



Human Rights

Eight Guiding Principles for the Digital Transformation of the Health Sector
Digital transformation toolbox

Policy Overview

ORGANIZATION, COORDINATION, AND DEVELOPMENT

Department of Evidence and Intelligence for Action in Health (EIH) of the Pan American Health Organization (PAHO), in collaboration with the Center for Implementation and Innovation in Health Policy (CIIPS), part of the Institute for Clinical and Health Effectiveness (IECS) of Argentina, a PAHO collaborating center.

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Abstract

Human rights constitute one of the eight guiding principles for the digital transformation of the health sector promoted by the Pan American Health Organization (PAHO). This policy brief presents key concepts, recommended lines of action, and monitoring indicators, with the objective of advancing human rights.

According to its PAHO definition, this principle is intended to “**mainstream human rights in all areas of digital transformation in health**”:

Ensuring the protection of human rights in digital health requires a thorough review of legal instruments related to the health sector. The individual and social dimensions of human dignity constitute one of the fundamental values of the digital transformation process, along with the environment in which people live. To be fair and equitable, a regulatory framework must be free of any geographic, educational, cultural, political, religious, or gender bias (1).

It is undeniable that technology has immeasurable potential to transform health care, especially in terms of access for the most neglected, impoverished, vulnerable, and remote communities.

However, these technological advances do not always reach the groups that need them most. We must not lose sight of the true goal of digital health: to contribute to achieving universal health coverage aimed at reducing inequities and enabling all people, without distinction of such factors as race, gender, creed, geography, or socioeconomic levels, to access the benefits provided by technological platforms.

Therefore, when planning a digital health agenda, it is essential to safeguard the protection of human rights. Progress in achieving this goal requires a thorough review of the legal instruments that affect the health sector.

It is necessary to ensure that the digital transformation of the health sector is accomplished in the short term, in an inclusive manner, and without violating people’s rights, while ensuring that these advances are distributed equitably and generate greater benefits in the most disadvantaged communities. Human rights violations are undoubtedly factors that adversely affect the physical, mental, and social well-being of all people.

This policy brief addresses the main gaps for the implementation of this guiding principle, and proposes lines of action and monitoring indicators associated with these actions. It ends with a set of recommendations for their implementation.

Keywords: *digital health, human rights.*

Introduction

Human rights constitute one of the eight guiding principles for the digital transformation of the health sector promoted by the Pan American Health Organization (PAHO). This policy brief presents key concepts, recommended lines of action, and indicators for monitoring, all with the objective of advancing human rights.

According to the PAHO definition, this guiding principle is intended to “**mainstream human rights in all areas of digital transformation in health**”:

Ensuring the protection of human rights in digital health requires a thorough review of legal instruments related to the health sector. The individual and social dimensions of human dignity constitute one of the fundamental values of the digital transformation process, along with the environment in which people live. To be fair and equitable, a regulatory framework must be free of any geographic, educational, cultural, political, religious, or gender bias (1).

The United Nations defines human rights as those rights “inherent to all human beings, regardless of race, sex, nationality, ethnicity, language, religion, or any other status. Human rights include the right to life and liberty, freedom from slavery and torture, freedom of opinion and expression, the right to work and education, and many more. These rights belong to all persons, without any discrimination” (2).

Advances in digital health can create challenges in terms of privacy and personal data security, putting the fulfillment of human rights at risk and exacerbating inequalities, stigma, and discrimination processes.

It is undeniable that information and communication technologies (ICTs) have immeasurable potential to transform health care, especially regarding the access of the most neglected, impoverished, vulnerable, and remote communities.

However, these technological advances do not always reach the groups that need them most. According to a report by the International Telecommunication Union (ITU), the United Nations specialized agency for ICTs, in 2019, approximately three billion people worldwide, nearly half of the global population over 10 years of age, had never used the internet (3).

Even when these groups do gain access to online technologies, privacy and security issues can exacerbate stigma and discrimination. According to the Director of the HIV and Health Group at the United Nations Development Programme (UNDP), “Between 2016 and 2017, there were over 1,300 recorded incidents of protected health information data breaches in 27 countries. Leaking this type of information can threaten the safety and wellbeing of vulnerable groups, such as people living with HIV, especially in the 75 countries around the world that criminalize HIV non-disclosure” (4).

We must not lose sight of the true goal of digital health: to contribute to achieving universal health coverage aimed at reducing inequities, enabling everyone to access the benefits provided by technological platforms. A similar idea was already expressed as early as 1946 by the Member States of the World Health Organization (WHO), when they agreed on a fundamental international principle, by virtue of which “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition” (5).

In 2007, the Ministries of Health of the Americas recognized that human rights rank among the “principles and values” of their Health Agenda for the Americas, and that in order to realize the right to the enjoyment of the highest attainable standard of health “countries should work toward achieving universality, access, integrity, quality and inclusion in health systems that are available for individuals, families, and communities” (6).

Therefore, when planning a digital health agenda, it is essential to ensure the protection of human rights. To advance this objective, a thorough review of the legal instruments related to the health sector must be conducted.

The individual and social dimensions of human dignity constitute one of the fundamental values of the digital transformation process, along with the environment in which people live. To be fair and equitable, the regulatory

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framework must be free of any geographical, educational, cultural, ethnic, political, religious, or gender bias.

For all these reasons, it is necessary to identify the current challenges for mainstreaming human rights

into all areas of digital transformation in health, and to identify the priority actions to be implemented and indicators necessary for adequate monitoring of the fulfillment of these objectives.

Current status and identification of gaps

Internet access is increasing worldwide but remains higher in higher-income economies and countries. According to the Special Report published by the Economic Commission for Latin America and the Caribbean (ECLAC) (7), in the Region of the Americas, 66.7% of the population had access to internet services in 2019, while “the remaining third have limited or no access to digital technologies owing to their economic and social condition, in particular their age and location.” A clear example of this situation is that 67% of urban households in the Region are connected to the internet, whereas in rural areas, only 23% of households are connected.

According to a survey conducted by the Organization for Economic Co-operation and Development (OECD) on health data infrastructure and governance in the 23 OECD member countries, there is a wide disparity among them in terms of health data use and governance (8). Although a rising number of countries are adopting digital solutions with security and quality standards, few have policies and practices in place to protect the privacy and security of health data and to encourage the development, use, accessibility, and sharing of national health datasets for statistical use and for clinical and academic research. In addition, there is a striking absence of evidence such as that resulting from this survey in the countries of the Region, so it is important to carry out local studies.

Moreover, according to a 2018 OECD study, the health sector invests less in ICTs compared to other sectors of the economy (9). Achieving successful digital transformation in the health sector, in addition to innovation and technological change, requires adapting and updating human attitudes and skills, work processes, and organization, as well as the legal and financial frameworks regulating the digital realm. Although digital technologies do not, by themselves, have the capacity to transform the health sector, they do provide

a number of tools and offer many potential benefits to health workers and patients.

During the coronavirus disease (COVID-19) pandemic, digital solutions were essential to accessing the necessary information to understand the situation and make decisions. However, in some cases, these same digital solutions and platforms were used to undermine citizens’ trust and to disseminate invalid or inaccurate content, which promoted uncertainty about prevention measures and recommendations from international experts, and even strategies implemented by governments to mitigate the impact of the pandemic. In this regard, States and international bodies had to formulate communication strategies aimed at combating the impact of such content.

Moreover, to achieve the digital transformation of the health sector, current legal and ethical frameworks must be reviewed in light of criteria and policies that consider the wide variety of issues that can affect respect for human rights and guarantees, including the following:

- Protecting the dignity of health system users, especially those who may suffer higher levels of stigma and discrimination
- Empowering health workers and enhancing their benefits, which makes processes more efficient and improves the effectiveness of interventions
- Providing adequate safeguards against possible lack of transparency or threats to the privacy of the data of patients and other users, as well as health workers

- Guaranteeing the reliability and transparency of information and data and access to public information, within the framework of citizens' right to access all information about actions carried out by government bodies using public funds

In the Region of the Americas, regulatory development has been uneven. Some countries, such as Colombia and Venezuela, consider this issue in their constitutional frameworks, while other countries, such as Argentina, Brazil, Chile, Paraguay, Peru, and Uruguay, have passed specific laws on personal data protection.

The challenge of digital transformation in health requires focusing efforts on how to better exploit the potential benefits of ICTs, with full respect for and promotion of human rights.

Lines of action

To mainstream human rights in all areas of digital transformation in health, and following the PAHO guiding principles (10, 11, 12) and the recommendations provided by the experts consulted, the following lines of action are proposed:¹

1. HIGHLIGHT THE UNDERLYING LEGAL PRINCIPLES REGARDING CITIZENS' PROTECTION AND SECURITY, BASED ON HUMAN RIGHTS, EQUITY AND EQUALITY IN ACCESS TO HEALTH, AND TRANSPARENCY

Here, it is necessary to conduct a diagnosis of the current comprehensive legal framework to ensure that these aspects are addressed explicitly in the body of regulations.

The advocacy of these principles in the legislative agenda, with the support of the different sectors and government and non-government stakeholders concerned, is a necessary condition for their sustainability over time.

2. CREATE APPROPRIATE REGULATORY INSTRUMENTS THAT CONSIDER THE PUBLIC INTEREST REGARDING INDIVIDUAL AND BIG DATA IN HEALTH CARE, SEEKING A BALANCE BETWEEN PROTECTING PUBLIC HEALTH AS A SOCIAL GOOD AND THE SENSITIVE DATA OF INDIVIDUALS, AS WHEN REPORTING TECHNOLOGIES IN EPIDEMIOLOGICAL SURVEILLANCE

A comprehensive review of the existing regulations is necessary to identify gaps and lack of regulation regarding specific issues in both the public and private sectors.

It is essential to have an updated legal framework that facilitates the development of activities promoting digital transformation in health, including such actions as innovation and research and the development of new digital tools that are safe, reliable, and accessible to citizens, public institutions, and private sector stakeholders.

3. CONFIRM WITH SCIENTIFIC DATA THAT THE BENEFITS OF DIGITAL HEALTH OUTWEIGH THE RISKS TO INDIVIDUAL RIGHTS AND FREEDOMS, MAINLY DURING PUBLIC HEALTH EMERGENCIES

Digital transformation measures can safely and effectively facilitate the assessment, diagnosis, and management of health issues, thereby furthering greater equity in access to timely care.

Governments must guarantee funds for conducting studies on the results and impact of the implementation of public policies aimed at digital transformation in general and in the health sector specifically, and for the systematic analysis of their benefits and risks to the population.

The generation of evidence is critical to furthering digital transformation and the benefits of investment to achieve it.

4. ENSURE THE RIGHT TO VERIFICATION, VALIDATION OF ALGORITHMS, AND EVALUATION OF DIGITAL TECHNOLOGY IN TERMS OF SAFETY, EFFECTIVENESS, AND SUSTAINABILITY

¹ On 23 November 2021, together with PAHO, an asynchronous policy dialogue was convened to advance the implementation of the roadmap for the digital transformation of the health sector in the

Region of the Americas. The participating experts identified points of reference for the topics addressed by the guiding principles.

It is essential to create governmental bodies (or to attribute relevant functions to existing bodies) to determine the following: applicable standards for interoperability; data security and integrity; validity of electronic records in general, and of health information and data specifically, and of electronic prescriptions; practices and services conducted on telehealth platforms; and certification bodies.

5. SAFEGUARD FUNDAMENTAL RIGHTS AND FOSTER THE DEVELOPMENT OF NATIONAL AND REGIONAL REGULATORY FRAMEWORKS THAT REGULATE POTENTIAL CONFLICTS OF RIGHTS. INTERNATIONAL ORGANIZATIONS AND NATIONAL AND SUBNATIONAL GOVERNMENTS MUST ADDRESS, TOGETHER WITH CIVIL SOCIETY, THE IMPROVEMENT OF INTERVENTION CAPACITIES AND HEALTH STRATEGIES, THROUGH THE VALIDATION OF PROCESSES LINKED TO DIGITAL HEALTH

Not only governments have a major role to play in this regard: Multilateral and regional agencies, such as WHO/PAHO, should continue to advocate digital transformation through technical assistance, fostering exchange between countries and regions, and monitoring progress toward this goal.

Stakeholder mapping is essential to update and modernize legal frameworks to be sustainable and to consider the roles and responsibilities of all public, private, and civil society stakeholders.

6. PROMOTE THE DEVELOPMENT OR MODERNIZATION OF SUSTAINABLE LEGISLATIVE ECOSYSTEMS IN DIGITAL HEALTH, ESPECIALLY REGARDING LAWS ON ACCESS TO PUBLIC INFORMATION, ENSURING THE PRIVACY OF CITIZENS' SENSITIVE DATA, WITH THEIR EXPRESS CONSENT

Regional, national, and local regulatory systems need to be modernized and adapted, incorporating digital health and ensuring its sustainability. This includes laws on access to public information that also have mechanisms to safeguard citizens' data and private information, and which address the issue of individuals' express consent regarding their use.

One of the specific actions that can contribute to this is to have available recent evaluations of the regulations, conducted by teams of experts, that identify where they need updating.

Monitoring indicators

To advance the mainstreaming of human rights in all areas of digital transformation in health, the following indicators are proposed. It is important to clarify that this is not an exhaustive list, but that each country or region can incorporate other indicators and define the necessary level of disaggregation and frequency of measurement.

CROSS-CUTTING INDICATORS OF THE EIGHT GUIDING PRINCIPLES FOR DIGITAL TRANSFORMATION IN HEALTH

- A national digital health strategy established through a regulatory framework
- A governmental organization structure to lead the digital transformation in health strategy
- A budget for a digital agenda that includes human resources and the necessary technology

SPECIFIC HUMAN RIGHTS INDICATORS FOR EACH LINE OF ACTION

1. Highlight the underlying legal principles regarding citizens' protection and security

- Diagnosis of the current comprehensive legal framework to identify explicit references in the body of regulations on principles of citizen protection and security

2. Create appropriate regulatory instruments that consider the public interest regarding individual and big data in health care

- Computer security and personal data protection instruments in the information and registration systems in force

3. Confirm with scientific data that the benefits of digital health outweigh the risks to individual rights and freedoms

- Number of results and impact studies and risk/benefit analyses on the implementation of public policies for digital transformation in the health sector
- Indicators on access of the population to health services and their quality, and on equity

4. Ensure fundamental rights and foster the development of national and regional regulatory frameworks that regulate potential conflicts of rights

- Governmental bodies (or the attribution of relevant functions to existing bodies) that determine the applicable standards for interoperability; data security and integrity; validity of electronic records in general, and of health information and data in particular, and of electronic prescriptions; and practices and services conducted on telehealth platforms

5. Promote the development or modernization of sustainable legislative ecosystems in digital health, especially regarding laws on access to public information

- Instruments for monitoring access to human rights in national and supranational regulatory frameworks

General recommendations

Ensuring the protection of human rights in the context of digital health requires a thorough review of legal instruments related to the health sector. Legislation should be aimed at ensuring health coverage for the most vulnerable populations and disadvantaged groups. This regulatory compendium must be governed by the principles of modern and open government, being accessible to citizens, health professionals, and service providers, in order to avoid legal cases in this area that could prevent the normal development of digital health policy.

Governments must have rules that establish control mechanisms for applications linked to the collection of health data. It is also necessary to have rules that guarantee data security and individual privacy. This is of vital importance, especially in those countries or jurisdictions where a complex legislative consensus is required. Agreements between countries and jurisdictions, in those countries with autonomous regulatory systems, are critical when it comes to developing a standardized and symmetrical regulatory ecosystem in digital health that respects ethical values and human rights.

Furthermore, institutional coordination efforts are required to implement sustainable digital health policies that do not lose sight of the principles of equality, solidarity, equity, and accessibility. An adequate and systematized legal framework must be generated, based on the compatibility of the different legal systems involved.

It is also essential to raise public awareness regarding the concept of personal data protection, and provide training to all public and private stakeholders in the provision of digital health services, such as business professionals, health workers, and the public. The ultimate goal here should be the genuine involvement and consent of patients, laying the foundation for trust and security regarding their data privacy, and ensuring government protection against malicious or inappropriate use of their data.

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