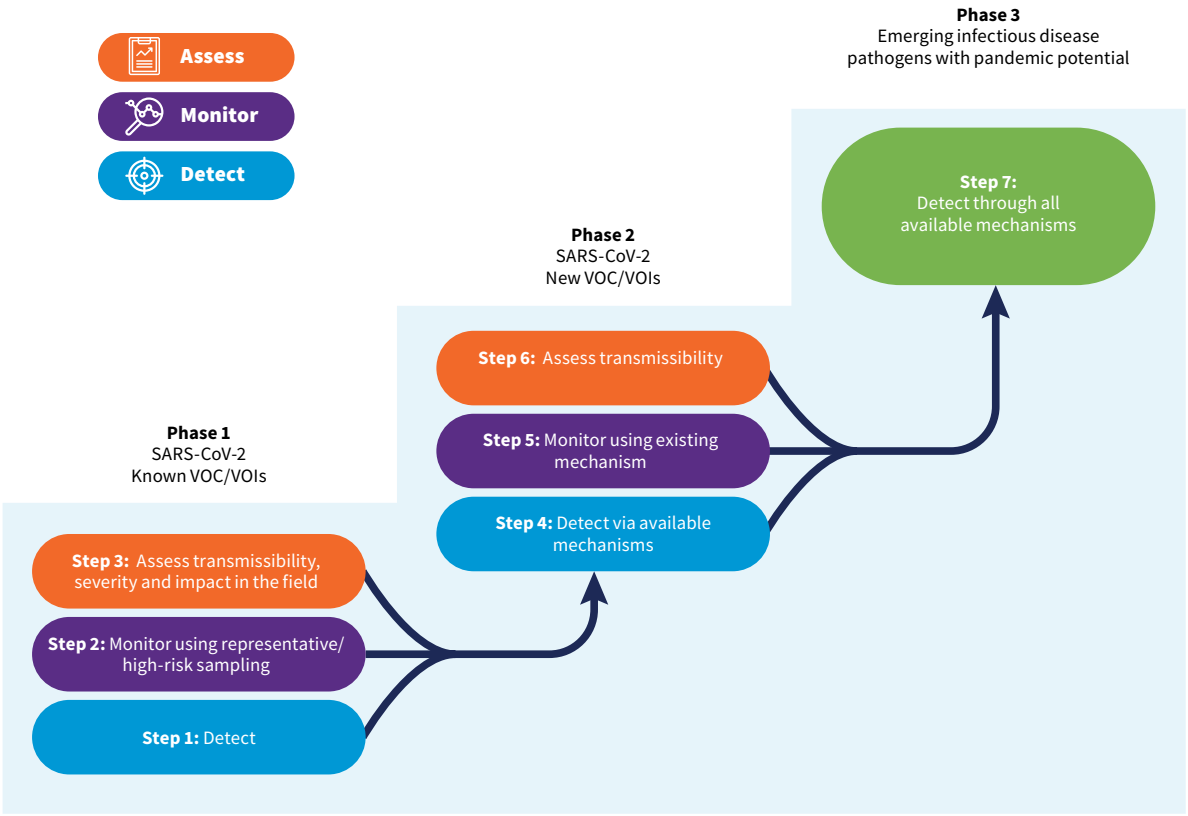
- In-country sequencing capability: 13 (48%)
- In-country sequencing capability without public health surveillance function: 1 (4%)
- Access to timely international referral system: 12 (44%)
- No capability/unknown: 1 (4%)

The WHO Western Pacific Regional Office launched the Western Pacific Region Emerging Molecular Pathogen Characterization Technologies (EMPaCT) Surveillance Network in September 2021 to support Member States in developing and strengthening access to sustainable genomic surveillance systems. The EMPaCT Surveillance Network, facilitated by WHO, provides a practical platform for partners to contribute to system development in Member States in a coordinated way.

The EMPaCT Surveillance Network has developed a seven-step approach to a sustainable in-country genomic surveillance system for Member States (Fig. 19). Steps 1–3 (the first phase) focus on detecting, monitoring and characterizing known SARS-CoV-2 variants of concern (VOCs)/variants of interest (VOIs). Steps 4–6 (the second phase) build on the preceding steps to enable the surveillance system to detect and assess new VOCs. The first six steps provide the foundation to support step 7, a comprehensive surveillance system that can detect, characterize and respond not only to SARS-CoV-2 but also to future emerging infectious disease pathogens. The system utilizes multisource information, including from clinical, epidemiological and laboratory settings, to support data-driven situation analyses and decision-making.

The seven-step approach incorporates the key principles and lessons of the *Asia Pacific strategy for emerging diseases and public health emergencies (19).*

Fig. 19. The seven-step approach of the EmPACT Surveillance Network in the WHO Western Pacific Region



SARS-CoV-2: severe acute respiratory syndrome coronavirus 2; VOCs: variants of concern; VOIs: variants of interest

2.2.12 Collaborating for excellence: Centre for Pathogen Genomics, University of Melbourne, Peter Doherty Institute for Infection and Immunity

The Centre for Pathogen Genomics based at the Peter Doherty Institute for Infection and Immunity, a joint venture between the University of Melbourne and the Royal Melbourne Hospital in Australia, is a centralized pathogen genomics hub to support infectious diseases preparedness and response. The Centre has been supporting genomic surveillance of key pathogens of public health interest through a programme of workforce capacity building and training, access to tools for data sharing and utility, and maximizing connectivity and networking across laboratories.

The Centre has supported workforce capacity building across wet lab, bioinformatics and genomics epidemiology, with training to support the access, use and reporting of genomic surveillance data across eight countries in the Asia-Pacific Region through a public health laboratory referral pathway network. The Centre is also supporting the implementation of pathogen genomics for public health in Bhutan, Cambodia, Fiji, Malaysia, Pakistan and Timor-Leste. Training approaches include short workshops and training courses online, in-country or at the Doherty Institute, ongoing mentoring and support, training for end users to support the interpretation of genomic data for public health, and development of guidance documents and resources to support genomic surveillance systems. The Centre is working with counterparts in public health laboratories to explore the utility of data analysis and visualization tools and platforms to support integrated, real-time genomic surveillance across variable settings with plans to pilot the use of a secure, cloud-based platform for real time bioinformatic data analysis, with the ability to integrate epidemiological data for robust analysis.

Bringing together the programmes of work to enhance genomic surveillance across the Region, in 2022 the Centre, alongside partners in Fiji, Japan, New Zealand, the Philippines and Singapore, established the Asia-Pacific Pathogen Genomics Network. This network focuses on supporting coordination of programmes in the use of genomics for public health and to formalize a framework for collaboration, as well as to provide a central resource for information sharing and teaching and training capabilities. The Asia-Pacific Pathogen Genomics Network is aligned with the WHO Regional Office for the Western Pacific EMPaCT priorities.

2.3 Partner initiatives and implementation

For the first year of the Strategy's roll out, WHO convened the Partners Coordination Group (PCG) comprising 30 institutions spread across the six WHO regions. The work of the group addresses different strategy objectives, in line with global, regional and country priorities. The PCG fostered collaboration and coherent implementation of the global strategy, aiming to maximize effectiveness and efficiency. Specifically, the PCG served as the stakeholder voice for the strategy in developing, aligning and implementing short- and long-term action

plans in the line with its five objectives. It also fostered greater engagement among interested partners to utilize their capacities and capabilities, towards achieving the strategy's key measure of success, namely that "by 2032, all 194 WHO Member States have, or have access to, timely genomic sequencing for pathogens with pandemic and epidemic potential".

Through its meeting held every other month, partners exchanged information on activities, gaps and needs, lessons learnt and other developments relating to the strategy. Partners helped to identify policy and implementation support tools needed to strengthen genomic surveillance in countries. This effort has spurred action, including by WHO, to develop normative products. WHO is currently working on a strategy support tool and a genomics laboratory costing tool to support countries technically. Section 3 provides additional information about these products.

The following institutions were involved in the Strategy's Partner Coordination Group:

1. **Africa CDC (Africa Pathogen Genomics Initiative)**
2. **ANRS | Emerging Infectious Diseases/Inserm, France**
3. **Asia Pathogen Genomics Initiative**
4. **Asia-Pacific Pathogen Genomics Network**
5. **Department of Foreign Affairs and Trade, Australia**
6. **Centers for Disease Control and Prevention, United States of America**
7. **Central Public Health Laboratory, Oman**
8. **Centre for Pathogen Genomics, University of Melbourne, Peter Doherty Institute for Infection and Immunity, Australia**
9. **Clinton Health Access Initiative**
10. **Chan Zuckerberg Biohub**
11. **CSIR-Institute of Genomics and Integrative Biology**
12. **Département de Virologie, Institut National d'Hygiène, Morocco**
13. **Exemplars in Global Health**
14. **FIND**
15. **Fiocruz, Brazil**
16. **Food and Agriculture Organization of the United Nations**
17. **Bill & Melinda Gates Foundation**
18. **GISAID at Bioinformatics Institute**
19. **National Institute of Allergy and Infectious Diseases of the National Institutes of Health, United States Department of Health and Human Services**
20. **Pasteur Network**
21. **Public Health Authority, Saudi Arabia**
22. **Robert Koch Institute, Germany**
23. **Rockefeller Foundation**
24. **Sanger Institute, United Kingdom of Great Britain and Northern Ireland**
25. **Sheikh Khalifa Medical City, United Arab Emirates**
26. **The Global Fund to Fight AIDS, Tuberculosis and Malaria**
27. **Tony Blair Institute for Global Change**
28. **UK Health Security Agency**
29. **United States Agency for International Development**
30. **Wellcome Trust**

2.3.1 Partner spotlights

The following spotlights shed light on various partner initiatives to strengthen genomic surveillance for pathogens with pandemic and epidemic potential.

2.3.2 The Global Fund: strengthening pandemic preparedness through investments in genomic surveillance

In 2020 the Global Fund to Fight AIDS, Tuberculosis and Malaria established the COVID-19 Response Mechanism, offering funding opportunities to countries to strengthen their health and community systems to mitigate the impact of COVID-19 on HIV, TB and malaria programmes. Since its initiation, a total of US$ 4.48 billion was allocated for distribution, including US$ 231 million in grant flexibilities *(20)*. The ever-changing nature of the COVID-19 pandemic led countries to prioritize genomic surveillance, and the Global Fund had the flexibility to adapt funding packets to support these activities. Approximately 40 countries purchased instruments, reagents and sequencing kits to the extent of more than US$ 15.5 million. A further US$ 1 million worth of support went to sequencing activities within the disease grants from the previous funding cycle.

Further activities included investments in wastewater surveillance through the Global Fund's centrally managed limited investment funding of Project Stellar. Four countries (Ethiopia, Kenya, Mozambique and Uganda) participated in a pilot programme using polymerase chain reaction (PCR)-based methodologies for detecting SARS-CoV-2 through the implementing partner, APHL. Initial success prompted a second round of funding, extending the methodologies to use of targeted NGS for environmental surveillance (Fig. 20, 21). An additional two countries (United Republic of Tanzania and Zambia) have since been added to the programme.

The Global Fund continues to support integrated laboratory system capacity strengthening as part of the 2023–2026 grant funding cycle, which includes funding to resilient and sustainable systems for health and pandemic preparedness. Genomic surveillance is an important component of the Global Fund's pandemic preparedness strategy and aligns their contributions with the *Global genomic surveillance strategy for pathogens with pandemic and epidemic potential 2022–2032*.

Global Fund staff continue to contribute to partner meetings, collaborations and work with regional bodies to further connectivity between disease programmes and to enhance surveillance networks.

Fig. 20. Wastewater sample collection for genomic sequencing in Kenya

Source: The Global Fund

Fig. 21. Swab removal from a manhole at a collection point in Kenya

Source: Association of Public Health Laboratories

2.3.3 UK Health Security Agency: New Variant Assessment Platform

Since its launch in April 2021, the NVAP led by the UK Health Security Agency (UKHSA) has established collaborations with 18 countries and six regional partners to strengthen SARS-CoV-2 and genomic surveillance capacity and capability. The NVAP fosters global partnerships through a pathogen agnostic strategy to strengthen selected national public health laboratories and regional hubs. The NVAP has bilateral agreements with nine countries for providing sequencing reagents, kits and consumables, in addition to training, technical assistance and mentorship provided to all partners (Fig. 22). The NVAP offered access to sequencing from the United Kingdom during the peak of the pandemic, when there was limited or no capacity in-country, sequencing 3,365 genomes in the UK and providing technical assistance to partners on the bioinformatics analysis and interpretation of findings.

The NVAP is collaborating with regional partners such as the WHO Eastern Mediterranean Regional Office to strengthen three designated regional hubs. The NVAP has worked closely with the WHO Regional Offices for Europe and South-East Asia to support the development of regional genomic surveillance Strategy and Roadmap. The NVAP has seconded a technical advisor to Africa CDC to support the Africa Pathogen Genomics Initiative. The NVAP has partnerships with the Caribbean Public Health Agency, the University of the West Indies and with the Government of Singapore to support development of their regional capabilities. Through NVAP, UKHSA has provided practical support to partners as below:

- Sequencing reagents, kits and consumables (SARS-CoV-2 & Mpox) to six countries for sequencing 5,000 samples each
- Equipment (1 sequencer, 19 liquid robotic handlers) to 7 institutions (6 countries)
- 24 high-specification computers to 6 institutions (5 countries)

With the NVAP support, partners deposited 88,891 genomes on publicly accessible platforms. So far, the NVAP sponsored 18 countries for sequencing external quality assurance scheme to help improve sequencing quality. The programme has delivered training courses on variant risk decision-making, bioinformatics, sequencing external quality assessment and variant epidemiology. These activities are enabling partners to increase sequencing capacity and capability to detect new variants of SARS-CoV-2 and pathogens of pandemic and epidemic potential.

The NVAP contributed to the Global genomic surveillance strategy for pathogens with pandemic and epidemic potential and is working with partners globally to implement it. The NVAP is actively engaged in the International Pathogen Surveillance Network (IPSN) through the Country Accelerator Forum and the WHO PCG for global genomic surveillance strategy implementation.

Fig. 22. Hands-on training and mentorship provided by the New Variant Assessment Platform to colleagues from the Caribbean Public Health Agency

Source: New Variant Assessment Platform team

> *"It is fantastic to see what the New Variant Assessment Platform has achieved working collaboratively with partners over the past year in providing practical support, training and surveillance expertise to so many countries and regions. Through NVAP we are helping to strengthen genomic surveillance systems across the world, and we are excited to continue this work further over the coming year with all our partners. Our collective efforts are helping towards the global ambition of the 100 Days Mission, better pandemic preparedness and global health security.*
>
> Leena Inamdar, Head, New Variant Assessment Platform and Global Health Lead, Science Group, UK Health Security Agency

2.3.4 Fungal disease surveillance and genomic capacity in the southern African region

The National Institute for Communicable Diseases (NICD) in South Africa is building a regional network in southern Africa for fungal disease surveillance, in collaboration with the CDC in the United States; Instituto Nacional de Investigação em Saúde in Angola; Instituto Nacional de Saúde and Centro de Investigação em Saúde de Manhiça in Mozambique; the University of Zambia in Zambia; the National Microbiology Reference Laboratory in Zimbabwe; and the National Public Health Laboratory and University of Botswana in Botswana (Fig. 23). As part of this capacity, genomic surveillance will be implemented for high-priority pathogens

such as *Cryptococcus* and the antimicrobial-resistant *Candida auris*. The initial strategy involves four primary programme outcomes: creating new cross-border partnerships in the southern African region; assessing the microbiological capacity of regional laboratories; designing a generic surveillance protocol that is adaptable to country settings; and optimizing pathogen genomic capacity at NICD.

In 2022, nine Ministry of Health-supported institutions were approached to establish partnerships; of these, five will immediately move forward as partners. A survey questionnaire was designed to assess the ability to culture, identify and classify fungal pathogens and conduct surveillance in target populations. Additionally, NICD has adopted the open-source, containerized bioinformatics pipeline MycoSNP for fungal genomes, is building a customized pipeline for expanded fungal genomic analysis and has joined FungiNet, a CoP for advancing fungal pathogen genomics in public health. Future efforts will involve NICD analysing the collected laboratory survey data; conducting training workshops for fungal pathogen identification, submission of isolates and/or DNA to NICD and sequencing for those laboratories with sequencing capacity; hosting regular stakeholder engagement meetings to support regional partnerships; disseminating surveillance reports; and linking the southern Africa regional network to the broader global genomic surveillance network.

> *"A surveillance network in southern Africa will strengthen capacity for fungal disease diagnosis, improve cross-border communication and, ultimately, help us to rapidly detect emerging fungal pathogens and control outbreaks.*
>
> Nelesh Govender, Head, Centre for Healthcare-Associated Infections, Antimicrobial Resistance and Mycoses, National Institute for Communicable Diseases, South Africa

Fig. 23. Mycology laboratory training conducted by the National Institute for Communicable Diseases at Instituto Nacional de Investigação em Saúde in Luanda, Angola in August 2023

Source: Nelesh Govender

2.3.5 ANRS|MIE: the AFROSCREEN project

The AFROSCREEN project was designed to strengthen genomic sequencing and surveillance capacities in sub-Saharan Africa, thereby responding to the need of equitable access to genomics for global health *(21)*. Coordinated by ANRS|MIE, the project is led by a consortium of three institutes: ANRS|MIE-Inserm, Institut Pasteur and the Research for Development Institute, and 25 partners in 13 countries in sub-Saharan Africa: Benin, Burkina Faso, Cameroon, Central African Republic, Democratic Republic of the Congo, Ghana, Madagascar, Mali, Niger, Côte d'Ivoire, Guinea, Senegal and Togo. It is carried out in coordination with the Africa CDC Pathogen Genomics Initiative and the WHO Regional Office for Africa with the aim of synergizing activities towards a common goal of equitable access to pathogen genomics throughout the continent.

AFROSCREEN provides training, mentorship, equipment and reagents to build partner capacity for sequencing and PCR screening of SARS-CoV-2 mutations and reinforce the competences of laboratory staff in bioinformatics. The implementation of screening PCR for SARS-CoV-2 mutations allowed identification of the Omicron variant in several countries. In 2022 AFROSCREEN provided sequencers to four laboratories and contributed to increasing the average number of sequences deposited on publicly accessible databases per month by the 13 countries (46 sequences/month were deposited in 2021 versus 78/month in 2022).

Furthermore, AFROSCREEN contributed to setting up and reinforcing a sentinel surveillance system for SARS-CoV-2. The major challenges faced so far concern delays in supplying equipment and reagents for genomic sequencing, due to the low priority given to African countries by suppliers and to complex and slow administrative procedures. AFROSCREEN facilitates development of pathogen detection, characterization and genomic monitoring to prepare for future epidemics in African countries. The consolidated platforms will also enable research projects to sustain scientific capacity while responding to the challenges of "One Health – Global Health".

2.3.6 Strengthening genomics capacity in low- and middle-income countries: reflections from scientists at FIND, the global alliance for diagnostics

What was your focus in strengthening genomic surveillance?

Our team focused on building tools to guide implementation and strengthening capacity for genomics in low- and middle-income countries (LMICs). Early in the pandemic, we published a sequencing technology landscape for COVID-19 to describe the utility of NGS for understanding SARS-CoV-2 and available tools for tracking evolution of the virus. We mapped genomic surveillance capacity globally to identify gaps in coverage and inform donors and implementers on support needs (Fig. 24). We also helped to build and scale NGS capacity for SARS-CoV-2 in Bangladesh, Botswana, Democratic Republic of the Congo, India and Indonesia, and more recently Sudan and Viet Nam.

Is there a particular highlight that you would like to mention?

It has been incredibly inspiring and rewarding to work collaboratively with partners (funders, implementers, policymakers, research institutions, the private sector and country representatives) bringing complementary expertise to enable genomic surveillance in LMICs. This was initially done through the Access to COVID-19 Tools Accelerator Diagnostics Pillar Genomic Surveillance working group and has progressed through the WHO PCG.

How do we extend this new capacity for SARS-CoV-2 genomics from being pathogen specific to being more pathogen agnostic?

The sequencing capacity established for SARS-CoV-2 across Africa, Asia and Latin America can and should be leveraged for countries' next disease priorities. Systematic country surveys to understand the priorities would help to determine focus areas where sequencing would bring value – anecdotally, these include TB, AMR, malaria and outbreak-prone pathogens. Practical considerations would include sample referral systems to ensure access to the samples at the existing sequencing facilities; volume and batching of samples – the more samples you can run at one time on a sequencer, the cheaper it is per sample; availability of affordable products for end-to-end workflows and protocols for different pathogens and applications; hands-on training on genomic techniques such as amplicon-based or targeted sequencing and metagenomics; resources for data analyses, sharing and management; functioning supply chain and logistics to ensure timely availability of quality reagents and consumables; external quality assessment; costing and forecasting tools for labs and programmes; and integration into existing surveillance and lab information systems to ensure that the generated genomic data is utilizable and actionable.

What is your vision for genomic surveillance in the future?

The pandemic experience showed that establishing genomics capacity in LMICs is possible. Our focus now is to ensure this capacity is scalable and sustainable and integrated into health systems and surveillance networks. While sequencing infrastructure can be a significant investment initially, genomics has tremendous potential to transform health care to inform public health response through surveillance, inform design of targeted diagnostics and vaccines and eventually to inform patient treatment decisions, for example in the context of drug resistance. Countries are already looking to incorporate genomics into their national strategic plans to ensure it can be budgeted within health systems, be it donor or domestic funding. We hope that FIND and other groups involved in genomics for global health as part of the PCG can play a key role in supporting countries to optimize investments in genomics to date and maximize the outcomes to their health programmes overall.

Fig. 24. FIND scientists: Swapna Uplekar (Principal Scientist, Genomics & Sequencing Unit) and Anita Suresh (Head, Genomics & Sequencing Unit)

2.3.7 Wellcome Sanger Institute

The Wellcome Sanger Institute collaborates with partners around the world to integrate genomic sequencing with epidemiological data to understand and monitor the evolution and spread of a range of microbial pathogens. Conducting studies over a time frame of decades and at multiple levels of spatial resolution, ranging from the local to global scale, allows us to characterize the intense evolutionary pressures applied by the use of drugs, vaccines and other public health interventions, as well as the impact of diet and lifestyle. The institute focuses on developing open data tools and data sets relevant to basic science and disease control and building close links with local and international health organizations. It also maintains a strong emphasis on endemic diseases of the developing world and a long-term commitment to research training and capacity building in LMICs.

Our work has revealed fundamental insights into the patterns of transmission, evolution of AMR and responses to vaccination for bacterial, viral and eukaryotic pathogens. We have used genomics to redefine the cause of pandemic cholera as specific Vibrio cholerae lineages adapted to human-to-human transmission rather than widespread transmission of environmental lineages. During the COVID-19 pandemic, the unprecedented scale of genomic surveillance efforts at Sanger was instrumental in our ability to identify, track and analyse variants of the SARS-CoV-2 virus as they have emerged. Finally, through the Global Pneumococcal Sequencing

(GPS) project, we have used large-scale whole-genome sequencing to generate a detailed understanding of how the circulating population of *Streptococcus pneumoniae* adapts to vaccine introduction by expanding existing lineages to fill the niche vacated by vaccine-susceptible strains *(22)* (Fig. 25). Insights from GPS have been used to inform which serotypes to include in the latest pneumococcal conjugate vaccines under development *(23)*.

Fig. 25. Participants at the recent Global Pneumococcal Sequencing/JUNO genomic surveillance workshop in Bangalore

Source: Wellcome Sanger Institute

3. Looking ahead: 2023 and beyond

This report highlights success in partnerships, implementation and joint progress in the pathogen genomic surveillance landscape. However, there are opportunities to further strengthen genomic surveillance for pathogens with pandemic and epidemic potential. WHO in collaboration with partners is working with countries to strengthen and sustain the gains made from the COVID-19 pandemic, to ensure all countries have access to timely sequencing for pathogens with pandemic and epidemic potential, and use genomic surveillance data for strategic decision making.

3.1 Opportunities to strengthen genomic surveillance for pathogens with pandemic and epidemic potential

Country, regional and partner initiatives are critical to sustaining the gains made. Despite the enormous progress in recent years, genomic surveillance is yet to be optimally utilized for pandemic and epidemic preparedness and response. Opportunities include improving equitable access to technologies (including reagents and consumables) for genetic sequencing and bioinformatics, workforce development, and capacity strengthening for countries to link genomic data with epidemiological and clinical data. There are opportunities to build and scale the existing siloed laboratory, surveillance and clinical systems within the public health architecture.

Initiatives and activities to strengthen genomic surveillance should consider the contextual realities and priorities of the countries. There should be coordination of resources, leveraging existing systems and assets towards strengthening our collective global health security. Using a One Health lens, a collaborative approach across disease programmes and diverse stakeholders at all levels will foster the effective and efficient use of genomic surveillance.

3.2 Initiatives and joint products

Countries remain at the centre for the Strategy implementation. In collaboration with key stakeholders, WHO at its three levels will continue to provide strategy and technical support to countries in sustaining and scaling genomic surveillance globally. This section provides more information below on some of the initiatives and joint products led by WHO to look forward to in 2023 and beyond.

3.2.1 Launch of the International Pathogen Surveillance Network

To support the implementation of the strategy, WHO has created the International Pathogen Surveillance Network (IPSN). The IPSN is designed to address the key

barriers to improved pathogen genomics related to financing, coordination, country scale-up and driving innovation. Its vision is that "every country has sustained capacity for genomic sequencing and analytics as part of its public health surveillance system".

The IPSN is a mutually supportive global network of genomic surveillance actors that amplifies and accelerates the work of its members to achieve a shared vision. The secretariat is hosted by WHO's Pandemic Hub for Pandemic and Epidemic Intelligence. After a detailed design and consultation phase, IPSN's design was finalized in December 2022. Informal first meetings of its operational bodies have also now been held. IPSN has three operational bodies:

A community of practice (CoP) for genomic data, designed to harmonize standards and protocols, drive the development analytic tools that are sustainable and fit for purpose across country contexts, and improve trust and incentives for data sharing. Additional CoPs will be established to address other high priority technical issues

The country scale-up accelerator, designed to harmonize and accelerate efforts to support countries in building genomic surveillance capacity, including through facilitating increased South-South exchange

The Funders Forum, designed to empower the network by facilitating small innovation grants, particularly for IPSN members from lower-income contexts, to test and prove concepts, as well as identifying and brokering support for larger capacity scale-up needs.

After these initial meetings, priority actions for 2023 have been identified. IPSN was publicly launched in May 2023 and its governance will be finalized with the formation of a Leadership Committee. Meanwhile, the secretariat and IPSN operational bodies will continue to drive the delivery of a set of global goods for pathogen genomics. These include a maturity model for country capacity scale up, a prioritization of genomics use-cases for country contexts and a global investment case for pathogen genomics.

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

WHO encourages and supports countries to articulate their plans for strengthening genomic surveillance capacities and capabilities. A number of countries are already developing national strategies or action plans, and others are seeking guidance for it. To support this, WHO is developing a strategy support tool that highlights key considerations in developing a national genomic surveillance strategy or action plan. This strategy support tool informs implementation approaches and advocates for the prioritization of genomic surveillance needs by key stakeholders in the Member States. The tool will be published in mid 2023.

3.2.3 Genomics costing tool

Based on country requests, in 2022 WHO worked with APHL, FIND, The Global Fund and UKHSA to develop a genomics costing tool. This tool assists countries in quantifying the resources needed to sustain sequencing within their public health surveillance systems.

Building on the laboratory test costing tool developed by the WHO Regional Office for Europe, as part of its Better Labs for Better Health initiative *(24)*, this costing tool will support short-and-long term financial planning for genomic sequencing infrastructure, reagents/consumables using different technologies, human resources (including training for wet laboratory sequencing and bioinformatics), and quality management.

Following the pilot exercises to be conducted in a small number of countries between June to August 2023, the tool will be launched and made publicly available on the WHO website by the end of 2023. This tool will be useful to country, regional and global policymakers, health administrators and economists, laboratory directors and quality managers, donor institutions, and other stakeholders.

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