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Date)

Circular Number : 01-17/2024

All Additional Secretaries,
Director General of Health Service,
All Deputy Director Generals of Health Service,
All Provincial Directors of Health Service,
All Regional Directors of Health Service,
All Directors,
All Heads of Health Institutes/Heads of Specialized Campaigns,

National Telemedicine Guidelines

Telemedicine/Telehealth modality have been used frequently in Sri Lanka for the healthcare delivery process since the COVID 19 pandemic. Also, Sri Lankan healthcare landscape continues to evolve, driven by advancements in technology and changing patient needs, Telemedicine/Telehealth has emerged as a vital tool in enhancing availability of healthcare services. However, the absence of standardized guidelines related to Telemedicine practices in Sri Lanka poses significant challenges, in maintaining the quality of health care provided to patients through Telemedicine platforms. Ministry of Health has drafted National Telemedicine Guidelines through collaborative efforts involving multiple stakeholders, including administrative, clinical and regulatory authorities. These guideline aims to ensuring patient safety, standardize practices and enhance regulatory compliance of Telemedicine practices in the country.

Therefore, it is advised to follow the Telemedicine guidelines 2024 V 1.0 attached here with (Annexure 01) for the planning, implementation and maintenance of Telemedicine/Telehealth related digital health projects. For further information please communicate with the Health information Unit of the MDPU.

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Annexure 01

Telemedicine Guidelines for Sri Lanka Version 1.0

2024

Health Information Unit, Ministry of Health.

Introduction to the necessity for Telemedicine Guidelines in Sri Lanka

Telehealth is the provision of healthcare remotely by means of telecommunications technology. Telehealth includes both curative and preventive aspects of healthcare delivery. Telemedicine, on the other hand, is the curative or the clinical part of Telehealth.

Telemedicine applications rapidly grew globally as well as in Sri Lanka following the COVID-19 Pandemic situation. It became a solution to the delivery failures of traditional healthcare delivery models to comply with social distancing and travel restrictions. Even after the pandemic ended, the trend continued due to its convenience for patients as well as healthcare providers.

Until the time of developing this document, there was no specific published framework, Guidelines, or legislation to guide the practice of Telemedicine, through video, phone, or web-based platforms in Sri Lanka. The common legal act which is used in the practice of all modalities of digital health including Telemedicine within Sri Lanka is the Electronic Transactions Act - No. 19 of 2006. This Act authorises the use of electronic filing of documents and assists domestic and international electronic commerce. Even the latest amendment on the Electronic Transactions (Amendment) Act, No. 25 of 2017 does not say any on medical document exchange.

The healthcare provider needs to be registered with the relevant regulatory council (eg. Sri Lanka Medical Council (SLMC), Sri Lanka Nursing Council (SLNC), Ayurvedic Council etc) for the legal practice of healthcare in Sri Lanka. Healthcare providers who practice Western Scientific Medicine need to be registered under SLMC and SLNC. For example, SLMC section 29 of the Medical Ordinance mentions that a medical practitioner should be registered with the Sri Lanka Medical Council (SLMC) to provide patient treatment including prescriptions. Also, Cosmetics Devices and Drugs (CDD) Act no 27 of 1980 and the National Medicines Regulatory Authority Act, No. 5 Of 2015 are the legal laws for the use of drugs and medications within Sri Lanka. Further, patient information is protected indirectly by a few general acts. The Personal Data Protection Act No 9 of 2022 is the latest and the rest are more

than a decade old (e.g. Information and Communication Technology Act - No. 27 Of 2003, Computer Crime Act - No. 24 of 2007 and Intellectual Property Act - No. 36 of 2003).

However, in day-to-day practice, the user-level Telemedicine practice is controlled by Health professionals by their code of ethics in the practice of medicine. Therefore, gaps in legislation and the uncertainty of rules create reluctance for both doctors and their patients to use Telemedicine.

Objective of the Guidelines

The objective of the Telemedicine Guidelines document is to provide overall guidance and standards for Sri Lankan healthcare providers, platform developers/vendors engaged in the design and delivery of Telemedicine services, and consumers/patients availing themselves of such services. This document aims to establish best practices, ensure the quality and safety of Telemedicine interactions, and foster a secure and effective Telehealth environment.

These guidelines will assist the health care providers in pursuing a sound course of action to provide effective and safe medical care founded on current information, available resources, and patient needs to ensure patient and provider safety.

Telemedicine consultations should be conducted by existing best practice clinical standards and models of care for face-to-face consultations. The guidelines have been written to provide guidance and advice to healthcare providers with the aim that Telemedicine consultations are delivered to the same standard as consultations conducted in person.

Who needs to use these Guidelines?

These guidelines are relevant to:

- Healthcare providers providing Telehealth/Telemedicine services to Sri Lankans
- Telehealth/Telemedicine service platform provider institutes within Sri Lanka
- Patients and the general public in Sri Lanka
- Policy makers and regulatory bodies

Definition of Telehealth.

“**Delivery of healthcare** at a distance using telecommunication technologies’. Telehealth includes both curative and noncurative aspects of healthcare delivery such as health education, health promotion, research, continuous medical education, professional training and administrative meetings.

Common technologies used to transfer information electronically include telephone, radio, fax, email, the internet, video conferencing, and satellite-based communications, among others.

Definition of Telemedicine

The curative or clinical part of Telehealth is called “Telemedicine” and is described as ‘the process of exchanging medical information from one site to another via electronic communications to improve **a patient’s clinical health status**’.

The types of information that can be transferred from site to site are medical documents, laboratory results, digital photographs, ECGs, radiological images, clinical-related video recordings, auscultatory sound from electronic stethoscopes and physiological examination parameters such as blood pressure, heart rate, haemoglobin saturation, and spirometry.

The communication can be between the patient and healthcare provider or between two or more healthcare providers (team) about the treatment of a specific patient and both parties are separated by distance, time or both. The information transfer can happen in real-time synchronously or pre-recorded and forwarded later. Also, this information can be related to remote monitoring and the use of mobile health.

These guidelines will mostly address the clinical part of Telehealth consultations related to individual care which is defined as Telemedicine. Therefore, mainly the term “Telemedicine” will be used in this document. However, the term “Telehealth” will be used in situations where there is provision of non-clinical related services along with individual clinical services.

Definition of Internet-based drug prescribing or remote prescribing

The act of issuing an online prescription would entitle the patient to receive the drugs from the pharmacy, following a distant teleconsultation without physical person-person consultation between the health provider and patient.

Definition of e-prescribing

Delivery of a valid web-based prescription electronically via the internet/intranet network to the pharmacy from the point of care after a normal face-to-face consultation with a doctor guiding the patient to collect drugs directly without a paper-based prescription.

Adhering to Sri Lankan legislation and Guidelines

All involved parties (technology provider, Telehealth service institute, Telehealth professional and Telehealth client) should adhere to below mentioned or forthcoming new updated versions of Sri Lankan legislation, policies and guidelines related to Telemedicine service delivery. This includes specifications for hardware or software, infrastructure building & maintenance as well as standards on data management, systems involved, standards and interoperability. Also, it is recommended to follow the ISO Standards in Telehealth to improve their services to global standards.

Legal Acts

- I. Medical Ordinance for Sri Lanka and its amendments
- II. Information and Communication Technology Act - No. 27 Of 2003
- III. Intellectual Property Act - No. 36 of 2003
- IV. Electronic Transactions Act - No. 19 of 2006
- V. Computer Crime Act - No. 24 of 2007
- VI. National Medicines Regulatory Authority Act, No. 5 Of 2015
- VII. Right to Information Act, No. 12 of 2016
- VIII. Personal Data Protection Act, No. 9 of 2022

Guidelines and Policies

- IX. Guidelines on Ethical Conduct by SLMC 2009
- X. National Digital Health Guidelines and Standards 2016, 2020
- XI. Health Information Policy 2016
- XII. National Health Policy 2016-2025
- XIII. Information Security Guideline for Healthcare Institutions 2021
- XIV. National Digital Health Blueprint 2023

Guidelines in detail

Guidelines to be followed by healthcare providers of medicine practices.

This section applies to doctors and other health care providers registered in Sri Lanka under the Sri Lanka Medical Council (SLMC)/ Sri Lanka Nursing Council (SLNC) and practising Telemedicine in Sri Lanka and/or overseas; as well as professionals who are overseas and provide health services through Telemedicine to patients in Sri Lanka. Also, these guidelines concentrate more on the consumer-to-provider modality of Telemedicine.

In an instance, a Healthcare provider providing health services to Sri Lanka-based consumers via Telemedicine, a medical practitioner or dentist or a specialist should be registered under the relevant section of the Medical Ordinance governed by SLMC. For example, when practising Telemedicine, a doctor will be subject to the same requirements needed to practice medicine physically in Sri Lanka.

In the instance of other healthcare providers delivering Telemedicine services, they should be registered under the relevant section in SLMC or the Sri Lanka Nursing Council (SLNC). These guidelines are for providing Telemedicine services to patients residing in Sri Lanka by the healthcare provider registered in SLMC or SLNC.

These guidelines don't address the following areas:

- Use of digital technology to conduct surgical or invasive procedures remotely.
- Use of Telemedicine for specific medical speciality uses (will be catered by detailed guidelines in the future)
- Other non-clinical aspects of Telehealth such as research and evaluation and continuing education of healthcare workers
- Does not provide for consultations outside the jurisdiction of Sri Lanka
- Details on professional charges, reimbursement and other financial aspects
- Healthcare providers not registered under SLMC or SLNC

1. Guidelines to be followed by the Healthcare provider (Clinical Aspect)

1.1 Informing the consumer/patient about Telehealth/Telemedicine

1.1.1 The patient or customer must be informed regarding Telemedicine as well as other pertinent options for the healthcare delivery process.

1.1.2 The patient or consumer is made aware of the responsibilities of each individual involved in providing Telehealth care.

1.1.3 The patient/consumer is advised that while standards-based solutions are employed to safeguard their data security and privacy, complete protection cannot be ensured. The patient or consumer is advised of any additional risks to quality, reliability, or security if non-standards-based solutions are being employed.

1.1.4 The patient or customer is made aware of any upfront costs associated with Telemedicine consultations in comparison to other accessible options.

1.1.5 The patient or customer needs to be aware of the procedure for filing a complaint against the Telemedicine service

1.2. Seeking consumer/patient consent

1.2.1 The consumer/patient needs to give informed consent to the use of the Telemedicine modality when he/she installs the Telemedical application. Thereafter, consent for each consultation can be **implied or explicit** if the consumer/patient initiates the Telemedicine consultation. However, explicit consumer/patient consent is needed if the health professional initiates a Telemedicine consultation. This may be in verbal or written format.

Appropriate consent should be obtained if the Telemedicine session is going to be videotaped or if the nature of the service is significantly different from standard care. Recordings of the consultations should **ONLY** be made with written consent and only for educational or assessment reasons.

1.3. Selecting appropriate consumers/patients for Telemedicine

(These guidelines are intended to be used for basic healthcare practices. (Separate guidelines need to be referred for specialized medical care using Telemedicine).

1.3.1 The healthcare organization should have a set of criteria about which consumers/patients are suitable for Telemedicine.

1.3.2 The patient/consumer and/or their authorised carer must be able and willing to take part in Telemedicine care.

1.3.3 The following factors are considered before using Telemedicine:

1.3.3.1 Clinical elements including shared care, continuity of care, and the best suitable model of care for each patient or customer

1.3.3.2 Useful elements include technology, local clinical workers, and the availability of specialists

1.3.3.3 Consumer/patient factors such as the ability of the consumer/patient and/or their informal care provider to travel, work and cultural situations.

Telemedicine guidelines mentioned in this document do not address below mentioned conditions in the instance of provider-to-consumer online Telemedicine consultations (the consumer/patient is being managed without the physical presence of a healthcare provider nearby).

- a. Management of consumers/patients with potentially serious, high-risk emergency medical conditions that likely to need a physical examination.
- b. When an internal examination cannot be deferred.
- c. Co-morbidities affecting the consumer/patient's ability to use the technology
- d. Consumers/patients who may find telecommunication difficulties
- e. Children under 2 years of age.
- f. Patient evaluation for Medico-Legal purposes

Specific requirements need to be provided for people with vision impairment, blindness, deafness, hard of hearing and speech difficulties.

- The Telemedicine platform should be compatible with assistive devices and screen magnification.
- The Telemedicine platform should have captioning capability during video conferencing.

- The Telemedicine platform should have the ability to use text-to-speech generators for speech-impaired individuals.

Specific guidelines will be developed in future for the specific practice of Telemedicine in medical specialties (Eg. Emergency Medicine, Dermatology, Surgery, etc.) with concurrence from respective professional colleges.

1.4. Using Telemedicine in delivering care

While conducting the consultation following needs to be considered

1.4.1 The role of Telemedicine in the overall management of the consumer/patient and continuation of care needs to be informed.

1.4.2 If there are any limitations to using Telemedicine, these are noted and reduced as far as possible and informed.

1.4.3 The referring health care provider verifies the patient's identity to the remote specialist or health service as well as verifies the identity and credentials of the distant specialist to the consumer/patient.

1.4.4 At the start of the session, the patient or customer is told about the estimated time required to provide care via Telemedicine.

1.4.5 A healthcare provider from the referring healthcare organization needs to be present with the consumer/patient for some or all of the video consultations with the specialist.

1.4.6 Whenever possible, evidence-based guidelines should be used to deliver Telemedicine. In cases when these are not applicable, the best-fit framework for a clinical purpose should be applied.

1.4.7 By considering the privacy issues associated with Telemedicine and creating protocols to manage privacy, the consumer's or patient's privacy is safeguarded.

1.4.8 When applying Telemedicine, protocols governing how various healthcare providers cooperate must be available. Some of these protocols are:

1.4.8.1 a process for determining the most appropriate referral routing. Since Telemedicine has significantly increased the number of referral choices, the referring practitioner must consider factors like how to prevent care fragmentation and if the specialist is available for an in-person appointment if necessary.

1.4.8.2 publication of a list of suitable health professionals for Telemedicine referral.

1.4.8.3 an explanation of the care offered needs to be given, including any modifications to the regular responsibilities of the healthcare professionals.

1.4.8.4 provides an overview of modalities in providing each type of care, such as ordering testing, prescription generation and follow-up needs to be documented.

1.4.8.5 an instruction explaining how the consultation ought to be documented. When two medical professionals interact with a patient or consumer simultaneously, they should each maintain separate medical record notes.

1.4.9 Issuing medical certificates via Telehealth consultations is not encouraged and needs to be regulated under Standards of Practice (SOP) documents.

1.4.10 Cross-border practices of Telehealth should only include health education and advice.

1.4.11 In case of a referral, access to patient records can be given to another practitioner with the consumer/patient's consent.

1.5. Skills of health care practitioners

1.5.1 There should be adequate training for Telehealth providers and are criteria set for the skills of the healthcare provider who uses Telehealth. This can be done by each Telehealth platform institution under the guidance of Health officials. Orientation on basic guidelines can be considered as the first step.

1.6. Evaluating the use of Telemedicine

1.6.1 Individual level - After their first use of Telemedicine, the consumer/patient needs to be asked for an evaluation of the experience. If the consumer/patient is making long-term use of Telemedicine, this evaluation should be repeated at regular intervals or if warranted by a change in the consumer/patient's condition.

1.6.2 Organisational level - At suitable intervals of time, the health care organisation evaluates the usefulness of Telemedicine across the organisation as a whole and makes decisions about the modalities and volume of Telemedicine used by the organisation.

If the condition can be appropriately managed via Telemedicine, based on the type of consultation, then the health professional may proceed with a professional judgement to:

- I. Provide Health Education as appropriate in the case; and/or
- II. Provide Counselling related to specific clinical conditions; and/or
- III. Prescribe Medicine (If registered under section 29/41/43/39b/67A and Act 15)

1.7 Prescribing Medicine

This can be done only by health professionals who are allowed to prescribe medicine under the SLMC medical ordinance.

Prescribing medications, following a Telemedicine consultation is at the professional discretion of the authorized medical professional. Professional accountability applied here is as same as for the traditional in-person consult. The same prevailing regulatory principle on diagnosis and prescribing will apply to Telemedicine consultation similar to the in-person physical consultation.

Authorized Medical professionals may prescribe medicine via Telemedicine ONLY when he/she is satisfied that he/ she has gathered adequate and relevant information about the consumer/patient's medical condition and prescribed medicines are in the best interest of the consumer/patient. Prescribing medicines without an appropriate diagnosis/provisional diagnosis will be not appropriate to ethical practices. Authorized Medical professional shall provide an eligible format of system system-generated photo, scan, digital copy of a signed prescription or system-generated online prescription to the consumer/patient via email or a given messaging platform. Second-type or system-generated internet-based prescriptions are encouraged. In case the medical professional is transmitting the prescription directly to a pharmacy, he/ she must ensure explicit consent of the consumer/patient that entitles him/her to get the medicine dispensed from any pharmacy of his/ her choice. Internet-based prescriptions should include data areas mentioned below.

The following indicators need to be included in an internet-based prescription.

Mandatory –Patient's name, age, date, and generic name of the medications.

Healthcare provider's name, registration number, qualifications, signature, rubber stamp image practitioner address, and current active contact details of doctor/institute for patient communication.

Optional: Presenting complaint, History, Symptoms, Signs, Investigations, Past medical surgical history, Allergic history, and Trade name of the medication.

1.8 Specific Restrictions

Certain limitations will apply to prescribing some medications via Telemedicine consultation. The categories of medicines that can be prescribed via tele-consultation will be as same for the physical consultations other than for controlled medications. These are medications enlisted by the National Medicinal Regulatory Authority (<https://nmra.gov.lk/>) as controlled substances. These medications have a high potential for abuse and could harm the patient or society at large if used improperly.

These medications should not be prescribed online through internet-based prescriptions unless healthcare providers must have a preestablished, legitimate patient-provider relationship before prescribing controlled substances via Telemedicine. Repeat prescriptions on controlled medications are discouraged.

2. Guidelines to be followed by Telemedicine provider institutes (Technical Aspects of Telemedicine)

All state sector institutes providing Telemedicine services to individuals who fall within the jurisdiction of Sri Lanka should enlist their Telemedicine solution platform in the software register maintained by the Health Information Unit (HIU) of the Ministry of Health as well as registered as health care-providing institute in the institute registry maintained by the HIU. The private providers shall register at the Private Health Services Regulatory Council (PHSRC) Ministry of Health, Sri Lanka Above mentioned steps are needed to receive the Point of Issue (POI) number from the Ministry of Health. This POI number is essential for the institute to issue Personal Health Numbers (PHN) for their consumers/patients in the Sri Lankan digital health echo system. PHN will be the unique identification key in the identification of patients and will assist the exchange of patient information between Telemedicine service providers in the forthcoming National Electronic Health Record (NeHR) under the national digital health blueprint architecture. Adequate methodology should be there to validate the identity of the patient who is facing the Telemedicine consultation. If a guardian who is registered on behalf of the patient is facing the consultation, his/her identity and relationship should be informed to the clinician.

2.1 Adequate performance of Telehealth provision equipment

2.1.1 It is needed to evaluate whether the information and communications technology used for Telehealth is appropriate for clinical purposes.

More specifically:

2.1.1.1 The equipment functions dependably and well over the locally available network and bandwidth

2.1.1.2 The equipment used in both sides of the consultation needs to be compatible with each other.

2.1.1.3 All healthcare organisations involved in teleconsultation need to meet the standards required for the security of storing and transmitting health information in line with country legislation and guidelines. Dual authentication is required to address security concerns in specific Telemedicine needs.

2.1.1.4 Peripheral devices are used in a manner that is suitable for both the patient and the clinician.

2.2 Commissioning of equipment

2.2.1 The equipment is installed according to the producer's guidelines, where possible in collaboration with the healthcare providers using the system. The Healthcare provider shall be responsible for the standards of the device used for the Telemedicine consultation.

2.2.2 The participating healthcare organisations need to test the equipment and connectivity together to make sure it performs as specified by the manufacturer.

2.3 A risk analysis is carried out to ascertain the probability and severity of problems that are anticipated.

2.3.2 Standard Operating procedure needs to be there for detecting, diagnosing and fixing equipment problems.

2.3.3 When the equipment is in operation, technical support services are offered.

2.3.4 A backup plan that is appropriate with the implications of failure exists to handle equipment or connectivity failure. If Telemedicine is going to be doing urgent work, think about adding a backup power source and an uninterruptible power supply.

The Technology Platform must ensure that there is a proper mechanism in place to address any queries or grievances that the end customer may have.

Exclusions:

Technology platforms based on Artificial Intelligence/Machine Learning are not allowed to give definite diagnosis or directly prescribe medicine to the patient.

3. Administrative features to be followed by the Telehealth institutes**Human resource management**

They are obligated to ensure that the consumers are consulting with registered medical practitioners/healthcare providers duly registered with national medical councils. Technology Platforms shall conduct their due diligence before listing any health professional on its online portal. The platform must provide the name, qualification, speciality details, registration number, and contact details of every medical practitioner/healthcare provider listed on the platform. It should be the responsibility of the platform provider to inform the consumer when the healthcare provider is out of the country.

In the event some non-compliance is noted in any health professional the technology platform should be required to report the same to SLMC/SLNC who may take appropriate action.

The healthcare organization has implemented Telehealth in a planned manner, including:

- 3.1.1 creating or implementing a strategy to maintain the sustainability of Telehealth services.
 - 3.1.2 review workflow and other modifications in staff that will take place with the introduction of Telehealth modality.
 - 3.1.3 authorising the modifications required for managing the Telehealth application.
 - 3.1.4 initiate and maintain training or professional development for Telehealth-related staff.
 - 3.1.5 continuous quality improvement of the Telehealth program
 - 3.1.6 ensure that professionals who deliver Telehealth services are covered by professional indemnity and insurance cover.
- 3.2 Management of Logistics
- 3.2.1 The healthcare organisation needs to make arrangements to reserve the providers, resources, and physical space required to provide Telehealth services.
 - 3.2.2 To guarantee continuity of care, suitable equipment needs to be used.
- 3.3 Platform should be technologically compatible for the notification of diseases

4. Areas to be educated to the Telehealth receiver/consumer to extract maximum benefit from a Telemedicine consultation.

4.1 Managing the patient's physical environment.

4.1.1 The room which is used for the session needs to include:

4.1.1.1 adequate physical space to perform the video consultations (e.g., evaluate gait, involve family or carers);

4.1.1.2 guarantees the patient's privacy and comfort (both mental and physical);

4.1.1.3 a supportive background environment that permits the equipment to be used efficiently (e.g., good lighting, little to no background noise, distance for optimal use of the camera).

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Annexure 02 (Stakeholders involved)

Editorial committee on Telemedicine Guidelines development

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Nominated representatives from the following Professional Colleges participated in the consultative meetings held in 2023

College of Medical Administrators of Sri Lanka

College of Community Physicians of Sri Lanka

Sri Lanka College of Health Informatics

Health Informatics Society of Sri Lanka

Sri Lanka College of Specialist Family Physicians

Sri Lanka College of Emergency Physicians

Sri Lanka College of Radiologists

The College of Surgeons of Sri Lanka

Sri Lanka College of Paediatricians

Sri Lanka College of Sexual Health and HIV Medicine

College of Medical Educationists Sri Lanka

College of Anaesthesiologists & Intensivists of Sri Lanka

College of Ophthalmologists of Sri Lanka

College of Pathologists of Sri Lanka

Sri Lanka College of Pulmonologists

Ceylon College of Critical Care Specialists

College of Forensic Pathologists of Sri Lanka

Nominated representatives from the following regulatory organizations participated in the consultative meetings held in 2023.

Sri Lanka Medical Council (SLMC)

Sri Lanka Nursing Council (SLNC)

National Medicines Regulatory Authority (NMRA)

Private Health Regulatory Council (PHSRC)