Methodologies for Establishing an Institutional and Regulatory Framework for Telemedicine Services in Greece

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Abstract— **Despite the numerous pilot telemedicine projects in Greece; there is still a lack of proper clinical application and adoption of telemedicine services. It is for this reason, that the Greek Ministry of Health and Social Solidarity announced last year a call for tenders to study and propose an institutional and regulatory framework to support telemedicine services in the Greek National Health System (GNHS). It is the purpose of this paper to explain our approach to the above study, and emphasise some of its elements that we deem important.**

More specifically, emphasis is placed on a number of methodology issues like, the mapping of the current situation, the roadmap to the proper construction of the telemedicine framework, and other human and organizational aspects of establishing telemedicine services in Greece. The ultimate goal of this paper is to demonstrate how the various multi-disciplinary methodologies can be applied to face the challenges posed by telemedicine services application problems. In so doing, numerous studies and results are utilised to enrich the theoretical grounds of the various approaches.

I. Introduction

OVER the last decade, the Greek National Health System (GNHS) has witnessed numerous efforts for the introduction of integrated systems intended to support health care provision services by electronic means [1]. There have been several programs funded mainly by the 3rd, 4th and 5th support frameworks of EU (e.g. Information Society & Technology, IST), as there are a few more funded by the 6th framework, which are still under development and within the scope of upgrading the provided service by Information and Communication Technology (ICT) means. Within these programs, one of the main ICT health care applications was (and still is) telemedicine.

In Greece, the notion of telemedicine was introduced some 15 years ago. Various Universities, Hospitals and Health Units participated in the different projects funded at a national or international level. For example, in 1992 the Greek Ministry of Health funded the installation of 12 units for telecommunication in Health Organizations. In that project, the Sismanoglio Hospital of Athens was denoted as the main installation centre to support some 40 remote health care centers (HCC) in the (distant) country side (mainly islands). In 1995, a Network for Tele-cardiology, named TALOS, was implemented to support the Primary Care Units and Health Units in the Region of Aegean Islands. HYGEIAnet was another project in the region of Crete, that also piloted telemedicine solutions and services. Another similar to the latter telemedicine program was the EPIRUS-NET, a wireless network for the transmission of medical data in the region of Epirus. The Citizen Health System (CHS), was an IST funded project, scientifically co-ordinated by the Lab of Medical Informatics at Aristotle University of Thessaloniki, that used the idea of a contact centre to pilot home care telemedicine clinical trials. Several other telemedicine networks have been implemented or are still under development by the academic and clinical communities. All these efforts cover all areas of medical application, namely, diagnosis, therapy, monitoring, provision, and education, and are funded by European research or other national technical boards [2].

However, most of the above applications have had a pilot character; a wider clinical orientation and adoption of telemedicine services is still missing in Greece. It is for this reason, that the Greek Ministry of Health and Social Solidarity announced a call for proposals last year, in order to start establishing an institutional and regulatory framework to support the telemedicine services in GNHS [3]. This call, still under evaluation at the time of writing this article, is the first “central” health policy attempt to illuminate the various telemedicine issues from a global/spherical point of view, rather than a mere technical one. It is the purpose of this paper to explain our approach to the above study, and emphasise some of its elements that we deem important.

In previous research works, we have underlined the important potential drawn by such pilot applications in the Greek e-health landscape [2]. That study revealed a strong

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belief that Greek telemedicine services could be crucial and effective in resolving data management concerns between doctors and citizens. In this work, and in the light of the above call by the ministry, emphasis is placed in two aspects of the study framework that seem to be important, namely, the operational and organizational aspects of the telemedicine services that need to be taken into account upon mapping the current infrastructure, and the roadmap to drawing an operational plan of action upon which guidelines and protocols of telemedicine services can then be built.

II. Methodology

A. The project scope and plan

The following table describes the approach the authors of this paper are proposing to the study as outlined in the call of the Greek Ministry mentioned in the introduction. The study is viewed as a project-plan with proper actions, deliverables, and time durations. However, for simplicity, only the work packages and their individual actions are listed in Table I.

The ultimate purpose of the study that will define the aforementioned telemedicine framework is threefold:

- To design a viable model for the provision of safe and functional telemedicine services
- To define criteria, priorities, and level of development for a range of such service applications
- To research the degree of relevance of new services (to be introduced via telemedicine) with already existing ones in GNHS.

Upon these directions, the framework supporting the provision of telemedicine services should be studied along the priority axes listed in Table II.

In the current paper, the focus is placed in the first two WPs (cf Table I). More specifically, the focus is placed on the methodologies to be used for (i) registering, assessing, and complementing the institutional-regulatory-legal frameworks for the deployment of a network of telemedicine services and (ii) imprinting the Greek technological infrastructures capable of supporting the implementation of telemedicine actions. Obviously, one of the first steps in adopting telemedicine in healthcare organizations is to map the existing ICT infrastructure in these organizations (in a national level). The scope is to come up with the following:

- List of ICT infrastructures that can support the adoption of telemedicine (in terms of basic telemedicine components)
- List the appropriate extensions in the existing infrastructure in order to maximise exploitation
- Propose appropriate organizational changes according to functional requirements of telemedicine projects for which the framework is designed
- Strategy to comply with national and international guidelines in the study of the framework
- Strategy to involve adequately educated personnel to support the infrastructure for implementing the telemedicine programs.

TABLE I
Project plan for the study of an institutional and regulatory framework to support the telemedicine structures in GNHS

WP #	Title of WP and of Specific actions/tasks
1	**Register, assess, and complement the institutional-regulatory-legal frameworks for the deployment of a network of telemedicine services**
a	Recording and evaluation of the Greek institutional and legal frames for the operation of a telemedicine network
b	Recording the European institutional frames for the operation of telemedicine networks
c	Comparative analysis for merging the European and Greek frames – SWOT analysis
d	Suggestions for complementing the Greek institutional and regulatory frames
2	**Imprinting Greek technological infrastructures capable of supporting the implementation of telemedicine actions**
a	Registration of medical/technological equipment per Health Unit
b	Registration of telecommunication infrastructures and services and imprinting the telecommunications map per geographic health region
c	Development of a telemedicine services catalogue - description of services for a health care program
3	**Determination of Objectives and Effects - Evaluation of success of telemedicine pilot projects**
a	Definition of generic objectives for the telemedicine structures
b	Analysis of new alternatives and potentials with the application of telemedicine systems
c	Presentation of social and financial effects
d	Development of a system for monitoring the effect indices
e	Synthetic presentation of system goals
4	**Development of the proposed organization/operational model of the GNHS telemedicine structures**
a	Description of the spectrum of the offered tele-services
b	Description of Administrative, Organisational and Operational structures
c	Definition of needs in personnel
d	Suggested plan for personnel adoption in telemedicine structures
5	**Definition of technical equipment requirements per node**
a	Presentation of the technological model of telemedicine structures
b	Definition of telemedicine nodes, actions supported per node
c	Technical solution description per node:
d	Suggested plan for exploitation of available equipment
6	**Costs of telemedicine services**
a	Evaluation of costs and benefits for the offered services
b	First installation budget
c	Funding sources/alternatives
d	Suggested plan for a viable form of telemedicine structure
7	**Personnel training needs**
a	Recording the current level of personnel literacy (training and experience)
b	Suggested forms of training per personnel category
8	**Publicity actions and communication**
a	Development of the publicity and inter-communication plan
b	Implementation of plan for social and financial actors/bodies
c	Implementation of plan for the end-users

TABLE II

PRIORITY AXES OF THE TELEMEDICINE FRAMEWORK STUDY AND ASSOCIATED RESULTS

AXIS	***Result of actions in this axis***
Organizational & functional matters	Report including analysis of: Legislation Organizational matters Functional requirements Requirements in personnel Educational Needs
Architecture of the telemedicine network	Design of Architectural model of telemedicine services Layers (technical) of installation Network of mobile units Infrastructure (technical characteristics)
Financial Planning	Cost-Benefit Analysis Report covering: Costs of initial investment Costs of operation & maintenance Costs of future extensions Alternatives of funding sources
Dissemination	Publication of Awareness and dissemination material referring to: Relevant social parties (e.g. municipalities, old people associations, organizations) Health care sector personnel General public, end users

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B. Assessing the Frameworks: Preparedness Characterisation model

To register and imprint the current situation, but also study the readiness of our country with respect to tele-care, one needs to first study the literature (and history in fact) especially in terms of any legal, ethical, and human aspects governing telemedicine services [4] (e.g. patient e-consent forms etc), as the latter appear in governmental laws and presidential decrees. There is also a need for an in depth analysis of critical factors and factors of quality, based on which the country readiness for telemedicine service operations can be characterised and justified. The idea is to analytically include a number of steps which they will be selected, through a set of criteria (factors) that play an important role in the configuration of the institutional framework. The end result may be a drawing that will have the significance of a characterization model [5] and will also allow the comparison of institutional frameworks of various countries (cf. Activity 1c in Table I).

C. Designing the framework: mapping the infrastructure

The proposed actions to be taken prior to designing telemedicine projects/services are suggested to be:

1) *Listing of biomedical infrastructure for each health care organization/health care unit*

2) *Listing of ICT infrastructure per region and creation of an "ICT infrastructure" map*

3) *Listing of the telemedicine services that will be provided within an organizational structure and creation of a "telemedicine services regional map"*

An important methodological step in mapping the existing ICT infrastructure, in view of allowing for the best possible distribution of equipment in health care provision points (health care organizations/units), is to create regional or national distributions of equipment in relation to the distribution of the population. For that purpose, a method incorporating the Gini co-efficient can be used [6], so that the best possible exploitation of equipment takes place. Statistically the Gini co-efficient, measures the development and the extent of inequalities with respect to the distribution variable. Its value ranges from 0 to 1: the further the value of the co-efficient is away from zero and approaches the unit, the more the distribution of the examined variable becomes uneven [7]. The mathematic expression for the calculation of the Gini co-efficient (G) is given by the relation:

$$G = 2\,\Sigma x_i \psi_i / xn^2 \qquad (1)$$

where x_i is the divergence of the observation from the median of observations, ψ_i is the exact place of divergence from the median, x the mean value of observations and n is the number of observations.

D. Designing an Operational Plan of Actions

Finally, prior to being operational, one needs to elicit specific guidelines for the offered services [8]. There have been many attempts in the literature where telemedicine guidelines are actually listed. The proposed, in his paper, method for drafting such guidelines, is to follow an operational plan approach [9, 10], and issue detailed guidelines for every single axis of "entrepreneural" interest [11]. As basic principles and simultaneously main objectives of any public/national health system are the equality, the effectiveness and the quality of provided services, to achieve these objectives, ones requires good organisation and effective administration - management in all the levels and sectors of the system. That is to say, in the functional and economic levels, as well as, the level of daily clinical work. This activity, therefore, constitutes substantially the planning out of an Operational Plan of Action for the adaptation of the operational framework of telemedicine structures in GNHS.

III. METHODOLOGY APPLICATIONS – PRELIMINARY RESULTS

The main scope of this section is to enrich the previously suggested methodological approaches with illustrations of preliminary results/studies that demonstrate their application and outline the envisaged outcomes.

A. Preparedness Characterisation model results

The ultimate objective of this model is the production of as more analytic as possible graphs that will illustrate in a succinct and sufficient graphic way the institutional readiness of Greece concerning a number of factors that will have been pre-selected and fixed beforehand. Fixing the telemedicine framework factors is a step-wise process that is illustrated in Fig. 1 below.

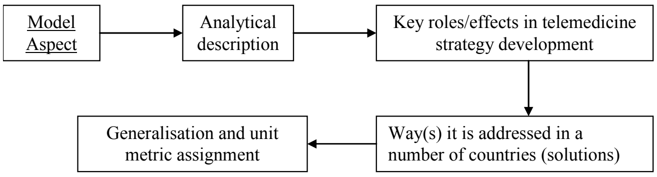

Fig. 1. Diagram showing how each aspect/factor affecting the national telemedicine strategy will be assigned a unit metric.

In the end result, the model takes the form of a tuple, the elements of which are what emerged (from an extended literature study) as the key factors, which appear to enable and/or impede the presumed telemedicine framework strategy. A particular feature of this model is our attempt to quantify and aggregate those factors so as to deliver a high level quantitative basis for evaluating and comparing nations. Thus, rather than seeking to elaborating the model to capture what is clearly a rich and complex problem area, we have sought to simplifying the situation, so as to deliver a broad measure with which a nations telemedicine preparedness can be assessed and compared. Fig. 2 illustrates a possible outcome of this attempt.

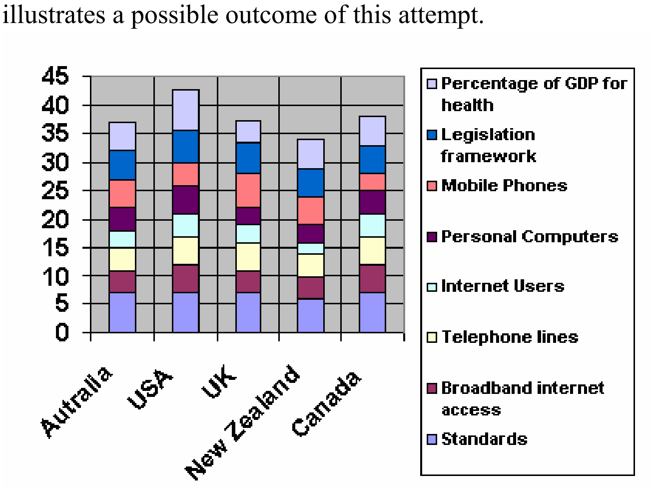

Fig. 2. An example diagram for characterizing the National Telemedicine Framework Readiness/Preparedness with regard to several infrastructure factors. Each aspect/factor is given a number (along a specific metric scale); numbers are piled up in a column to obtain overall preparedness degree. In this diagram, a comparison of five (5) developed countries is presented.

B. Mapping the infrastructure: Gini-distributions results

The Gini-distributions may be studied in accordance with Lorenz curves, the latter being curves of cumulative frequencies of observations. Distributions of interest are compared with the distribution of a variable of homogeneous distribution, that represents equality and is depicted by the diagonal (cf. Fig. 3); the larger the divergence of the Lorenz curve from this diagonal, the more uneven the distribution. G is fixed as double the region between the diagonal (even distribution) and the Lorenz curve of interest and receives values between 0 until 1.

TABLE III
DISTRIBUTION OF PUBLIC MRI SCANNERS IN GREEK REGIONS FOR YEAR 2001: GINI= 0.651

Geographical area	**Population covered (census 2001)**	**MRI scanners**	**Number of MRI scanners/10^6 inhabitants**	**Proportion of population**
Central Greece	3.883.212	4	1,03	970.803
Macedonia	2.315.280	2	0,86	1.157.640
Peloponnese	1.174.916	1	0,85	1.174.916
Thessaly	796.174	1	1,26	796.174
Crete	578.251	1	1,73	578.251
Aegean Islands	486.680	0	0,00	-
Epirus	396.732	1	2,52	396.732
Thrace	369.383	0	0,00	-
Ionian Islands	214.911	0	0,00	-
Greece	**10.215.539**	**10**	**0,98**	**1.021.554**

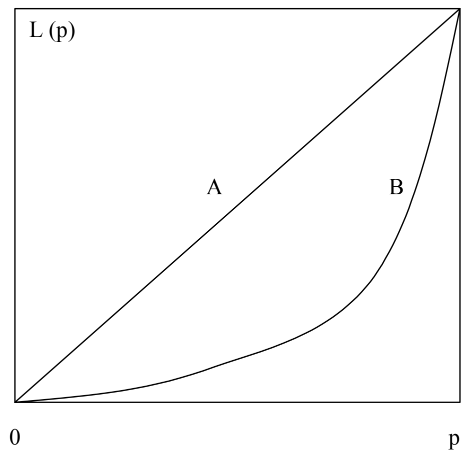

Fig. 3. Lorenzian curves for studying the quality of distributions. Diagonal (A) is even, B is uneven.

A good application example is given in Table III, where the regional distribution of the Greek population and the number of MRI scanners is presented for year 2001.

C. Mapping the infrastructure: listing of telemedicine equipment

One of the main obstacles upon listing any biomedical infrastructure is the coding of the biomedical instruments and then sorting and grouping per organization or per region. Any attempt to list the instrumentation should be based in a coding system like that proposed by ECRI. The purpose is to create a list with three basic components: 1. the model, 2.the manufacturer, 3.the group/device class, so that a device database is formed for any current or future equipment use. The quality and readiness for use of any existing instrumentation should be also an outcome of the opinion of the personnel who uses it and can be evaluated through questionnaires. For this, a number of parameters should also be available: Telemedicine Network Description, Digital recording capacity, Interoperability capability, Security options, Quality/reliability control, Effectiveness measures, Compliance with medical informatics standards, Upgrade capabilities through Interfaces, etc.

The next step is to study for the best distribution of the equipment in all health care providers (health care organizations/units) in a specific region or nationally in relation with the distribution of population. For that purpose the Gini co-efficient can be used, so that the best possible distribution and exploitation of the equipment takes place. So, a detailed account of the steps taken to list the biomedical equipment that may be utilized in telemedicine infrastructures is given in the following figure.

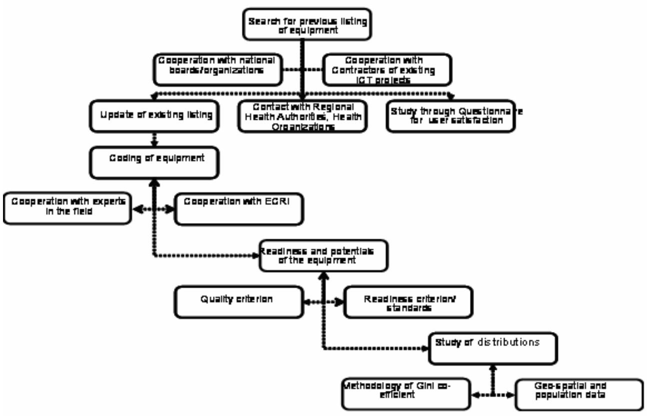

Fig. 4. A detailed list of interconnected steps taken upon mapping the biomedical instrumentation to be utilized in telemedicine infrastructures.

Similar listings of the ICT infrastructure per region are necessary to create the layer of the “telemedicine map”. In Greece, there exists a national “Infosociety observation center”, as well as, other national or regional boards that possess such listings. These should be taken into account, but focus should be given to all available network connections like HellasSat, WANs, ADSL, Wi-Fi networks, broadband networks or combinations. The infrastructure should be evaluated with criteria as shown in Table IV.

Finally, a GIS solution should be sought, so as to couple all the above listings, codings, and distribution characteristics under a common geographical notion.

TABLE IV

CRITERIA FOR EVALUATING THE NETWORK INFRASTRUCTURE FOR THE OPERATION OF THE TELEMEDICINE FRAMEWORK

	Network e.g. WAN	Mobile	Wi-Fi network	Other
Health Care Provider	XXXXX			

Where XXXXX is a combination of the following factors (present or absent from any network solution):
C stands for Confidentiality of data
I stands for Integrity of data
A stands for Authentication
Ac stands for Accountability of personnel
Av stands for Availability

When a property is missing dash is used e.g. C---Av stands for Confidentiality of data and Availability

D. Operational Plan – Axes of interest

The suggested operational plan is distinguished in eight (8) axes/directions of actions and is developed at specific subsections of specialisation. The matter (implementation actions) assembled after initial recordings and registrations is also structured in tables which interlink the actions at the original axes with their subsections. In this way they reveal the affinities of actions horizontally at the axes and vertically at specialisations such as Operation/Function, Organisation, Equipment/Facilities and Infrastructures, Human Potential. The eight axes are as follows:

1) Reference Centres – Pillar Hospitals
2) Regional Units
3) Interlinking and Technical Support Centres (Co-ordination Centres)
4) Mobile Units / Ambulances (National First Aid Centre/EKAB)
5) Hospitals – Inclusion of Telemedicine in Hospital on-call system
6) Regional Health Authorities – Inclusion of Telemedicine in the Regional Projects for the installations of Integrated Hospital Information Systems
7) Insurance bodies and ongoing potentials
8) Insurance of telemedicine procedures/clinical actions

For each of the above axes, we develop specialisation subsections which relate to:

a) The program operation with respect to the axes entities
b) The organization of the axes entities
c) The infrastructure and facilitation of the axes entities
d) The human resource recruiting for the axes entities and their corresponding telemedicine training/education.

Finally, the idea is to enable the development of specific telemedicine guidelines for every possible combination of the axes and their specialisation subsections, so that it is nothing but succinct and clear how to go about developing telemedicine in every single health unit using taking into account a specific set of actions.

IV. DISCUSSION

The purpose of this work was to define a methodology framework to support the design and implementation of projects that provide health service through telemedicine in an integrated way. The work is presented as an answer to a recent call for proposals by the Greek Ministry of Health and Social Solidarity. It is not the intention of the paper to present in detail results obtained from the studies mentioned, but rather to shed light in the methodology that one may be based in order to establish an institutional and regulatory framework for telemedicine national structures. More specifically, this paper focused on the human and organisational methodology steps that a multi-disciplinary approach can offer by outlining Information Technology Infrastructures, the Resources in Personnel and the overall Organizational matters. There are obviously many more parameters and methods/techniques one can follow upon studying other aspects of this problem. In fact, the richness of actions detailed in Table I, may witness the truth of the above statement. However, to get into such a level of detail was beyond the scope and the space of this publication.

The approach outlined and demonstrated through the specific sets of preliminary studies undertaken by the authors, offers a more scientific way of establishing a successful infrastructure of telemedicine services. It remains to see, of course, whether the actual, measurable effect of such an approach will have the envisaged outcome or not. However, the scientific origin and the multi-disciplinary approach to every aspect of the WPs in Table I, offers some kind of guarantee for the success of the project, elements of which have been presented in this paper.

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