MINISTRY OF HEALTH
PUBLIC HEALTH INSTITUTE OF MALAWI

MALAWI GENOMIC SURVEILLANCE IMPLEMENTATION PLAN

(2023-2030)

Second Edition
June 2025

Disclaimer

The Malawi Genomic Surveillance Implementation Plan 2.0 has been produced with technical support from the Africa CDC - Africa Pathogen Genomics Initiative (Africa PGI) through funding from Bill & Melinda Gates Foundation grant INV-018278. The funders had no role in the design, data collection, or writing of this publication. The contents of the Implementation Plan 2.0 are the sole responsibility of Public Health Institute of Malawi (PHIM).

Contents

ABBREVIATIONS

ABBREVIATION	FULL VERSION
AMR	Antimicrobial Resistance
ASLM	African Society for Laboratory Medicine
AST	Antimicrobial Susceptibility Testing
BMGF	Bill and Melinda Gates Foundation
BSL	Biosafety Level
CDC	Centres for Disease Control and Prevention
CE-IVD	Conformité Européenne-In Vitro Diagnostics
CHAI	Clinton Health Access Initiative
COVID-19	Coronavirus Disease 2019
CSF	Cerebrospinal Fluid
DAPP	Development Aid from People to People
DBS	Dried Blood Spot
DHIS2	District Health Information System, version 2
DNA	Deoxyribonucleic Acid
DR	Drug Resistance
ELISA	Enzyme-Linked Immunosorbent Assay
EQA	External Quality Assessment
FETP	Field Epidemiology Training Program
GoM	Government of Malawi
HEU	Health Education Unit
HIV	Human Immunodeficiency Virus
HSSP III	Health Sector Strategic Plan III
ICT	Information and Communication Technology
IDSR	Integrated Disease Surveillance and Response
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IRB	Institutional Review Board
I-TECH	International Training and Education Centre for Health
IVD	In-Vitro Diagnostics
JHPIEGO	Johns Hopkins Program for International Education in Gynaecology and Obstetrics
KUHeS	Kamuzu University of Health Sciences
LIMS	Laboratory Information Management System

MBS	Malawi Bureau of Standards
MCM	Medical Council of Malawi
MLW	Malawi Liverpool Wellcome Trust
mNGS	Metagenomic Sequencing
MoH	Ministry of Health
MoU	Memorandum of Understanding
NGC	National Genomics Committee
NGS	Next-Generation Sequencing
NHRL	National HIV Reference Laboratory
NHSRC	National Health Sciences Research Committee
NP	Naso-pharyngeal
NSP	National Strategic Plan
NTP	National Tuberculosis and Leprosy Program
OHSP	One Health Surveillance Platform
OP	Oral pharyngeal
PCR	Polymerase Chain Reaction
PEPFAR	President's Emergency Plan for AIDS Relief
PGI	Pathogen Genomics Initiative
PHA	Public Health Authority
PHIM	Public Health Institute of Malawi
PIH	Partners in Hope
PMRA	Pharmacy and Medicines Regulatory Authority
R4H	Riders for Health
RNA	Ribonucleic Acid
SADC	Southern African Development Community
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SOP	Standard Operating Procedure
SWOT	Strengths, Weaknesses, Opportunities, and Threats
UMB	University of Maryland, Baltimore
USAID	United States Agency for International Development
VPD	Vaccine-Preventable Diseases
VHF	Viral Haemorrhagic Fever
WHO	World Health Organization

TERMS AND DEFINITIONS

TERM	DEFINITION
Antimicrobial Resistance (AMR)	Occurs when microorganisms (such as bacteria, viruses, fungi, and parasites) develop resistance to antimicrobial agents, including antibiotics, antivirals, antifungals, and anti-parasitics.
Bioinformatics	The scientific discipline of using computer tools to analyze biological datasets.
Deoxyribonucleic Acid (DNA)	A double-stranded molecule that carries genetic instructions for the development, function, growth, and reproduction of all known organisms and many viruses.
DNA Sequencing	A method to determine the precise order of nucleotides (A, T, G, C) in a DNA or RNA molecule.
Database	An organized collection of biological information, such as sequence data or annotations, is stored for easy access (e.g., GenBank, European Molecular Biology Laboratory (EMBL)).
Genome	The complete set of genetic material in an organism, including all its genes and non-coding sequences.
Genomics	The study of the structure, function, and evolution of genomes.
Genomic Surveillance	The process of constantly monitoring pathogens and analyzing their genetic similarities and differences.
Gene Variant	A mutation or alteration in a gene may lead to different phenotypes or diseases.
High-Throughput Sequencing	Modern sequencing methods are capable of processing millions of DNA or RNA molecules simultaneously, a technique also known as next-generation sequencing.
Illumina Sequencing	A widely used high-throughput sequencing technology that generates short reads by detecting fluorescently labelled nucleotides.
Molecular Epidemiology	A branch of epidemiology that uses molecular biology tools and techniques to study the distribution, determinants, and dynamics of diseases within populations. It focuses on understanding the role of genetic, environmental, and lifestyle factors at the molecular level in the development, spread, and control of diseases.

Mutation	A change in the DNA sequence can affect the structure or function of a gene or protein.
Next-Generation Sequencing (NGS)	Advanced sequencing technologies enable the rapid and massively parallel sequencing of DNA or RNA.
Oxford Nanopore Sequencing	A nucleic acid sequencing technology developed by Oxford Nanopore Technology utilizes synthetic micropore pores to analyze nucleic acids, enabling the excitation and reading of passing bases through electric profiles.
Pathogens of Epidemic Potential	Refers to the likelihood of a disease, bacteria, viruses, and other microorganisms spreading rapidly and causing significant harm to humans within a specified region.
Pathogens of Pandemic Potential	Refers to bacteria, viruses, and other microorganisms that are likely highly transmissible and capable of wide, uncontrollable spread in human populations and that are highly virulent, making them likely to cause significant morbidity and/or mortality in humans.
Priority Pathogens	Microorganisms (including bacteria, viruses, fungi, and parasites) that health organizations have recognized as significant public health threats due to their high resistance to existing treatments, potential to cause severe disease outbreaks, and substantial impact on morbidity and mortality.
Ribonucleic Acid (RNA)	RNA is a single-stranded molecule that plays a crucial role in various biological processes, including gene expression and protein synthesis.
Whole-genome sequencing (WGS)	Sequencing the entire genome of an organism to identify all genetic variations.
Disease X	Represents a hypothetical scenario for an unknown pathogen with epidemic potential.
Use-case	A specific, practical application or scenario in which genomic data or technologies are utilized to achieve a defined goal or solve a particular problem in research, clinical practice, or public health.

ACKNOWLEDGMENTS

The Ministry of Health (MOH) would like to thank and acknowledge all organizations and individuals who actively contributed to the development and finalization of the implementation plan. The following individuals, in their various organizational capacities, made invaluable contributions to the development of the plan.

NAME	ORGANIZATION
Alex Mwanyongo	Public Health Institute of Malawi (PHIM)
Alinune Kabaghe	United States Centers for Disease Control (CDC)
Angella Nazombe	Riders for Health (R4H)
Annie Mwale	Public Health Institute of Malawi (PHIM)
Ben Chilima	Public Health Institute of Malawi (PHIM)
Benjamin Kumwenda	Kamuzu University of Health Sciences (KUHeS)
Bernard Mvula	Public Health Institute of Malawi (PHIM)
Bessie Phiri	Public Health Institute of Malawi (PHIM)
Blessing Marondera	African Society for Laboratory Medicine (ASLM)
Bilaal Wilson	Department of HIV/AIDS and Viral Hepatitis
Billy Banda	National TB Reference Laboratory
Brigitte Denis	Malawi Liverpool Welcome Trust (MLW)
Chifundo Banda-Maseko	National HIV Reference Laboratory (NHRL)
Chifundo Chipungu	Partners in Hope (PIH)
Chifundo Hiwa-Kamuloni	Zomba Central Hospital (ZCH)
Chimwemwe Chinyama	University of North Carolina (UNC) Project
Collins Mitambo	Public Health Institute of Malawi (PHIM)
Christopher Mwase	Valiant Impact Consultants
Christel Saussier	International Training and Education Center for Health (I-TECH)
Christina Kaliwo	Public Health Institute of Malawi
David Chaima	Kamuzu University of Health Sciences (KUHeS)
David Kamangira	Chitendze Research Station
Doreen Kachingwe	Department of National Parks and Wildlife
Dorothy Moyo- Kalata	Public Health Institute of Malawi
Elizabeth Kampira	United States Centers for Disease Control (CDC)
Enoch Gama	University of Maryland, Baltimore (UMB)
Evelyn Chitsa-Banda	Public Health Institute of Malawi (PHIM)
Francis Farai Chikuse	Africa Centres for Disease Control and Prevention (Africa CDC)
Fred Bangala	United States Centers for Disease Control (CDC)
Gama Bandawe	Malawi University of Science and Technology (MUST)
George Bello	International Training and Education Center for Health (I-TECH)
Gladson Kamwendo	Central Veterinary Laboratory Services (CVLS)
Gladys Gwazenga	African Society for Laboratory Medicine (ASLM)
Godfrey Mwankenja	Public Health Institute of Malawi (PHIM)

Gwendolyn Umali	Malawi Police
Happy Manda	Public Health Institute of Malawi (PHIM)
Harry Milala	Public Health Institute of Malawi (PHIM)
Henry Limula	Public Health Institute of Malawi (PHIM)
James Jere	Public Health Institute of Malawi (PHIM)
Joseph Bitilinyu-Bangoh	Public Health Institute of Malawi (PHIM)
Joseph Wangendo	Africa Centres for Disease Control (Africa CDC)
Louis Panja	Public Health Institute of Malawi (PHIM)
Limbikani Chaponda	Public Health Institute of Malawi (PHIM)
Limbikani Kanyenda	United States Agency for International Development (USAID)
Lucious Ziba	Public Health Institute of Malawi (PHIM)
Mabvuto Chiwaula	Public Health Institute of Malawi (PHIM)
Mark Mwalabu	Public Health Institute of Malawi (PHIM)
Martias Joshua	Ministry of Health
Matthew Kagoli	Public Health Institute of Malawi (PHIM)
Mercy Mwalwanda	Public Health Institute of Malawi (PHIM)
Mirriam Nyenje	Public Health Institute of Malawi (PHIM)
Moses Chitenje	Public Health Institute of Malawi (PHIM)
Mphatso Bukhu	Public Health Institute of Malawi (PHIM)
Mphatso Mussa Gama	Ministry of Health (MoH)
Mphatso Kachule	Riders for Health (R4H)
Mtisunge Yelewa	Public Health Institute of Malawi (PHIM)
Pocha Kamdumuli	Centre for International Health Education and Biosecurity (CIHEB)
Patrick Buleya	Public Health Institute of Malawi (PHIM)
Patrick Musicha	Malawi Liverpool Wellcome Program
Reuben Mwenda	International Training and Education Center for Health (I-TECH)
Richard Luhanga	Dream Project
Scotch Kaunda	Public Health Institute of Malawi (PHIM)
Sosten Lankhulani	National Malaria Control Program
Sosten Mtalika	National TB Control Program
Shenton Kacheche	Public Health Institute of Malawi (PHIM)
Takondwa Kauta	Ministry of Health (MoH)
Teferi Beyene	Baylor College of Medicine
Thokozani Noniwa	Queen Elizabeth Central Hospital
Tresa Sumani	Public Health Institute of Malawi (PHIM)
Watipaso Kasambara	Public Health Institute of Malawi (PHIM)
Yamikani Chiwere	Public Health Institute of Malawi (PHIM)
Yollam Chavula	Public Health Institute of Malawi (PHIM)
Patrick Buleya	PHIM
Gladys Kezich Gwazenga	ASLM
Marvin Phonera	Cental Veterinary

FOREWORD

This costed plan guides the implementation of genomic surveillance for pathogens of pandemic and epidemic potential into public health systems in Malawi. It is crucial in times of unprecedented health challenges such as Cholera, Mpox, Marburg, Antimicrobial resistance (AMR), coronavirus disease 2019 (COVID-19) and other emerging and re-emerging infectious diseases. The utilization of whole genome sequencing (WGS) and metagenomics in outbreak detection, response and infection control has produced impactful public health, clinical and economic outcomes in Africa. This costed plan provides a comprehensive roadmap of genomic surveillance and its role in disease detection, prevention and control in Malawi.

Malawi is determined to integrate pathogen genomic surveillance into public health systems, research and development. Thus, cutting-edge sequencing and surveillance technologies are being utilised to identify, prevent, and control disease outbreaks. In addition, Malawi will utilize genomic surveillance data to aid vaccines, diagnostics, and therapeutics production at local, regional and continental level.

This costed plan is a result of multi-sectoral collaboration with experts in health, agriculture, animal, environment and homeland security. We collaborated with both the public and private sectors to develop the costed plan, engaging researchers, policymakers, the public, and other key stakeholders and partners. It represents a shared vision of how we will responsibly integrate genomic surveillance into public health systems, research and development.

I would like to express my sincere gratitude to all those who contributed to the development of this plan, especially tremendous technical and financial support provided by the Africa Pathogen Genomics Initiative (PGI) of the Africa CDC. Much appreciation goes to individuals and organizations that provided other support and time towards the development of this plan.

I applaud the Malawi Government for recognizing the importance of genomic surveillance in public health and taking steps to strengthen the country's capacity and infrastructure for genomic surveillance. This plan serves as a critical tool in addressing the current and future health challenges in Malawi. I am therefore pleased to present the second edition of the Malawi Genomic Surveillance Implementation Plan (2023-2030).

Hon. Khumbidze Kandodo Chiponda, MP
Minister of Health

PREFACE

The Ministry of Health (MoH), through the Public Health Institute of Malawi (PHIM), initiated the process of developing the costed Malawi Genomic Surveillance Implementation Plan (2023-2030). This aligns with the PHIM Strategic Plan (2023-2030), which recommends the development of a genomics surveillance implementation plan to guide Malawi's detection, prevention and response to disease outbreaks. The need for genomics to inform public health decisions cannot be over-emphasized, for example, mpox clade 1b discovery has been used to guide tailor made interventions as well as in detection and response to Cholera, Ebola, Mpox and Marburg outbreaks.

The costed Malawi Genomics Surveillance Implementation Plan has been developed through a consultative process. Stakeholders, including government departments, implementing partners, and academic institutions, contributed significantly to its development. This is the second implementation plan for genomic surveillance in Malawi. It encompasses seven (7) priority thematic areas: Research and Surveillance; Health Systems Strengthening; Capacity Building for Human Resource; Data management; Resource mobilization, financing and sustainability; Governance, regulation and policy; Stakeholder engagement.

The costed implementation plan is one of the most critical steps towards integration of genomics into public health systems in Malawi.

The immediate implementation requires collaborations and support from all government agencies, private sector, donors, implementing partners and academia. The Government of Malawi is committed to facilitate the successful implementation of this costed plan.

Dr Samson Kwazizira Mndolo
Secretary for Health

1. BACKGROUND

1.1 Introduction

Genome sequencing is a powerful molecular technique that deciphers the entire genetic code of an organism, providing essential insights into its biology. This forms the foundation of genomics, a broader scientific field that investigates the structure, function, and behavior of genetic and epigenetic material. A key application of genomics is genomic surveillance—the continuous monitoring of pathogens to detect and analyze genetic variations. Coupled with bioinformatics, which utilizes computational tools to process and interpret sequencing data, genomic surveillance has emerged as a transformative approach for disease tracking and response.

These technologies have greatly enhanced the capacity of public health systems, especially within the framework of the One Health approach, to detect, monitor, and respond to infectious diseases. Genomic surveillance has proven invaluable in managing threats such as COVID-19, tuberculosis, HIV/AIDS, cholera, conjunctivitis, and Ebola virus disease, providing timely evidence for guiding diagnosis, treatment, prevention, and control strategies. It also supports the development of vital medical tools, including vaccines, diagnostics, and therapeutics, while enabling data-driven, locally informed interventions.

The PHIM is mandated to provide strategic leadership and coordination through multidisciplinary and multisectoral preparedness and response to public health emergencies and threats, disease detection and control, and the generation of information that informs policy and practice to achieve public health security.
The PHIM, as Secretariat of the National Genomics Committee, coordinates national genome sequencing of pathogens that are critical to public health, particularly those with pandemic and epidemic potential. As part of disease surveillance, the institution is responsible for detecting outbreaks and guiding responses to them, as well as other public health events of national and international concern related to outbreak control and management. The framework for response is provided through a multi-hazard emergency response plan guided by a strategic risk assessment that the institution coordinates.

In advancing the country's public health response to infectious diseases, PHIM led the development of the National Genomic Surveillance Implementation Plan. The first edition of the implementation plan was launched in 2023 and serves as a strategic roadmap for establishing and expanding national genomic surveillance systems in Malawi. It also outlines the framework for integrating genomic data into public health decision-making, ensuring a robust and proactive response to current and future disease threats. The second edition of the implementation plan features a revised monitoring and evaluation framework, as well as added algorithms for genomic surveillance of select pathogens.

The monitoring and evaluation framework for the Malawi National Genomic Surveillance Implementation Plan serves as a strategic tool to assess the plan's success, identify challenges, and promote accountability and transparency.

PHIM has incorporated and costed the activities that ensure the objectives are met, resources are efficiently used, and outcomes are aligned with national priorities. The primary goal of integrating monitoring and evaluation into the National Genomic Surveillance Implementation Plan is to track the progress of genomic surveillance systematically and effectively.

Use-cases are employed in a range of epidemic-prone diseases—including viral hemorrhagic fevers (VHFs), respiratory infections (such as severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza, and RSV), diarrheal diseases, arboviral infections, and vaccine-preventable diseases (VPDs) that pose significant public health threats, particularly in low- and middle-income countries. Accurate and timely detection of these diseases is critical for effective surveillance, diagnosis, treatment, and response. Each disease group follows a specific testing algorithm that outlines case definitions, sample collection procedures, and laboratory requirements. In this implementation plan, these frameworks guide the systematic identification of infections and support national preparedness and response efforts. Additionally, a molecular testing algorithm has been proposed for "Disease X," a hypothetical emerging pathogen, to enhance readiness at national reference laboratories (Refer to Appendices 4–9 for detailed algorithms). Antimicrobial resistance (AMR) occurs when microorganisms (bacteria, viruses, fungi, and parasites) evolve to resist the effects of antimicrobial drugs (like antibiotics, antivirals, antifungals, and antiparasitics). As a result, infections become harder or impossible to treat. (Refer to Appendix 10.)

This plan intends to guide the implementation of national genomic surveillance for pathogens of pandemic and epidemic potential.

1.2 Global and National Situational Analysis

Over 100 disease outbreaks are reported worldwide each year.[1] Despite the increasing availability of genomic sequencing technology worldwide, significant inequalities persist in access to this technology between countries. This was more evident during the COVID-19 pandemic. Only 13 out of 189 countries (6.8%) were able to sequence 5% or more of their total confirmed COVID-19 cases in the first two years of the pandemic (2020–2022). [2] Key contributing factors to the disparities in genomic sequencing capacity between countries include varied investment priorities in national health, research, and development programs.[3] Eighty-six (86) out of 189 countries sequenced 0.5% of their COVID-19 confirmed cases, and the rest were unable to do any sequencing.[4] A majority of countries that sequenced at least 0.5% of their confirmed COVID-19 cases were high-income countries. Very few low- and middle-income countries were able to do so.

During the COVID-19 pandemic, high-income countries leveraged existing genomics networks and infrastructure to conduct genomic surveillance of SARS-CoV-2. For most low- and middle-income countries, particularly in sub-Saharan Africa, such networks and infrastructure were either non-existent or not fully established.

The Africa Centres for Disease Control (CDC) reported in September 2022 that 42 of 54 African

[1]. World Health Organization. (2023, March 17). Disease Outbreak News. Emergencies. https://www.who.int/emergencies/disease-outbreak-news

[2]. Brito, A.F., Semenova, E., Dudas, G. et al. Global disparities in SARS-CoV-2 genomic surveillance. Nat Commun 13, 7003 (2022). https://doi.org/10.1038/s41467-022-33713-y

[3]. Stark, Z., Dolman, L., Manolio, T. A., Ozenberger, B., Hill, S. L., Caulfied, M. J., ... & North, K. N. (2019). Integrating genomics into healthcare: a global responsibility. The American Journal of Human Genetics, 104(1), 13-20.

[4]. Tegally, H., San, J. E., Cotten, M., Moir, M., TegoMoH, B., Mboowa, G., Martin, D. P., Baxter, C., Lambisia, A. W., Diallo, A., Amoako, D. G., Diagne, M. M., Sisay, A., Zekri, A.-R. N., Gueye, A. S., Sangare, A. K., Ouedraogo, A.-S., Sow, A., Musa, A. O. et al. The evolving SARS-CoV-2 epidemic in Africa: Insights from rapidly expanding genomic surveillance. Science 378, eabq5358, doi:doi:10.1126/science.abq5358 (2022)

countries (78%), including Malawi, were capable of producing SARS-CoV-2 genomes. Only eight of the 42 countries were able to generate all the genomes in-country. The rest, which again included Malawi, had some genomes generated in-country, while others were generated outside the country.

There is limited policy guidance and funding for genomic sequencing in Malawi. The Government of Malawi (GoM) has expressed interest in increasing investments in genomic surveillance and capacity building. The World Health Organization (WHO) recently published the Global Genomic Surveillance Strategy for Pathogens with Pandemic and Epidemic Potential (2022-2032). [5] which will support the government's efforts to expand its capacities and implement harmonized approaches to robust local-to-global genomic surveillance.

1.3 SWOT Analysis

The GoM, through the PHIM, provided national leadership in developing the Malawi Genomic Surveillance Implementation Plan (2023-2030). Seven thematic areas were identified in line with the WHO's Global Surveillance Strategy for Pathogens with Pandemic and Epidemic Potential (2022-2032). [6] An analysis was conducted to identify the strengths, weaknesses, opportunities, and threats (SWOT) associated with genomic surveillance in Malawi (See Appendix 1). Each of the seven thematic areas was analyzed. Issue statements, strategic objectives, and activities for this plan were derived from the outcomes of the SWOT analysis.

[5]. World Health Organization (2022). Global genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032. Geneva.

[6]. Global genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

[7]. Executive Board, 142. (2018). WHO reform: better value, better health Strategy and implementation plan for value for money in WHO: report by the Director-General. World Health Organization. https://apps.who. int/iris/handle/10665/273978 accessed 9 March 2022.

1.4 Guiding Principles for the Implementation Plan

The GoM will maximize the benefits of genomic surveillance by adhering to the following guiding principles:

1.4.1. Commitment and Ownership:

The GoM will set priorities for genomic surveillance through the National Genomics Committee (NGC) with its Secretariat at PHIM. The GoM will lead the development of activities, work plans, and outputs for genomic surveillance. It will integrate genomic surveillance into the national laboratory and surveillance systems. The GoM, in collaboration with the NGC, will also drive fundraising efforts for genomic surveillance. This includes securing domestic financing through the Treasury. The GoM will also source international funding from donors. It will also strengthen and maintain links with national, regional, and international networks for genomic surveillance.

1.4.2. Maximizing Return on Investment

The GoM will take WHO's five-dimensional approach to maximizing return on investment. The dimensions are economy, efficiency, effectiveness, equity, and ethics. [7] The GoM will ensure the effectiveness of genomic surveillance through strong quality assurance systems. It will drive equity in genomic surveillance by prioritizing the most vulnerable and hard-to-reach populations. The GoM will implement an ethical genomic surveillance program by ensuring that the inputs, outputs, and outcomes of the program uphold respect, goodwill, and justice and do not cause any harm.

1.4.3. Sustainability

The GoM will take a stepwise approach to build capacity in genomic surveillance. It will continually assess needs and opportunities to optimize and align with Malawi's priorities for the surveillance of pathogens of pandemic and epidemic potential.

It will promote partnerships that invest in and support the sustainability of genomic surveillance.

1.4.4. Shared Responsibility

The GoM will collaborate with national, regional, and global partners to achieve the goals and objectives of the genomics program. Key partners include Africa CDC, the United States CDC, the WHO, academia, the private sector, civil society, non-governmental organizations, and others.

1.4.5. Local and Global Outlook

The GoM will establish Malawi's genomic surveillance with both local and international interfaces. Public health actions at the sub-national and national levels have ripple effects at the regional and global levels. Pathogens with pandemic and epidemic potential know no borders. The GoM will participate in local, regional, and global efforts to respond to emerging and re-emerging pathogens of pandemic and epidemic potential.

1.4.6. Ethical Considerations and Management

The GoM will implement ethical genomic surveillance by ensuring that the inputs, outputs, and outcomes of the program uphold respect, goodwill and justice and do not cause harm. The NGC will collaborate with the National Health Sciences Research Committee (NHSRC) and other local institutional review boards (IRBs) to ensure the ethical conduct of genomic surveillance research. The GoM will maintain an open dialogue with the public, patients, patient interest groups, and other stakeholders to ensure the ethical implementation of all genomic surveillance activities.

1.5. Implementation of the Plan

Successful implementation of the genomic surveillance plan will require the following enabling factors:

1.5.1. Building on and aligning with existing assets:

The GoM recognizes that genomics is a cross-cutting field that requires a wide range of expertise. MOH will work with donors, implementing partners, research and academic institutions, and other sectors to identify priority areas, available resources, and assets for genomic surveillance in human, animal, and environmental health.

1.5.2. PHIM's leadership

PHIM will provide overall leadership in implementing this plan and ensure that end-to-end surveillance and laboratory systems are strengthened and sustained.

1.5.3. Partnerships and Networks

Genomics requires local and international, multi-sectoral engagement. The GoM will promote partnerships that will strengthen Malawi's ability to detect, analyze, and utilize genomic surveillance data for public health action. The GoM will leverage local and international partnerships to address the significant demand for sequencing and bioinformatics.

1.5.4. Financing:

Genomic sequencing and surveillance require substantial investments in human resources, infrastructure, supply chain, and other areas. The GoM, the private sector, and donors will collaboratively finance this implementation plan (See Appendix 2).

1.6 The Role of PHIM in the Implementation of the Genomic Surveillance Plan

The NGC and its secretariat at PHIM will serve as the central coordination unit for implementing this plan. It will:

1. Coordinate resource mobilization activities.
2. Lead capacity building for genomic surveillance.
3. Develop and maintain a national, regional, and global genomics network.
4. Monitor the progress of stakeholders in implementing the plan (See Appendix 3).

1.7 Rationale

Strengthening genomic surveillance capacity requires a strategic and collaborative effort. To this end, PHIM coordinated the development of the National Genomic Surveillance Implementation Plan to serve as a roadmap for implementing genomic surveillance nationwide. This plan outlines key areas for investment, including workforce development, equipment procurement, and infrastructure support. Additionally, the plan emphasizes the use of sustainable approaches to enhance genomic surveillance systems nationwide.

1.8 Overall Goal

The goal of the Implementation Plan is to establish a comprehensive genomic surveillance system that enhances public health response and health security.

1.9 Specific Objectives

The specific objectives of the plan are:

1. Cultivate a skilled and diverse genomics workforce through targeted training and capacity building.
2. Harmonize genomic surveillance efforts among different stakeholders to achieve national public health goals.
3. Establish a robust national coordination system that integrates diverse sectors to advance genomics.
4. Integrate genomics into key sectors, strengthening its application in clinical services, public health, forensics, and research.
5. Establish an overarching data governance for data quality, sharing, utilization, protection, and storage.
6. Mobilize resources for genomic surveillance in Malawi to effectively respond to public health threats.
7. Identify and prioritize public health threats for genomic surveillance.

1.10 Linkage with Policy Documents

Pillar 7 of the Health Sector Strategic Plan III (2023-2030) (HSSP III) [8] is health research. One of the strategies under this pillar is to develop evidence-based policies in the health sector. This will be achieved through the intensification of knowledge generation, translation, and utilization of research. Genomic surveillance will generate knowledge through genomic sequencing and surveillance of pathogens of epidemic and pandemic potential. It will also compile and analyze disease and event surveillance data to support the detection of outbreaks and the implementation of international health regulations. The HSSP III also highlights the multi-sectoral nature of health and, by extension, genomic surveillance. It intends to strengthen vector and vermin control, pandemic and disaster preparedness and response, and surveillance of diseases. It encourages collaboration between the health sector and other sectors in conducting disease surveillance and response.

PHIM's Strategic Plan (2023-2030) recognizes advances in genomics as an opportunity to guide public health practice. PHIM is committed to advancing public health surveillance and

[8]. Ministry of Health (2022). Health Sector Strategic Plan III (2023-2030). Lilongwe,

epidemiology in Malawi, as outlined in Objective 3 of its strategic plan.

This plan is also in line with the Malawi National Strategic Plan for HIV and AIDS 2020-2025. [9] It refers to HIV drug resistance monitoring as one of the game-changing strategies in the fight against HIV. Genomic surveillance is the backbone of HIV drug resistance monitoring. The HIV program is determined to use HIV drug resistance monitoring to achieve its set targets in the next five years. This will set Malawi on the path to reaching Sustainable Development Goal Target 3.3 to end the AIDS epidemic by 2030 and contribute to the country's national health and development goals.

The implementation of genomic surveillance in Malawi is also linked to the National Tuberculosis and Leprosy Control Strategic Plan (2021-2025). [10]

The National Tuberculosis Program has a strategy to expand the coverage of new tuberculosis diagnostics and drug resistance detection. Genomic surveillance will support these efforts. Genomic surveillance will help the tuberculosis program to effectively detect, track, and treat cases of drug-resistant and multi-drug-resistant tuberculosis in Malawi.

Genomic surveillance is cross-cutting. The GoM will coordinate efforts across different disease control programs to identify priority pathogens for surveillance. The GoM will remain flexible to plan and respond to emerging pandemics (e.g., COVID-19) and epidemics (e.g., cholera) as the situation demands.

[9]. National AIDS Commission (2020). National Strategic Plan for HIV and AIDS 2020-2025. Lilongwe, Malawi.

[10]. Ministry of Health (2021). National Tuberculosis and Leprosy Control Strategic Plan 2021-2025. Lilongwe, Malawi.

2. THEMATIC AREAS

2.1. Genomic Surveillance and Research

2.1.1. Pathogen Genomic Surveillance

2.1.1.1. Inclusion of genomics in routine surveillance

The GoM will integrate genomic surveillance into standard practices for disease prevention, preparedness, and response. This initiative will enable rapid identification of outbreak sources, track the transmission of pathogens, and develop targeted interventions to prevent further spread. Additionally, the GoM will create and implement a data-sharing platform designed to facilitate the exchange of genomic data among public health agencies and researchers. The National Genomics Research Network will conduct pilot studies to evaluate the feasibility and effectiveness of incorporating genomic sequencing into routine surveillance practices. Furthermore, it will establish guidelines and standard operating procedures for the routine use of genomic surveillance in disease detection, prevention, preparedness, and response.

2.1.1.2. Timely detection of emerging pathogens and variants

The emergence of new pathogens/variants is a significant public health challenge. Early detection of these emerging pathogens/variants is critical for understanding their potential impact on public health and developing effective countermeasures. To strengthen the timely detection of emerging pathogens variants, there is a need to increase genomic surveillance efforts, cross-border collaboration, and monitoring of high-risk populations.

The GoM will leverage its partnerships with academic institutions and research organizations to increase sequencing capacity and expand the geographic coverage of genomic surveillance efforts by establishing more strategic sequencing centers and networks nationwide. Surveillance systems will be established to monitor high-risk populations, including healthcare workers, vulnerable populations, individuals with immunocompromised conditions, and frequent international travelers. Protocols for timely reporting of cases of infection with emerging pathogens/variants and targeted interventions in high-risk populations will be developed and implemented to prevent the spread of emerging pathogens/variants.

A cross-border working group will be established with neighboring countries to share information on genomic surveillance efforts and emerging pathogen discovery. The working group will develop protocols for the exchange of data, samples, and expertise. It will also conduct joint investigations to identify and respond to potential outbreaks of emerging pathogens. The working group will develop and implement data-sharing policies that ensure the protection of sensitive data and patient privacy.

2.1.1.3. Capacity of genomic surveillance systems in emergencies

Surge exercises will be conducted to test the capabilities of genomic surveillance systems. The exercises will simulate an increase in the number of cases of a specific pathogen or the emergence of a new disease to test the system's ability to promptly keep up with the rapid or increased demand for sequencing and analysis. PHIM will design surge exercises to simulate an outbreak of a specific pathogen, or a new pathogen guided by standard operating procedures (SOPs) that will stipulate how genomic sequencing will be implemented during outbreaks.

PHIM will use the surge exercises to identify any weaknesses or bottlenecks in the genomic surveillance system. These may include sequencing capacity limitations or delays in data analysis. The GoM will develop and implement strategies to address these weaknesses and bottlenecks. The exercises will be repeated regularly to assess the effectiveness of the genomic surveillance system's improvements.

2.1.2. Pathogen Genomics Research

Research on pathogen genomics necessitates careful planning, effective resource allocation, and active stakeholder engagement. To strengthen stakeholder partnerships and collaboration, a National Genomics Research Network shall be established, with membership comprising experts in genomic sequencing and surveillance, healthcare providers, patient advocacy groups, and government agencies. The NGC will identify research priorities that align with the national health agenda and develop criteria for prioritizing research areas based on disease prevalence, morbidity, mortality, and social impact. Due to limited resources, the committee will use established criteria to identify research priorities and allocate resources based on the identified priority areas. The National Genomics Research Network will utilize genomic data to conduct research on the identified priority areas, leading to product innovation, including, but not limited to, drug and vaccine development.

The government, through the NGC, will also engage with healthcare providers, patient advocacy groups, and government agencies to gain support and collaboration for the research program. A monitoring and evaluation plan will be developed and used to track progress and ensure the delivery of desired research outputs.

2.1.3. Preparedness and readiness for emergencies

Genomic research and surveillance are valuable tools. They also come with risks and challenges, including the possibility of the release of hazardous/infectious materials, breaches of privacy, and ethical concerns about genetic data collection and use. This may compromize biosafety and biosecurity standards. To ensure the safety of both personnel and the wider community, genomic sequencing and surveillance facilities must develop comprehensive emergency plans and regularly update them. These plans will encompass various scenarios, including natural disasters, accidental releases of hazardous or infectious materials, cyber-attacks, and other emergencies.

The facilities will also conduct regular risk assessments to identify potential hazards and vulnerabilities. They will use this data to prioritize preparedness activities and tailor emergency plans to specific risks. The facilities will establish effective communication protocols that enable the rapid dissemination of information to relevant stakeholders, including employees, emergency responders, and the public. They will train all staff in emergency procedures and protocols. The facilities will also maintain emergency supplies on hand to ensure that essential operations can continue in the event of an emergency.

2.2 Health Systems Strengthening

2.2.1. Infrastructure and equipment for genomic sequencing

The ministries involved in One Health will ensure the availability of infrastructure that provides a safe and conducive working environment. They will invest in the necessary infrastructure and equipment for genomic sequencing. Regular needs assessments will be conducted to evaluate the state of this infrastructure and equipment. These ministries will collaborate with stakeholders to develop budgets and secure funding for the required equipment and infrastructure. They will acquire appropriate next-generation sequencing platforms based on identified needs and will construct or refurbish sequencing laboratories to accommodate this equipment. Additionally, the

ministries will invest in computing infrastructure, including data storage systems, computers, servers, networking equipment, and bioinformatics platforms. They will also equip all sequencing laboratories with dry and cold storage equipment, power backups, and reliable water supply.

2.2.2. Collaboration with local and international partners

The ministries involved in One Health shall collaborate with other institutions both locally and internationally to increase access to equipment and expertise as needed. They will also engage with private laboratories, academic institutions, and industry partners to share knowledge, expertise, and best practices.

2.2.3. Sustainable equipment maintenance plans

The ministries involved in One Health, through the Physical Asset Management Unit, will conduct thorough assessments of equipment inventory for genomic sequencing to identify the types of equipment and their specific maintenance requirements. Both frequently maintained equipment and infrequently maintained equipment shall be listed. A maintenance schedule that outlines the frequency and type of maintenance required for each piece of equipment shall be developed based on a prioritized list. The ministries shall also continuously monitor and evaluate the effectiveness of the maintenance plan, identify areas for improvement, and adjust as needed.

The ministries involved in One Health shall also develop an equipment donation policy to ensure that the country receives appropriate equipment that can be easily maintained and sustained. The MOH shall establish equipment maintenance contracts with equipment manufacturers and train local engineers on the maintenance of the equipment.

2.2.4. Quality management systems for genomic sequencing laboratories

All genomic sequencing laboratories shall be required to implement a quality management system, including mandatory participation in external quality assurance (EQA) programs coordinated by PHIM. The EQA programs shall include software validation and evaluation besides the wet lab processes.

The ministries involved in One Health shall identify local, regional, or international EQA providers that offer EQA programs. The EQA program will include the types of genomic sequencing tests, reporting of results, and the provision of feedback. Institutions performing genomic sequencing will develop and implement improvement plans to address any identified areas for improvement. The ministries involved in One Health shall track EQA progress to ensure that the program is effective and that any improvements are sustained over time. This shall include ongoing monitoring of EQA results and participant feedback.

2.2.5. Supply chain management and logistics

The supply chain is a crucial component of genomic sequencing. A well-coordinated supply chain system helps to have the right commodity in the right quantity at the right place, at the right time, and in the right condition, which is key to avoiding service interruption due to stock-outs and expiries.

The ministries participating in the One Health initiative, along with other stakeholders, will manage the supply chain through national diagnostics supply chain specialists. These specialists will collect data, assess needs, and procure necessary commodities. They will also handle the distribution of these commodities and monitor their consumption and storage. Additionally, they will conduct regular physical inventories. The ministries involved in One Health will provide training for facility focal points on

managing genomic sequencing commodities. A list of reagents and consumables, based on the equipment and targeted organisms, shall be developed and revised periodically. Despite careful planning and management, unexpected events such as supplier delays, equipment breakdowns, and natural disasters can disrupt the supply of reagents and consumables. The genomic sequencing laboratories shall develop contingency plans that shall outline how the laboratory will respond to such events and ensure that the plan is regularly reviewed and updated.

The ministries involved in One Health shall standardize equipment to simplify its supply chain and shall procure WHO-prequalified or 'CE-IVD' marked equipment and reagents. Two to three types of pre-qualified next-generation sequencing equipment shall be in use to encourage competition among suppliers. The sequencing equipment will be selected based on price, usability, and other factors.

The ministries involved in One Health shall invest in improved storage capacity in all laboratories providing genomic sequencing services to safeguard the quality of reagents. The ministries shall also procure and install appropriate laboratory refrigerators and freezers and invest in on-site dry storage facilities.

2.2.6. Sample collection, transportation, and storage

High-quality samples, well-designed sample transport systems, and optimal sample storage conditions are essential for delivering quality centralized genomic sequencing services. The ministries involved in One Health shall develop standardized processes by adopting advanced logistics for a safe and efficient sample transportation system, along with appropriate monitoring mechanisms that enhance efficiency. The ministries involved in One Health shall train adequate staff to collect samples at all genomic surveillance sentinel sites. All sentinel sites shall be equipped with adequate sample collection materials and storage equipment. Ministries involved in One Health shall train couriers on the transportation and safety of samples. They shall also monitor the adherence of couriers to the sample transportation procedures.

2.2.7. Capacity of genomic surveillance systems in emergencies

The capabilities of genomic surveillance systems will be validated through surge exercises. To test the system's ability to meet increased or rapid demand for sequencing and analysis in a timely manner, the exercises will simulate the emergence of a new disease or a surge in cases of a specific pathogen. To replicate an outbreak of a particular pathogen or a novel pathogen, PHIM will create surge exercises under the direction of SOPs that specify how genomic sequencing will be used during outbreaks.

The purpose of the surge exercises is to test the capabilities of genomic surveillance systems by simulating an increase in the number of cases of a particular pathogen or the emergence of a new disease, thereby evaluating the system's ability to promptly keep up with the rapid or increased demand for sequencing and analysis.

2.3. Capacity Building for Human Resources

2.3.1. Staffing, training, and certification

The GoM will advocate for the recruitment of sufficient laboratory scientists, bioinformaticians, epidemiologists, and other staff. These will support sequencing, analysis, reading, and interpretation of findings for different disease pathogens.
Trained laboratory staff will be required to participate in EQA exercises periodically and in inter-laboratory comparisons to maintain the quality and consistency of their results.
Training for genomic surveillance personnel will

be a priority. The GoM will ensure that its staff are trained and certified accordingly. The GoM will ensure that its staff are up to date on novel genomic sequencing and surveillance techniques. The GoM will also advocate for adequate training and certification of staff working in other genomic sequencing laboratories and surveillance institutions. It will leverage its partnerships with CDC Malawi, the Institute of Pathogen Genomics (IPG) at Africa CDC, the African Society for Laboratory Medicine (ASLM), local academic institutions, and other partners to provide relevant training.

The GoM will engage with partners and academic institutions to develop comprehensive curricula and standard operating procedures (SOPs) for on-the-job training. The GoM will ensure master trainers are identified to train others. The master trainers will also provide mentorship as needed. The mentorship will include sequencing, troubleshooting of EQA, data collection, reporting, and other areas.

2.3.2. Training programs in genomic surveillance

The GoM will routinely assess training needs and provide appropriate training opportunities to employees. The GoM intends to attract, develop, and retain a highly skilled, motivated, and dedicated genomics workforce to achieve Malawi's vision for genomic surveillance. The GoM will clearly define career paths for scientific and clinical roles in genomics. It will specify the number of higher-level specialist scientist training positions in bioinformatics and genomics in the HSSP. It will also collaborate with academic institutions to establish genomic surveillance courses and provide scholarships for employees. The courses shall be a combination of classroom modules, e-learning modules, workshops, and hands-on training.

2.3.3. Knowledge exchange programs

The GoM will identify partners for knowledge exchange programs. The GoM and partners will clearly define the goals of the knowledge exchange programs. They will plan knowledge exchange activities that will include workshops, conferences, webinars, and online forums. The GoM will routinely assess the impact of the exchange programs on the target audiences. The GoM will secure funding from various sources to evaluate the effectiveness of the programs as needed. The GoM will make appropriate changes to improve the effectiveness of the programs based on participant feedback.

2.3.4. Genomics curricula in professional training institutions

The GoM will engage local academic institutions to include genomic surveillance in their training curricula. This will include genomic surveillance for human and animal health. It will also include updating the content of existing bioinformatics programs. The GoM will also work with academic institutions to update curricula for biomedical engineers to include maintenance of genomic sequencing equipment.

2.4 Data Management

Data management is a very important aspect of genomic surveillance. The GoM will adopt strategies and methodologies to ensure the optimal utilization of genomic data.

2.4.1. Data and information management systems

The GoM will implement digital systems for capturing, storing, processing, and utilizing data. The GoM will ensure that the data management systems are secure, easy to use, scalable, interoperable, and sustainable.

2.4.2. Hardware, software, and networking equipment

The data management systems will require advanced hardware, software, and networking equipment. The GoM will regularly assess its information and communication technology (ICT) infrastructure to establish needs. The assessments will cover computer hardware, software, and networking equipment. Private and research institutions will be required to do the same. The GoM will standardize the hardware, software, and networking equipment used for genomic surveillance.

2.4.3. SOPs for data management

The GoM will develop standard operating procedures (SOPs) to guide the setup, use, and maintenance of data management systems. The SOPs will ensure uniformity of systems among all stakeholders.

2.4.4. Data sharing agreements

The GoM will develop data-sharing agreements with both local and international partners. This will be aimed at enhancing data sharing and use. The GoM will use these agreements to safeguard the privacy and security of the data.

The GoM will develop a framework that provides guidance and consensus on data and meta-data standards. These standards will uphold privacy, security, and national sovereignty. They will also regulate the sharing of contextual information to accompany genomics data.

2.5 Resource Mobilization, Financing and Sustainability

Implementation of comprehensive genomic surveillance requires significant investments in human resources, infrastructure, supply chain management, and other key areas.

The required resources cannot be met solely by the government. The GoM will explore partnerships at the national, regional, and global levels to mobilize resources for implementing genomic surveillance.

2.5.1. Health Financing

The main sources of financing for genomic surveillance in Malawi are government and donors. However, to meet the cost of genomics, out-of-pocket payments will also be considered. Examples of out-of-pocket payments include genomic sequencing for legal purposes, walk-in requests, and other similar scenarios. Other sources of funding include employer-financed schemes through health insurance companies.

The Health Sector Strategic Plan III (2023-2030) (HSSPIII) outlines health financing priorities aimed at improving the sustainability and efficiency of public health financing in Malawi. Pillar 7 of the HSSP III is health research, under which genomic surveillance falls.

2.5.2. Establishment of sustainable funding models

Malawi shall consider equitable financing models to integrate an effective and cost-efficient framework for genomic surveillance of pathogens. The first source of financing is the government treasury budget. The government shall scale up incentive-based financing for genomic surveillance. The government shall also explore the financing of genomic surveillance initiatives in a manner that generates some revenue. Other methods, such as co-payments, income-based insurance schemes, and out-of-pocket payments, shall be used as some of the income-generating activities.

2.5.3. Establishment of cost-effectiveness plan and monitoring and evaluation strategy

Appropriate indicators shall be used to evaluate and report on the cost-effectiveness of genomic surveillance services. These indicators shall be reviewed monthly within each department and displayed on noticeboards, websites, and departmental reports. Malawi shall build incentives into its financing systems to ensure

that funds are used efficiently and equitably. Cost containment strategies and right-sizing should be considered for every component of the genomic surveillance system. Malawi shall ensure that the costs of implementing and maintaining genomic surveillance of pathogens result in savings over the costs of not having a surveillance program supported by pathogen genomics. While capital investment costs are likely to be high in the early implementation phases, they are expected to decline gradually over time.

2.5.4. Funding from the Government

PHIM will lobby for government funding for genomic surveillance through the Treasury. PHIM will collaborate with different government departments and ministries to plan and prioritize resources for genomic surveillance. PHIM will also collaborate with government departments and ministries to mobilize resources for any identified gaps.

2.5.5. Funding from donors and partners

The GoM will continue to collaborate with donors and implementing partners to secure funding and other resources for genomic surveillance.

2.5.6. Collaboration with regional and global institutions in mobilizing resources

The GoM will strengthen its collaboration with regional and global partners, such as the United States CDC, Africa CDC, and WHO, in mobilizing resources for genomic surveillance. The GoM will collaborate with these institutions to apply for regional and global grants to strengthen genomics in Malawi.

2.5.7. Collaboration with private sector, research, and higher learning institutions

The GoM will collaborate with both the private sector and research institutions to maximize the use of available resources for genomic surveillance. The GoM will co-apply for grants with local research institutions to finance research in priority areas for genomic surveillance.

2.5.8. Public-private partnerships

The GoM will strengthen public-private partnerships to benefit genomic surveillance. The GoM will negotiate pricing agreements with manufacturers and suppliers of reagents, laboratory equipment, ICT equipment, software, and other resources.

2.5.9. Income-generating activities

PHIM will leverage its infrastructure to support sustainability goals through income-generating activities. Part of the generated income will be allocated to genomic surveillance.

2.6 Governance, Regulation and Policy

Genomic surveillance necessitates robust governance, policies, and regulations to protect the interests of the public and enhance health outcomes. Successful implementation of governance, policy, and regulations will require multi-sectoral collaboration. Once finalized, the plan shall be reviewed and approved by the NGC.

2.6.1. National Genomics Committee

The NGC will operate by the terms of reference outlined in Appendix 11 and establish priorities for genomic surveillance in Malawi. It will also oversee policies relating to genomics in Malawi. The NGC will oversee public, private, and academic institutions involved in genomics. The Secretary for Health will chair the committee, and PHIM will host the committee's Secretariat. The government will ensure that the Secretariat is adequately staffed and funded to carry out its activities.

The Secretariat will provide quarterly updates to the national committee to keep members informed about ongoing genomic surveillance

activities in the country. This will be done in line with PHIM's objective of improving coordination and collaboration in the implementation of international health regulations.

2.6.2. Networks

Malawi shall strengthen and establish networks that include local laboratories to ensure both geographic coverage and timely referral and testing of specimens. These laboratories include the National Reference Laboratory, Kamuzu University of Health Sciences, Malawi University of Science and Technology, the Malawi Liverpool Wellcome Program, the Animal Health Laboratory, and others. The government shall establish a governance structure linking local laboratories. It will designate a laboratory to lead and coordinate the national network and establish a hierarchical structure for the network with clear roles and responsibilities for the laboratories. The network shall adhere to the World Health Organization (WHO) Good Laboratory Practice (GLP) and encourage the participation of member laboratories in EQA schemes for genomics and data analytics. The network shall facilitate the harmonization of norms, standards, benchmarks, and reference materials.

Malawi shall participate in regional, continental, and global collaborations, as pathogens do not respect borders. These collaborations shall assist Malawi in areas where it has limited laboratory capacity to detect pathogens through sample referral systems. These networks shall include the Africa Pathogen Genomics Initiative, H3ABionet, African Bioinformatics Institute, and others.

2.6.3. Implementation of continuous improvement strategy

Malawi will develop a strategy for continuous improvement in genomic surveillance. PHIM will lead continuous improvement initiatives to ensure laboratories remain responsive to client needs and relevant to public health decision-making. The strategy shall include monitoring and evaluation activities to determine progress in implementing genomic surveillance activities over a defined time and the program's effectiveness.

2.6.4. Use of research and information in strategic decision making

Information derived from genomic surveillance of pathogens shall be used to identify gaps in public health research and guide policymakers in making evidence-based decisions. To ensure comprehensive research, pathogen genomics should be integrated into epidemiological networks. This integration will enable more rapid detection of any public health emergencies. Research and collaboration can also support the identification of priority pathogens for genomic surveillance. Improved knowledge of pathogens advances public health disease control and response and how this can be applied to priority pathogens, given that resources are limited. Malawi shall leverage genomic data and information gathered through routine surveillance and research to revolutionize its approach to combating infectious diseases. This data-driven strategy shall fuel advancements in diagnostics, vaccines, and therapeutics, leading to a more precise and effective public health response.

2.6.5. Multi-sectoral policy on genomics

The GoM will develop a multi-sectoral policy on genomic surveillance in line with the One Health approach. All stakeholders, including PHIM and all government departments, will follow the same national policy on genomic surveillance. The policy will also outline the rules of engagement for the various government ministries involved.

2.6.6. Ethical practices and regulation

Genomic surveillance raises significant ethical concerns regarding privacy, data ownership, and the responsible use of genetic information. From time to time, the NHSRC and other local Institutional Review Boards (IRBs) will review

and update guidelines on the ethical collection, storage, and use of genomic surveillance data. The IRBs will consult with stakeholders, including patient advocacy groups, healthcare providers, and government agencies, to ensure that the guidelines reflect a diverse range of perspectives.

The IRBs will also conduct public education and awareness programs. The programs will provide information about genomic surveillance research and its ethical implications. The IRBs and all stakeholders will conduct public forums, educational campaigns, and outreach activities that engage the public and promote a better understanding of the science behind genomic surveillance research.

Implementation of regulatory activities for genomic surveillance will require interagency collaboration within the government.

The Pharmacy and Medicines Regulatory Authority (PMRA) will regulate the registration of genomic sequencing equipment and reagents. The Medical Council of Malawi (MCM) will certify laboratory staff and infrastructure for sequencing. The Malawi Bureau of Standards (MBS) will enforce compliance with standards for genomic sequencing laboratories as may apply. Academic institutions will certify bioinformaticians and other staff involved in genomic surveillance.

2.6.7. Quality management systems for genomic surveillance

PHIM will lead the implementation of quality management systems for genomic surveillance in Malawi. This includes sample collection and transportation, sequencing, data management, interpretation, and use of genomic surveillance information.

2.6.8. Biosafety and biosecurity

The GoM will adhere to stringent international biosafety and biosecurity guidelines on the management of pathogens. This will ensure the protection of laboratory staff and containment of pathogens.

2.7. Stakeholder Engagement

2.7.1. Collaboration with Partners

Collaboration with established research institutions can help leverage resources and expertise, lower costs, and accelerate research progress. The GoM will identify potential partners for collaboration in genomics research. These include academic institutions, government agencies, healthcare providers, and the private sector. The National Genomics Research Network will be established to conduct research in line with the national research agenda.

The GoM, in collaboration with its stakeholders, will co-develop research proposals and standard operating procedures (SOPs) for specimens, data, and information sharing. Regular meetings and workshops will be conducted to promote collaboration and information sharing.

2.7.2. Targeted collaboration with One Health partners

Malawi shall implement genomic surveillance through the One Health approach. This will provide a transformative opportunity to address these issues by integrating data on human, animal, and environmental health. Malawi shall leverage partnerships with global and local One Health stakeholders, such as:

- Medical Council of Malawi
- Malawi Police Service
- Ministry of Justice
- Wildlife Department
- Ministry of Agriculture
- Ministry of Higher Education

- Academia
- Private sector
- International organizations and collaborators
- And others

2.7.3. Updates to relevant technical working groups

PHIM will provide quarterly updates on genomic surveillance to relevant technical working groups within disease programs as needed.

2.7.4. Sensitization of the public, patients, and healthcare providers

The GoM will conduct sensitization activities for the public, patients, and healthcare providers. The Health Education Unit (HEU) will lead these activities. The HEU will develop materials and organize activities for sensitization. HEU will also collaborate with the media on these activities.

The sensitization activities will aim to increase awareness and understanding of the potential benefits of genomic surveillance.

The GoM will engage in open and honest conversation about what is involved in genomic surveillance.

2.7.5. Support from implementing partners

There is a need to increase awareness about genomic surveillance in the country. The GoM will require support from implementing partners. The GoM will advocate for the inclusion of budgets for sensitization activities in the annual plans of implementing partners. Implementing partners will support the government in conducting the activities in their geographic areas of support.

2.7.6. Basic genomic surveillance information in curricula of primary and secondary schools

The GoM will intensify awareness of genomic surveillance in primary and secondary schools. The Ministry of Education, Science, and Technology will include basic information about genomic surveillance in the primary and secondary school curricula. This initiative aims to increase awareness and understanding of genomic surveillance among primary and secondary school students. It is also designed to help students consider pursuing careers in genomic surveillance.

3. APPENDICES

Appendix 1: SWOT Analysis of Genomic Surveillance in Malawi

NO.	THEMATIC AREA	STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS	STATEMENTS ON THE ISSUES	STRATEGIES/OBJECTIVES FOR ADDRESSING IDENTIFIED ISSUES
1	Research and Surveillance	1. Existing disease-specific surveillance, i.e., HIV, sentinel COVID-19/ influenza, tuberculosis, cholera 2. Availability of IDSR structures 3. Availability of trained staff to conduct surveillance at district and community levels. 4. Availability of FETP graduates 5. The existence of an FETP program that can train surveillance staff 6. Availability of health information management system (DHIS2) platform 7. Availability of LIMS 8. Staff from animal health and human health were trained in integrated surveillance 9. Availability of surveillance systems both in animal health and human health 10. Availability of sample transportation system 11. Availability of research laboratories	1. Integration of animal and human health surveillance not fully done 2. Low research capacities at the district level 3. Poor transmission of quality data to the national level 4. Few pieces of sequencing equipment and no national database for genomic system 5. No fully established LIMS in the district hospital 6. Isolated LIMS 7. Limited surveillance systems in government structures 8. Limited expertise 9. Inadequate resources 10. Limited funding 11. Lack of capacity to service the sequencing equipment 12. Reliance on external support 13. Lack of funding for specific disease surveillance	1. National research agenda available. Details priority research areas where genomic surveillance can build from. 2. Established research and surveillance division within the public health institute of Malawi 3. Existing corroboration with genomics experts from research institutions and academia	1. Global economic crisis 2. Emerging or re-emerging of new diseases 3. Donor fatigue 4. Competing priorities 5. Misaligned interest in surveillance 6. Funding for disease-specific surveillance	1. Lack of awareness and advocacy for the value of genomic surveillance among policymakers to integrate genomics into national disease control strategies. 2. Genomic surveillance for pandemic and epidemic preparedness and response would be most successful by encouraging linkages to build on existing strengths and capacities. 3. There is a need to build and sustain the country's readiness to use and surge genomic surveillance appropriately for emergencies	1. Implement priority research on genomic sequencing 2. Include genomic sequencing research in the national research agenda 3. Improve access to tools for better geographical and pathological representation 4. Maintain preparedness and readiness for emergencies 5. Strengthen timely detection of emerging variants 6. Implement targeted collaboration with One Health partners for comprehensive, integrated surveillance 7. Leverage existing networks to support and facilitate data, specimen, and information sharing to foster effective, rapid collaboration to drive public health action 8. Support and strengthen national networks in routine, epidemic, and pandemic contexts

NO.	THEMATIC AREA	STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS	STATEMENTS ON THE ISSUES	STRATEGIES/ OBJECTIVES FOR ADDRESSING IDENTIFIED ISSUES
2	Health Systems Strengthening: Infrastructure and Equipment	1. Availability of equipment for sequencing 2. Availability of storage equipment for samples and reagents 3. Available data computation and storage infrastructure from government institutions 4. Availability of technical support for equipment service and maintenance within the region	1. Poor infrastructure 2. Lack of storage and transportation equipment in peripheral sites 3. Lack of collaboration with other countries 4. Individual genomic surveillance laboratories have separate data servers 5. Slow internet network 6. Lack of calibration of equipment and ancillary items 7. Lack of reliable backup power	1. Available networks for collaboration or joint projects 2. Space available for construction of new infrastructure 3. Funders available to fund the renovation of existing laboratories and purchase more equipment 4. Basic infrastructure available for scale-up of genomic surveillance services 5. Availability of equipment on the markets 6. Availability of infrastructure that can be renovated for genomic sequencing laboratories	1. No service contracts for equipment 2. No plan for upgrade of equipment 3. Reliance on donors for the purchase of equipment and infrastructure development 4. Manufacturers not committed to all-inclusive deals 5. Expensive to maintain, hence difficult to sustain	1. Sequencing instruments available in some facilities within the country 2. Lack of a centralized biobank for different samples 3. Reliable and sustainable backup power is required in many institutions 5. Need for a standalone national referral genomic sequencing laboratory 6. Lack of storage and transportation equipment and infrastructure in peripheral sites 7. Lack of collaboration with others within the region and beyond 8. Lack of equipment for storage of large volumes of data	1. Have in place long-term plans for equipment service and maintenance 2. Increase and centralize the storage capacity of biorepositories 3. Link genomic sequencing laboratories to the national data center 4. Install reliable and sustainable power backup to support operations 5. Strengthen laboratories to conduct multi-pathogen genomic sequencing through procurement of latest high throughput technologies and associated supplies 6. Lobby for provision of storage and transportation equipment and infrastructure at peripheral sites 7. Enhance good collaboration within Africa and beyond 8. Increase laboratory space (renovation and construction)

NO.	THEMATIC AREA	STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS	STATEMENTS ON THE ISSUES	STRATEGIES/ OBJECTIVES FOR ADDRESSING IDENTIFIED ISSUES
3	Capacity Building (Human Resources)	1. Laboratory personnel trained in genomic sequencing 2. Establishment of bioinformatics training at KUHeS 3. Availability of FETP program 4. Availability of trained sample collectors at sentinel sites	1. Limited capacity to conduct genomic research 2. Limited personnel specialized in genomic sequencing 3. Reliance on partner-supported staff 4. Lack of trained bioinformaticians 5. Lack of staff retention 6. Lack of funding to recruit more laboratory and computational personnel	1. Availability of committed funds to train more people 2. Committed leadership to provide and train more people 3. Good collaboration with teaching institutions 4. Availability of specialized training in genomic sequencing in and outside of the country	1. Reliance on external training institutions 2. Availability of international jobs 3. Slow absorption of trained staff into the system 4. Reprogramming of committed funding due to other priority needs, including reagents	1. Enough in-country human resources to support genomic sequencing, but there is a need to train available human resources 2. Increasing demand for genomic sequencing coming up, which calls for more human resources 3. A significant governance effort to establish and bolster genomic sequencing capabilities within the country. Backed by support from the Ministry of Health (MOH) and the donor community, the program aims to cultivate a domestic workforce of specialized professionals, ensuring long-term sustainability and expertise in genomic sequencing.	1. Have all well-trained staff to support genomic sequencing testing services 2. Recruit and train data staff to support data quality and management 3. Have a National Strategic Plan with costed human resources and capacity-building activities 4. Support the development of SOPs and curriculum for sample collection and testing training

NO.	THEMATIC AREA	STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS	STATEMENTS ON THE ISSUES	STRATEGIES/ OBJECTIVES FOR ADDRESSING IDENTIFIED ISSUES
4	Supply Chain Management and Logistics	1. Availability of supply chain management system 2. Availability of genomic sequencing reagents on the market 3. Capacity to quantify supplies in the country using appropriate tools 4. Availability of trained staff 5. Availability of partners (CDC, WHO, UNICEF, Global Fund) for funding of supply chain management and logistics 6. Availability of a national transportation system 7. Availability of national storage space for room temperature commodities and frozen cold chain commodities	1. Lack of storage space at the laboratory level 2. Lack of capacity in-country to meet cold or frozen transportation conditions (dry ice, liquid nitrogen) 3. Weak distribution system of commodities at the national level and inability to re-distribute 4. No clear policy for the disposition of commodities and equipment 5. Unavailability of rapid response transportation system 6. Donor dependency 7. Lack of equipment harmonization, which affects commodity procurement 8. Lack of quality data to be used for quantification exercises	1. Supply chain management training available for staff 2. Availability of paper-based inventory management systems 3. Funding for more commodities procurement to scale up genomic sequencing 4. More commodities becoming available, which will make commodities cheaper 5. Political will supporting the genomic sequencing 6. Availability of qualified personnel who could be trained in genome sequencing 7. Availability of specialized training where more staff could be trained 8. Genome sequencing national strategic plan being developed, which will guideline introduction, scale up and implementation	1. Unforeseen program or policy changes that would affect the scale-up of genomic surveillance 2. Effects of travel restrictions on the importation of commodities due to pandemics or natural disasters 3. High cost of reagents making it difficult to sustain 4. Inconsistency of available and committed funding 5. Change in priority of policy or donor commitment due to outbreaks and pandemics of different diseases 6. Discontinuation of the use of different machines available in the country 7. Unavailability of commodities with the manufacturers	1. Though the country has an existing system with confirmed funding, it is important to consider evaluation of the system to accommodate the following: a. How best does the current supply chain system accommodate genomic sequencing b. How much funding is required c. What areas in the supply chain need investment d. What innovations should be supported by the genomic sequencing National Strategic Plan e. What commodities are used/needed based on the available existing platforms	1. Have defined and costed National Strategic Plan with a commodity budget 2. Standardize equipment to be used for genomic sequencing in the country 3. Train more laboratory supply chain specialists and pharmacists to understand genomic sequencing commodities 4. Support quality data availability for proper quantification of commodities

NO.	THEMATIC AREA	STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS	STATEMENTS ON THE ISSUES	STRATEGIES/ OBJECTIVES FOR ADDRESSING IDENTIFIED ISSUES
5	Data Management	1. Availability of a Digital Health Division to support the implementation of digital health solutions 2. Availability of government's well-equipped data centers for data storage, processing, and management 3. Availability of reliable and stable internet (fiber, broadband, mobile, etc.) 4. Availability of LIMS that is scalable and can accommodate genomic sequencing workflows 5. Availability of surveillance data management system OHSP in DHIS2 6. Availability of legal framework to help protect patient data (Access to Information Act 2016, Electronic Transactions Act 2016, Malawi National Health Information Policy	1. Limited expertise in bioinformatics 2. Siloed data management systems 3. Disease-specific data management systems 4. Non-existence of an integrated national health information management system for all diseases	1. Collaboration amongst institutions 2. Opportunities for funding from partners 3. Political will and government commitment to prioritize genomic sequencing 4. With the impact of COVID-19, genomics has been one of the priorities to improve data management in managing epidemics 5. Availability of governance system in alignment with digital health	1. High costs for purchasing and sustaining data management equipment 2. Limited financial resources to train staff in data management 3. Heavy reliance on donor funding, which compromises sustainability	1. Need for sufficient funding to train more bioinformaticians 2. Need to utilize newly constructed and equipped data centers to host MOH systems that must include genomic sequencing system 3. Need to develop genomic sequencing workflows and management of testing and results in existing LIMS 4. Need to improve LIMS to create a multi-disease system that must include genomic sequencing 5. Standards must be applied to genomic surveillance systems to ensure that data is effectively interpreted and shared and that essential metadata is captured for maximum utility 6. Need to provide strong leadership for proper management of digital health solutions in Malawi	1. Train more bioinformaticians 2. Buy more servers or opt to use cloud-based storage facilities 3. Expand the capacity and scope of the existing LIMS to become a multi-disease system 4. Develop consensus on data and metadata standards that respect data privacy and national sovereignty while balancing the importance of contextual information to accompany genomic sequencing data 5. Establish explicit data sharing and access principles that are widely agreed upon to promote transparency and rapid and equitable dissemination

NO.	THEMATIC AREA	STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS	STATEMENTS ON THE ISSUES	STRATEGIES/ OBJECTIVES FOR ADDRESSING IDENTIFIED ISSUES
		2015, SOP on Data Access and Release, Digital Health Strategy 2020-2025) 7. Availability of partners supporting the implementation of digital health solutions 7. Availability of laboratory personnel with basic training and experience in data management					6. Ensure that data-sharing agreements are already in place prior to acute events to promote timely collaboration and coordination
6	Resource Mobilization, Financing, and Sustainability	1. Existing donor agencies and implementation partners (CDC, USAID, PIH, UMB, CHAI, DAPP, JHPIEGO) 2. Government political will and inclusion of the genomic surveillance agenda in the PHIM strategic plan	1. Lack of overall national budget for genomic sequencing 2. Lack of dedicated government funding for genomic sequencing 3. Lack of National Strategic Plan 4. No existing policy on genomic sequencing 5. National disease programs have fragmented approaches toward genomic sequencing	1. Existing potential funders: ASLM, BMGF, Africa CDC, World Bank, Global Fund, Unitaid, USAID, US CDC, European Union, etc. 2. African CDC leadership to mobilize resources for Member States at the global level 3. Domestic resources from the GoM 4. Involve SADC in genomic sequencing and disease surveillance	1. Balance between regional and global health surveillance systems to own and manage genomic sequencing data (competition for funding: funders interested in global approach as opposed to regional approach) 2. Inequitable sharing of resources (e.g., low prioritization for the African region, unfavorable pricing structure for supplies)	1. Robust local donor and implementing partner community 2. Strong government political will 3. Unavailable government funding for genomic sequencing and surveillance to guarantee sustainability 4. Lack of overarching coordinated national policy on genomic sequencing 5. Strong international partner willingness to fund genomic sequencing	1. Lobby for genomic sequencing funding from the government 2. Collaborate with donors and implementing partners to mobilize resources for genomic sequencing 3. Develop a multi-sectoral policy on genomic sequencing 4. Collaborate with SADC, ASLM, and Africa CDC in mobilizing resources for genomic sequencing

NO.	THEMATIC AREA	STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS	STATEMENTS ON THE ISSUES	STRATEGIES/ OBJECTIVES FOR ADDRESSING IDENTIFIED ISSUES
				5. Partnerships with academic and research institutions 6. Leverage resources for non-communicable diseases and One Health 7. Multi-sectoral accountability framework (accountability, data sharing) with the next meeting to invite representatives from various sectors (ICT, immigration, policymakers, high-level meetings, etc.). 8. Industry partners, e.g., diagnostic equipment manufacturers, ICT companies, banks, etc. 9. Conduct local manufacturing of diagnostics and therapeutics		6. Moderate collaboration with local academic and research institutions 7. Weak One Health approach towards genomic sequencing (low involvement of immigration, environmental, agriculture, policymakers, etc.) 8. Weak collaboration between regional and global institutions	5. Strengthen collaboration with local academic and research institutions in pooling resources for genomic sequencing

NO.	THEMATIC AREA	STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS	STATEMENTS ON THE ISSUES	STRATEGIES/ OBJECTIVES FOR ADDRESSING IDENTIFIED ISSUES
7	Governance, Regulation, and Policy	1. Availability of the national One Health Committee 2. Availability of the Genomic Sequencing Secretariat 3. Availability of the PMRA 4. Availability of the MCM 5. Availability of MBS 6. Availability of the National Quality Assurance Framework	1. Lack of overarching national policy for genomic sequencing 2. Inadequate enforcement of laws, policies, and regulations about medical technologies 3. Fragmented implementation of governance and regulatory activities for genomic sequencing	1. Availability of support to strengthen governance, regulation, and policy for genomic sequencing from Africa CDC, ASLM, WHO 2. Presence of international quality assurance programs for genomic sequencing	1. Introduction of unregistered equipment and reagents for genomic sequencing by suppliers 2. Access to and export of genomic sequencing specimens by unauthorized institutions or individuals 3. Access to and sharing of genomic sequencing data by unauthorized institutions or individuals	1. Active One Health Committee 2. Active Genomic Sequencing Secretariat 3. Functional regulatory institutions (PMRA, MCM, MBS) 4. Weak national laboratory quality management systems for genomic sequencing 5. No policy for genomic sequencing and surveillance 6. Poor enforcement of laws, policies, and regulations for medical technologies 7. No integrated implementation of governance and regulatory activities for genomic sequencing 8. Strong support from regional bodies (ASLM, Africa CDC, WHO) on governance, regulation, and policy for genomic sequencing 9. Strong international quality assurance programs for genomic sequencing	1. Strengthen the capacity of the One Health committee to govern and regulate genomic sequencing activities in Malawi 2. Strengthen the Genomic Sequencing Secretariat to support the implementation of genomic sequencing activities in Malawi 3. Implement integrated regulatory activities for genomic sequencing in collaboration with PMRA, MCM, MBS 4. Strengthen national laboratory quality management systems for genomic sequencing 5. Collaborate with regional and global institutions on the governance, regulation, and policies for genomic sequencing 6. Enrol in international laboratory quality assurance programs for genomic sequencing

NO.	THEMATIC AREA	STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS	STATEMENTS ON THE ISSUES	STRATEGIES/ OBJECTIVES FOR ADDRESSING IDENTIFIED ISSUES
						10. Weak biosecurity of genomic sequencing specimens 11. Weak data governance systems for genomic sequencing	7. Improve the biosecurity of genomic sequencing specimens 8. Strengthen data governance systems for genomic sequencing
8	Diagnostics	1. Availability of equipment 2. Availability of human resources 3. Availability of the national biorepository	1. Inconsistency in the provision of reagents and supplies due to lack of a dedicated budget, procurement delays, and local suppliers 2. Limited number of competent staff 3. Limited funding for training	1. Availability of genomic diagnostics training institutions 2. With the impact of COVID-19, genomic diagnostics has been one of the priorities in the management of epidemics 3. Availability of diagnostic governance system 4. Availability of samples with existing pandemic/epidemic 5. Internal and external collaboration among institutions in genomic diagnostics 6. Opportunity to expand the scope of accreditation	1. Heavy reliance on donor funding 2. Challenges in servicing diagnostics equipment 3. Lack of water and power backup 4. Lack of local manufacturers of reagents and supplies 5. Unavailability of products due to global demands	1. Need to improve training for diagnostics staff and funding for sustained provision of reagents and maintenance of equipment 2. Need to maintain quality in all aspects of genomic sequencing to ensure the accuracy of data	1. Lobby for more funding for training and purchase of reagents and supplies and maintenance of equipment 2. Develop and roll out training packages in genomic diagnostics to enhance skills and support decision-making 3. Establish knowledge exchange programs to disseminate and share best practices that build capacity, address common challenges, and strengthen cross-national collaboration 4. Implement external quality assessment programs for genomic sequencing

NO.	THEMATIC AREA	STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS	STATEMENTS ON THE ISSUES	STRATEGIES/ OBJECTIVES FOR ADDRESSING IDENTIFIED ISSUES
9	Stakeholder Engagement (Patients/ General Public)	1. Political willingness and buy-in from the government on genomic sequencing 2. Presence of various structured forums of engagement at the national level (technical working groups, steering committee with good stakeholder representation) 3. Inclusion of genomic sequencing elements in professional training institutions 4. Presence of HEU, which can be used for public sensitization 5. Presence of print and electronic media with interest in health	1. Inadequate information on genomic sequencing and surveillance for the public 2. Genomic sequencing is a new initiative for the public 3. Most stakeholders may not have genomic sequencing initiatives in their plans 4. Pathogens affecting patients go unidentified 5. Inadequate engagement of school-going age groups due to inadequate information sharing 6. Lack of basic genomics information at primary and secondary education levels 7. Lack of a comprehensive list of stakeholders for appropriate mapping and outreach 8. Little involvement of media and civil society in genomics awareness	1. Availability of global support and advocacy by major stakeholders (Africa CDC, ASLM, CDC, PEPFAR, SADC, USAID)	1. Spread of false information among the public	1. Strong government support for the implementation of genomic sequencing 2. Strong national structures for stakeholder engagement 3. Inadequate information on genomic sequencing surveillance for the public 4. Moderate inclusion of some genomic sequencing elements in professional training institutions 5. Reliable health education unit for MOH 6. Robust media institutions 7. Little to no inclusion of genomic sequencing awareness activities in plans of stakeholders 8. No engagement of primary and secondary students in the basics of genomic sequencing and surveillance	1. Provide quarterly updates to MOH senior management on genomic sequencing and surveillance 2. Provide quarterly updates on genomic sequencing to stakeholders through relevant technical working groups 3. Conduct public sensitization campaigns on genomic sequencing and surveillance in collaboration with HEU and media 4. Strengthen the inclusion of comprehensive genomic sequencing curricula in professional training institutions 5. Advocate for inclusion of genomic sequencing awareness activities in annual plans of stakeholders 6. Lobby for inclusion of basic genomic sequencing

NO.	THEMATIC AREA	STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS	STATEMENTS ON THE ISSUES	STRATEGIES/ OBJECTIVES FOR ADDRESSING IDENTIFIED ISSUES
			9. Weak coordination among the stakeholders (working in silos) 10. Weak information security systems			9. No comprehensive list of stakeholders to be provided with genomic sequencing information 10. Weak involvement of media in genomic sequencing 11. Poor coordination of stakeholders in sensitization activities on genomic sequencing 12. Weak privacy and security systems for managing genomic surveillance information	information in curricula of primary and secondary schools

Appendix 2: Financing and Costing

INPUTS	KEY ACTIVITIES	STATUS	2023	2024	2025	2026	2027	2028	2029	2030	AVAILABLE FUNDING	FUNDING GAP	TOTAL COST PER SECTION
2.1 Research and Surveillance	2.1.1 Conference to Develop Priority Research Activities	Partly Funded	$8,060		$8,060		$8,060		$8,060		$2,000	$30,241	$642,178
	2.1.2 Establish new genomic sequencing centers	Funded	$50,000		$50,000		$50,000		$50,000		$5,000	$195,000	
	2.1.3 Quarterly cross-border working group meetings	Partly Funded	$36,036	$36,036	$36,036	$36,036	$36,036	$36,036	$36,036	$36,036	$30,000	$258,287	
	2.1.4 Workshop to develop emergency plans for genomic research and surveillance	Partly Funded	$15,206	$15,206	$15,206	$15,206	$15,206	$15,206	$15,206	$15,206	$20,000	$101,649	
2.2 Health Systems Strengthening	2.2.1 Infrastructure assessment	Partly Funded	$11,227		$11,227		$11,227		$11,227		$10,000	$34,909	$12,843,039
	2.2.2 Procurement of ultra-low temperature freezers	Partly Funded	$50,000				$50,000			$50,000	$40,000	$110,000	
	2.2.3 Training of genomic sequencing personnel	Partly Funded	$16,011	$16,011	$16,011	$16,011	$16,011	$16,011	$16,011	$16,011	$40,000	$88,088	
	2.2.4 Semi-annual conference to share genomic sequencing best practices	Partly Funded	$7,614	$7,614	$7,614	$7,614	$7,614	$7,614	$7,614	$7,614	$20,000	$40,909	
	2.2.5 Conduct needs assessments for genomic sequencing laboratories	Funded	$3,757			$3,757			$3,757		$11,270	$11,270	
	2.2.6 Train laboratory personnel on equipment maintenance	Partly Funded	$16,282	$16,282	$16,282	$16,282	$16,282	$16,282	$16,282	$16,282	$2,000	$128,257	
	2.9.7 Develop an equipment donation policy	Not Funded			$59,221						$0	$59,221	
	2.2.8 Establish equipment maintenance contracts with equipment manufacturers	Partly Funded	$60,000	$60,000	$60,000	$60,000	$60,000	$60,000	$60,000	$60,000	$80,000	$400,000	
	2.2.9 Train local engineers on maintenance of genomic sequencing equipment	Not Funded		$15,943							$0	$15,943	
	2.2.10 Enrol genomic sequencing laboratories in EQA	Partly Funded	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$6,000	$10,000	$38,000	

INPUTS	KEY ACTIVITIES	STATUS	2023	2024	2025	2026	2027	2028	2029	2030	AVAILABLE FUNDING	FUNDING GAP	TOTAL COST PER SECTION
	2.2.11 Monitor EQA results and participant feedback	Partly Funded	$5,292	$5,292	$5,292	$5,292	$5,292	$5,292	$5,292	$5,292	$5,000	$38,334	
	2.2.12 Implement knowledge exchange activities with local and international partners	Partly Funded	$9,150	$9,150	$9,150	$9,150	$9,150	$9,150	$9,150	$9,150	$23,000	$53,200	
	2.2.13 Evaluate the effectiveness of the knowledge exchange programs	Partly Funded	$3,224			$3,224			$3,224		$3,000	$6,673	
	2.2.14 Procure new genomic sequencing instruments	Partly Funded		$400,000			$400,000			$400,000	$200,000	$1,000,000	
	2.2.15 Procure supplies for genomic sequencing	Partly Funded	$1,250,000	$1,250,000	$1,250,000	$1,250,000	$1,250,000	$1,250,000	$1,250,000	$1,250,000	$3,750,000	$6,250,000	
	2.2.16 Train sample collectors at sentinel sites	Partly Funded	$37,928	$37,928	$37,928	$37,928	$37,928	$37,928	$37,928	$37,928	$100,00	$203,420	
	2.2.17 Train sample couriers on proper transport methods and safety	Partly Funded	$10,727	$10,727	$10,727	$10,727	$10,727	$10,727	$10,727	$10,727	$33,000	$53,815	

INPUTS	KEY ACTIVITIES	STATUS	2023	2024	2025	2026	2027	2028	2029	2030	AVAILABLE FUNDING	FUNDING GAP	TOTAL COST PER SECTION
2.3 Capacity Building for Human Resources	2.3.1 Recruit human resources (laboratory scientists, molecular epidemiologists)	Partly Funded	$32,400	$32,400	$32,400	$32,400	$32,400	$32,400	$32,400	$32,400	$32,000	$227,200	$386,985
	2.3.2 Conduct workshops to determine the needs for training workforce in genomics	Partly Funded	$16,011			$16,011			$16,011		$10,000	$38,033	
	2.3.3 Provide appropriate training opportunities to employees	Partly Funded	$10,000	$10,000	$10,000	$10,000	$10,000	$10,000	$10,000	$10,000	$10,000	$70,000	
	2.3.4 Assist academic institutions in establishing genomics courses	Not funded		$6,715					$6,715		$0	$13,430	
	2.3.5 Train bioinformatics specialists	Not funded	$0	$14,000		$14,000			$14,000		$0	$42,000	
2.4 Data Management	2.4.1 Develop computerized genomic sequencing data and information management systems	Partly Funded	$73,540								$50,000	$23,540	$386,985
	2.4.2 Procure hardware, software, network equipment, and printers	Partly Funded	$39,554								$20,000	$39,554	
	2.4.3 Develop SOPs for general genomic sequencing data and information management system	Partly Funded	$6,505								$3,000	$3,505	
	2.4.4 Develop a framework for data and metadata standards	Partly Funded	$6,505								$3,000	$6,505	

INPUTS	KEY ACTIVITIES	STATUS	2023	2024	2025	2026	2027	2028	2029	2030	AVAILABLE FUNDING	FUNDING GAP	TOTAL COST PER SECTION
	2.4.5 SOP Genomic sequencing SOP review meetings	Partly Funded	$6,505		$6,505		$6,505		$6,505		$10,000	$26,020	
	2.4.6 Replace desktop computers	Partly Funded				$22,044					$10,000	$12,044	
	2.4.7 Annual support for computerized genomic sequencing data and information systems	Partly Funded		$20,423	$20,423	$20,423	$20,423	$20,423	$20,423	$20,423	$20,000	$122,958	
	2.4.8 Cost of annual printing	Partly Funded	$8,732	$8,732	$8,732	$8,732	$8,732	$ 8,732	$8,732	$8,732	$20,000	$49,859	
2.5 Resource Mobilization, Financing, & Sustainability	2.5.1 Collaborate with different government ministries to plan and prioritize resources for genomic sequencing and surveillance	Partly Funded	$16,587	$16,587	$16,587	$16,587	$16,587	$16,587	$16,587	$16,587	$30,000	$102,700	$132,700
2.6 Governance, Regulation, and Policy	2.6.1 Quarterly meetings for One Health Committee	Partly Funded	$24,153	$24,153	$24,153	$24,153	$24,153	$24,153	$24,153	$24,153	$50,000	$143,221	$3,710,341
	2.6.2 Develop multi-sectoral policy on genomic sequencing and surveillance	Partly Funded		$59,221							$50,000	$9,221	
	2.8.3 Organize monthly meetings for the National Genomics Committee	Partly Funded	$54,702	$54,702	$54,702	$54,702	$54,702	$54,702	$54,702	$54,702	$0	$437,618	
	2.6.4 Quarterly visits to genomic sequencing laboratories to check compliance with local regulations	Partly Funded	$7,938	$7,938	$7,938	$7,938	$7,938	$7,938	$7,938	$7,938	$20,000	$43,500	

INPUTS	KEY ACTIVITIES	STATUS	2023	2024	2025	2026	2027	2028	2029	2030	AVAILABLE FUNDING	FUNDING GAP	TOTAL COST PER SECTION
	2.6.5 Bi-annual quality management system training for all staff in genomic sequencing laboratories	Partly Funded	$54,597	$54,597	$54,597	$54,597	$54,597	$54,597	$54,597	$54,597	$20,000	$416,780	
	2.6.6 Enrol laboratories in local, regional, and global accreditation programs	Partly Funded	$195,000	$195,000	$195,000	$195,000	$195,000	$195,000	$195,000	$195,000	$100,000	$1,460,000	
	2.6.7 Transport and dispose of pathogens	Partly Funded	$120,000	$120,000	$120,000	$120,000	$120,000	$120,000	$120,000	$120,000	$360,000	$600,000	
2.7 Stakeholder Engagement	2.7.1 Provide monthly updates to PHIM senior leadership on genomic sequencing and surveillance	Funded	$2,028	$2,028	$2,028	$2,028	$2,028	$2,028	$2,028	$2,028	$16,225	0	$1,121,853
	2.7.2 Provide monthly updates on genomic sequencing and surveillance to the NGC	Partly funded	$42,854	$42,854	$42,854	$42,854	$42,854	$42,854	$42,854	$42,854	$2,000	$340,835	
	2.7.3 Provide quarterly updates on genomic sequencing to technical working groups	Partly funded	$52,686	$52,686	$52,686	$52,686	$52,686	$52,686	$52,686	$52,686	$2,000	$419,485	
	2.7.4 Conduct public sensitization activities on genomic sequencing and surveillance	Not funded	$38,979	$38,979	$38,979	$38,979	$38,979	$38,979	$38,979	$38,979	$0	$311,831	
	2.7.5 Develop genomic sequencing curricula for local universities	Not funded		$13,851							$0	$13,851	
	2.7.6 Advocate for inclusion of basic information about genomic sequencing and surveillance in primary and secondary school curricula	Not funded			$7,813			$7,813			$0	$15,626	

INPUTS KEY ACTIVITIES	STATUS	2023	2024	2025	2026	2027	2028	2029	2030	AVAILABLE FUNDING	FUNDING GAP	TOTAL COST PER SECTION
Yearly Totals		$2,405,790	$2,661,054	$2,294,151	$2,210,360	$2,677,117	$2,159,137	$2,270,824	$2,601,324			
									Available Funds			$5,222,495
											Funding Gap	$14,057,264
									Total Funds Needed			$19,279,759

Appendix 3: Monitoring and Evaluation Framework

THEMATIC AREA	STRATEGIES	ACTIVITIES	INDICATORS	BASELINE	TARGET	RESPONSIBLE INSTITUTION	YEARS							
							2023	2024	2025	2026	2027	2028	2029	2030
2.1 Genomic Surveillance and Research	Implement priority research on genomic sequencing	Extend membership of the NGC to include more stakeholders	Number of stakeholders engaged in the NGC	8	123	Secretariat	8	8	18	19	20	21	22	23
		Identify research priorities that align with the national health agenda	Number of research publications produced from priority research areas The success rate of genomics research in improving health outcomes in the targeted areas	1	62	Researching institutions	1	2	12	22	32	42	52	62
	Collaborate with genomics research stakeholders	Establish a National Genomics Research Network	Number of institutions or organizations that are part of the network	8	18	Secretariat	8	8	18	19	20	21	22	23
		Conduct regular joint meetings and workshops with partners	Number of regular joint meetings and workshops held	3	27	Secretariat	3	3	7	11	15	19	23	27
	Establish new sequencing centers	Number of new sequencing centers established	4	10	National Genomics committee	4	7	7	8	8	9	9	10	
	Strengthen timely detection of emerging pathogens/ variants of public health importance	Develop guidelines and standard operating procedures for routine use of genomic sequencing data.	Existence of guidelines and SOPs for the routine use in genomic sequencing. Training records on the guidelines and SOPs	30%	100%	Individual institutions (18 facilities)	40%	50%	60%	70%	80%	90%	100%	100%
		Develop and implement a data-sharing platform	Availability of data-sharing platform	0	1	National Genomics Committee	0	0	1	1	1	1	1	1

THEMATIC AREA	STRATEGIES	ACTIVITIES	INDICATORS	BASELINE	TARGET	RESPONSIBLE INSTITUTION	YEARS							
							2023	2024	2025	2026	2027	2028	2029	2030
			Number of institutions accessing the database	8	18	Secretariat	8	8	18	19	20	21	22	23
			The proportion of sequenced samples shared on the platform	0	100%	Secretariat	0	0	100%	100%	100%	100%	100%	100%
			Number of MOUs for data sharing	0	100%	Secretariat	0	0	100%	100%	100%	100%	100%	100 %
2.2 Health Systems Strengthening	Improve infrastructure and equipment for genomic sequencing	Conduct an annual needs assessment to determine the state of infrastructure and equipment	Number of annual needs assessments conducted	0	1	National Genomics Committee	0	0	1	1	1	1	1	1
		Collaborate with local and international stakeholders to develop budgets and secure funding for equipment and infrastructure	Lobbying of genomic institutions on funding dedicated to equipment and infrastructure maintenance	0	1	National Genomics Committee	0	0	1	1	1	1	1	1
		Construct or refurbish sequencing laboratories	Number of sequencing laboratories constructed or refurbished	4	10	National Genomics Committee	4	7	7	8	8	9	9	10
		Select and standardize equipment	Availability of equipment standardization manual	0	1	National Genomics Committee	1	1	1	1	1	1	1	1
	Sustain functionality of genomic	Establish long-term service contract	Number of sequencing platforms on service level agreements	30%	100%	Individual facilities	30%	30%	100%	100%	100%	100%	100%	100%

THEMATIC AREA	STRATEGIES	ACTIVITIES	INDICATORS	BASELINE	TARGET	RESPONSIBLE INSTITUTION	YEARS							
							2023	2024	2025	2026	2027	2028	2029	2030
	sequencing infrastructure and equipment	agreements with instrument manufacturers to guarantee equipment maintenance												
	Strengthen the supply chain system	Train local engineers on maintenance and calibration of ancillary equipment for genomics laboratories	Number of local engineers trained on maintenance and calibration of ancillary equipment for genomics laboratories	1	5	PHIM; PAM	0	0	1	2	1	0	0	0
		Conduct regular assessments to establish types and volumes of reagents and consumables required	Number of forecasting exercises conducted annually	0	4	National Genomics Committee: Individual institutions	0	0	1	4	4	4	4	4
		Procure and distribute genomic sequencing commodities	Percentage of genomic sequencing laboratories supplied with commodities	0	100%	HTSS; PHIM	0	0	0	100%	100%	100%	100%	100%
		Orient staff on commodity management, inventories, and reporting	Number of staff trained on management, tracking, and inventories for commodities	0	90	Individual laboratories	0	0	30	20	10	10	10	10
		Develop contingency plans for individual laboratories that will respond to disruptions in reagents and consumable supplies	Percentage of laboratories with contingency plans	0	100%	Individual laboratories	0	0	80%	100%	100%	100%	100%	100%

THEMATIC AREA	STRATEGIES	ACTIVITIES	INDICATORS	BASELINE	TARGET	RESPONSIBLE INSTITUTION	YEARS							
							2023	2024	2025	2026	2027	2028	2029	2030
	Implement a quality management system program for genomic sequencing laboratories	Participate in interlaboratory comparison with accredited laboratories	Number of laboratories participating in interlaboratory comparison	0		Individual laboratories	0	0	12	9	6	3	0	0
		Enrol genomic sequencing laboratories in EQA programs	Number of facilities enrolled in genomics EQA	2	18	Individual laboratories	2	2	6	9	12	15	18	18
		Enrol genomic sequencing laboratories in accreditation programs	Number of laboratories enrolled for accreditation	2	18	Individual laboratories	2	2	6	9	12	15	18	18
			Number of laboratories accredited by a recognized accrediting body	2	18	Individual laboratories	2	2	6	9	12	15	18	18
	Sample collection and transport	Train staff on sample management (collection, packaging, transportation, storage, retrieval and disposal	Percentage of facilities trained on sample management	20	100%	HTSS; PHIM; Individual facilities	15%	20%	30%	50%	70%	80%	90%	100%
	Test the ability of genomic surveillance systems to stretch during emergencies	Perform annual surge exercises to simulate an increased number of cases of a specific pathogen	Number of samples collected and sequenced during surge exercises	0	96	Individual laboratories	0	0	96	192	288	384	480	576

THEMATIC AREA	STRATEGIES	ACTIVITIES	INDICATORS	BASELINE	TARGET	RESPONSIBLE INSTITUTION	YEARS							
							2023	2024	2025	2026	2027	2028	2029	2030
			Accuracy of sequencing and analysis results during surge exercises (percentage)	>98	>98	Individual laboratories	>98	>98	>98	>98	>98	>98	>98	>98
		Establish communication protocols (within genomic sequencing institutions)	Effectiveness of communication protocols during emergencies, as measured by feedback from stakeholders	0	1	National Genomic Committee	0	0	1	1	1	1	1	1
		Train staff on emergency procedures and protocols (within genomic sequencing institutions)	Percentage of staff members trained in emergency procedures and protocols	0	100	National Genomic Committee	0	0	10	20	50	80	90	100
2.3 Capacity Building for Human Resources	Assess staff training needs	Conduct training needs assessment	Availability of assessment report	0	1	Genomics Committee; Human resources	0	0	0	1	1	1	1	1
	Establish knowledge exchange programs	Develop the structure of the program	Availability of curriculum for the program	0	1	National Genomics Committee	0	0	1	1	1	1	1	1
		Lobby for funding for the program	Existence of a specific budget line	0	1	National Genomics Committee: Individual institutions	0	0	1	1	1	1	1	1
		Assess the competency of staff in the program	The Number of staff who passed the competency	0	100%	Individual institutions	100%	100%	100%	100%	100%	100%	100%	100%

THEMATIC AREA	STRATEGIES	ACTIVITIES	INDICATORS	BASELINE	TARGET	RESPONSIBLE INSTITUTION	YEARS							
							2023	2024	2025	2026	2027	2028	2029	2030
	Establish genomics curricula in professional training institutions	Advocate for inclusion of short-term genomics curricula in professional training institutions	Availability of short-term genomics curricula in professional training institutions	0	1	Individual institutions	0	0	1	1	1	1	1	1
	Develop staffing strategy	Conduct human resource needs assessment	Availability of human resource needs assessment report	0	1	Individual institutions	0	0	1	1	1	1	1	1
		Lobby for allocation of more staff to support genomic sequencing laboratories based on needs assessment	The proportion of staff allocated based on assessment	50%	100%	Individual institutions, Human resources	50%	60%	70%	80%	90%	100%	100%	100%
		Lobby for the establishment of bioinformatician posts in government genomic sequencing laboratories	Number of positions established	0	8	Individual institutions, Human resources	0	0	0	8	8	8	8	8
		Hire bio-informaticians in testing laboratories	Number of positions filled	0	8	Individual institutions, Human resources	0	0	0	8	8	8	8	8
		Hire data clerks for data entry and management in government testing laboratories	Number of data clerks hired per reporting period	0	8	Individual institutions, Human resources	0	0	0	8	8	8	8	8

THEMATIC AREA	STRATEGIES	ACTIVITIES	INDICATORS	BASELINE	TARGET	RESPONSIBLE INSTITUTION	YEARS							
							2023	2024	2025	2026	2027	2028	2029	2030
		Train technical staff on sequencing	Number of trained testing staff at laboratories	20	180	Individual laboratories	20	20	40	100	120	140	160	180
		Train staff on bioinformatics	Number of staff trained in bioinformatics	8	50	National Genomics Committee; Individual laboratories	6	8	15	30	35	40	45	50
		Train data clerks	Number of trained data clerks	10	54	Individual laboratories	10	10	20	30	40	50	54	54
		Train staff in emergency procedures and protocols (within genomic sequencing institutions)	Percentage of staff members trained in emergency procedures and protocols	0	100	National Genomics Committee	0	0	10	20	50	80	90	100
2.4 Data Management	Develop genomic sequencing data and information management systems	Develop digital systems for capturing, storing, processing, and sharing data	Availability of digital systems	0	1	PHIM: Individual laboratories	0	0	1	1	1	1	1	1
		Include genomic sequencing workflows into existing LIMS	Proportion of workflows included	50%	100%	Individual institutions	50%	50%	50%	56%	67%	78%	88%	100%
	Develop SOPs for general genomic sequencing data and information management system	Develop SOPs on data usage and management (collection, storage, archiving, data sharing, data use)	Proportion of procedures with SOPs available	50%	100%	Individual institutions	50%	50%	50%	100%	100%	100%	100%	100%

THEMATIC AREA	STRATEGIES	ACTIVITIES	INDICATORS	BASELINE	TARGET	RESPONSIBLE INSTITUTION	YEARS							
							2023	2024	2025	2026	2027	2028	2029	2030
	Share data with the international scientific community.	Upload sequencing data on public databases	Proportion of generated sequence data shared on public databases	50%	100%	Individual institutions	50%	50%	70%	80%	90%	100%	100%	100%
	Establish data-sharing mechanisms	Develop MOUs on data sharing	Proportion of sequencing institutions with MOUs	0	100%	Individual institutions	0	0	100%	100%	100%	100%	100%	100%
2.5 Resource Mobilization, Financing, and Sustainability	Develop a guide on mobilizing genomic resources.	Incorporate genomic resource mobilization with sustainable government funding models by the MoH Health Financing Strategy	Genomic resource mobilization incorporated with government sustainable funding models	0	1	National Genomics Committee	0	0	1	1	1	1	1	1
		Incorporate other sources of funding from paying services such as out-of-pocket payments (legal issues, paternity testing, walk-in requests)	Funding strategy available	0	1	GoM	0	1	1	1	1	1	1	1
2.6 Governance, Regulation, and Policy	Set up NGC	Set up the NGC	NGC in place	0	1	NGC	0	0	1	1	1	1	1	1
		Develop TORs for the NGC	TORs for NGC in place	0	1	NGC	0	0	1	0	0	0	0	0
			Availability of implementation roadmap	0	1	NGC	0	1	1	1	1	1	1	1

THEMATIC AREA	STRATEGIES	ACTIVITIES	INDICATORS	BASELINE	TARGET	RESPONSIBLE INSTITUTION	YEARS							
							2023	2024	2025	2026	2027	2028	2029	2030
2.7 Stakeholder Engagement	Formulate and schedule genomics technical working group	Develop a schedule for the technical working group (including research discussion, curricula approvals, updates, and innovations discussions)	The Technical working group approved the schedule available	0	1	NGC	0	1	1	1	1	1		
	Establish a cross-border working group	Engage stakeholders in neighboring countries	Number of joint meetings conducted with neighboring countries	0	1	PHIM	0	1	1	1	1	1	1	1
			The proportion of regional investigations conducted with neighbouring countries	0	100%	PHIM	0	100	100	100	100	100	100	100
	Enhance collaboration with local and international partners	Conduct joint meetings and workshops with partners locally	Number of joint meetings and workshops conducted annually with local collaborators	0	2	Secretariat	0	0	2	2	2	2	2	2
		Conduct joint meetings and workshops with partners across borders	Number of joint meetings and workshops conducted annually with partners across borders	0	1	Secretariat	0	0	1	1	1	1	1	1

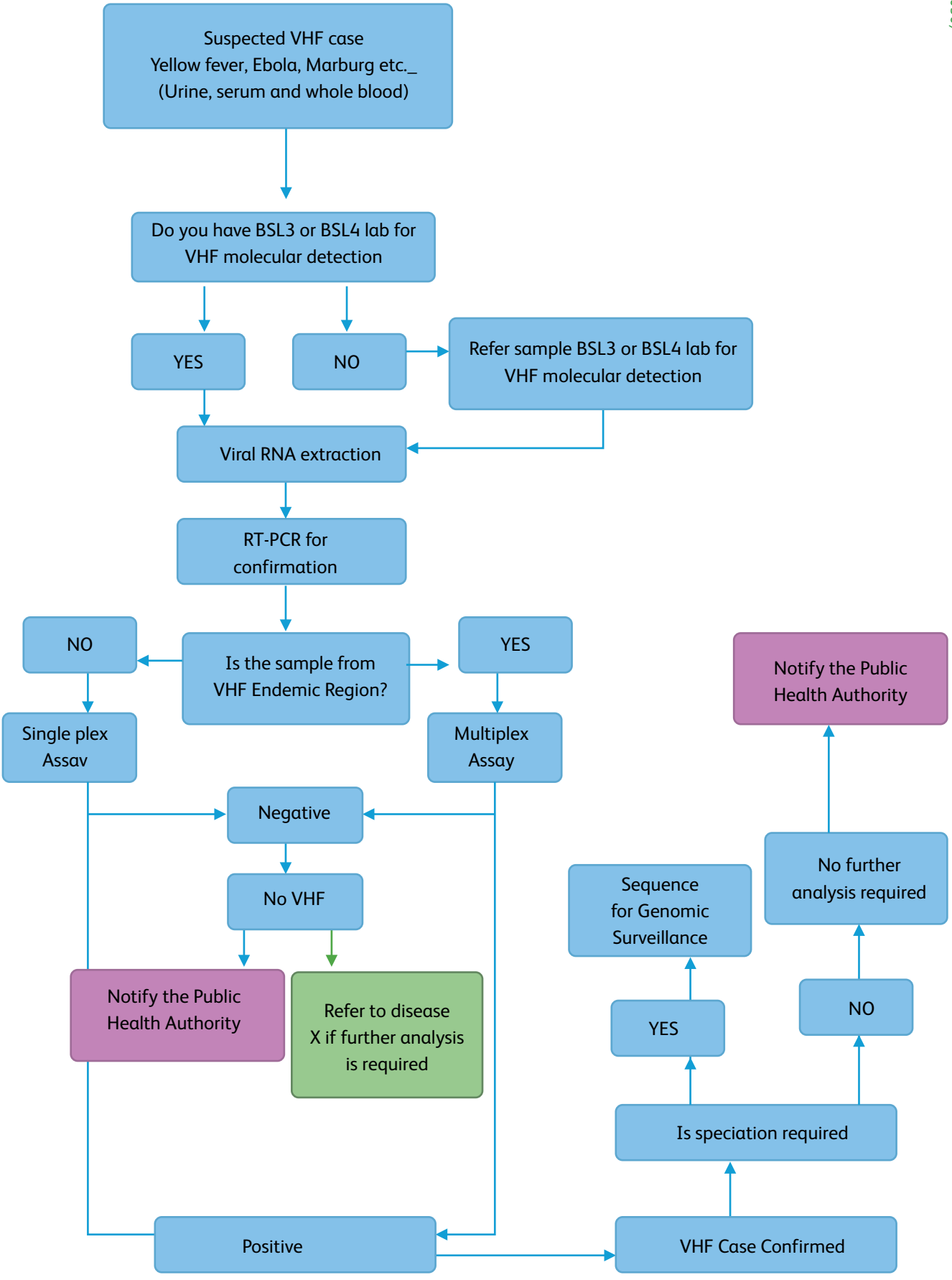
Appendix 4:

Genomic surveillance algorithm for viral haemorrhagic fevers

Viral haemorrhagic fevers (VHF) are a group of diseases that can lead to epidemics and are caused by various distinct viral families, such as filoviruses and arenaviruses. The testing procedure for VHF involves an initial assessment of the patient for symptoms and exposure history. This is followed by the collection of samples that meet the case definition. Proper laboratory procedures and precautions are essential when collecting these samples.

Case Definition:

Clinical criteria for a suspected case of VHF (e.g., Ebola, Marburg, Lassa) include acute onset of fever (greater than 38.5°C) within the past 3 days, along with one or more of the following haemorrhagic signs: bleeding gums, bloody vomit or diarrhoea, unexplained bruises or oozing from mucous membranes. Epidemiological criteria include a history of recent travel to or residence in a VHF-endemic area prior to symptom onset, contact with a suspected, probable, or confirmed case, occupational exposure (working in a laboratory or healthcare setting), and exposure to animals and/or environments known to harbour VHF.


Suspected VHF case
Yellow fever, Ebola, Marburg etc._
(Urine, serum and whole blood)
Do you have BSL3 or BSL4 lab for VHF molecular detection
YES
NO
Refer sample BSL3 or BSL4 lab for VHF molecular detection
Viral RNA extraction
RT-PCR for confirmation
NO
Is the sample from VHF Endemic Region?
YES
Single plex Assay
Multiplex Assay
Negative
No VHF
Notify the Public Health Authority
Refer to disease X if further analysis is required
Notify the Public Health Authority
Sequence for Genomic Surveillance
No further analysis required
YES
NO
Is speciation required
Positive
VHF Case Confirmed

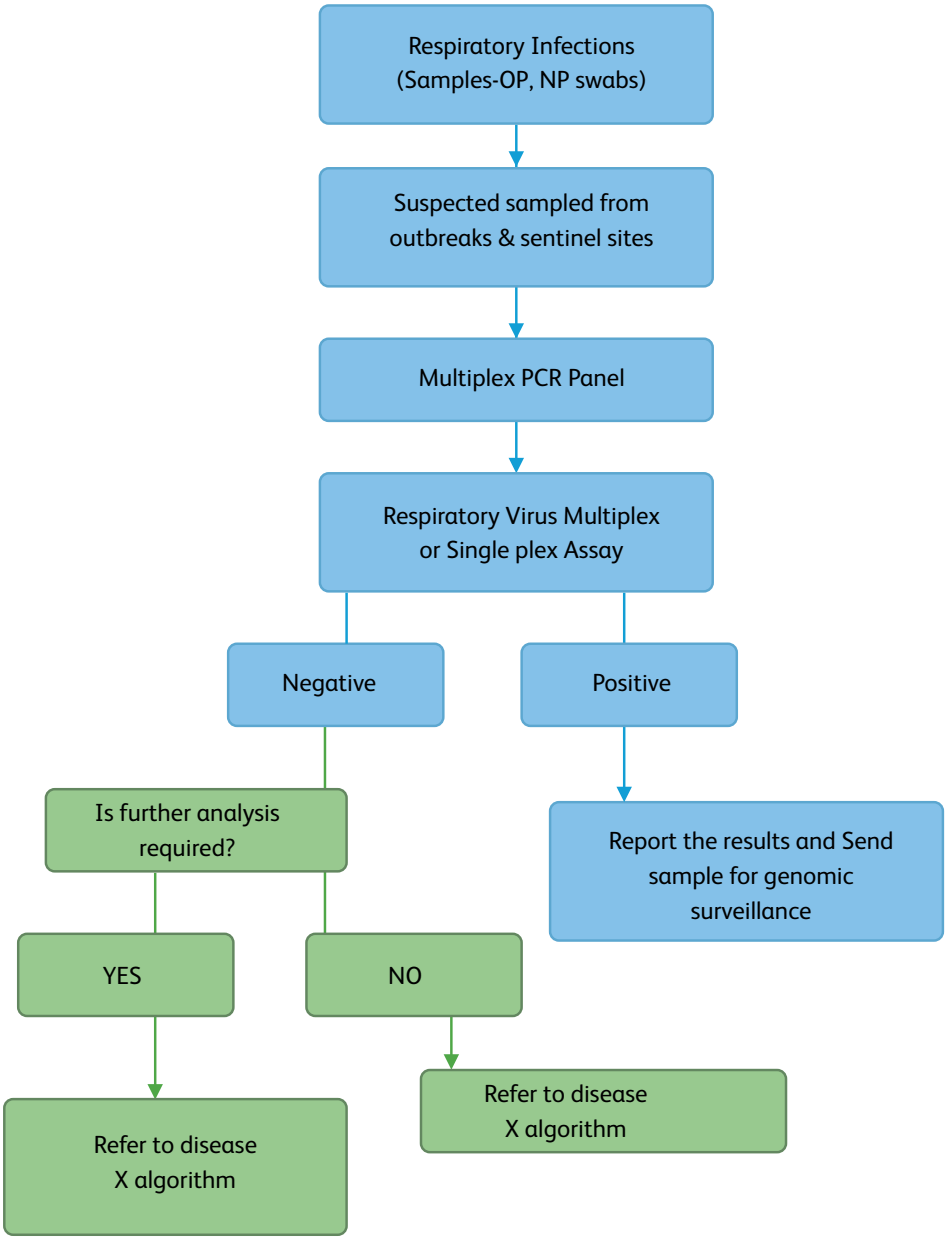
Appendix 5:

Genomic surveillance algorithm for respiratory infection cases

Influenza and other respiratory virus infections cause substantial annual morbidity and mortality worldwide, including in Africa. The testing algorithm for SARS-CoV-2, influenza viruses, and respiratory syncytial virus (RSV) provides a systematic approach to diagnosing infections, identifying variants, and guiding treatment. Below is an overview of potential testing algorithms for each virus.

Case Definition:

Clinical criteria for a suspected case of respiratory infection include cough or difficulty breathing, along with fever (greater than 38°C). This definition can be further tailored to specific priority pathogens (e.g., influenza, COVID-19, etc.) based on surveillance priorities.



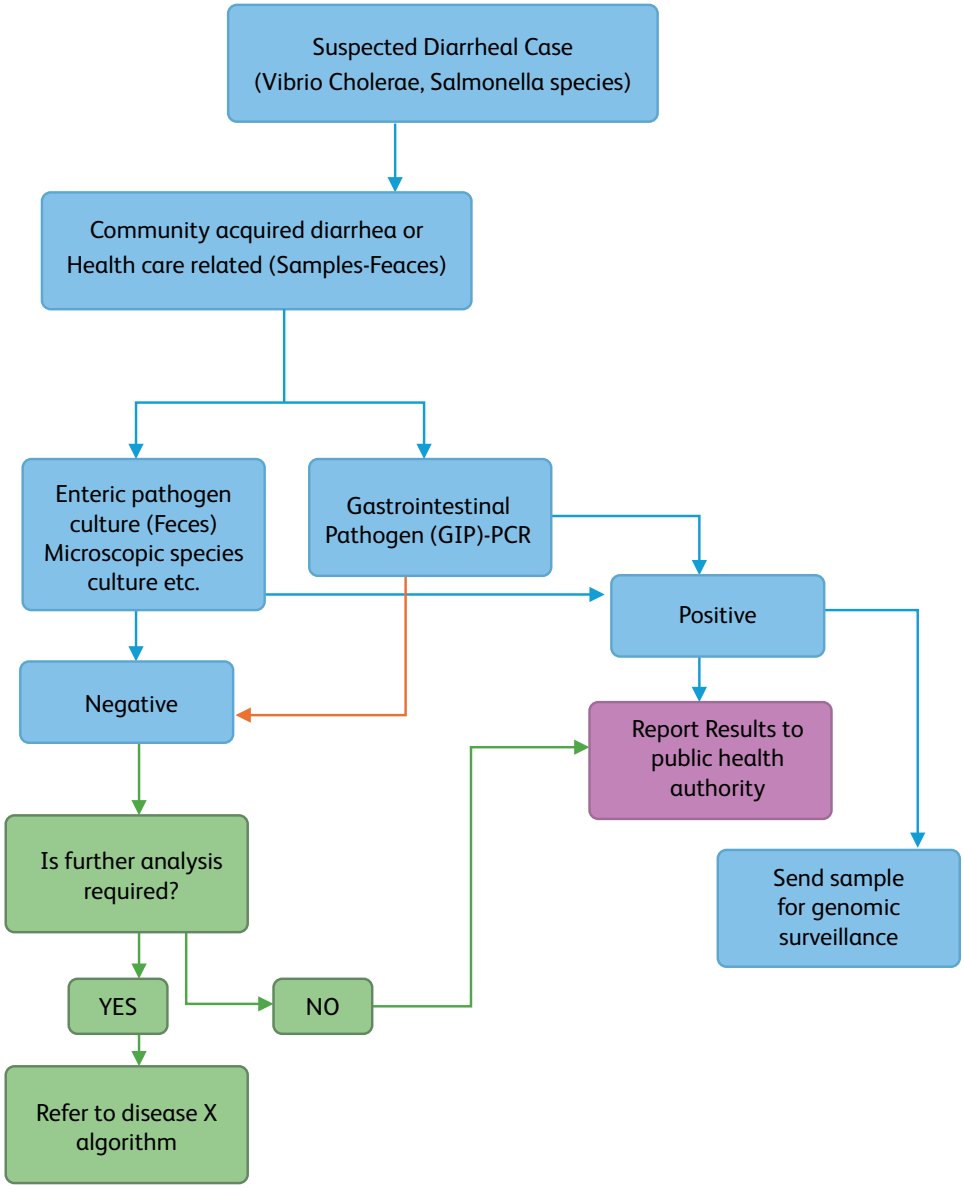
Appendix 6:

Genomic surveillance algorithm for suspected cases of diarrhoea

Diarrheal diseases are caused by various pathogens (e.g., Vibrio cholerae, Salmonella species) and are a significant public health concern globally, particularly in low- and middle-income countries. The accurate detection of these diseases is crucial for effective management and control. This detection algorithm aims to provide a comprehensive framework for diagnosing and managing diarrheal diseases, incorporating various aspects such as case definition, testing technologies, surveillance, laboratory capacity, and reporting for response.

Case Definition:

Clinical criteria for a suspected case of diarrhea include acute onset of diarrhea (three or more loose stools in 24 hours) and at least one of the following: fever, abdominal cramping, or vomiting, with laboratory confirmation of a diarrheal pathogen (e.g., cholera, rotavirus, etc.).



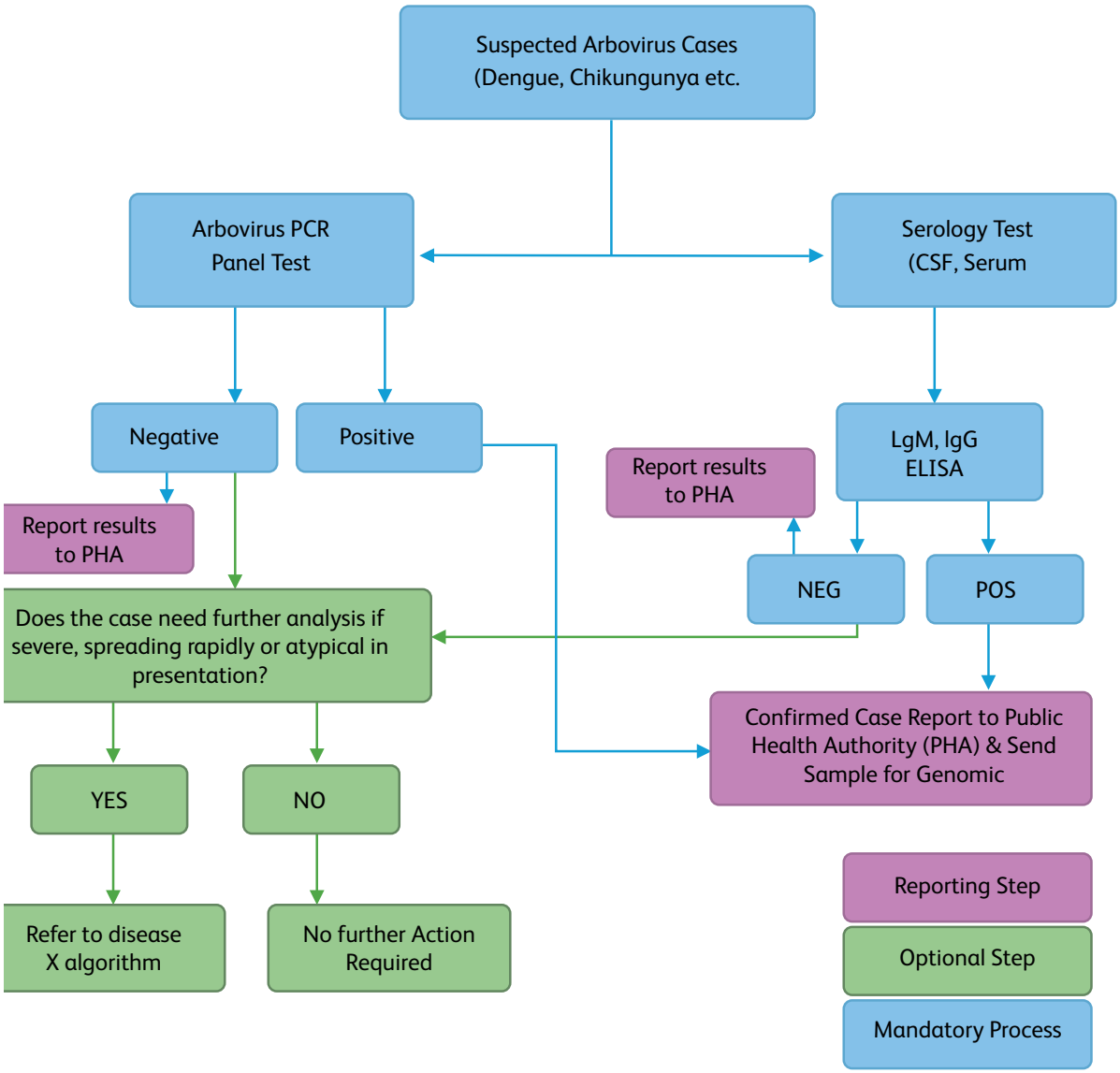
Appendix 7:

Genomic surveillance algorithm for suspected cases of arbovirus infection

Arthropod-borne viruses cause arboviral diseases, posing significant public health challenges on the African continent. Annually, arboviruses are responsible for significant morbidity and mortality. There has been a rapid change in the disease burden attributed to arboviruses. National capacity for early detection and response to arboviral diseases is important.

Case Definition:

Clinical criteria for a suspected arboviral disease case include acute onset of fever (greater than 38.5°C) and one or more of the following: headache, muscle pain, joint pain, and rash. This definition can be adapted to specific arboviruses (e.g., dengue, chikungunya) circulating in the region.



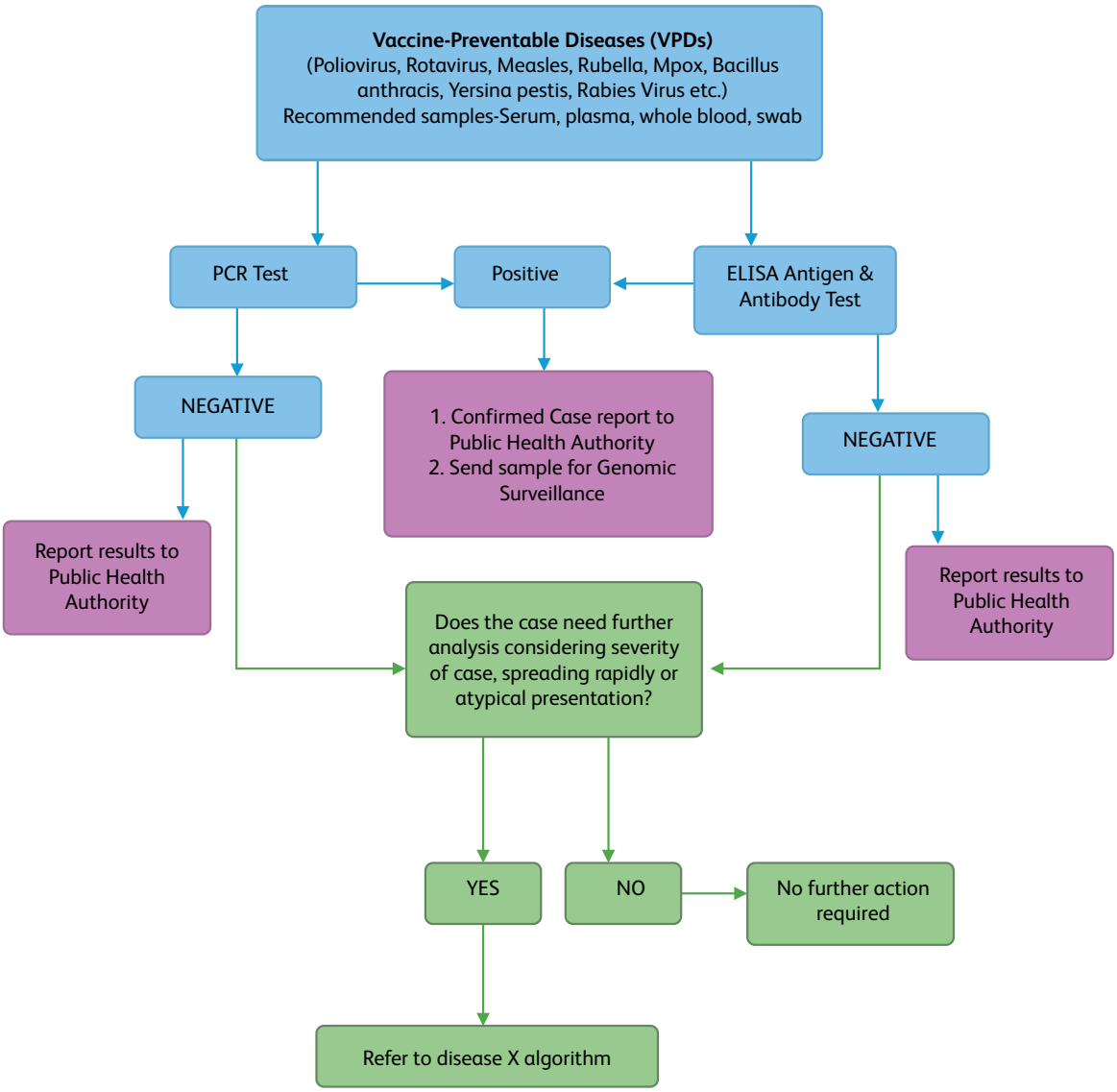
Appendix 8:

Genomic surveillance algorithm for vaccine-preventable diseases

The development of a comprehensive detection algorithm for vaccine-preventable diseases (VPDs) is crucial for effective public health surveillance and timely response. This algorithm focuses on the detection of several key VPDs, including mpox virus, poliovirus, rotavirus, Bacillus anthracis, rubella (measles) virus, rubella virus, Yersinia pestis, and rabies virus (lyssavirus).

Case Definition:

A suspected VPD case will be based on the specific disease in question. Existing national guidelines for VPD case definitions should be followed.



Appendix 9:

Genomic Surveillance Algorithm for Disease X

Disease X represents a hypothetical scenario for an unknown pathogen with epidemic potential. This section outlines the approach for molecular testing for Disease X at national reference laboratories. The proposed algorithm (Figure X) is designed to enhance the molecular testing capacity of national reference laboratories, assuming that these laboratories are equipped to handle high-risk samples and possess advanced molecular diagnostic tools, such as broad-spectrum polymerase chain reaction and next-generation sequencing (NGS). Metagenomics sequencing (mNGS) is a powerful tool for the unbiased detection of microbes from a wide array of sample types. For samples that test negative on relevant VPD and syndromic testing algorithms, mNGS may be considered to identify potential causative agents. However, the decision to escalate a case to a candidate for mNGS must take into consideration both epidemiological data and laboratory data.

Case Definition:

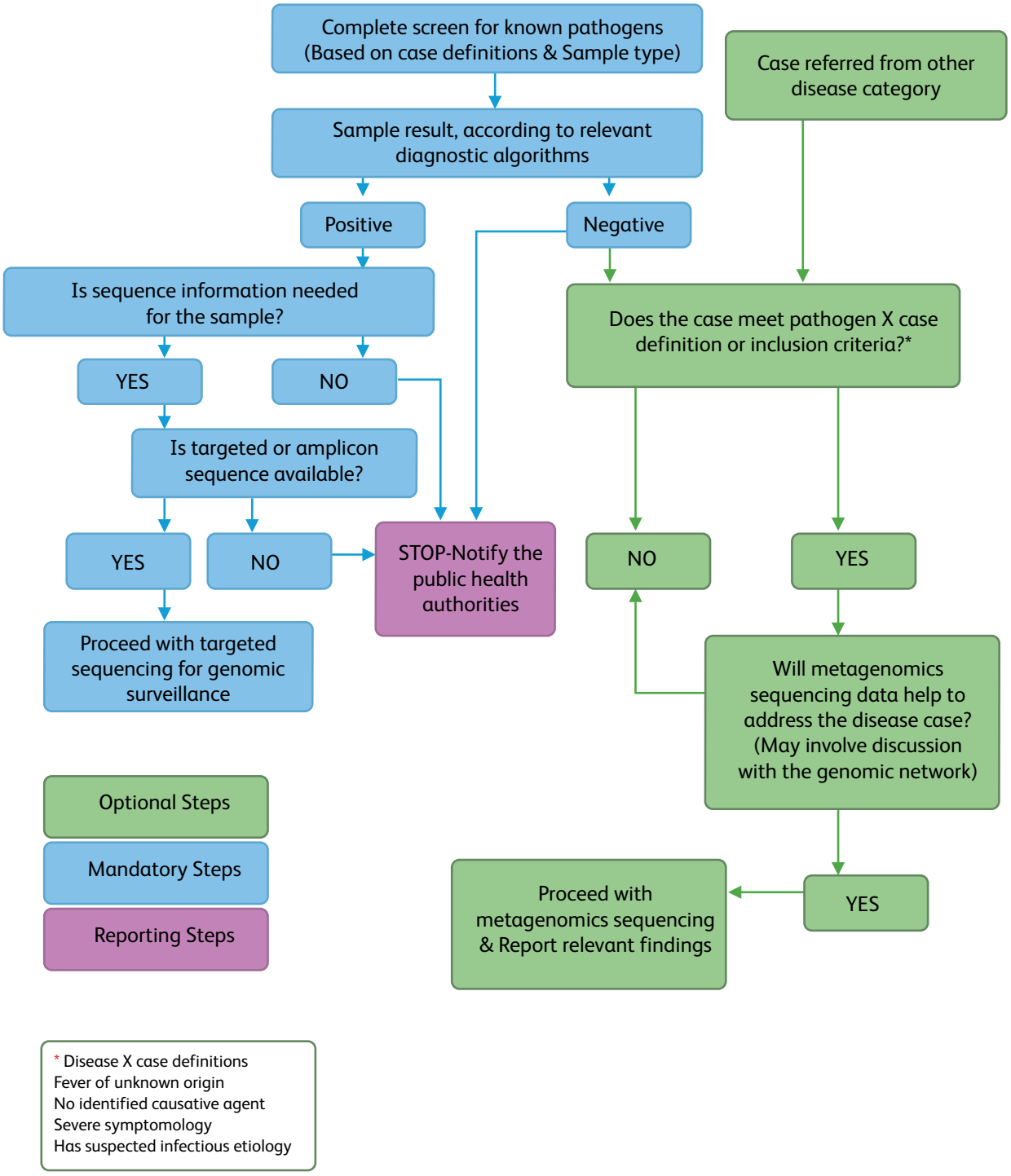
These case definitions are intended as general guidelines for when mNGS data may be impactful to surveillance or response efforts. Cases should be reviewed with referring clinicians and epidemiologists to understand if unbiased sequencing data will be valuable within the context of a specific case or investigation. Candidate case for mNGS testing: An individual with a fever of unknown origin or severe symptomology with a suspected infectious aetiology based on symptoms, clinical, and laboratory findings with no identified causative agent.

OR

An individual who is a member of a cluster of cases of fever of unknown origin or severe symptomatology with no identified causative agent and suspected infectious aetiology.

OR

An individual with the disease with a suspected infectious aetiology where identifying the aetiological agent may have substantial epidemiological or public health implications (e.g., hospital acquired infections, member of a vulnerable or immunocompromised community, member of a cluster or disease of unknown aetiology, etc).


Complete screen for known pathogens (Based on case definitions & Sample type)
Case referred from other disease category
Sample result, according to relevant diagnostic algorithms
Positive
Negative
Is sequence information needed for the sample?
Does the case meet pathogen X case definition or inclusion criteria?*
YES
NO
Is targeted or amplicon sequence available?
YES
NO
STOP-Notify the public health authorities
NO
YES
Proceed with targeted sequencing for genomic surveillance
Will metagenomics sequencing data help to address the disease case? (May involve discussion with the genomic network)
Optional Steps
Mandatory Steps
Reporting Steps
Proceed with metagenomics sequencing & Report relevant findings
YES
* Disease X case definitions
Fever of unknown origin
No identified causative agent
Severe symptomology
Has suspected infectious etiology

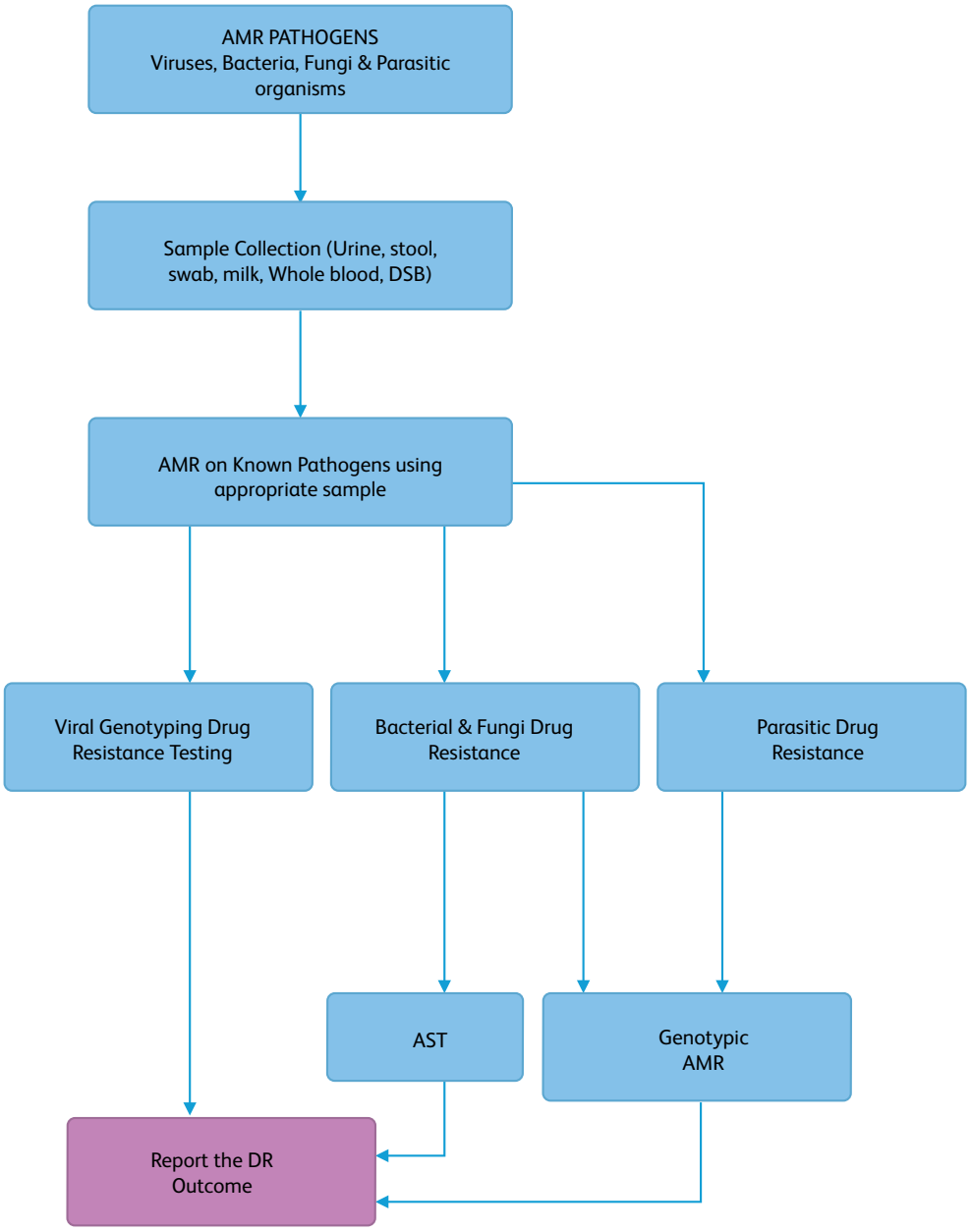
Appendix 10:

Genomic surveillance algorithm for antimicrobial resistance

Antimicrobial resistance (AMR) occurs when microorganisms (bacteria, viruses, fungi, and parasites) evolve to resist the effects of antimicrobial drugs (like antibiotics, antivirals, antifungals, and antiparasitics). As a result, infections become harder or impossible to treat.

Case Definition:

Suspected cases of AMR depend on the particular organism.



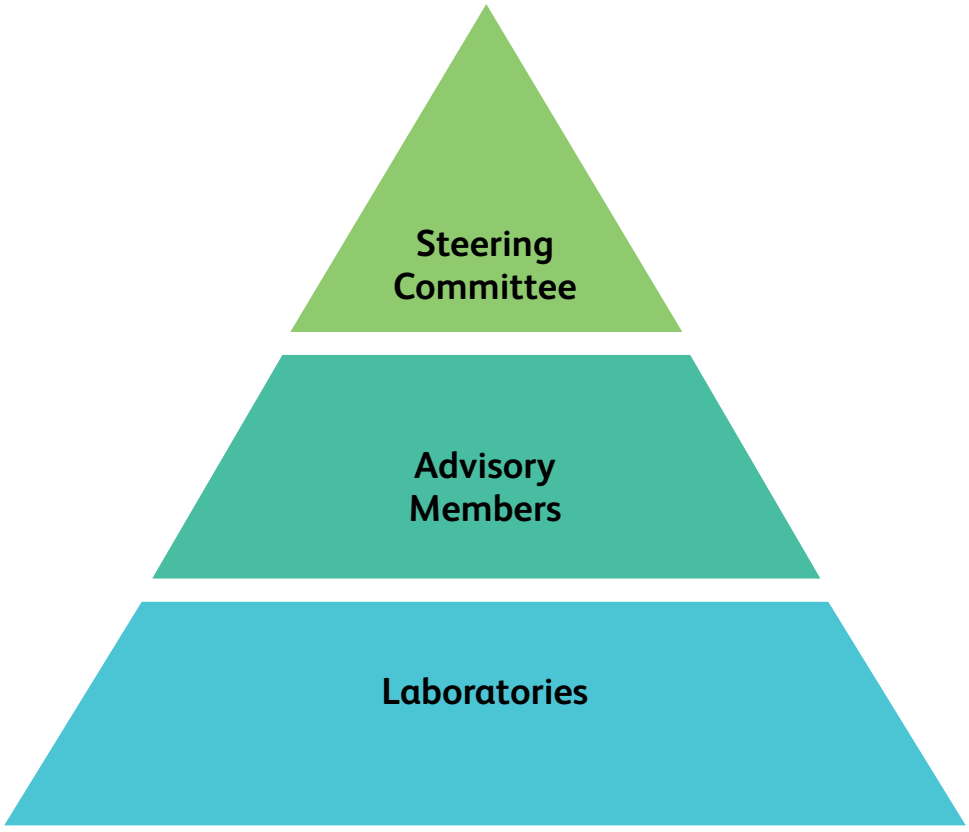
Appendix 11: National Genomics Committee

Introduction

The pandemics of Ebola, Mpox, Marburg, Chikungunya, Zika, and COVID-19 have demonstrated that countries need to develop and/or strengthen their health systems to predict, prevent, and respond effectively to outbreaks and pandemics promptly.

Genomic sequencing is an important tool being promoted across Africa, with support from institutions such as the United Nations agencies, the Africa CDC, ASLM, and other partners, to monitor and respond to emerging and re-emerging pathogens of public health importance in all countries, including Malawi. It is essential to have effective coordination mechanisms to guide and supervise the national response regarding the application of genomics in areas such as surveillance and monitoring of pathogen control programs. A national committee on genomics is an important tool in spearheading this task. A national genomics committee under the One Health approach was proposed and constituted following a recommendation by senior management in the Ministry of Health.

Hierarchy of National Genomics Committee



Description and Functions

A. Steering Committee

This is the highest committee in the hierarchy, composed of the Minister of Health and the Minister of Agriculture.

Functions of the Steering Committee:

1. Support national coordination, partnerships, collaboration, and resource mobilization
2. Provide strategic guidance and vision for the development of genomic sciences in healthcare and the life sciences in the country, utilizing the One Health approach.
3. Develop, review, monitor, and promote a national genomic surveillance implementation plan to harness the benefits of genomic studies for One Health.
4. The Steering Committee is responsible for recruiting members of the Advisory Committee.

B. Advisory Committee

The Advisory Committee is the section of the hierarchy that presents issues to the Steering Committee and provides advice to laboratories. The Advisory Committee is composed of institutions or individuals that have technical expertise in genome sequencing. The Steering Committee will select committee members.

Functions of the Advisory Committee:

1. Present issues to the Steering Committee on expertise and skills development through research, training, and education.
2. Guide laboratories on the selection of equipment, assays, and technologies for genomics, as well as advice on operational activities that directly impact or overlap with member institutions.
3. Provide advice to the Steering Committee on the use and dissemination of genomic data.

C. Laboratory Networking Committee

The Laboratory Networking Committee is a subgroup of the larger national genomics committee that facilitates collaboration and resource sharing among genomics laboratories, researchers, and professionals under the One Health framework.

Functions of the Laboratory Networking Committee:

1. Facilitate collaboration among committees and organize workshops, conferences, webinars, and other networking events to bring together genomics laboratories and researchers.
2. Share best practices and resources in genomics research (e.g., sharing protocols, data, and software).
3. Support education and training opportunities for researchers and technicians in genomics techniques and technologies.
4. Promote standards and guidelines for genomic testing, analysis, and interpretation to ensure consistency and accuracy.

D. Secretariat

The Secretariat is the office or personnel responsible for managing the National Genomics Committee and handling the day-to-day operations of all the committees. PHIM is the Secretariat of the National Genomics Committee.

Functions of the Secretariat:

1. Provide support services and administrative functions
2. May also have a role in decision-making

Committee Rules of Order

1. Membership. The total number of members has not been finalized; however, it will be limited to a manageable number of 23, including members of the Secretariat. This position may be revised from time to time.

2. The National Genomics Committee shall have a Chairperson and Vice Chairperson. The PHIM, as the Secretariat, serves as a permanent co-chair for all committees.

Tenure of Office

The tenure of the National Genomics Committee is valid for two years. Members of the National Genomics Committee, once approved, shall remain on the committee unless they withdraw for valid reasons.

For each new cycle term, the Secretariat shall ensure that a minimum of 50% of previous members are returned to maintain institutional memory on the committee.

Recruitment of Members

For the Steering Committee, all members shall be recruited through the Secretariat. Committee members may also propose who or which organizations should be included in the committee based on the stipulated acceptance and rejection criteria for selection. Approval for any new or additional applications or nominations shall be by consensus or simple majority.

Alternate Members

Substitution of a member is not allowed.

1. If a member is unable to attend a meeting or participate in person, they may delegate a suitable senior official to represent them or the institution.

2. The delegated member cannot replace the original member in the position on the committee, except where the members agree in consensus or by majority to endorse the change. Such a change cannot be reversed for convenience.

3. All discussions, comments, and commitments by the delegated official are binding on the original member and the institution being represented.

Orientation and Training of Members

The orientation of members shall be appropriated by the Secretariat.

Termination, Disqualification, and Resignation from Membership

1. To maintain decent working principles, anyone who intends to resign should put the intention in writing to the Chairperson before actual withdrawal and, where possible, may suggest a suitable replacement.

2. The same principles shall apply in the case of termination or disqualification, where the decision to remove the member originates with the Committee in a majority vote or with the Chairperson, provided there is clear justification.

Remuneration of Members

Committee members receive no remuneration for their services. Membership is on the principle of voluntary public service.

Convening and Conduct of Sessions

1. The Committee shall execute its functions by observing decent, respectful, and pro-active working principles. No member will wait to be told what to do or say, especially if an action is needed and obvious.

2. The Committee will normally hold plenary sessions every quarter, and the meeting shall be conducted either physically or virtually.

3. Meetings shall be arranged by the Secretariat,

which shall be responsible for identifying the venue and dates and mobilizing logistics.

4. All meetings shall be conducted in the presence of the Chairperson or designated representative.

5. All members will receive proposals or be asked to make proposals and make comments in relation to problems and issues under consideration.

6. Where he or she deems the urgency to be sufficiently great, the Chairperson, in consultation with the Secretariat and members, shall call for an ad hoc meeting.

Decision Making

1. All decision-making shall be taken on the consensus of the Committee or at least by a simple majority with a quorum.

2. Any major objections identified will be discussed and documented.

3. Where voting is necessary, a decision shall be taken according to the majority. In the event of a tie, no decision shall be made or implemented. In these rare cases, the Secretariat must take up the matter for further consultation with experts elsewhere and bring it back into the committee for voting.

4. All decisions taken are binding on all members, whether present or absent in the meeting.

Meeting Agenda

1. The Secretariat will develop the meeting agenda in consultation with the Chairperson and members.

2. The agenda will then be shared with the rest of the members at least 10 working days before the meeting to allow adequate time for calendar updates, revisions, and consensus.

Minutes of Meetings

1. Members will formally approve the minutes. The Secretariat shall send the draft minutes to all members, requesting their feedback.

2. If a member has not responded within five working days, they are considered to have accepted the minutes as provided.

3. Should comments or corrections be raised by members, the Secretariat shall revise the minutes and reissue them, thus restarting the five-day cycle. In the event of a dispute, the Chair shall make the decision.

4. All members are expected to contribute to follow-up actions after meetings as agreed and/or mentioned in the minutes.

5. Minutes shall be circulated and approved in the next committee meeting.

Attendance / Quorum

1. Committee members must endeavor to limit their absences to below 30% of meetings. This implies that for a meeting to be convened, at least 70% of the members should have confirmed their availability for the set dates.

2. Members who expect to be absent, after prior confirmation, shall be obliged to notify the Chairperson (or their designate) of their absence with an apology. Such members can indicate if a delegate will attend instead. The confirmation is considered in the decision: a) to hold a meeting at all; b) to determine the quorum.

3. Whether absent or sending a delegate, the member can provide input before the meeting. Delegation or advance input shall not include voting on decisions made after deliberations on the issue during the meeting if the issue is on the agenda.

4. Decisions made during the meetings shall be binding on all members, including those who are absent.

Implementation of Decisions

1. Decisions on project-specific issues, new standards, technical updates, changes in rules, and clarifications will be made after rigorous consultations.

2. The Secretariat is responsible for circulating action points and timelines to the members.

3. The Secretariat is responsible for coordinating the implementation of committee decisions and tasks, including those assigned to members.

Confidentiality

1. Under their membership, committee members will have direct or indirect access to information that may be confidential (e.g., unpublished government data). This information may come from their institutions, others, or the government. It is expected that members exercise utmost confidentiality when they access sensitive or confidential information.

2. All committee discussions and decisions are confidential.

3. Any real or perceived conflict of interest must be declared to the committee through the Chairperson and Secretariat. All members, including the Chairperson, are responsible for identifying matters of a confidential nature.

Amendments of the Terms of Reference
The Terms of Reference shall be consulted from time to time, and reference will be made to it during discussions and other engagements. If modifications are required, the committee may amend these Terms of Reference by a basic majority vote.

Appendix 12:

Oath to be taken and signed by all members of the NGC

Before attending the first meeting, every member must sign the following oath:
"I solemnly declare that I shall perform my duties as a member of the Advisory Committee honorably, faithfully, impartially and conscientiously.

Subject to my responsibilities to the National Genomics Committee, I shall not disclose, even after the termination of my functions, any confidential or proprietary information or any other confidential information coming to my knowledge by reason of my duties as a member."

Full name: _____

Institution: _____

Signature: _____

Date: _____

Tenure of office: From .....To.....

Summary - Document Changes/Updates

Compared to the First Edition, the Second Edition is aligned to Africa CDC Pathogen Genomics Surveillance Policy Framework and contains

a) List of priority pathogens and use cases for genomic surveillance in Malawi and the region.

   Limited optimal sequencing capacity necessitates prioritization of pathogens and use-cases that have the highest local and regional public health impact. This approach also supports the sustainable integration of genomics into Malawi's Integrated Disease Surveillance and Response (IDSR) strategy.

b) Robust Monitoring and Evaluation of seven priority areas.

   The summary of the monitoring and evaluation matrix adheres to the conventional programmatic M&E structure, encompassing strategies, activities, indicators, baseline and target of each activity and the responsible institutions. The M&E plan is to establish a system that is robust, comprehensive, fully integrated, harmonized and well-coordinated to guide monitoring of the implementation of the plan and evaluate impact.

c) National Genomics Committee (NGC) comprising steering committee, advisory group and laboratories from public, private and academia.

   NGC will coordinate, guide and supervise the national response regarding the application of genomics in areas such as surveillance and monitoring of pathogen control programs. NGC under the One Health approach was proposed and constituted following a recommendation by senior management in the Ministry of Health in line with the Africa CDC Pathogen Genomics Surveillance Policy Framework.

Partners and Collaborators