



دائرة الصحة
DEPARTMENT OF HEALTH

POLICY ON GENOMICS

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ABOUT DEPARTMENT OF HEALTH (DOH)

The Department of Health (DOH) is the regulatory body of the Health System in the Emirate of Abu Dhabi and seeks excellence in Health for the community by regulating and monitoring the health status of the population. DOH defines the strategy for the health system, monitors and analyses the health status of the population and performance of the system. In addition, DOH shapes the regulatory framework for the health system, inspects against regulations, enforce regulations, and encourages the adoption of best practices and performance targets by all health service providers. DOH also drives programs to increase awareness and adoption of healthy living standards among the residents of the Emirate of Abu Dhabi in addition to regulating scope of services, premiums and reimbursement rates of the health system in the Emirate of Abu Dhabi.

The Health System of the Emirate of Abu Dhabi is comprehensive, encompasses the full spectrum of health services and is accessible to all residents of Abu Dhabi. The health system encompasses, providers, professionals, patients, Insurers and the regulator. Providers of health services include public and private services and the system is financed through mandatory health insurance (with the exception to Thiqa) and has three main sources of financing: Employers or Sponsors, the Government and Individuals. The Health Insurance scheme places responsibilities on any Insurer, Broker, Third Party Administrator, Health Provider, Employer, Sponsor (including educational establishments), Limited Income Investors and Insured Persons to participate in the Health Insurance Scheme.



Table of Content

1. Introduction	7
2. Purpose of This Policy	7
3. Scope	7
4. Vision, Goal and Guiding Principles.....	8
4.1. Vision	8
4.2. Goal	8
4.3. Guiding Principles.....	8
5. Policy Priorities, Objectives and Strategies.....	9
5.1. Priority 1: Application of genomics in health service delivery	9
5.2. Priority 2: Genomic data protection and sharing	9
5.3. Policy Priority 3: Research and innovation	10
5.4. Policy Priority 4: Resources for genomics	11
6. Implementation Arrangements	12
6.1. Institutional framework	12
6.2. Department of Health.....	12
6.3. Stakeholders.....	12
7. Enforcement and Compliance	13
8. Monitoring and Evaluation	13
9. Appendix – 1.....	14

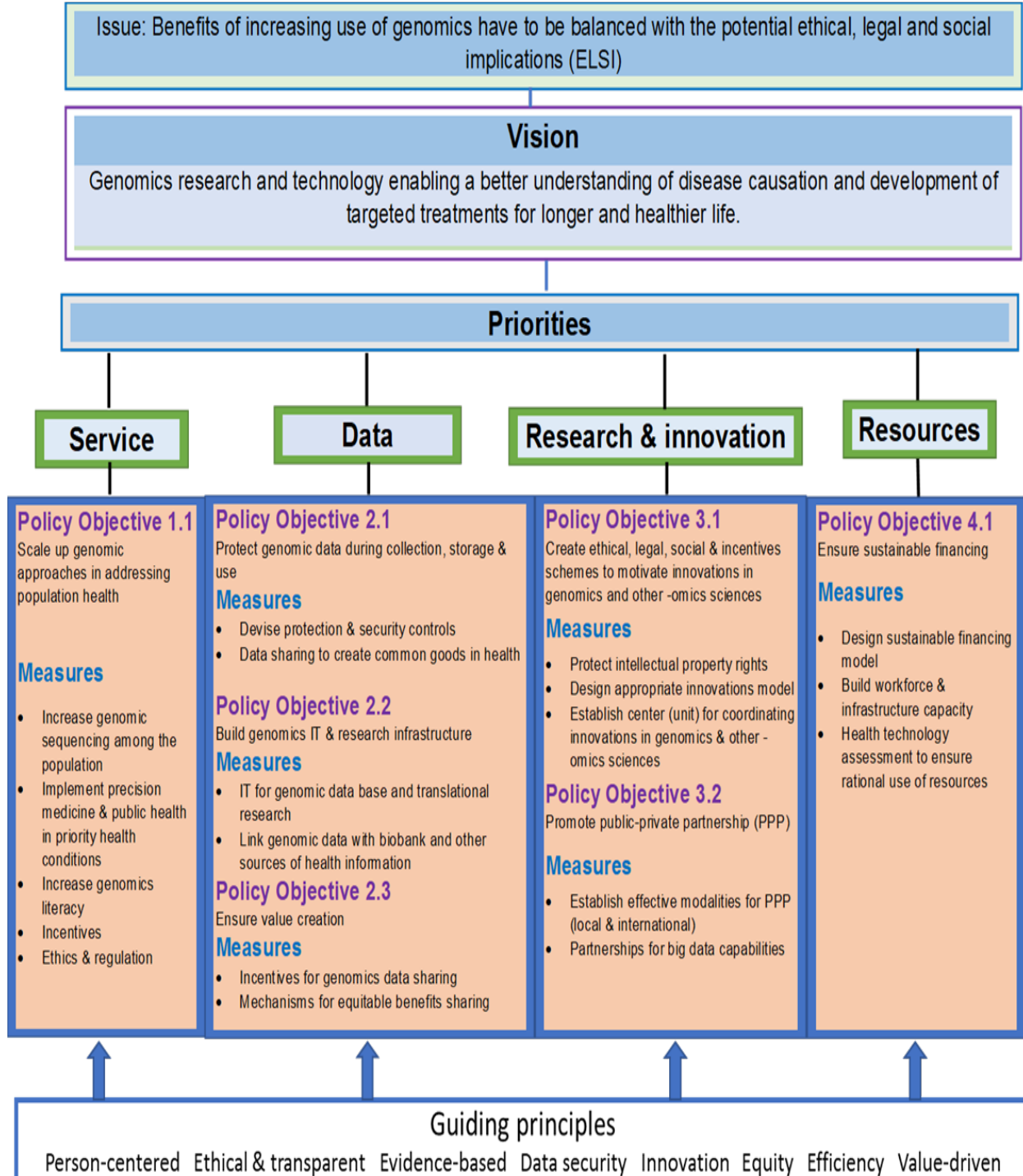


Glossary

Term	Definition
Biobank	Biobanks are generally large collections of human biological materials (biospecimens) linked to relevant personal and health information (which may include health records, family history, lifestyle and genetic information) and held specifically for use in health and medical research.
Clinical genomics	Using an individual patient's genotypic information in their clinical care.
Genome	A person's complete set of genetic material.
Human genomics	The study of the entire human genome and the corresponding large amounts of data generated from it.
-omics	A field of study in biology that ends with -omics, such as genomics, transcriptomics, proteomics, etc., which aims to detect, characterize and understand complete biologic molecules, often to give insights into disease pathways or processes.
Personalized medicine	Although used synonymously with precision medicine, currently "precision medicine" is the preferred term.
Precision medicine (PM)	The use of diagnostic tools and treatments targeted to the needs of the individual patient on the basis of genetic, biomarker, or psychosocial characteristics. PM does not imply the creation of medicines or devices that are unique to a patient, but rather ability to stratify individuals into groups that differ in their susceptibility to a specific disease or their response to a specific treatment.
Translational research	A type of research that aims to validate new genetic tools, assays and other analytical processes and to assess their clinical validity and utility before their introduction in the clinic.
ICT	Information and Communication Technology



Genomics Policy Framework





1. Introduction

Advances in genomics in the past few decades have transformed our understanding of human health and disease. After the first complete sequencing of human genome in 2003, technological advances have made it possible to analyze a person's whole genome with improved accuracy, shorter time and lower cost, generating a wealth of information that can be used to predict the risks of developing certain health conditions/diseases, develop targeted treatments and ultimately improve individual and population health outcomes.

However, despite the benefits that accrue from the developments in genomics, it raises important ethical, legal and social challenges. Much as sharing of genomic data has the potential to advance precision and personalized medicine, it also comes with privacy concerns for individuals and their relatives.

To maximize the benefits of genomics to patients, society and the economy of Abu Dhabi, appropriate laws, policies and guidelines on genomics research and applications should be in place and keep pace with the developments to ensure that opportunities are not missed. Moreover, it is imperative to have the necessary infrastructure in place in order to integrate genomics into the health system without compromising the risks associated with it.

In 2019, the Abu Dhabi Department of Health (DOH) in collaboration with locally based technology leader Group 42 and other international partners launched the Genome Program aimed at using large scale genomic data to improve the health and well-being of the population. Against this backdrop, it is necessary to formulate a policy that will facilitate utilizing the benefits of genomics without causing harm to the population and in a way that is tailored to the cultural context.

2. Purpose of This Policy

This policy outlines the vision, policy goals, strategic directions and governance requirements that provide the basis for harnessing use of genomic data and technologies to improve health outcomes and health system performance in an ethical, safe and secure way.

3. Scope

The scope of this policy includes the collection, storage and use of genomic information. This applies to all stakeholders including, healthcare providers, healthcare professionals, private entities involved in genomics research and development, government entities, academic institutions, researchers, scientists and individuals providing their genomic data.



4. Vision, Goal and Guiding Principles

4.1. Vision

Genomic research and technology that enable a better understanding of disease causation and development of targeted treatments leading to longer and healthier life.

4.2. Goal

Genomic data will be used widely in a responsible manner to address priority health issues.

4.3. Guiding Principles

The following are the principles underpinning the policy focus:

1. **Personalized:** genomic research and technology should be tailored to the needs of the person and society taking into consideration the cultural context.
2. **Ethical and transparent:** genomic knowledge should be applied taking into consideration ethical, legal and social implications (ELSI).
3. **Evidence-based:** the application of genomics in health care is based on sound research and knowledge.
4. **Data security:** genomic data should be appropriately secure and de-identified.
5. **Innovation:** genomics data and technologies should advance the discoveries of new treatments and diagnostic methods that will improve individual and population health.
6. **Equity:** all parties should have a fair share of benefits from shared genomics data.
7. **Efficiency:** genomic knowledge and tools should deliver benefits that will improve health system efficiency.
8. **Value-driven:** value creation should drive research and development in genomics.



5. Policy Priorities, Objectives and Strategies

5.1. Priority 1: Application of genomics in health service delivery

<p>Policy Statement</p> <p>Genomics shall be incorporated into practice to deliver personalized effective continuum of healthcare services in an equitable and efficient manner.</p>
<p>Policy objective 1.1</p> <ol style="list-style-type: none"> 1. Scale up genomic approaches to establish a genomic database of the Emirati and non-nationals residing in Abu Dhabi
<p>Measures</p> <ol style="list-style-type: none"> 1. Increase genomic sequencing among the population. 2. Implement precision medicine and public health initiatives for priority health conditions. 3. Increase population's literacy in genomics to facilitate engagement and informed participation. 4. Incentivize research, innovations and investments in cost-effective genomic applications in health care. 5. Ensure that necessary ethical principles, guidelines and regulations are in place to protect the population from any potential harm. 6. Utilize genetic information to improve the Diagnosis, treatment and prevention of Diseases Such as cancer, rare and metabolic diseases and the application of genetic information in patient care like pharmacogenomics.

5.2. Priority 2: Genomic data protection and sharing

<p>Policy Statement</p> <p>Genomic data shall be collected, stored and used responsibly and ethically for its intended purposes and to create value to the person/population.</p>
<p>Policy objective 2.1</p> <p>Ensure protection of genomic data in its collection, storage and use.</p>
<p>Measures</p> <ol style="list-style-type: none"> 1. Include the governance and consent process with patients as the collected data will be part of the research data base. 2. Devise appropriate controls to keep genomic data protected and secure during its entire lifecycle including collection, storage, processing, analysis, sharing, use and disposal. 3. Facilitate genomic data sharing for the purpose of creating common good in health



4. Data ownership belongs to the UAE government, all research data will be shared according to designated security levels, according to the stakeholder's role, data security laws and research related laws in the country (Appendix 1).

Policy objective 2.2

To ensure quality of genomic data, stakeholders must put measures minimize data quality issues in addition to Adhere to the national and local information securities regulations, for that providers must build the necessary IT and research infrastructure that protects genomic data while harnessing its benefits and mitigating its potential risks.¹

Measures

1. Refine data in order to avoid data quality issues that can stem from duplicate data, inaccurate data, incomplete data, different data formats, or the difficulty accessing the data.
2. Mandatory fields for ID's number with specific format within an electronic form in order to ensure safety of data
3. Establish needed IT facilities for genomic database and translational research.
4. Install IT systems to link genomic data with other available sources of health information currently available including biobanks and electronic medical records

Policy objective 2.3

Ensure that value is created from shared genomic data and benefits the person/population, innovators and all other relevant stakeholders equitably.

Measures

1. Introduce an incentives scheme to motivate sharing of genomic data.
2. Data can be shared for research (Basic/Clinical Trials) purposes after acquiring appropriate approval or authorization from Abu Dhabi Health Research and Technology Committee

5.3. Policy Priority 3: Research and innovation

Policy Statement

Appropriate measures shall be implemented to stimulate genomics-driven innovation considering the ethical, social and legal issues involved.

Policy objective 3.1

Create appropriate ethical, social, legal and incentive schemes conducive for health/health system innovations based on genomics and other -omics sciences.

¹ For example: No legal implications or regulation have been spoken about nor taken into consideration in this section that could create a strong framework on data protection.



Measures

1. Devise mechanisms for the protection of intellectual property rights to encourage private research and development (R&D).
2. Design appropriate innovations model to fast track translation of genomics discoveries for the prevention, diagnosis and treatment of diseases.
3. Establish a center (unit) for the coordination of innovations in genomics and other - omics fields.

Policy objective 3.2

Promote public-private partnerships to support research and innovation in genomics.

Measures

1. Establish modalities for effective public-private partnership (local and international) including funding for research and innovation in genomics.
2. Develop partnerships to harness big data capabilities to deliver precision/personalized medicine and public health.

5.4. Policy Priority 4: Resources for genomics

Policy Statement

Adequate financial and human resources shall be mobilized to promote cost-effective genomics research and innovation.

Policy objective 4.1

Ensure sustainable financing to promote research & development in genomics and applications to improve population health.

Measures

1. Design a sustainable financing model to raise needed resources.
2. Build workforce and infrastructure capacity.
3. Ensure availability of health technology assessment capabilities to ascertain that innovations developed are cost-effective and demonstrate rational use of scarce resources



6. Implementation Arrangements

6.1. Institutional framework

This policy recognizes the DOH's stewardship role of providing strategic leadership, coordinating and fostering partnerships among the various stakeholders, and monitoring and evaluating implementation to safeguard the population's well-being and enhance performance of the health system. Successful outcomes will depend on the collaboration of and synergy among all stakeholders including government entities, public and private healthcare providers, insurance companies, academia and research institutions, data science and ICT organizations, non-governmental entities and individuals who are the primary source of the shared data. The inter-dependent roles played by the different actors are outlined below.

6.2. Department of Health

The DOH shall ensure:

- that the required ethical, social, secure and legal frameworks are in place to facilitate genomic data collection, storage and use and its protection.
- the performance of suitable risk assessment procedures of the potential harms associated with precision medicine and genomics and taking necessary precautions to mitigate those risks;
- availability of the necessary workforce and infrastructure for genomic research and innovation.
- scaling up of genomic sequencing in Abu Dhabi.
- that literacy in genomics is increased among the population.
- that genomic data is used for improving health of the population and health system performance.
- equitable sharing of benefits of genomic research among all parties.
- establishment of public-private partnerships to foster collaboration in genomics financing & R&D.
- that efficient innovation models are in place to speed up use of genomic discoveries.
- protection of intellectual property rights to encourage private research and innovation in genomics; and
- that the cost-effectiveness of genomic technologies is assessed through appropriate health technology assessment.
- Develop an appropriate action plan that involves all stakeholder's engagement

6.3. Stakeholders

Private stakeholders including individuals and other public entities shall collaborate with the DOH in promoting genomics and its applications to improve the health of the population and performance of the health system. Among other things, this collaboration includes collection of genomics information, R&D and financing.



7. Enforcement and Compliance

All DOH-licensed healthcare service providers, insurers and other participating stakeholders must comply with the terms and requirements of this Policy. DOH may impose sanctions in relation to any breach of requirements under this Policy in accordance with the Complaints, Investigations, Regulatory Action and Sanctions Policy, Healthcare Regulator Manual.

8. Monitoring and Evaluation

A monitoring and evaluation framework will be developed to monitor and evaluate the effectiveness of this Policy, and where necessary adopt changes to ensure continuous improvement within the health system.

9. Appendix-1

Data flow diagram

