Quality and Governance Framework for the National Telemedicine Network in Greece

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Abstract—**This study examines the quality and patient safety dimensions of telehealth with regard to existing standards and regulative provisions aiming to the development of a standard practice framework for the National Network of Telemedicine in Greece. The main purpose of the Greek National Telemedicine Network (EDIT) is to improve healthcare access in Greece, especially on isolated islands and distant mountainous regions. The expansion of EDIT network currently, foresees the establishment of a significant number of new telemedicine stations and the installation of home-care units. This signifies the progression of the system and the growing level of coverage of the population and the provision of services at a larger scale. The present study focuses on the determination of the preconditions, operational rules, elements of the governance framework, and the functional specifications of EDIT as a regulative basis to be established in Greece. Moreover, this work aims to support the implementation of tele-health services in the country by safeguarding all quality aspects of the service including the safety and experience of the user as well as the adequacy of the applied resources. The examined set of prerequisites and quality criteria revealed essential adjustments to the current regulative framework and the ethical code of practice for healthcare professionals in Greece.**

Keywords-e-health; telemedicine; framework; healthcare; Greek national telemedicine network.

I. INTRODUCTION

The application of information technology at the level of health and social care provides nowadays the possibility of comprehensive support and monitoring of both chronic patients and those with low-prevalence diseases, while at the same time promoting the culture and knowledge of prevention and public health. However, financial issues are not the only challenge. Inequalities in access to health resources and structures are evident even among citizens of the same country and health system. In many cases, telehealth and telemedicine services can keep those in need of medical care safely at home and out of hospitals or clinics, providing timely access to diagnosis and treatment, and monitoring chronic problems on a systematic basis [1]. Telehealth does not imply an increase in the quantity of healthcare services offered, but rather the provision of more streamlined and efficient services by healthcare practitioners. Adopting telehealth can present difficulties, but it is undoubtedly achievable [2].

More recently, telehealth has been intensively proposed as a tool to improve the efficiency of health services, as it allows the sharing and coordination of resources that are geographically distant or the redesign of health services to optimize the use and management of available resources (human and logistical).

There is a changing trend in healthcare delivery towards more personalized and patient-focused solutions, through technological advancements, which will provide a significant opportunity to increase healthcare access, particularly in underserved or rural regions, and for individuals who may encounter obstacles in accessing conventional health services.

Responding to these challenges, the Greek Ministry of Health has been investing in the expansion of the National

Telemedicine Network, particularly to extend healthcare coverage of the isolated islands and rural mountainous regions, and other inaccessible areas, fulfilling its constitutional mandate of providing equal healthcare access to all citizens, regardless of their location of residence.

Greece's National Telemedicine Network (EDIT), currently, consists of:

- 66 Patient- Doctor Telemedicine Stations (PDTS) located in hospitals, health centers, and multipurpose regional clinics
- 21 Consultant Telemedicine Stations (CTS) are located in 12 Regional Hospitals and tertiary hospitals within the 2nd Greek Health Region (HR) and the National Emergency Centre (NEC)
- More than 170 Home Care Stations (HCS), which are situated in the homes of in-patients or social care facilities inside the 2nd Greek HR's international boundaries.

Additionally, the existing system will be upgraded in the 2nd HR to include more regional equipment and subscription services. Some of the additions are the following:

- Three hundred and fifty-five new Patient Doctor Telemedicine Stations - PDTS - will be placed in particular Health Facilities nationwide.
- Thirty-five new Telemedicine Consultant Telemedicine - CTS will be placed in designated Health Facilities. CTS stations are categorized based on space availability data and operational requirements of each Health Facility.
- Five Telemedicine Training Stations with CTS and PDTS features will serve as training centers for new system users and will be placed in University Hospitals nationwide.
- Home Monitoring Systems - HCS: 3,000 units with direct communication with the EDIT and related software.
- Three new regional Control Centers and one Command & Control Centre at the Ministry of Health.

Teleconsultation services in Greece during the period 2016 to 2023 showed a notable increase in mental health services, and more specifically, telepsychiatry sessions were the most common type of teleconsultation, followed by telepsychiatry for children, diabetology-related consultations and teleconsultations for chronic disease management [1].

In addition, it is proven that telemedicine services in Greece are progressing and offer a valuable chance to enhance healthcare accessibility, especially in underserved or isolated regions, and for individuals facing barriers to traditional health services [2]. An important prerequisite for EDIT to meet its purpose and operational goals is the adoption of appropriate rules and conditions to achieve quality results and desirable clinical outcomes.

In the aftermath of the COVID-19 pandemic, the World Health Organization (WHO) published a study, with the aim of understanding the evolution of digital health, including the physical and technical characteristics of the infrastructure that supports it, its promotion and utilization, and the barriers that may hinder its widespread adoption [3].

The study concludes that in response to the outbreak of the pandemic, an increasing number of countries are developing organized and systematic telemedicine services. Simultaneously, they are proceeding with the implementation of regulatory interventions with relevant legislation or strategies aiming to create conditions for the sustainable and quality provision of wide-ranging telehealth services. Sixty percent (60%) of Member States stated that their telemedicine services have improved due to the pandemic, while 59% of Member States have issued new relevant legislation, strategy, policy or guidelines to support the provision of telehealth services [3]. The area that requires more focus is the evaluation of the services provided in terms of efficiency criteria and the systematic planning of resources and financing of telemedicine services to ensure their uninterrupted and sustainable operation [3]. The contribution of this study is to examine the quality and patient safety dimensions of telemedicine by analyzing existing standards and regulations integrated into a practice framework that meets quality, operational, and user safety objectives in a unified approach. The remainder of this study is organized as follows. Section II presents the methodology for developing the operational quality requirements for the National Telemedicine Network in Greece. The Code of Practice is presented as a baseline in accordance with the multidimensional model for telehealth. In addition, relevant international standards are used to select complementary specifications to cover all functional, technical, resource-related, and procedural areas. In section III, the main results of the previous analysis are elaborated, concluding with the proposed quality framework with the requested criteria and conditions to be applied for the deployment of EDIT. Finally, section IV discusses digital health initiatives and challenges, while section V concludes the study with future steps and objectives.

II. METHODOLOGY

The study carried out by the scientific team and the collaborators of the University had as a main goal to formulate a proposal for the minimum requirements and specifications that the regulatory framework in Greece should adopt, with the aim of applying quality and safety criteria to the expanded operation of the National Telemedicine Network in Greece.

To develop the appropriate requirements, the existing framework of the Code of Good Practice for telehealth services at the European and at international level was reviewed, and all the individual dimensions of quality and safety for health services for telemedicine as defined in the literature were analyzed. On this basis, relevant standards published by the International Organization for Standardization (ISO) and international healthcare accreditation bodies were examined for all quality aspects and functional dimensions through a scientific review. The unique perspective of this study is its integrated approach. While the reference framework examined (international standards,

regulatory requirements, ethical codes) focuses on specific areas of telemedicine, the aim was to go beyond the provisions of the codes of practice to cover safety, person-centeredness, effectiveness, resource competence, and ethical dimensions in a unified manner. In addition, governance aspects for the sustainable development and operation of EDIT were considered, and key roles and responsibilities across the network were incorporated into the proposed framework. Based on this research, the specifications and operational goals developed as the essential prerequisites at an organizational-technical-functional level. The relevant provisions also included requirements concerning the human factor both in terms of the competence of the healthcare professionals providing telehealth services and in relation to the engagement of the beneficiaries (citizens, patients, caregivers). The synthesis of all the above-mentioned provisions was conducted by using the multidimensional model of telehealth [4].

A. Multidimensional Model

Telehealth is supported by a complex business operation involving a set of multi-layered socio-political, economic, organizational, professional, cultural, human, legal, technological and strategic factors. It is therefore very important that all these factors are considered collectively when planning, implementing, developing and evaluating telehealth services, which requires numerous changes and transformations at the micro, meso- and macro-level of the services provided. This study was based on this combination of factors to determine the minimum operational requirements that will frame efficient, effective, value-adding, sustainable, and secure telehealth services of the national network [5].

The study focused on analyzing a multidimensional model to gain a deeper comprehension of the various ways in which telehealth services can manifest in terms of complexity.

The multidimensional model that was studied serves a better understanding of the complexity of the different forms that the use cases of telehealth services can take [4][6]. The reference domains of the multidimensional model are provided in Table 1.

TABLE 1. MULTIDIMENSIONAL MODEL - REFERENCE DOMAINS

Technology	The transition from a physical to a virtual environment, as new challenges or risks usually appear, pre-requests significant changes in the related operations, through application of rigid processes imposed by technology, ergonomics and design or new ways of virtual communication that differ from interpersonal contact.
Human factors	The issue of human-technology interaction raises cognitive and human concerns for implications in terms of cognition, habits, behaviors, memory, mental and cognitive components, psychomotor factors, and individual psychosocial and cultural characteristics. Technology is a set of artifacts that must consider the peculiarities and characteristics of the individual user.
Organization	Health care organizations are complex social systems, with heterogeneity and diversity of individual and group cultures, dynamics, interests, and behaviors. Telehealth services, as a socio-technical objective, could cause a re-definition of balances, workflows and powers, thus creating conflicts of professional and organizational jurisdiction.
Fiscal /policy & regulatory framework	The health sector is usually governed by a strict regulatory framework. The evolution of standards and certification requirements or providers' obligations (e.g., quality, safety - security and privacy), financial and technical policies related to telehealth can create a multitude of unforeseeable consequences that demand a prompt reengineering of services and procedures.

B. Code of Practice, the Existing Provisions

The main precondition for the successful development of telehealth is trust by the health professionals and the service users, and trust is cultivated ultimately by setting standards and external controlling procedures. In the study, the European Code of Good Practice for Tele-Health services, which is a fundamental regulatory document, was examined as a basic reference framework of service requirements.

The European Code also prefaced the International Code of Practice for Telehealth Services, which also offers a standardized approach and a guide for the conformity assessment and the certification of services. By the application of these two documents, a quality benchmark can be created according to which telehealth services (including tele-care) can be assessed [7]. The content of the European and International Code of Good Practice for Tele-Health services is presented in Figure 2 [8].

C. International Standards for Quality Assurance Leading to Certification or Accreditation of Telemedicine Services

Standards and guidelines aim to spread good practices and guarantee a certain level of requirements in the use of telehealth solutions. As in any context of services provided, in telehealth services, it is very important to review already established specifications, conditions and operational objectives to adequately ensure the basic attributes that safeguard quality as well as ethical and safety principles in the provision of services [9][11][12][13][14][15][16][17].

Furthermore, the technical requirements deriving from the relevant standards aim to ensure interoperability between different devices, units, providers' entities and health systems, and thus, it is fundamental to create conditions whereby applications are compatible with other systems.

Quality assurance in health care can be verified and validated by obtaining certification and / or accreditation as a strong indication of an organization's commitment to high-level quality criteria. Figure 1 displays the multi-dimension concept of healthcare access,

D. Special ISO Standard for Telemedicine Services

For the operation of telehealth services, the recently published standard ISO 13131:2021 provides specific quality criteria and control points for the implementation of telehealth services, integrating risk management objectives and procedures as well as quality elements in the form of service design guidelines. The adoption and implementation of the standard aims to optimize the provided services through continuous improvement of applied procedures, standardization of communication aspects, coordination of resources, and clarification of accountabilities, ultimately benefiting both healthcare providers and patients [9].

This standard covers issues regarding:

— Management of processes related to the quality assurance of telehealth services

— Design and implementation of strategic and operational processes related to regulations, best practices and guidelines

— Healthcare procedures involving the beneficiary/ patients

— Management of financial resources for the provision of telehealth services

— Secure management of the information that is circulated and used in the context of telehealth services
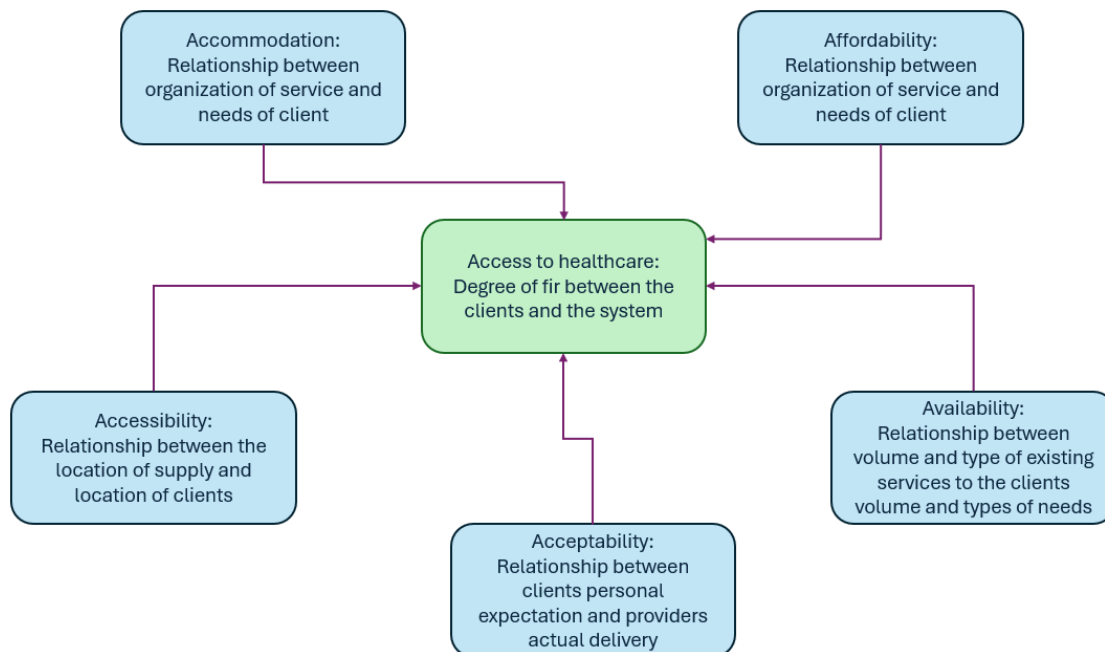

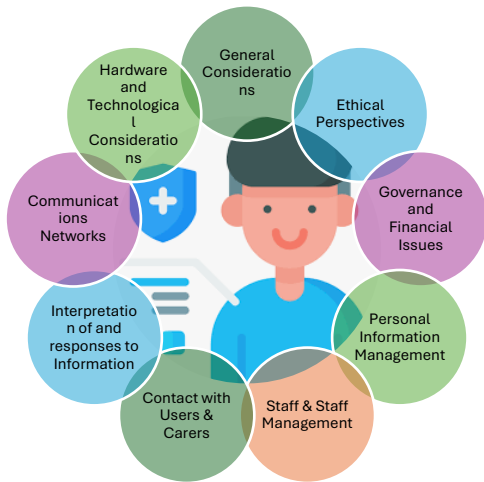Figure 1. The multi-dimensional concept of health care access

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Figure 2.   International & European Code of Good Practice for Telehealth Services – Contents

Processes related to the design and provision of human resources, infrastructure facilities, and technological resources for use by telehealth services. Additionally, there are accreditation bodies whose quality standards and criteria are developed to control and evaluate telehealth services aspects.

The technical adequacy and acceptance of these standards on an international scale are ensured through their validation and accreditation by the international organization International Society for Quality in Health Care External Evaluation Association (ISQua EEA) ISQua EEA provides third-party external assessment services to health and social care external assessment organizations and standards development bodies worldwide [10]. An overview of the key health-related accreditation bodies is provided in Table 2.

TABLE 2.   KEY HEALTH-RELATED ACCREDITATION BODIES

✓ Joint Commission International (JCI)
✓ Temos International Healthcare Accreditation
✓ National Committee for Quality Assurance (NCQA)
✓ Accreditation Canada
✓ Global Healthcare Accreditation
✓ Utilization Review Accreditation Commission (URAC)

After studying the accreditation programs implemented by healthcare providers including the provision of telehealth, it is concluded that the adaptation of an integrated model of compliance assessment may have a direct impact to human resources engagement and to the upgrade of the quality level and reliability of the services pursuing better performance and clinical efficiency in telemedicine services.

III. RESULTS

As a result of the processing and alignment of requirements and specifications with the services dimensions as indicated by the codes of practice for telemedicine, the minimum requested criteria and conditions have been developed as a framework proposal for adaptation regarding the operation of EDIT including the governance model to be applied for the network.

A. Proposed Framework Requirements for Quality and Safety Assurance of Telehealth Services

i. Licensing procedures to authorize telehealth providers: Healthcare providers who simultaneously provide telemedicine services, regardless of the context in which they operate, should be fully licensed in accordance with relevant administrative, legislative, and regulatory requirements. They are also required to implement the specifications' framework and ensure comprehensive documentation and proof of its implementation.

ii. Quality Assurance System for Telehealth Services (SSP T-Y): in this section, the provisions of a Quality Management System (QMS) to be developed by the provider are described, covering the entire scope, context, purpose, and objectives of the offered services. The outline of the applied processes and protocols and the method for the evaluation of outcomes should be determined. Furthermore, entities responsible for any part of the services, including third parties (health care units, supporting organizations, manufacturers, suppliers, and health service insurance organizations), must be well defined, and relevant authorizations should be addressed.

iii. Risk Management System: The provider, in addition to the standardization of the applied procedures, should have in place a risks' identification and risks' mitigation process towards the achievement of the system objectives, through which the evaluation of the external and internal factors of the organization will be carried out, followed by the prioritization of risks that can prevent each organization from achieving its objectives.

iv. Resources Management System: The provider should ensure quality, suitability, continuity, reliability, effectiveness, availability, safety, sustainability aspects and usability of the infrastructure and equipment, proper support of the remote services, adequacy of devices and technology used for the provision of telehealth services.

v. Special Quality Assurance Issues

▪ Available Resources: In this section, special provisions have been included for mainly interconnection and telecommunications requirements, which should always be satisfied for each category of telehealth service, namely:
  - Methods of communication and applications
  - Availability of infrastructure and technologies

- Connectivity for interactive meetings
- Systems' interoperability

▪ Acquiring new skills and competence of healthcare professionals: The minimum required criteria regarding the formal qualifications, necessary knowledge, skills and specialized certifications of healthcare professionals should be determined so that they can provide telemedicine services. Among the most important competence elements to be certified is knowledge of basic aspects and guidelines for:

- the provision, documentation and reporting of telehealth services (use of the digital systems applied),
- the available options, telehealth protocols and prescribing requirements that apply both domestically and in the context of cross-border care,
- risks management and limitations of telehealth services,
- benefits and limitations of telehealth services.

▪ Ethical and Consensus Issues: Issues of securing the patient such as his identification, information, informed consent and participation in decision-making for care, but also the respect for the confidentiality and privacy of the circulating information are some key points that are specialized in this point of the study.

▪ Aspects that must also be covered are (i) the use of appropriate means of communication and applications that have the appropriate authentication, confidentiality and security parameters necessary for proper use, (ii) the availability of infrastructure and technologies using up-to-date security software, (iii) the connectivity for real-time interactive meetings based on bandwidth and frame rate, (iv) interoperability with EHR systems to sustain continuous service provision and integrated care.

B. Governance Model

The governance framework designed for the National Network of Telemedicine serves as a guiding map for all accountabilities and functions that govern the network to ensure alignment with regulatory requirements, compliance with ethical and technical standards, and alignment with stakeholder expectations, while promoting innovation and excellence in the practice of telemedicine. A brief description of the basic principles of governance is provided in Table 3.

TABLE 3. BASIC PRINCIPLES OF GOVERNANCE

Accountability: Creating mechanisms for assigning responsibilities.
Transparency: Enhancing transparency in decision-making processes, policies and actions related to telehealth governance.
Equity: Ensuring equitable access to telehealth services and adequacy of resources for the population, regardless of geographic location, socioeconomic status, or demographic characteristics.
Risk Management: Identifying, assessing and mitigating the risks associated with telehealth services, including technical, operational, legal and ethical risks.
Collaboration and coordination: Strengthen collaboration and coordination among telehealth stakeholders at local, regional, national and international levels.
Quality assurance: The establishment of operational standards, guidelines and quality assurance mechanisms is the basis for ensuring the application of all critical principles for telehealth services.
Regulatory Compliance: Compliance with applicable laws, regulations and standards governing telehealth operation, data privacy, security and interoperability.
Sustainability: Ensuring a sustainable governance framework for telehealth services that can adapt to the changing needs of healthcare, the healthcare ecosystem and technological developments.
Ethical issues: Operating according to established principles and values in telehealth governance, including respect for patient autonomy, privacy, confidentiality and informed consent.
Legal Framework: A strong legal framework that provides clear guidelines and rules governing telehealth practices.
Data Governance: Development of comprehensive data governance policies and procedures that will govern the collection, storage, use, management and protection of health data that are circulated in telehealth systems.
Interoperability Standards: Adoption of interoperability standards and protocols for the seamless access, interconnection and exchange of health information across different telehealth platforms, systems and electronic health record systems Health Record).
Training and Education: Provide training and education programs to build capacity and proficiency in telehealth standards, technology use, and workflow integration.
Technological Proficiency and Innovation: Invest in a robust, scalable technology infrastructure to support telehealth services.
Evaluation and Research: Conducting systematic evaluation and research reports

In the proposed governance model, the senior management (Ministry of Health) provides the strategic direction while the operational management is carried out by the Coordination Directorate with the support of 3 new departments: (i) Business Operations, (ii) Technological Infrastructure and Innovation and (iii) Department of

Communication, Publicity and Digital Media, with responsibilities of coordination, guidance and support of the Operational Centers (servicing the telemedicine stations) in order to meet the needs of smooth daily operation through technological excellence.

Operational Centers are created at each Health Region, which is also responsible for the training and certification of new users, development of partnerships, and supervision and control of the system for routing technical requests to treating gaps and failures of the system.

Ministry of Health regional policies and guidelines for the implementation and operation of telehealth should align with regional healthcare priorities and public health goals. An important part of the strategic planning is the allocation of the corresponding resources.

A Coordinating Committee serves as a high-level advisory and decision-making body, responsible for the supervision of the overall direction and implementation of the national telehealth program. The regional coordination committees are intended to facilitate cooperation between regional bodies involved in the implementation and operation of telehealth and to monitor and evaluate the performance and impact of telehealth services at the local level.

A quality committee is responsible for overseeing quality assurance and improvement efforts within the national telehealth program. It focuses on ensuring that services comply with established standards of care, safety, and effectiveness and that continuous quality improvement processes are in place to improve service delivery and patient outcomes.

The technology standards committee focuses on defining technology standards and protocols related to telehealth technology infrastructure, interoperability, and security. The telehealth user advisory committee represents the voice of patients and community members in telehealth program design, implementation, and evaluation.

C. Proposed Code of Ethics for the Provision of Telehealth Services

The lack of a universally accepted code of ethics creates challenges regarding the quality and ethics of service delivery, ensuring at the same time the protection of patients' rights and the professional integrity of providers. Table 4 describes the proposed code of ethics for the provision of telehealth services.

TABLE 4.   PROPOSED CODE OF ETHICS FOR THE PROVISION OF TELEHEALTH SERVICES

1. Tele-health services refer to all versions of interaction and communication between healthcare professionals and the user- patient that take place remotely, as well as the provision of tele-health services as defined internationally/ in a national context.
2. The doctor / healthcare professional must ensure that the beneficiary of the services (citizen-patient) meets predefined inclusion criteria for the requested service (as determined by the relevant telemedicine protocols).
3. The doctor / healthcare professional must ensure the informed consent and consensus of the patient / citizen to use telehealth services.
4. Every type of telecommunication in the provision of tele health services must respect the healthcare professional-patient relationship and individual needs ensuring mutual trust, evidence-based decision making and practice, patient autonomy, privacy and confidentiality of communications.
5. In any type of telecommunication, the identification method of both the doctor/healthcare professional and the patient/ service user must be ensured.
6. The content and outcome of each session must be recorded in the clinical file of the patient/ service user.
7. When the patient participates in a telehealth session in the form of remote consultation, it should be carried out under conditions comparable to a face-to-face visit and the availability of the necessary information should be ensured.
8. The patient has the right to access evidence of the health professional's competence to accept the provided telehealth services.
9. The doctor/healthcare professional who provides tele-consultation services to another health professional may provide scientific opinion, recommendation or clinical decisions only if he considers that the exchanged information is sufficient and relevant. In cases where a doctor asks for the opinion of his colleague, he is responsible for the recommendations provided to the patient in the case the recommendations issued remotely by the other doctor.
10. The doctor/ healthcare professional must recommend the clinical assessment in physical presence, if not possible to obtain the patient's consent after being informed about the implementation of the tele-health service or when it is impossible to implement the tele-session according to the leges- artis.
11. The doctor / healthcare professional must ensure that security measures are implemented to protect the medical / health record.
12. The doctor/health professional and the patient have the freedom and complete independence to decide whether to use or refuse the telehealth service application.
13. The doctor/healthcare professional must ensure that the training and competence of other collaborators involved in the transmission or delivery of data is sufficient.
14. The doctor must ensure that he has public liability insurance for the use of telemedicine services.

> 15. In the event of a breach of confidentiality of which the doctor/health professional becomes aware, the doctor must directly inform the patient.

IV. DISCUSSION

Digital Health initiatives such as telehealth, mobile health, and clinical decision-support systems may provide alternative solutions to accessible care, continued surveillance, risk mitigation, clinical outcomes' monitoring, and containment of the disease.

The development of an integral and sustainable national network for remote access to healthcare services requests a thorough study of all the essential components of the implemented systems and a governance structure to supervise and support the continuous improvement of safe and clinically effective operations. A huge challenge for both patients/ service users and telehealth providers is how to determine the reliability, appropriateness and compliance of the applied systems with functional requirements and technical standards.

While Digital health tools are part of the overall frame of Health Technology Assessment, there is a definite need to organize resources and evaluation programs with regard to their compliance against public health requirements and quality criteria and based on their impact on clinical service and the level at which they meet health needs.

V. CONCLUSION

National networks for telehealth services should be governed by clear policies and strategies at the health system level. These policies should define the role of telehealth in the delivery of healthcare and determine clear structures and service requirements while essential implementation acts are required to satisfy quality criteria and functional specifications that must be addressed by a suitable and properly applied regulatory framework.

At a next phase, the assessment exercise for the National Network of Telemedicine in Greece should be based on a well-structured system of key performance indicators reflecting compliance with the defined standard practice framework and the impact and outcomes to the service users.

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