



NATIONAL GENOMIC SURVEILLANCE STRATEGY FOR PRIORITY DISEASES/PATHOGENS

ISLAMIC REPUBLIC OF PAKISTAN

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Abbreviations and Acronyms

AJ&K	Azad Jammu and Kashmir
AMR	Antimicrobial Resistance
BSL	Biological Safety Level
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus disease 2019
DRAP	Drug Regulatory Authority of Pakistan
EOC	Emergency Operations Center
EQA	External Quality Assessment
GAP	Gap Analysis Program
GB	Gilgit Baltistan
GISAID	Global Initiative on Sharing Avian Influenza Data
GLASS	Global Antimicrobial Resistance and Surveillance System
HEC	Higher Education Commission
HIV	Human Immunodeficiency Virus
HR	Human Resource
ICT	Islamabad Capital Territory
IDIMS	Idaho National Engineering and Environmental Laboratory Data Integration Mediation System
IDSR	Integrated Disease Surveillance and Response
IPC	Infection Prevention and Control
IT	Information Technology
LIMS	Laboratory Information Management System
MB	Molecular Biologist
MeaNS	Measles Nucleotide Surveillance
RubeNS	Rubella Nucleotide Surveillance
MoU	Memorandum of Understanding
NAP	National Action Plan
NCBI	National Center for Biotechnology Information
NCOC	National Command & Operation Center
NGC	National Genomic Center
NGS	Next Generation Sequencing
M/o NHR&C	Ministry of National Health Services Regulations & Coordination
NIBSC	National Institute For Biological Standards and Control
NIH	National Institute of Health
PASS	Pakistan AMR Surveillance System
POE	Points of Entry
PPHRL	Provincial Public Health Reference Laboratory
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SOP	Standard Operating Procedure
SWOT	Strengths, Weaknesses, Opportunities, and Threats
TB	Tuberculosis
UKHSA	United Kingdom Health Security Agency
WHO	World Health Organization

Introduction

Genomic surveillance provides key evidence to demonstrate the potential of pathogen transmission and extent within the infected communities. This also helps to get insights into the initial introduction and local transmission events of pathogens. This critical role of genomics surveillance in investigation of outbreaks, epidemics and pandemics helps to devise response and develop strategies to track pathogen evolution and determine its impact on virulence, pathogenesis, transmission, diagnostics, and vaccine effectiveness. An effective genomic surveillance program should be efficient and make data publicly available in a timely manner to enable prompt decision-making by public health officials and vaccine manufacturers.

Pakistan is endemic for several infectious diseases and by developing and implementing a genomic surveillance strategy for priority diseases, it can strengthen the ability to control outbreaks, epidemics and pandemics as well as prepare for future public health threats. The National Institutes of Health (NIH) has established a genomic center that works closely with the national genomic consortium of SARS-CoV-2 comprising of laboratories/institutions located across the country (Annex-A). Building on the lesson learned from COVID-19 pandemic, there is a need to develop a national genomic surveillance strategy which focuses on all priority diseases with the aim to facilitate connectivity with other disease control programs and surveillance networks.

SWOT Analysis: GAP Strategic Objectives

The objectives outlined in the “*WHO Global Genomic Surveillance Strategy for Pathogens with Pandemic and Epidemic Potential 2022-2032*”¹ were used as a reference for conducting a SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis (Annex-B). A Technical Working Group of the National Institutes of Health (Annex-C) conducted discussions and deliberations based on these objectives to generate statements. The strategy was also reviewed by national genomic consortium of SARS-CoV-2 (Annex-D) and their inputs were added accordingly.

Objective 1: Improve access to tools for better geographic representation

Statements

- The M/o NHR&C in coordination with provincial health departments, is responsible for establishing a national genomic consortium for priority pathogens of Pakistan. The consortium should consist of representatives from the public and private sectors of all provinces and regions, including following professionals but not limited to:
 - Molecular Biologist
 - Microbiologist
 - Pathologist
 - Epidemiologist
 - Biostatistician
 - Veterinarian
 - Academician
 - technical expert from all PPHRL’s
- The national genomic consortium shall review and update the list of priority diseases of Pakistan and prepare list of priority pathogens.
- The consortium shall map existing pathogen genomic sequencing capacities in the country. Following components should be evaluated but not limited to:
 - Laboratory Infrastructure (Sequencing incl. NGS)
 - NGS Equipment
 - Bioinformatics infrastructure (equipment, software, data storage etc.)
 - HR
 - Data sharing mechanism
 - Needs for sustainability
 - Legislation
- The national genomic consortium should use the mapping results to identify and recommend the minimum sequencing capacity needed for real-time surveillance of priority pathogens at the national level, including provinces and regions such as

¹ <https://www.who.int/publications/i/item/9789240046979>

ICT/AJ&K/GB. The recommendations should consider geographical representativeness and decentralization.

- The national genomic consortium shall develop guidelines regarding the minimum testing volume using standardized assays required for genomic surveillance of priority pathogens.
- The national genomic consortium shall advocate and submit its recommendations to M/o NHR&C and provincial health departments for establishment and strengthening of genomic surveillance protocols.
- The M/o NHR&C and provincial health departments shall provide all the necessary support (including financial) for the establishment and sustainability of genomic sequencing facilities in view of the recommendations made by national consortium.
- The national genomic consortium will develop guidelines for genomic surveillance of priority pathogens in accordance with national laboratory policy and national laboratory biosafety and biosecurity policy.

Objective 2: Strengthen the workforce to deliver at speed, scale, and quality

Statements

- HEC and other relevant stakeholders should promote the inclusion of pathogen genomics, including NGS/bioinformatics, as a core subject at both graduate and post-graduate levels.
- The M/o NHR&C and provincial health departments should allocate relevant positions, such as bioinformaticians and molecular biologists, as needed to support pathogen genomics initiatives.
- Public and private sector institutions involved in pathogen genomics should develop in-service and pre-service training modules/programs and ensure that relevant staff are enrolled in these programs.
- Training modules/programs should be regularly reviewed and updated by the respective institutions.
- The M/o NHR&C and provincial health departments should maintain and regularly update a federal and provincial HR database for pathogen genomics, including information on NGS and bioinformatics training.
- EQA programs for pathogen genomics should be developed at the federal and provincial levels, with all genomics labs participating in national and/or international EQA programs.
- The national genomic consortium should establish a monitoring and evaluation committee to oversee the above matters.

Objective 3: Enhance data sharing and utility for streamlined local to global public health decision-making and action

Statements

- Public and private sector institutions involved in genomic surveillance of priority pathogens shall establish a MoU regarding data sharing.
- A national repository for uploading genomic data of all priority pathogens shall be developed and managed by the National Institute of Health.
- The national genomic consortium shall determine the minimum meta-data parameters required for each priority pathogen.
- Genomic and meta-data of all priority pathogens shall be deposited on national and global databases (such as NCBI, GenBank, GISAID, GLASS, etc.) in a timely manner and shared with relevant stakeholders on a regular basis. Guidelines for data sharing, backup, security, and confidentiality shall be developed by the national genomic consortium.
- The M/o NHR&C and provincial health departments shall provide resources and training on genomic data management to the institutes involved in genomic surveillance, in coordination with the national genomic consortium.

Objective 4: Maximize connectivity for timely value-add in the broader surveillance architecture

Statements

- Current platforms/networks shall be expanded to include pathogen genomics.
- The Integrated Disease Surveillance and Response (IDSR) system shall be expanded and implemented at all levels, including federal, provincial, and district levels, and shall include data from public and private sector labs/institutes.
- Targeted collaboration with One Health partners shall be established.
- A mechanism for public and private sector linkages shall be developed.
- A mechanism should be established to strengthen coordination with laboratories, Points of Entry (POEs), and relevant stakeholders for timely detection, identification, and reporting of introduction/importation of pathogens.
- An efficient specimen referral system shall be established.
- IT system infrastructure shall be established at all levels.

Objective 5: Maintain a readiness posture for emergencies

Statements

- The NGC shall formulate a national plan for preparing and responding to infectious diseases with epidemic and pandemic potential, with an emphasis on genomic surveillance. The plan should address, but not be limited to:
 - Governance
 - Assessment of genomic surveillance capabilities (infrastructure, human resources, financial resources, etc.) with a view to emergency preparedness and response
 - Planning for surge exercises/simulations
 - Coordination at national, provincial, regional, and international levels
 - Advocacy for the allocation of funds for genomic surveillance of pathogens (from federal and provincial health budgets) – Emergency Fund
 - Screening at POEs
- The technical and material resources required for enhanced molecular testing and sequencing capacity shall be continuously maintained in laboratories.
- Relevant stakeholders shall collaborate on joint projects to enhance the early warning alert response system, establish trust, and improve its functionality during emergencies.
- Periodic monitoring and evaluations or after-action reviews shall be introduced to continuously improve genomic surveillance within the public health surveillance architecture.
- A pre-defined mechanism shall be established to ensure regular supplies of testing materials.
- Surge plans shall be developed and implemented to manage increased demand for testing

ANNEX-A

National Consortium for Genomic Surveillance of SARS-CoV-2

S.No	Institute	Location
1	National Institutes of Health (NIH)	Islamabad
2	Institute of Biomedical & Genetic Engineering (IBGE)	Islamabad
3	University of Veterinary and Animal Sciences (UVAS)	Lahore
4	University of Health Sciences (UHS)	Lahore
5	PPHRL, Punjab AIDS Control Program (PACP)	Lahore
6	University of Karachi (UOK)	Karachi
7	National Institute of Blood Diseases (NIBD)	Karachi
8	Aga Khan University (AKU)	Karachi
9	Dow University of Health Sciences (DUHS)	Karachi
10	Khyber Medical University (KMU)	Peshawar
11	Abbasi Institute of Medical Sciences (AIMS)	Azad Jammu & Kashmir
12	Provincial Headquarter Hospital (PHQ)	Gilgit-Baltistan
13	Fatima Jinnah General & Chest Hospital- (FJGC&H)	Quetta

ANNEX-B

SWOT ANALYSIS

Objective 1: Improve access to tools for better geographic representation

Strengths	Weaknesses
<ul style="list-style-type: none"> • National Laboratory policy available • National Laboratory Biosafety & Biosecurity policy is available • National Laboratory Quality Standards are under review • National Strategic Framework for containment of AMR • Tiered level of labs is defined • Federal and provincial health care commissions functional • DRAP is regulating medical devices and testing material • Availability of genomics/bioinformatics facility at national and partially at provincial level • Availability of trained workforce for genomic surveillance at federal and partially at provincial level • Genomic data of some priority pathogens is available • SOPs/Protocols for the genomic surveillance of some priority pathogens available • Liaison with international collaborators for providing the resources for genomic surveillance of some priority pathogens • Mobile labs available to support outbreak investigations in remote areas 	<ul style="list-style-type: none"> • No national genomic consortium exists for all priority pathogens • Inventory of Labs (BSL-2 and BSL-3) at federal and provincial level is missing • Limited trained workforce and facilities at federal and provincial level • Limited resources/funding available for genomic surveillance at federal and provincial level • Lack of standardized training tool kit for genomic surveillance at federal and provincial level • Lack of coordination among stakeholders at federal and provincial level
Opportunities	Threats
<ul style="list-style-type: none"> • The genomic surveillance system established for COVID-19, Influenza, Polio, Measles, TB, HIV, Hepatitis etc. can be used as a platform for the genomic surveillance of other priority pathogens • Political commitment and realization towards pathogen genomic surveillance • Awareness and willingness of scientific community at national and provincial level on pathogen genomics surveillance • Funding and technical support available from donors and international organizations for capacity building of HR and infrastructure on genomic surveillance of some priority pathogens 	<ul style="list-style-type: none"> • Sustainability of human resource and funding for genomic surveillance

Objective 2: Strengthen the workforce to deliver at speed, scale, and quality

Strengths	Weaknesses
<ul style="list-style-type: none"> • Bioinformatics program for master and PhD is available in curriculum of universities • Trainings related to bioinformatics and NGS are conducted on and off • Skilled workforce (Molecular Biologists/bioinformaticians/Lab tech) developed during the COVID pandemic • Research towards genomics is being conducted by various private and public institutes • Staff trained on IPC at provincial/district level • Master trainers available for bioinformatics and molecular biology (NGS) • National EQA program for molecular testing of COVID-19 has been developed and has been rolled out to more than 150 labs by NIH 	<ul style="list-style-type: none"> • Partial skilled workforce for bioinformatics and NGS available at district/provincial level • Limited standardized trainings delivered on bioinformatics and NGS at all levels • Lack of national database/inventory of bioinformatician and molecular biologists available in the country • Lack of training programs at institutional level both for pre-service and in-service at all levels • No EQA programs available for NGS • Limited indigenous capacity available to develop the national EQA programs for all priority pathogens • Retention of skilled staff for NGS and Bioinformatics/Molecular Biology
Opportunities	Threats
<ul style="list-style-type: none"> • Political commitments and realization towards pathogen genomics • Awareness and willingness at federal and provincial level on genomics • Funding and technical support available from donors and international organizations for capacity building of HR on pathogen genomics • Master trainers available to conduct standardized cascade trainings on pathogen genomics 	<ul style="list-style-type: none"> • Sustainability of human resource, funding on pathogen genomics • Conflict of interest among stakeholders • Reluctance among staff to work in remote areas

Objective 3: Enhance data sharing and utility for streamlined local to global public health decision-making and action

Strengths	Weaknesses
<ul style="list-style-type: none"> • Availability of genomic data on international databanks (NCBI, GISAID etc.) for some priority pathogens, representativeness of different geographical locations of the country • Partial data sharing system exists for some priority pathogens (Influenza, Polio, TB, AMR, Measles, HIV, dengue etc.) • IDSR for surveillance of some priority pathogens is partially operational • LIMS functional at some health institutes at federal and provincial levels for some priority pathogens 	<ul style="list-style-type: none"> • No national genomic database available for priority pathogens • No integration of meta and genomic data at national and provincial level • Limited reporting of genomic surveillance data to health authorities for all priority pathogens • Lack of timely data sharing from provincial level to federal level and vice versa • Lack of guidelines for timely sharing of data for all priority pathogens • Lack of trust and ownership • Lack of standardized metadata guidelines at provincial and district level • Unavailability of legal agreements for data sharing at all levels • Limited resources/HR for data collection, storage, and analysis (including NGS data) • Unavailability of internet access in remote areas • Lack of monitoring and evaluation of genetic data quality uploaded to international databanks (GISAID, NCBI)
Opportunities	Threats
<ul style="list-style-type: none"> • Availability of international funding for data sharing • Availability of international guidelines for data management • Availability of international public repositories (NCBI, GISAID, MeaNS/RubeNS etc.) • Availability of training opportunities for public health related staff and students 	<ul style="list-style-type: none"> • Data security at all levels • Sustainability of resources • Misuse of genomic data

Objective 4: Maximize connectivity for timely value-add in the broader surveillance architecture

Strengths	Weaknesses
<ul style="list-style-type: none"> • NCOC/EOC platform is present at national level • IDSR and IDIMS, PASS, GLASS, for surveillance of some priority pathogens is partially operational • One Health platform for surveillance of some priority pathogens is partially available • WHO supported surveillance activities primarily during outbreak situations • Nation-wide network of vertical programs such as Malaria, TB, HIV etc. • The laboratory-based surveillance network for some priority diseases including COVID-19, Influenza, Polio, Measles, Rubella, Rotavirus, Typhoid, Cholera, Diphtheria, pertussis, and Hepatitis etc. • Networking with International Labs/Institutes such as CDC (USA), UKHSA, NIBSC (UK) WHO etc. 	<ul style="list-style-type: none"> • Lack of coordination between public and private sector/Institutes • Limited integration of surveillance data of priority pathogens at national level • Lack of coordination between Human, Animal and Environmental sectors • Lack of coordination between Lab and relevant POE staff • Specimen referral system • Limited infrastructure and Internet access in remote areas
Opportunities	Threats
<ul style="list-style-type: none"> • Connecting data between the existing surveillance system is more efficient than creating the new one • Knowledge and experienced gained during COVID-19 pandemic can be used to develop strategies for genomic surveillance of other priority pathogens • Engaging existing healthcare commission at provincial level • Expand existing collaboration between Animal and Human sector 	<ul style="list-style-type: none"> • Sustainability of resources • Conflict of interest among stakeholders • Transfer posting of trained workforce

Objective 5: Maintain a readiness posture for emergencies

Strengths	Weaknesses
<ul style="list-style-type: none"> • National Action Plan for COVID-19 • Pakistan preparedness and Response Plan COVID-19 • Federal and provincial public health reference laboratories are fully functional with genomic testing capacity • Existing platform of COVID-19 genomic surveillance • Existing network of laboratory surveillance programs can be utilized for any outbreak/ emergency • Some experience related to inter and after-action reviews gained during COVID-19, pandemic • Experience to deal with outbreak/epidemic of some priority pathogens including Dengue, Typhoid, Polio, Measles, pertussis, Cholera, Diphtheria and Influenza • Trained laboratory staff available 	<ul style="list-style-type: none"> • Lack of training modules and preparedness plan for outbreak situations • Lack of inventory of available resources included infrastructure, workforce, (equipment and reagents) • Non availability/ delayed adaptation of new technology at the time of emergency at all levels • No dedicated funds to respond to public health threats (esp. for genomic surveillance)
Opportunities	Threats
<ul style="list-style-type: none"> • Expand existing surveillance network for genomic surveillance • Outbreak response exercise available for polio can be adapted for other priority pathogens • Technical support available from global reference laboratories • Liaison with local experts in academia/ research institutes to support during emergency 	<ul style="list-style-type: none"> • Trained workforce shortage • Biosafety and biosecurity concern relevant to handling of infectious material during emergency • Delay in supply chain • Timely DRAP approval of testing material • Pre allocation of budget for emergency/ Outbreak response

ANNEX-C**List of participants in preparing initial draft**

S.No	Participants	Designation
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6	Afreenish Amir	Microbiologist AMR Project, NIH
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ANNEX-D

List of participants in reviewing initial draft

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4	Shah Jahan	Associate Professor, Center of Excellence in Biomedical Sciences	University of Health Sciences (UHS), Lahore
5	Hasnain Javed	Molecular Biologist	PPHRL, Punjab AIDS Control Program (PACP), Lahore
6	Ishtiaq Ahmad Khan	Assistant Professor, International Center for Chemical and Biological Sciences	University of Karachi (UOK), Karachi
7	Zahra Hassan	Professor, Department of Pathology and Laboratory Medicine	Aga Khan University (AKU), Karachi
8	Saeed Khan	Program Director Provincial Public Health Reference Lab	Dow University of Health Sciences (DUHS), Karachi
9	Yasar Yousafzai	Director Public Health Reference Laboratory	Khyber Medical University (KMU), Peshawar
10	Mumtaz Ahmad	Head of Pathology	Abbasi Institute of Medical Sciences (AIMS), Azad Jammu & Kashmir
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