Guidelines and Standards for Telemedicine

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Introduction

Telemedicine is here to stay and grow. Adherence to standards and guidelines facilitates realization of full potential of this Telemedicine. Scope of the standards covers Telemedicine related equipment, practices and technologies used by health care facility participating in this service and includes standards for electronic transmission, software and hardware. This article covers some of the recommended typical standards for different sub-systems of a Telemedicine facility. Among other things, it briefly addresses to Data Standards; Data Exchange Messaging Standards, medical image capture, storage and transmission standards (HL7, DICOM); IT Infrastructure Technical Standards for Interconnectivity, interoperability and scalability; and process guidelines. The highlights of the document "Guidelines and standards for practice of Telemedicine in India" published by the Department of Information Technology are presented.

1.0 Preamble

Inspired by recent advances in the provision of health care and medical education through the use of Information and communications technology;

Recognizing the common interest of the health and community welfare of the people of India;

Believing that the promotion of Telemedicine will contribute to the availability of high quality medical services to the needy irrespective of socio economic and geographical disparities;

Believing that the Telemedicine services envisaged in the country should be available for the benefit of all people located in rural, remote and inaccessible places, and to further enhance its end-to-end capability;

Recognizing the right to privacy and confidentiality in health matters;

Recognizing the advancement in the communication and information technology in India, which is the forerunner for its adaptation in Telemedicine;

Desiring to contribute to broad international cooperation in the scientific, legal, and ethical aspects of the use of Telemedicine;

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Believing that such cooperation will contribute to the development of mutual understanding and strengthen the friendly relations between states and people;

Encouraging to provide continued support for the advancement of Telemedicine/ Telehealth, its applications and its greater relevance to India;

Realizing the importance of Information and Communication Technology (ICT) in Telemedicine programs, a set of guidelines/ standards will go a long way in optimally leveraging existing technologies, while ensuring its continuity to the evolving and advancing technical innovations;

Realizing the necessity of delivering cost effective solution for Telemedicine technology and indigenous enterprise for providing software/hardware for Telemedicine;

Government of India is convinced that a set of standards and guidelines on Telemedicine be defined, that will further the goal of providing all people with a practically attainable standard of health care, which is sustainable in an integrated manner.

As part of this endeavor, Department of Information Technology (DIT), Ministry of Communications and Information Technology (MCIT), has taken initiative on the evolution and adaptation of standards for practice of Telemedicine, under the aegis of the "Committee for Standardization of digital information to facilitate implementation of Telemedicine systems using information technology (IT) enabled services."

The committee is supported by a Technical Working Group (TWG), consisting of members drawn from different government and private agencies/institutions with a mandate to evolve and submit a document on suitable standards and guidelines for Telemedicine practice in India.

1.1. Need for Telemedicine standards

With the advances in technology the delivery of healthcare to even remote locations has become feasible through methods like Telemedicine interoperability and interconnection become difficult to achieve.

With Telemedicine services being developed into multiple and disparate networks in an operational mode in the country, there is an imminent need to evolve standards and guidelines to facilitate growth of practice of Telemedicine that is uniform and scientific.

Standards imply technical compliance with rigid and defined criteria.

In addition to technical standards, clinical protocols and guidelines are needed. Clinical protocols for Telemedicine practice include preliminary scheduling procedures, actual consultation procedures and Telemedicine equipment operation procedures (such as telecommunications transmission specifications).

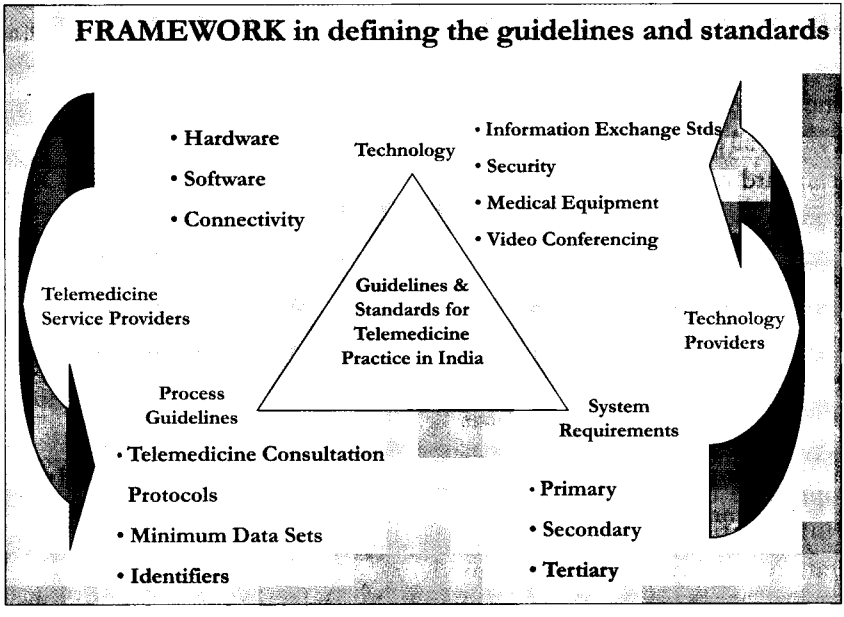
1.2. Key Objectives in defining standards

- To promote the growth of Telemedicine
- To Increase availability of quality medical service to those in need

- To Improve quality of medical services, as it facilitates access to expert opinion leading to better diagnosis, treatment and prognosis
- To define usage of Telemedicine technology that is appropriate to the Indian environment
- To identify the mechanisms for protecting the privacy & confidentiality of individuals' health data.
- To define processes for scientific practice of Telemedicine
- To contribute to broad international cooperation in the scientific, legal and ethical aspects of the use of Telemedicine.
- To encourage continued support for the advancement of Telemedicine and its applications globally to keep the standards contemporary
- To provide a framework for interoperability and scalability across Telemedicine services within the country and outside.

1.3. Framework in defining the guidelines and standards

Key considerations in Defining Guidelines & Standards include – Interoperability, Compatibility, Scalability, Portability and Reliability. This framework has been so adopted to ensure - Inclusion of all the stakeholders, Making recommendations vendor neutral, Making standards technology neutral. For a better and complete understanding of these concepts, please refer Annexure-1.



1.4. Scope of the Standards

The scope of the standards include the standards and guidelines for Telemedicine Infrastructure, connectivity, Data Interchange and Exchange along with Minimum Data sets and security.

1.5. Classification of Telemedicine Centres

The Telemedicine Centres can be broadly classified into three classes- Primary Telemedicine Centre (PTC), Secondary Telemedicine Centre (STC) and Tertiary Telemedicine Centre (TTC).

These could be further sub classified as three major levels L1, L2 and L3 depending on the size and facilities available, the smallest being L1.

The Hardware requirements/standards are referred in the context of Telemedicine Consulting Centre (TCC) and Telemedicine Specialist Centre (TSC).

1.6. Details about the recommended standards

This section provides the specifications recommended.

1.6.1. Telemedicine platform

The hardware platform in most of the Telemedicine systems consists of a personal computer – PC/workstation. Depending on the application and space constraints, the platform can also be of different types like mobile system, handheld system or system for home use, the hardware platform can also be a laptop or palmtop computer, a PDA (Personal Digital Assistant) or even a dedicated box (set-top-box) with a processor. This also includes the software requirements like the operating system, licensed Telemedicine software with appropriate user interface and Back-end data base with the mandatory tables / fields as applicable.

1.6.2. Clinical devices

These include digital ECG, X-ray Digitiser, Ultra sound (Sonography Machine), Glucometer, Portable X-ray machine, Pulmonary Function Test (PFT) machine, Fetal Heart Rate (FHR) monitor, Tele-Pathalogy Microscope (and Trinocular tube) etc., for use in different applications like tele-radiology, tele-cardiology, tele-pathology and tele-ophthalmology etc.

1.6.4. Video-conferencing units

Video-conferencing units are offered in four distinct configurations with the Telemedicine systems. One is a stand-alone box with a network interface with camera, microphone and display and may be sharing the same communication channel. The second type is PC add-on card, with Codec implemented using a dedicated hardware on the add-on card, plugged inside the Telemedicine system with accompanying software for control and configuration. The third type is the one where a small camera with built-in encoder, and accompanying software for decoding,

control and configuration is used. Also, another type - Software based desktop videoconferencing using web camera is an economical option when low bit rate channel less than 64 kbps are used. The standards are recommended for all these types of units.

1.6.5. Communication hardware:

Connectivity is required to enable the transmission/exchange of diagnostic data/ images between Telemedicine systems. To provide connectivity, communication hardware is used. Various connectivity options are available for Telemedicine services. Based on these options, the communication hardware can be terrestrial links or wireless/satellite links.

The hardware for terrestrial links can be further divided into three major categories - PSTN/POTS, ISDN and LAN.

For terrestrial links, standards are recommended for PSTN/POTS (which are used when the Telemedicine data transfer/ exchange does not require very high bit rate, or no other option is available), ISDN (which is used when the Telemedicine data transfer/ exchange requires higher speed terrestrial link) and LAN (when connectivity is mostly required between various Telemedicine Systems within a hospital).

The hardware for wireless/satellite links consists of – wireless LAN, CDMA, GSM/ GPRS/G3. The standards are recommended for all of these devices.

1.6.6. Patient Information Records (PIR) to be supported by the software

The PIR created as part of the data acquisition process can be in terms of both structured and unstructured information. It may also involve different files like- audio, video, graphics, text etc.

The typical data captured as part of the PIR are PATIENT DEMOGRAPHICS, PATIENT HISTORY, Details of EXAMINATIONS, INVESTIGATIONS and DIAGNOSIS, ATTACHMENT OF AUDIO FILES, ATTACHMENT OF VIDEO/ IMAGES, ATTACHMENT OF FILES (other than audio and video images), REPORT(S) based on examinations. This can also potentially involve graphical representations.

Some of the important information relating to the Telemedicine Consultation that the software should be capable of capturing are also identified & defined.

1.6.7. Storage and Transmission Formats for PIR:

Storage and Transmission Formats for the PIR are to be supported by the Telemedicine Systems.

Guidelines are provided for the encoding of the data structures for exchange. Some guidelines are also provided for actual interchange of the data in terms of the Transport mechanisms. Further, it is recommended that not only should the

technologies be compatible in terms of interoperability between applications from different vendors, but newer versions of these S/W products must also be compatible with earlier versions of the S/W products.

Data interchange/exchange Standards - DICOM

DICOM (Digital Imaging and Communications in Medicine) is an industry standard widely recognized for Medical Imaging Communication. It was originally developed to facilitate the transmission and storage of X-ray images but was subsequently generalized to deal with a wide variety of medical image types. It defines a standard network interface and data model for imaging devices, which can facilitate information systems integration. Essentially the DICOM standard enables image acquisition, display of images for reporting and diagnosis, image transmission, an archive medium for Long term and compatibility. DICOM is the recommended standard because of its key advantage that it allows interoperability between equipment from different manufacturers. Image acquisition devices (e.g. Computer Tomography), image archives, hardcopy devices and diagnostic imaging workstations from different vendors can be connected into a common information infrastructure and integrated with other information systems (e.g. PACS, HIS/RIS).

1.6.8. Exchange of clinical messages among systems – HL7:

HL7 stands for Health Level Seven; The term "Level 7" refers to the highest level of the Open System Interconnection (OSI) model of the International Organisation for Standardization (ISO). HL7, an ANSI standard for Messaging in the Clinical environments, is the identified standard to interchange Clinical Messages among disparate Telemedicine Systems.

The HL7 Standard addresses the interfaces among various systems that send or receive patient Admissions/registration, Discharge or Transfer (ADT) data, queries, orders, results, clinical observations, billing and master file update information.

The standard is continuously evolving and there are various versions of the standard in use. Various Telemedicine Systems may interface using different versions of the standards. The issues addressed by the HL7 standard are – definitions of the application data to be exchanged, the timing of the exchanges, and the communication of certain application specific errors between applications. However, as a matter of pragmatic necessity the HL7 specifications also define the presentation of the information like the strings of text that represent it. HL7 refers to these as the "encoding rules".

The HL7 version 3.0 encodes messages using XML and is the recommended standard.

1.6.9. Identifiers – ITIH Initiatives:

The identifiers to be used by different persons/ entities would be as per the identifier standards defined by the ITIH initiative. The currently proposed identifiers are – Unique Patient Identifier & Unique Provider Identifier.

1.7. Security

The following are some examples of security measures that must be built-in or addressed in any Telemedicine application system: -

- Who can have access to individuals' health information?
- What kind of security technology is used for the above authentication, such as password, fingerprint and smart card?
- What kind of encryption is used for storing medical data?
- What kind of encryption is used for transmitting medical information?

Security elements to address these issues include storage security, network security, data encryption, audit trails etc. Networks should be reliable and secured to ensure user confidence, system and data integrity, and robust system operation.

1.8. Conclusion

It is important to follow the required standards as delineated in various chapters of TWG Report for Practice of Telemedicine. However it is essential to know the local conditions of a particular Hospital especially the hospitals in the rural areas when applying certain standards. For example in many hospitals the X Ray/ CT/MR may not have DICOM in the older versions of the machine. In this case methods of provision for Dicomising the image are possible. That is, image & patient information are integrated as a single image so that no body can change the image of patient data. With adaptation of HL-7 it is to be noted that aspects of Admission Discharge Transfer (ADT) & Clinical Data architecture (CDA) in the form of basic minimum essential fields need to used.

References

1. Digital Imaging and Communications in Medicine, version 3.0
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3. Health Level 7, version 2.4
4. Clinical Document Architecture, Health Level 7, version 2.0
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6. TWG Report on "Recommended Guidelines and Standards for practice of Telemedicine in India"