Telehealth Application Guidelines
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The national committee of clinical guidelines for telehealth.

Code of ethics for patient privacy and confidentiality

The NHIC aims to provide quality, knowledge and integrated services to the Saudi health system assuring to meet the standards of global best practices. NHIC supports the privacy and confidentiality of health information by providing standards and regulations and best practices in the field of digital health.
Introduction

Telehealth is “the use of electronic information and communication technologies to support virtual clinical healthcare practice, patient and professional health-related education, public health and health administration” (1). It allows long-distance patient and clinician contact, care, advice, education, intervention, monitoring, and remote care pathway delivery (2). When in rural settings, lack of transport, a lack of mobility, conditions due to outbreaks, epidemics or pandemics, decreased funding, or a lack of staff, restricted access to care, telehealth may bridge the gap(3) as well as provide distance-learning; meetings, supervision, and presentations between practitioners; online information and health data management and healthcare system integration(4).

In the light of the global and local acceleration of the adoption of telehealth technology, which has proven to facilitate the provision of healthcare to everyone regardless of geographical location and assisted in preventing the spread of diseases mainly during the covid-19 pandemic. This adoption has shown a great value to everyone including healthcare professionals, healthcare facilities and patients. However, it has raised a great risk regarding the safety of the provision of healthcare and required the intervention to organize the practice to ensure the overall safety of patients and the privacy of their health information.

Therefore, this document comes as an integral document to organize the practice of telehealth in the Kingdom of Saudi Arabia to provide safe and efficient telehealth practice. It aims to create guidelines for the practice of telehealth for healthcare professionals, virtual hospitals and mobile apps. Accordingly, it covers the requirements for telehealth services, the basic steps when using telehealth services, patient rights and technical requirements of telehealth services. In addition, this document is not considered as a clinical guideline for any specific specialty nor a disease, but it aims to help Healthcare professional (HCP) using telehealth technologies to provide the best care to patients.
Selecting patients for telehealth:

Physicians should determine which patients are suitable for telehealth based on available resources, technology and the urgency of medical care. Physicians providing telehealth consultation services should determine whether a telehealth consultation is the most appropriate type of consultation for each patient.

The decision to use telehealth incorporates the following factors:
Practical: availability of appropriate technology and patient-end support. The quality of the technology at the remote site will play a significant role in the information gained during the clinical consultation.

Note: all content provided in this document are subject to evolve for their improvement in line with scientific literature or suggested comments. These guidelines are subject to review and update on a yearly basis. Any changes will be communicated by the NHIC.
## Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td><strong>Telehealth</strong></td>
<td>The use of electronic information and communication technologies to support long-distance virtual clinical healthcare practice, patient and professional health-related education, public health and health administration. (1)</td>
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<tr>
<td><strong>Telemedicine</strong></td>
<td>The use of medical information exchanged from one site to another via electronic communications to improve patients' health status.</td>
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<tr>
<td><strong>A telehealth solution provider (TSoP)</strong></td>
<td>A digital enabler to virtual care services. The tool may be a hardware and/or a software, and may be a medical device.</td>
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<tr>
<td><strong>A telehealth service provider (TSeP)</strong></td>
<td>An entity providing a remote clinical health service.</td>
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<tr>
<td><strong>licensed Health care professional</strong></td>
<td>Anyone authorized to practice health professions. This includes the following categories: physicians and dentists, pharmacology specialists, health technicians (in radiology, nursing, anesthesia, laboratory, pharmacy, optics, epidemiology, prostheses, physiotherapy, dental care and installation, CT imaging, nuclear therapy, laser, and operations), psychologists, social workers, nutritionists, public health, midwifery, ambulance, speech and hearing treatment, occupational rehabilitation, occupational therapy, medical physics, and other health professions that are An agreement between the Ministry of Health, ministry of human resources and social development and the Saudi Commission for Health Specialties.</td>
</tr>
<tr>
<td><strong>health worker</strong></td>
<td>A healthcare professional who delivers care and services to the sick and ailing either directly as doctors and nurses or indirectly as aides, helpers, laboratory technicians.</td>
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<tr>
<td><strong>Medical Guardian</strong></td>
<td>An adult who is considered legally responsible for the care and custody of a minor or another adult determined to be unable to provide self-care or otherwise incompetent.</td>
</tr>
<tr>
<td><strong>Informed consent</strong></td>
<td>A Legal documented process regulates the conduct of medical relationship between the patient and the healthcare professional.</td>
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</table>
## Glossary

| **Biomedical device as per FDA/SFDA standards** | The FDA categorizes medical devices into one of three classes – Class I, II, or III – based on their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness.  
Class I: Common, low risk devices with low complexity  
Class II: moderate risk, partially implanted devices with more complexity  
Class III: high-risk, fully implanted devices. |
| **licensed organization** | Telemedicine or telehealth organization that is licensed for the purpose of administering services in the scope of telemedicine or telehealth. |
| **Physiologic monitoring** | Is the use of digital technologies to monitor and capture medical and other health data from patients and electronically transmit this information to healthcare professionals for assessment and, when necessary, recommendations and instructions. |
| **Remote patient monitoring** | The use of synchronous or asynchronous electronic information and communication technology to collect personal health information and medical data from a patient at an originating site that is transmitted to a healthcare professional at a distant site for use in the treatment and management of medical conditions that require frequent monitoring. |
| **Store-and-forward technology** | The asynchronous transmission of a patient’s medical information from a healthcare professional at an originating site to a healthcare professional at a distant site. |
| **Medico-legal** | The evaluation of all processes and procedures in case of any dispute that requires review if the medical practice is following the best practice. |
| **Secondary use of data** | Unidentified use of data for any purpose such as research, analysis, AI, data mining. |
| **Local data storage** | refers to anything that is “on premise” or “on-prem” such as a hard drive, flash drive, local file server, or Network Attached Storage drive (NAS drive) |
| **The assisting HCP** | A HCP in a tele-assistance encounter, who provides a technical assistance remotely. |
| **Expert HCP** | A HCP in a tele- expertise encounter, who provides an expert medical opinion remotely. |
| **Triage of patients** | Patient prioritization and categorization according to medical and management needs, such as illness/injury, severity/complexity, prognosis and resource availability and referral to specialized care as indicated by case. |
| **Point-of-care testing** | A medical diagnostic testing outside a clinical laboratory can be near or at the patient site of care. |
### Abbreviations

<table>
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<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>AI</td>
<td>Artificial Intelligence</td>
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<tr>
<td>CT</td>
<td>Computerized Tomography</td>
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<td>CHI</td>
<td>Council of Health Insurance</td>
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<tr>
<td>COPD</td>
<td>Chronic Obstructive Pulmonary Disease</td>
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<tr>
<td>CXR</td>
<td>Chest X-Ray</td>
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<tr>
<td>DLP</td>
<td>Data Loss Prevention</td>
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<tr>
<td>DOSTM</td>
<td>Health Catalyst Data Operating System</td>
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<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
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<td>EMR</td>
<td>Electronic Medical Records</td>
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<td>EHR</td>
<td>Electronic Health Record</td>
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<tr>
<td>FECC</td>
<td>Far End Camera Control</td>
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<tr>
<td>FDA/SFDA</td>
<td>Food and Drug Administration/ Saudi Food and Drug Authority</td>
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<tr>
<td>HCP</td>
<td>Healthcare professional (referred to consulted/consulting, accepting/referring) this has been specified within the document.</td>
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<tr>
<td>ICU</td>
<td>Intensive Care Unit</td>
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<td>CST</td>
<td>Communications, Space &amp; Technology Commission</td>
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<td>KSA</td>
<td>Kingdom of Saudi Arabia</td>
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<td>NDMO</td>
<td>National Data Management Office</td>
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<td>NHIC</td>
<td>National Health Information Center</td>
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<td>MRI</td>
<td>Magnetic Resonance Imaging</td>
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<td>MoH</td>
<td>Ministry of Health</td>
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<td>MRN</td>
<td>Medical Record Number</td>
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<td>SeHe</td>
<td>Saudi Health Information Exchange</td>
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<td>SLA</td>
<td>Service Level Agreement</td>
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<td>RPM</td>
<td>Remote Patient Monitoring</td>
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<tr>
<td>TLA</td>
<td>Tele-Assistance</td>
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<tr>
<td>TLC</td>
<td>Tele-Consultation</td>
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<tr>
<td>TSeP</td>
<td>A telehealth service provider</td>
</tr>
<tr>
<td>TSoP</td>
<td>A telehealth solution provider</td>
</tr>
<tr>
<td>VNA</td>
<td>Vendor Neutral Archive</td>
</tr>
<tr>
<td>SCFHS</td>
<td>The Saudi Commission for Health Specialties</td>
</tr>
<tr>
<td>PACS</td>
<td>picture archiving and communication system</td>
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<tr>
<td>POCT</td>
<td>Point-of-care testing</td>
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Initiation of virtual practice

Health information and identity
Liability and malpractice
Patient rights and dispute resolution
Clinical service continuity of care
Insurance coverage
Technical aspects of telehealth
Telehealth data management
Health Information and Identity:

Provider-Patient Relationship:
It is crucial that a valid patient-physician relationship must be established before the provision of telemedicine services, through (5–13):
The provider agrees to undertake diagnosis and treatment of the patient, and the patient, or a medical guardian for the patient, agrees to be treated—whether or not there has been an in-person encounter between the patient and the provider.
The Provider Must:
Verify and authenticate the patient’s identity by checking at admission, registration & presentation at every encounter.
Use a patient identification across all health information systems in order to support patient unified records.
Treat a patient via telemedicine and confirm key identifiers, to ensure the proper medico-legal documentation, medical notes and electronic systems used match the patient in process of an intended care.
Confidence of the HCP in assessing the patient condition and establishing the medical diagnosis without the need for in-house physical examination that could not be achieved with the virtual physical examination and investigation solutions.
Check the patient’s identity and match it with their intended care throughout their continuity of care. Also, ensure this has been correctly documented.
Follow key essential approved identifiers that can be used to ensure the right patient is matched with the right procedure. These include:
Name (family and given names), Governmental ID, Date of birth, Gender
Medical record number, or Individual healthcare identifier
7. Confirming that telehealth/telemedicine services are appropriate for that patient’s individual situation and medical needs.
8. Evaluating the indication, appropriateness and safety of any prescription in keeping with best practice guidelines and any formulary limitations that apply to the electronic interaction.
9. Documenting the clinical evaluation and prescription.
Healthcare Professional (HCP) Identity:

HCP should disclose his or her identity and applicable credential(s) to the patient; and obtain appropriate informed consent after any relevant disclosures regarding the delivery models and treatment methods or limitations, including any special informed consents regarding the use of telehealth technologies.

Informed consent in telehealth practice:

A Legal documented process regulates the conduct of medical relationship between the patient and the healthcare professional or the treatment of the healthcare facility according to the laws, regulations and medical requirements. Informed consent documentation aims to explain the elements of the treatment agreement conducted between the patients and the HCP or the healthcare facility. Further, it guarantees the compliance of the parties with the non-emergency treatment agreement and resolves the conflict between the parties to the agreement by explaining the rights, duties, and obligations of each party towards the medical procedure taken and determined in advance. Moreover, it explains the method, mechanism, outcome, and possible complications of the procedure.

Informing the patient about telehealth & obtaining the consent:

Before conducting a telehealth consultation when applicable, physicians should ensure patients understand how the consultation will proceed. This may include:
1. Providing the patient with plain language information about the intended telehealth service.
2. Informing patients of the other available care options.
3. Informing patients of any out-of-pocket charges for telehealth consultations, compared to other available options, if applicable.

HCP may need to liaise with the patient-end health worker or related caregiver to ensure the patient is sufficiently informed. In cases where there is no health worker at the patient end, the HCP will need to ensure that the patient has been given adequate information regarding the telehealth consultation.
**Seeking patient consent:**

1. HCPs should verify that patients have consented to participate in the telehealth consultation.
2. In cases where the patient is not competent and does not have the capacity to give consent, consent should be obtained in the same way as in a face-to-face consultation.
3. The HCP or patient-end health worker may have to arrange for consent to be given by a family member or friend who has the requisite legal authority (for example, enduring guardianship) to give consent on the patient’s behalf.
4. In cases where a recording is to be used for education or assessment purposes, the patient should be informed of this and give consent to how the recording is to be used. The patient should be told the reasons why the consultation is recorded, how it will be stored and for how long.
5. Patient verbal and written consent is documented.

**Privacy and confidentiality of health information:**

In compliance with the Saudi personal data protection law which is based on ten governance principles (Appendix A)(14). Telehealth consultations should be private and confidential, and physicians should have processes in place to facilitate this as per standard face-to-face consultations. The patient’s privacy and confidentiality should be maintained at all times. The patient's privacy is protected by considering what risks there are to privacy when using telehealth, and developing procedures to manage such risks.
Requirements of Telehealth Data Management:
1. Activate data governance (operating model) that insures data sharing across organizations are done securely and safely. This should comply with national data protection laws and regulations in case of a national scope. Otherwise, all relevant laws and regulations in case of multi-jurisdictional telehealth scope.
2. Provide data analysis means that enhance telehealth care.
3. Provide immediate access to data at the bedside or in Emergency department.
4. Decentralized and hybrid systems of healthcare data management improve treatment between medical centers with fully synchronized medical records.
5. Cloud computing systems and other emerging technologies allow clinics and hospitals to offload the majority of their data into a centralized hub that can be more secure and less expensive. This should be in compliance with NCA and NDMO policies regarding data storage and cloud computing.
6. Automated cloud data allows for automatic policy-based cleanings, which allows for the deletion of irrelevant data to keep more space free.
7. Improved data management helps in reduction of patient costs and leads to a better business and private decisions making.
8. Creation of a more streamlined information’s exchange and enhancing patient service and security.
9. Ensuring the quality and interoperability of information.

Data Management Best Practices for Hospitals and Medical Facilities:
Implementing accurate data management systems is imperative to ensure the efficient storage and transfer of patients' information. Data management best practices also improve the confidentiality, reliability and comprehensiveness of this information.

To reap the benefits of exceptional data governance, hospitals and medical facilities must work together to better manage, organize, protect and transfer information between patients and providers.

The following are few key ways via which healthcare facilities (hospitals or clinics) can best practice medical data management.
Liability and Malpractice:

Responsibility/Liability in the course of telehealth is a shared responsibility between the healthcare facility, the HCP and the patient-end health worker. Each healthcare professional shall be responsible based on their individual contribution to make appropriate management and legal decisions. The legal basis and requirements relating the medico-legal professional responsibility is subject to the decision on a case-to-case after thorough review.

Responsibility/Liability:
1. The healthcare facility should be licensed to perform Telehealth services.
2. The healthcare facility shall ensure presence of governing policy and guidelines is in place throughout the duration of the telehealth service.
3. All HCP involved in telehealth practice must be fully educated and aware about the policy and guidelines that cover the telehealth services governing guidelines on national basis and within the healthcare facility.
4. The HCP liability will be assessed based on provided information during consultation.
5. In a telehealth service involving two or more healthcare professionals, each healthcare professional shall be responsible based on their individual contribution. (Provider to provider model).
6. The patient’s site referring HCP is fully responsible to treat the patient within his clinical capacity and provide the best available healthcare service at that moment. In certain cases, when further medical opinion becomes essential, telehealth service might support to provide a higher optimum care.
7. The accepting HCP should accept the professional responsibility in providing the intended healthcare service to the referring HCP.
8. The HCP should access all information needed before proceeding with telehealth consultation.
9. In a telehealth service involving two or more healthcare professionals, each healthcare professional shall be responsible based on their individual contribution:

- The responsibility is divided based on each HCP contribution
- The responsibility is subject to the limit of practice
- The responsibility is subject to the privileges Specialty, level of privilege and level of credentials and specific case situation.
- The accepting HCP is responsible to make the appropriate clinical decision, treatment plan and the appropriate care pathway based on the accessibility of the information.
- The referring HCP is responsible to conduct the consulted HCP clinical decision, treatment plan and the appropriate care pathway based on his/her clinical capacity and the availability of the resources.
- Medical documentation should be followed.

10. If Store-and-forward “asynchronous” consult used, liability will be fully on the consulted doctor except in second opinion situations. Patient consent does not declare the doctor from liability associated with medical malpractice.

11. In a direct and live services “synchronous” (doctor-to-patient) are provided (no third party or assistance at the referring site), the consulting doctor accepts full responsibility (and potential liability) for the patient’s care.
Credentialing and privileging:

1. The practice of telehealth shall be restricted to the healthcare professionals who are credentialed to practice within the jurisdiction of the Kingdom of Saudi Arabia (18).

2. The registered and classified physicians, nurses and allied health professionals must be privileged to provide telehealth services.

3. Privileging is an internal process implemented within a healthcare facility for the purpose of verifying and integrating the training and experience of the healthcare professional within the scope of telehealth services offered by the facility.

4. The originating site may choose to use the credentialing and privileging decision from the distant site to make a final privileging decision. If this option is chosen, the organization must ensure the delineation of privileges granted at the originating site only reflect those services that will be provided to that entity.

5. Telehealth services must comply with laws and regulations of KSA and work within the scope of their license, specialty and granted privileges.

6. Healthcare professionals providing telehealth services shall comply with the professional registration and classification requirements.

7. Nurses and other healthcare professionals may provide telehealth services related to diagnosis and treatment based on their credentials and privileges given to them by the credentialing and privileging committee within their healthcare facility.

8. A healthcare facility licensed by the MoH for providing telehealth services shall privilege its staff to provide telehealth services by specialty and document it in the staff’s records.

9. The healthcare facility providing telehealth services is preferred to be accredited by a recognized accreditation organization for telehealth services.

10. The license of a telehealth service or solution can be revoked in case of medical errors. This decision should be preceded by the responsible licensing entity evaluation and investigation.
Patients’ Rights and Dispute Resolution:

Patient’s Bill of Rights:

1. The patient has the right to considerate and respectful care.
2. The patient has the right to and is encouraged to obtain from physicians and other direct caregivers relevant, current, and understandable information concerning diagnosis, treatment, and prognosis.
3. Except in emergencies when the patient lacks decision-making capacity and the need for treatment is urgent, the patient is entitled to the opportunity to discuss and request information related to the specific procedures and/or treatments, the risks involved, the possible length of recuperation, and the medically reasonable alternatives and their accompanying risks and benefits.
4. Patients have the right to know the identity of physicians, nurses, and others involved in their care, as well as when those involved are students, residents, or other trainees.
5. The patient has the right to know the immediate and long-term financial implications of treatment choices, insofar as they are known.
6. The patient has the right to make decisions about the plan of care prior to and during the course of treatment and to refuse a recommended treatment or plan of care to the extent permitted by law and hospital policy and to be informed of the medical consequences of this action. In case of such refusal, the patient is entitled to other appropriate care and services that the hospital provides or transfer to another hospital. The hospital should notify patients of any policy that might affect patient choice within the institution.
7. The patient has the right to every consideration of privacy. Case discussion, consultation, examination, and treatment should be conducted to protect each patient’s privacy.
8. The patient has the right to expect that all communications and records pertaining to his/her care will be treated as confidential by the hospital as required by law. The patient has the right to expect that the hospital will emphasize the confidentiality of this information when it releases it to any other parties entitled to review information in these records.
9. The patient has the right to review the records pertaining to his/her medical care and to have the information explained or interpreted as necessary, except when restricted by law.

10. The patient has the right to expect that, within its capacity and policies, a hospital will make a reasonable response to the request of a patient for appropriate and medically indicated care and services. The hospital must provide evaluation, service, and/or referral as indicated by the urgency of the case. When medically appropriate and legally permissible, or when a patient has so requested, a patient may be transferred to another facility. The institution to which the patient is to be transferred must first have accepted the patient for transfer. The patient must also have the benefit of complete information and explanation concerning the need for, risks, benefits, and alternatives to such a transfer.

11. The patient has the right to ask and be informed of the existence of business relationships among the hospital, educational institutions, other health care providers, or payers that may influence the patient’s treatment and care.

12. The patient has the right to consent to or decline to participate in proposed research studies or human experimentation affecting care and treatment or requiring direct patient involvement and to have those studies fully explained prior to consent. A patient who declines to participate in research or experimentation is entitled to the most effective care that the hospital can otherwise provide.

13. The patient has the right to expect reasonable continuity of care when appropriate and to be informed by physicians and other caregivers of available and realistic patient care options when hospital care is no longer appropriate.

14. The patient has the right to be informed of hospital policies and practices that relate to patient care, treatment, and responsibilities. The patient has the right to be informed of available resources for resolving disputes, grievances, and conflicts, such as ethics committees, patient representatives, or other mechanisms available in the institution. The patient has the right to be informed of the hospital's charges for services and available payment methods (19–23).
Patient Rights in Telehealth Settings:

1. An informed patient consent shall be recorded, preferably online, before any telehealth activity.
2. The consent template in appendix (B) is defined by the NHIC.
3. Patients may refuse and/or cancel any participation in a telehealth activity, at any time, without the need to justify.
4. Patients may request a telehealth activity.
5. Patients should receive relevant education on telehealth if needed.
6. A protocol shall be defined by the healthcare facility in case of technical incidents stopping an activity.
7. A protocol shall be defined by the healthcare facility in case of a medical emergency occurring during an activity.
8. Patients should receive continuity of care (24).
Clinical service continuity of Care:

Facilities must have business continuity plan that is activated in case of clinical or technical disruption to ensure the continuity of care to all patients and guarantee an alternative plan (B) to be ready.

Insurance coverage:

1. The malpractice insurance of HCPs shall include telehealth practice.
2. Health insurance coverage of telehealth activities shall be applied in accordance with the regulations on health insurance coverage of CHI in KSA.

Technical aspects of telehealth:

Basic requirement of telehealth:
The information and communications technology used for telehealth should be fit for the clinical purpose of the consultation (26–29). Specifically:

• The equipment is reliable and works well over the locally available network and bandwidth.
• The equipment is compatible with equipment used by the patient-end health worker.
• The equipment and network secured, and privacy and confidentiality during the consultation can be ensured.
• The equipment is of a high enough quality to facilitate good communication between all participants and accurate transfer of clinical information.
• Exchange of data shall be governed by the same overarching guidelines on privacy, security and accurate representation of truth e.g. high-quality imagery of diagnostic studies, body parts, etc.
Telehealth Data Management:

Health Data Management in general is the process of developing and executing plans, policies, initiatives, and practices to enable entities to manage and govern their data. This is mainly to achieve the aspired value, with data considered an organizational asset. Furthermore, managing data would enable an organization to track and inventory data like a physical asset (30–45).

While, Telehealth Data Management in particular means having a data-operating system in place that serves as the foundation for getting data controlled under a discrete authority (regardless of the database structure, whether centralized, decentralized, or hybrid). This is to ensure the confidentiality, integrity and availability of such data used for telehealth purposes and that, first, this data is available a timely manner for authorized HCP and used in across any organization (e.g. hospital or clinic) participating or willing to participate in telehealth services. Second, unauthorized HCP and users are not granted access to such data. Finally, only authorized users can update this data to make sure it is complete and accurate.

Health data includes, but is not limited to the following:
- Patient demographics
- Hospitalization
- Medical notes
- Laboratory test results
- Procedures and surgeries
- Imaging, like x-rays, computerized tomography (CT), and magnetic resonance imaging (MRI)
- Laboratory tests
- Treatments and Prescriptions
- Diagnosis
- Referrals and other communication
- Physiologic monitoring data
- Provider information
- Patient insurance
- Administrative information
Requirements of Telehealth Data Management:

1. Activate data governance (operating model) that insures data sharing across organizations are done securely and safely. This should comply with national data protection laws and regulations in case of a national scope. Otherwise, all relevant laws and regulations in case of multi-jurisdictional telehealth scope.

2. Provide data analysis means that enhance telehealth care.

3. Provide immediate access to data at the bedside or in Emergency department.

4. Decentralized and hybrid systems of healthcare data management improve treatment between medical centers with fully synchronized medical records.

5. Cloud computing systems and other emerging technologies allow clinics and hospitals to offload the majority of their data into a centralized hub that can be more secure and less expensive. This should be in compliance with NCA and NDMO policies regarding data storage and cloud computing.

6. Automated cloud data allows for automatic policy-based cleanings, which allows for the deletion of irrelevant data to keep more space free.

7. Improved data management helps in reduction of patient costs and leads to a better business and private decisions making.

8. Creation of a more streamlined information’s exchange and enhancing patient service and security.

9. Ensuring the quality and interoperability of information.

Data Management Best Practices for Hospitals and Medical Facilities:

Implementing accurate data management systems is imperative to ensure the efficient storage and transfer of patients’ information. Data management best practices also improve the confidentiality, reliability and comprehensiveness of this information.

To reap the benefits of exceptional data governance, hospitals and medical facilities must work together to better manage, organize, protect and transfer information between patients and providers.

The following are few key ways via which healthcare facilities (hospitals or clinics) can best practice medical data management.
Technology Use:

- Electronic health records (EHRs) are preferred to be accessible in order to reduce treatment errors that result from gaps in knowledge regarding past medical history, allergies, or medications, especially when multiple providers are treating patients.
- Hospitals and clinics adopting telehealth services are advised to implement EHRs, since they are often the most accessible. The widespread adoption fosters the creation of more unified data management systems.
- If EHR cannot be implemented then using scanned standardized manual records, reports and data can facilitate the use of Telehealth via proper communication channels including video and audio conferencing.

Data Standardization:

- Ensure consistent data shared between systems.
- Standardize capturing, defining and transmitting data for interoperability.
- Promoting consistent or comprehensive data requires unifying the hospital systems as possible with the ability to access the EHR or manual record for any patient at any place in the Kingdom by an authorized healthcare professional using his/her national identification number (ID).
- Medical institutions can focus on achieving standardized data within their facilities by implementing a single shared data management system and server.

Seamless Information Exchange Enabling:

- Streamlining information transfer should follow standardization of data input. Both app-centric format and more of patient-centric view should be streamlined in order to ensure up-to-date deployment and security of the application whether desktop or mobile, in-house or cloud. This will facilitate the seamless exchange of clinical information to stakeholders, health providers and patients.
- Implementing systems like vendor-neutral archives provide interoperability among departments and allow harmonious data and imaging exchange.
- A Vendor Neutral Archive (VNA) stores images generated by medical devices and scanners using a standard format. It enables interoperability between the systems that store the images in the Picture Archiving and Communication Systems (PACS). Medical staff can view images from across the organization and remotely using multiple screens or devices.
A Comprehensive View Formation:

- After creating more standardized data and facilitating its exchange, medical institutions should improve the information’s reliability, thus forming a comprehensive 360-degree view of both providers and patients. This complete picture helps organizations understand where healthcare professionals practice and what patients they see.
- It is essential to link information from various profiles including name, address and National/Iqama ID, Mobile number and Hospital Medical Record Number (MRN) to the same provider. This practice ensures no one overlooks pieces of information and data is consistent between profiles.
- Patients’ contact information need continuous updating and consolidation. For example, if a physician overlooks a vital piece of information, like an allergy, this could result in medical malpractice and adverse reactions in the patient. Thus, it is best to prompt patients to provide updated data whenever possible.

Sensitive Data Protection:

- Data breaches compromise sensitive data and can be very costly for providers.
- Appropriate data management practices include setting policies to ensure this protection, such as a mobile device policy, which governs what data users can store on apps and mobile gadgets.
- Organizations should also secure wireless networks, encrypt portable devices and educate staff members about different violations.
- Data Backup is critical to ensure organizations can recover from various types of data losses.
- Data Protection using data loss prevention (DLP), storage with built-in data protection, firewalls, encryption, and endpoint protection.
- With the Health Catalyst Data Operating System (DOS™) Solution, data is pulled in from a wide variety of source systems, providing a single control point where individual access rights can be granted. From there, the organization can establish data governance and track data lineage as data is enriched and spread to the edges of the organization.
- Individual organizations such as hospitals or health systems usually provide access to their data to their internal staff. Larger collaborations for example in the execution of Telehealth programs can provide mediated or collaborative access to clinical data repositories for eligible authorized participating individuals.
Data Storage Considerations:

- Medical data is sensitive and must adhere to national data protection laws and regulations in case of a national scope. Otherwise, all relevant laws and regulations in case of multi-jurisdictional telehealth scope.
- Data storage should be hosted within Saudi Arabia’s geographical boundaries.
- Data storage should be able to meet and have the future capability for scalability in both data storage and connectivity.
- Backup of high availability in disaster recovery
- Recommendation should be at least tier 3 tier 4 for remote patient management of critical cases.
- In cases of connectivity sudden interruption, the point of care devices should be able to store the data locally and be able to forward the data once the connection is restored.
- Best practice is when a telehealth network covers a wide geographical area uses cloud service through a cloud service provider approved by CST and compliant with the data security and privacy act of health care information.
- Accessibility for integration with national health platform services.
- Data security and privacy on a cloud is a joint responsibility of both cloud service provider and the healthcare facility.
- Data custody and ownership should follow the policy and procedures of the national guidelines and acts in case of a national scope. Otherwise, a consensus needs to be reached all relevant laws and regulations in case of multi-jurisdictional telehealth scope.
Scope of Virtual practice

- Service & application
- Tele-consultation
- Tele-diagnosis
- Remote patient monitoring
- Tele-management
- Tele-surgery
- Tele-assistance
- Tele-expertise
- Tele-education
- Cross-border access
- Emerging technology
Service and application:

Getting patient set up with telehealth technology:

Telehealth services in emergency can be provided based on the following criteria:

Medical indication for telehealth:

1. Telehealth in emergency cases can deliver consultation to the patient in an emergency whenever a specialty consult is needed in a timely manner.
2. Whenever a requirement to have an access to a certified and an experienced staff to assess in deciding a reliable and effective further treatment plan.
3. In the case of a patient who may require a transfer to another advanced facility for further care plan.

Requirements to conduct telemedicine services:

1. A suitable technology platform that provide a real-time video call, vital signs evidence, performing a remote applicable diagnostic exams such as ECG, REAL TIME US.
2. In emergency cases, the biomedical device should meet the international standards of FDA of biomedical devices classification as class II.
3. Capability of continuity of care can provided through tele-monitoring.
4. The emergency telemedicine services should be initiated/ conducted through a technology platform that is locally hosted in Saudi Arabia.
5. The telemedicine platform should provide the HCP the clinical documentation capability.
6. Provide the capability of remote physiological monitoring and recording.
7. This information should be archived, retrieved and audited when needed according to the national regulation and information archiving law.
Patient Management

- If the condition can be appropriately managed via telemedicine, then the HCP may take a professional judgment to either:
  - Provide teleconsultation and guidance related to specific clinical condition
  - Request additional information such as lab diagnostics and others.
  - Provide specific treatment by prescribing medication via approved prescribing channels.
  - Exchange patient information via telehealth means safely and securely according to the national health exchange platform.
  - Patients shall not be subject to ‘first experience’ interventions. An exception can be made with complete informed consent of the patient or their representative in extreme circumstances where it is the only way to save a life or prevent permanent damage.

Services allowed to be provided through telehealth:
1. Triage of patients.
2. Diagnosis.
3. Video sighting of clinical signs.
4. Tele-mental health services.
5. Tele-monitoring.
6. Tele-prescription.
7. Tele-pathology & Tele-radiology:
   - Pathology requests can be sent to any healthcare professional.
   - Ordering and interpretation of patient lab results.
8. Tele-Referral where applicable and relevant for the case.
9. Follow up care and case management.
10. Issuance of sick leave.
11. Patient and family education and counselling.
12. Any other tele-consultation medical services approved by the healthcare facility. Examples may include provision of rehabilitation, speech and physical therapy.
Tele-consultation:

Definition:
Teleconsultation (TLC) is a remote medical consultation between a patient and a HCP.

Description:
Teleconsultation: the patient can call the HCP or vice versa, based on a booking such as in a virtual clinic or Tele-clinic. In addition, the patient can call the HCP instantly for any support needed such as in tele-triaging or via call centers that support chronic disease patients at home by HCP.

Teleconsultation includes the following encounters:

• Tele-triaging: Initial teleconsultation by patients using various channels for a new instant medical need, who has no previous registration or unknown medical history. During the teleconsultation, the patient requires an evaluation with instructions for measures that can be taken initially, and/or directions based on the urgency level to the suitable healthcare service such as calling an ambulance, immediate visit to the emergency department, primary HCP or visiting a specialized HCP.

• Tele-clinic: tele-consultation mainly for the first visit of the patient to a remote specialized HCP (if it’s not done in-person), where the patient have to visit a near-by clinic equipped for the tele-consultation devices including all the accessories needed for the patient evaluation and with a presence of assistance to apply/use these instruments, to achieve a proper specialized evaluation.

• Virtual-clinic: a remote consultation between a patient and a HCP anywhere using video conference technology, which may utilize an integrated accessories and instruments for clinical evaluations. This consultation can be planned with a booking such as a patient with chronic disease follow-up or home healthcare follow-up or instantly based on the patient’s needs such as patient having a new complain, whether the patient is seeking support on the same primary condition or consulting for a newly emerged clinical problem.
Examples:

- Tele-triaging: artificial intelligence can be one of the useful channels that can provide or augment this service. After the required SFDA approval.
- Tele-clinic: patient consulting a remote cardiologist from a nearby clinic with the presence of a physician/nurse (based on the need).
- Virtual clinic:

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<th>Virtual clinic examples</th>
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<td>Instant consultation</td>
<td>instant consultation to a related pre-existing condition (chronic disease)</td>
<td>instant consultation to an unrelated complain to the pre-existing condition</td>
</tr>
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</table>

Minimum requirements:

- Medico-legal:
  - The HCP should confirm that the settings of the session are appropriate to conduct the consultation.
  - The HCP should confirm that the patient has a proper daylight exposure for a proper clinical evaluation.
  - In case of mentally retarded patients, a family caregiver should be attending the session.
  - The HCP should know the limitations of the remote clinical evaluation using the attached accessories and should decide whether the patient needs a physical visit or not.
  - The HCP should give the patient medication needed and/or directions to the proper service he needs.
  - The HCP should give the patient instructions according to the possibility of the progression of the patient’s case.

The HCP should give the patient instructions about the medication usage and assure that the patient and/or the caregiver understands and perform it properly. For example, the use of insulin injections and Salbutamol inhaler.
• Setup:

- The systems and devices used should comply with the Saudi personal protection law and any national privacy requirements by the National Data Management Office (NDMO) and the cyber security authority.
- Access to the session between the patient and the HCP should require two-factor authentication.
- In all tele-consultations except tele-triaging, the HCP is preferred to be able to have an access to the patient’s historical data and previous documentations.
- HCP is preferred to be able to have access to the patient’s medical records, in cases of frequent follow-ups, in order to review the previous medical history and documentations and continuously update on the same medical record.
- The instructions for the bandwidth required should be given to both parties using teleconsultation.
- The session should be encrypted.
- Recording the tele-consultation sessions is not required, except in certain medico-legal needs. Such as, some of the mental health cases, criminal related evaluations.
• Technical:
  ◦ Tele-clinic: For each specialized tele-clinic, connected devices and accessories should be available at the bedside.
  ◦ Virtual clinic: the patient may utilize an integrated accessories and instruments for clinical evaluation.
  ◦ Tele-triage: if artificial intelligence is utilized to give direct instructions/directions, then an SFDA approval is required for the use of that Artificial intelligence.
  ◦ Alternative channels such as telephone calls can be provided for some of the urgent clinical needs, such as tele-triaging hotline, home healthcare cases, and rehab.
• Personnel:
  ◦ Tele-clinic: The bedside HCP should be trained to use the connected devices and accessories to support the remote HCP in doing a proper evaluation in addition to do some required bedside evaluations techniques.
• Patient experience and patient rights:
  ◦ Virtual clinic: The patient or the caregiver should be trained to use any accessories or IoT devices used at the bedside for a better evaluation and monitoring purposes.
  ◦ Tele-triaging:
    ▪ The patient should understand the tele-triaging is a screening service that will not achieve a final diagnosis.
    ▪ The patient should understand the tele-triaging would help mainly in evaluating the urgent clinical condition in order to get instructions about initial interventions and directions to the proper needed service.
Tele-Diagnosis:

Definition:
The use of telecommunications technology to facilitate the remote interpretation and/or diagnosis of the remotely performed Studies by a HCP without synchronous interaction with the patient or the requesting professional (47).

Description:
The use of telecommunications technology to enable HCP such as radiologist, cardiologist, histopathology consultant to perform interpretation and/or diagnosis of the remotely performed Studies such as diagnostic imaging, electrocardiogram, and image-rich pathological, without synchronous interaction with the patient or the requesting professional.

The process require transferring and visualizing the images in a clinical standard accepted format and resolution.

The HCP in the interpretation may require further evaluation or studies for example requesting performing special clinical evaluation, cardiovascular system examination or performing further study such as CXR, or blood gas, to support ECG interpretation in the differential diagnosis.

The Artificial Intelligence (AI) will be playing a major role in augmenting HCP initially, and supporting the screening programs by reduce the cost, using a highly sensitive AI that transfer only the abnormal studies to the HCP, so we can perform more studies with a lesser number of HCP. Furthermore, AI will perform eventually full Tele-Diagnosis services, but to assure the reliability and safety it requires detailed studies that support the process registration for each service, and use case.
Examples:

- Tele-Radiology: the practice of a radiologist interpreting medical images while not physically present in the location where the images are generated (48).
- Tele-ECG: the Practice of a cardiologist interpreting and evaluating electrocardiogram, remotely taken by handheld tele-electrocardiogram while not physically present in the location where it is taken.
- Tele-Pathology: The use of telecommunications technology to facilitate the transfer of image-rich pathology data between remote locations for the purposes of diagnosis, education, and research.

Minimum requirements of:

- Medico-Legal:
  - The images should be captured using the medico-legally accepted format and resolution
  - The images resolution should maintained unchanged during transfer or storage.
  - The professional should evaluate and study the images using a medico-legally accepted display device with the required resolution for each study category
  - The studies should be labeled with patient and facility demography.
  - The requests should be labeled based on urgency level by the requesting practitioner, to fulfill the required service level agreement (SLA).
  - The professional should receive the required report about the case to perform proper evaluation.
  - The professional should receive training on the devices used in the evaluation process such as diagnostic modality, and the display tools.
  - The Medico-legal disputes resulting from the remote interpretation and/or Diagnosis of the HCP is similar that of the regular HCP practice within the healthcare facilities.
• Setup:
  ◦ The system used should comply with the Saudi personal protection law and any national privacy requirements by the NDMO and the cyber security authority.
  ◦ The system used should assure the required availability, to fulfill the respond time for the most urgent expected cases based on the urgency level.
  ◦ The devices/ display used by the reading professional should be calibrated based on the recommended by the manufacturing company.
  ◦ The system should capture and store all the multimedia files, requesting forms, all transactions timestamps, urgency level and the reporting document during the process for medico-legal purposes.
  ◦ Any AI to be used in the service should be registered in SFDA.
• Personnel:
  ◦ The professional should receive training on the devices used in the evaluation process such as diagnostic modality, and the display tools.
  ◦ All legal requirements applied to a HCP in the Kingdom of Saudi Arabia shall be applied to the practice of tele-Diagnosis.
  ◦ All patients are eligible to benefits from Tele-Diagnosis by a remote HCP if:
    ▪ The required multimedia materials captured, delivered, and visualized with the medically accepted quality to perform the evaluation required.
    ▪ Requested HCP registered, certified, and trained, to provide the requested evaluation.
    ▪ The service and tools must be certified by SFDA for medical practice. (for example AI in Mammogram screening)
  ◦ The following is not eligible for Tele-Diagnosis request:
    ▪ If the diagnosis requires a clinical evaluation that needs a local presence of HCP, or life evaluation tools that is not under the classification of Tele-Diagnosis service.
Service and application:

Getting patient set up with telehealth technology:

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3. Capability of continuity of care can be provided through tele-monitoring.

4. The emergency telemedicine services should be initiated/conducted through a technology platform that is locally hosted in Saudi Arabia.

5. The telemedicine platform should provide the HCP the clinical documentation capability.

6. Provide the capability of remote physiological monitoring and recording.

7. This information should be archived, retrieved and audited when needed according to the national regulation and information archiving law.

Patient experience and patient rights:

- The images should be stored and transferred using technology that provide the required privacy and confidentiality.

- Patient consent should be taken, as Patients may need for a tele-Diagnosis at any time.

- HCPs practicing tele-diagnosis should respect their obligations and ethical responsibilities.

- The secondary use of the patient unidentified data should follow the governmental governance and regulation (IRB approval) in that regard.

- The secondary use of identity bounded patients data for research requires the patient approvals.

Technical:

- The devices used for study evaluation should provide the minimum medico-legally accepted resolution for each of study.

- The devices used for evaluation should be calibrated in frequent manner, based on the manufacturing recommendation, to maintain the accuracy and performance.
Remote patient monitoring:

Definition:
Remote patient monitoring (RPM) is a technology that enables monitoring of patients outside a conventional clinical setting, such as home or a remote area to trigger clinical interventions as needed. The technology increases access to care at the right time and decreases healthcare delivery costs (49,50).

Description:
RPM is the use of digital technologies to monitor and capture medical and other health information from patients. Also, electronically transmit this information to HCP for assessment, recommendations and instructions, if needed. RPM allows HCP to continue tracking healthcare data from patients if they are discharged or at home. It also encourages patients to observe their health status.

Examples:
• Blood pressure monitor: With remote blood pressure monitors, HCP can perform ongoing virtual monitoring and enables the treatment of hypertension/high blood pressure
• Blood glucose monitor: Practitioners can use the data captured by a remote blood glucose-monitoring device to detect potential alarming changes in glucose levels and take immediate action.
• Spirometry testing: plays an essential role in diagnosing lung diseases as well as assessing and monitoring conditions virtually such as asthma and chronic obstructive pulmonary disease (COPD).

Minimum requirements of:
• Medico-Legal:
  ◦ Intermittent readings of RPM tools for patients that need continuous monitoring cannot be accepted, and the frequency of monitoring intervals should be configured as per each patient clinical requirements.
  ◦ Integration minimum requirements as the NHIC interoperability standards.
  ◦ Safety and security measures should be applied on the service at all stages (collection, transfer, and store).
  ◦ A clear plan for the remotely monitored patient should be designed by his primary physician for the accepted normal parameters range and advices for the interventions for the common expected problems and when the patient requires a hospital admission.
Tele-consultation:

Definition:
Teleconsultation (TLC) is a remote medical consultation between a patient and a HCP (46).

Description:
Teleconsultation: the patient can call the HCP or vice versa, based on a booking such as in a virtual clinic or Tele-clinic. In addition, the patient can call the HCP instantly for any support needed such as in tele-triaging or via call centers that support chronic disease patients at home by HCP.

Teleconsultation includes the following encounters:
• Tele-triaging: Initial teleconsultation by patients using various channels for a new instant medical need, who has no previous registration or unknown medical history. During the teleconsultation, the patient requires an evaluation with instructions for measures that can be taken initially, and/or directions based on the urgency level to the suitable healthcare service such as calling an ambulance, immediate visit to the emergency department, primary HCP or visiting a specialized HCP.
• Tele-clinic: tele-consultation mainly for the first visit of the patient to a remote specialized HCP (if it’s not done in-person), where the patient have to visit a near-by clinic equipped for the tele-consultation devices including all the accessories needed for the patient evaluation and with a presence of assistance to apply/use these instruments, to achieve a proper specialized evaluation.
• Virtual-clinic: a remote consultation between a patient and a HCP anywhere using video conference technology, which may utilize an integrated accessories and instruments for clinical evaluations. This consultation can be planned with a booking such as a patient with chronic disease follow-up or home healthcare follow-up or instantly based on the patient’s needs such as patient having a new complain, whether the patient is seeking support on the same primary condition or consulting for a newly emerged clinical problem.

Setup:

Most RPM technologies follow a general architecture that consists of the components below:
◦ Sensors on a device that is enabled by wireless communications to measure physiological parameters. Any device that is responsible of detecting one of the targeted parameters to measure must be certified and graded by SFDA.
◦ Sensors must be connected to a central database by Wi-Fi or cellular communication protocols depending on the manufacturer.
◦ Local data storage at patients’ site that interfaces between sensors and other centralized data repository and/or healthcare facilities.
◦ Centralized repository to store data sent from sensors, local data storage, diagnostic applications, and/or healthcare facilities.
◦ Diagnostic application software that develops treatment recommendations and intervention alerts based on the analysis of collected data
• Personnel:
◦ The professional should receive a proper training that insures effective tele-monitoring delivery
◦ The healthcare facility should be licensed to perform Remote patient monitoring service.
◦ Patients should be educated on the device pre-hospital discharge.
• Patient experience and patient rights:
◦ HCPs practicing Remote patient monitoring should respect their obligations and ethical responsibilities.
◦ Patient should be consented prior to using the RPM tool.
◦ The patient must educated about the expected outcome, instruction of use, indication, automated reporting method, basic troubleshooting skills.
◦ Scheduled calls and checkups to make sure the patient follows the instructions of use.
Tele-management:

Definition:
Tele-management is the remote management of inpatients by remote HCPs.

Description:
Utilizing telemedicine technology in order to provide a complete management of inpatients remotely. Tele-management provides a better care management in case of scarce or no medical resources adapted to patient needs on patient site. Where a credentialed and privileged HCP is in charge of managing patients admitted in a remote hospital with an accessibility to the patient medical record and streaming of clinical information required to perform this responsibility (for example, vital signs, ECG, ventilators parameters, two-way video communication and accessing the monitors of evaluations tools,) based on the case and the performed rules.

Examples:
• Tele-ICU: a remote expert team manages an intensive care unit without intensivist physicians on site through Tele-ICU technologies.
• Tele-Stroke: a neurologist manages a stroke patient remotely from another center, starting from evaluation, diagnosis, and treatment.
• Tele-Round: a HCP managing patients remotely using robotics technology for routine rounds, utilizing connected clinical evaluation devices such as camera, Stethoscope, Otoscope, Ophthalmoscope, endoscope, thermometer, pulse-oximeter and sphygmomanometer.

Minimum requirements of:
• Medico-legal:
  ◦ Similar to regular clinical practice, managing HCP should continuously write his documentation in the patient medical record including all the clinical evaluations, notes, diagnosis, healthcare professionals communication, hand-offs, physician orders and treatment.
  ◦ Communication between HCPs should be documented using electronic means.
  ◦ Any addendum or amendment occur on the physician orders should be communicated to the HCP at the patient site, documented, time stamped and e-signed.
  ◦ There should be the ability to access and review current data from both the tele-managing physician and bedside HCP to facilitate communication and decision making process.
  ◦ HCP at the patient site should have a full capability to perform the expected emergency procedures that may occur for the admitted patient according to the patient needs and/or orders/instructions of the remote managing HCP.
  ◦ Alternative communication method should be available between the two HCPs in the remote and the patient’s sites (such as landline or mobile phone) to be used in case of disconnect of the tele-management communication system.
Setup:

- A unified electronic medical record (EMR) is preferred to be used for both the remote healthcare site and the patient site. Otherwise, the integration between the multiple systems should have instant synchronization to avoid latency between orders and administrations of medication or performance of the orders.
- Technology should be able to optimize audio and visual clarity for enhancement of clinical assessment. Options include:
  - Real time
  - Two-way/one-way high-definition audio-visual solutions
  - Zooming capability and day lighting to support visual evaluation
  - Audio support via traditional phone access as a backup alternative line.
- Adequate telecommunications bandwidth and security to connect near and far end equipment.
- Adequate telecommunications availability should be provided based on the criticality of the services provided.

Personnel:

- HCPs providing tele-management services shall have the necessary clinical preparation, orientation and ongoing education to ensure they possess the necessary competencies to promote quality care and patient safety.

Patient experience and patient rights:

- All remotely managed inpatients and families shall receive information, which includes the role and benefit in using the tele-management services in improving patient care and assure the confidentiality, availability and safety of this technology.
• Technical:

◦ Devices shall have up-to-date firmware and security requirement.
◦ Healthcare professional’s personal computer or mobile device has the latest security patches and updates applied to the operating system and third party applications.
◦ Mobile devices should be configured to utilize an inactivity timeout function that requires a passphrase or re-authentication to access the device after the timeout threshold has been exceeded. Timeout should not exceed 15 minutes.
◦ Unauthorized persons shall not be allowed access to sensitive information stored on the device, or use the device to access sensitive applications or network resources.
◦ Healthcare and institutional IT professionals should have the capability to remotely disable or remove data from any mobile device containing PHI or sensitive institutional data, should the device be lost or stolen.
◦ Remote management of the system should permit far end camera control (FECC), maintenance or diagnostic capabilities such as auto restart, remote configuration, proactive monitoring and/or alerts.\(^{51,52}\)
◦ System should allow point-to-point connectivity from within or outside of the healthcare facility.
◦ Audio and video transmission secure by using point-to-point encryption that meets recognized and accepted standards based on local standards.
◦ Proper testing and maintenance for all functionalities for each system upgrade, newly installed firmware, new infrastructure or endpoint.
◦ Implement planned and unplanned downtime procedures that ensure continued service and may include the use of appropriate backup technologies.
◦ Documentation, storage, and retrieval of health records consistent with the organizational, industry and governmental standards.
◦ Seamless flow of information between patient information systems to enhance clinical support and promote continuity of care.
Tele-Surgery:

Definition:
Any remote surgical procedure performed by a surgeon or a surgical team, at any
distance from the patient and theatre.
Note: When remote HCPs provide synchronous support during a surgery or
intervention to another HCPs performing at the patient site, this is not tele-surgery but
tele-assistance.

Description:
• Tele surgery uses wireless networking and robotic technology to allow surgeons
(HCP) to operate on patients who are distantly located, by combining advances in
imaging, video, robotics and sensors, the system gives surgeon the full sensory
experience of hands-on surgery. The surgeon performs the operation sitting at a
console that displays a high-resolution image of the patient. Allows collaboration
and assistance between senior-to-senior and senior to junior surgeons in providing
a variety of advanced surgical care to patient at rural or any distant site.
• AI might have a role in augmentation of surgeon for performing automated surgeries.

Examples:
• Tele-proctoring and tele-accreditation: extensions of tele-mentoring, involve
educational or professional assessment techniques for documentation and granting
privileges.
• Tele-robotics: It is an application of robotic surgery where the surgeon performs the
surgery with the help of a surgical robotic system, locally or remotely that permit
surgeon to operate on patient using robotic system and instrument like robotic arm
e.g., Laparoscopic surgery. The relationship between the tele robot and the surgeon
called Master-Slave relationship.
• Tele-presence: Is a novel technology allowing the surgeon to perform a surgery
without seeing or touching the patient directly, it is a computerized interface at the
surgical workstation in the remote operative site (53). Technology of telepresence
creates an illusion for the surgeon, giving him or her a feel of a complete immersion
into another environment, which could be real or synthetic. Through the virtual
reality, the surgeon will feel like he is in a real environment using the tele robot to
telecast their hand motion by conveying sensory feedbacks like sight, haptic, and
acoustic to the remote operating room. e.g., vascular surgery, organ excision in
trauma surgery (54–59).
Applications:

- Provides high-quality surgery to medically underserved locations such as rural areas, battlefields, spacecraft, and peripheral hospitals.
- Allows for surgical collaboration amongst surgeons at different medical centers in real-time.
- Training and mentoring new surgeons.

Minimum requirements of:

- Medico-Legal:
  - Licensure requirements and regulatory regimes of both the jurisdiction where they practice and where their patients are located should be granted.
  - If the surgeon truly does not believe that these procedures will benefit his or her patients then traditional methods should be retained.
  - Full approval from the ethical/institutional review boards of both parties (remote and local site) involved must be obtained prior to initiating the surgery and Responsibilities must be clearly delineated.
  - All details such as medical privileges and reimbursement for the surgeons and insurance coverage for the patient should be completed prior to undertaking this type of operations.
  - The remote surgeon, in addition to the local surgeon, would have to accept liability for the perioperative welfare of patients.
  - Measures to evaluate the quality of medical services must be in place, in order to ensure the highest standard diagnostic and treatment services are offered to patients.
  - In case of critical incidents such as intra-operative complication or even patient death, the responsibility of the owner of the robot should be also investigated.
• Setup:

◦ The robotic system and the communication system and link must be reliable, secure, and compliant with the Saudi data protection law, thus reducing the risk of interruptions to the connection.
◦ The surgical teams must also be able to provide effective surgical care if systems fail or communication is lost.
◦ Assistant surgeon must be always present at the operating table.
◦ Technical and support team and backup plans must be ready during the surgery to maintain the speed and if any disconnection or other technical problem happens.
◦ All systems and components should be interoperable. Both the remote site (location of surgeon) and the local site (patient location) must have system components that can cooperatively interact with other medical systems.
◦ Tele-surgery systems should be capable of robust interaction with supporting technologies such as imaging. Furthermore, all operating room systems should use hardware and software standards that facilitate interoperability.
◦ The robotic system should be proven to be used for each specific procedure and all accessories needed for that procedure should be available. In addition, the HCP should be trained for this procedure.
• Personnel:

◦ The organization should have a licensing requirement and fully developed training programs and competency-based practice and guidelines for HCP practicing tele surgery and standard operating protocols (including that for equipment maintenance)
◦ The health care organization should be accredited and certified by CBAHI to perform and offer Tele surgery service.
◦ Medical centers that offer tele-surgery services must employ a specialist in the patient site that would deal with the intra and post-operative complications.
◦ The medical centers and doctors must have insurance that covers robotic assisted-surgery and tele surgery services.
◦ Measures to evaluate the quality of medical services must be in place, in order to ensure the highest standard diagnostic and treatment services are offered to patients.
◦ Physician should be fully aware of the rationale behind, the limitations (including patient’s clinical evaluation, technology failure, and remote monitoring limitations) and alternative options must be understood when providing telehealth to avert disputes and minimize legal risks.
Patient experience and patient rights:

- Patients should be fully informed of the rationale behind, the limitations (including the possibility of intra or post-operative complication, and technology failure), and alternative options available when choosing tele surgery in order to avert disputes and minimize legal risks.
- HCPs practicing tele surgery should follow medical ethical principles, maintain confidentiality and privacy, quality of the medical services, take patient’s valid consent and providing all the information the patient wants or needs to make an informed decision, collecting and storage of data relating to the medical act.
- Patient has the right to refuse doing the operation under the tele surgery approach.
- Tele surgery should not be anonymous: both patient and tele surgeon need to know each other's identity.
- HCP must exercise due diligence in protecting patients' data when using telecommunication devices, transmitting data to third parties (e.g., other healthcare professionals) and follow the governmental governance and regulation in that regards.
- Patient records, reports, documents, images, diagnostics, data etc. (Digital or non-Digital) utilized in the tele surgery should be retained by the HCP at the patient file in both sites.

Technical:

- Latency time which is defined as the time delay in transferring auditory, visual, and even tactile feedback between the two distant locations it is ideal to be less than 100 milliseconds.
- Availability of connectivity must be similar to the availability of electricity in the operation rooms; both locations must have redundancy in connectivity by having a DIA (dedicated internet access) with the required speed from at least two different aggregators, and avoid any intra-facility points of failure.
- A healthcare facility that has the tele-surgery machine must define a Quality of service (QoS) and take in consideration the level of the LAN network within the facility and the Wide area networking (WAN) to assure the quality of audio and video.
- Secure, and encrypted high-speed data connections with sufficient bandwidth and high-quality audio-visual systems are required.
- The technology must have haptic feedback that enables transmission of tactile information to the tele-operator.
- The equipment, devices, and system quality and safety should be routinely assessed based on the manufacturing recommendation, to maintain the accuracy and performance.
**Tele-assistance:**

**Definition:**
Tele-Assistance (TLA) is a synchronous remote technical or medical expert support provided by a healthcare professional (HCP) at the patient site -such as a doctor or a nurse- to a requesting HCP during a technical intervention.

**Description:**
The use of telecommunications technology to assist the requesting HCP to manage the patient’s condition remotely. Such assistance might include interpreting laboratory or diagnostic studies, planning a therapeutic or a palliative care plan. In addition, it can facilitate transfer of the patient to a higher level of care or transfer of HCPs, medical equipment, blood products, test samples, organs, etc. to the bedside.

AI: can assist practitioners and enhance their capabilities

**Examples:**
- Tele-ICU: a critical care expert provides further management guidance to a non-critical care physician.
- Tele-EM: an emergency medicine expert provides further management guidance for a HCP working in an emergency department.
- Tele-case management: Groups of experts receive and manage requests for patient’s transfer between healthcare facilities.
- Tele-operation: remote advisory support during surgical operations or clinical procedures.
- Tele-mentoring: Enables a remote specialist surgeon to guide and/or monitor surgeon(s) to act as instructor for surgeons who actually performing the surgery at a remote patient end. It facilitates training sessions by experienced surgeons.
- Online medical control for Emergency Medical Services: an emergency-medicine expert provides further care instructions to pre-hospital providers during patient transfer.
Minimum requirements of:

• Medico-legal:
  ◦ The request for tele-assistance shall be treated as a consultation and documented as such; Documentation of the exchange between the requesting and the assisting HCP shall be a permanent part of the patient care record.
  ◦ The tele-assistance exchange shall contain the patient identifiers such as name or ID number to access the patient clinical data with minimal level needed to cover the specific encounter. Such as transferred documented information, access to the information EMR, recorded telephone calls by repeating of the medical information between the HCPs.
  ◦ Patient safety is the ultimate responsibility of the HCP at the bedside. Any interventions proposed by the remote HCP shall be viewed as recommendations that are subject to the limits of practice imposed on the HCP at the bedside by license, privileges, protocols, scope of practice, certifications, etc.
  ◦ The burden of describing the patient complete condition that contains all the details pertinent to the assistance requested falls on the requesting HCP and the assisting HCP shall not be held liable for assistance provided based on incomplete consultation.
  ◦ Following recommended interventions and their effect is a shared responsibility between requesting HCP and the assisting HCP.
  ◦ Exchange of data shall be governed by the same overarching guidelines on privacy, security and accurate representation of truth e.g. high-quality imagery of diagnostic studies, body parts, etc.
  ◦ Medico-legal disputes resulting from tele-assistance shall be arbitrated as if the consult was conducted physically at the place of work for the requested HCP based on his contribution, based on the data received.

• Setup:
  ◦ Healthcare facilities receiving TLA requests on regular basis may elect to develop protocols to minimize variability of care provided.
  ◦ It is preferred that the assisting HCP keeps a record of cases discussed and recommendations given. The cases must be documented, and both parties should have an agreed report.
  ◦ The assisting HCP is not required to be located in a designated site and can be anywhere.
• Personnel:
  ◦ Requesting and assisting HCPs shall have formal training on protocols, communication equipment utilization, and the limitations of requesting and assisting HCPs.
  ◦ Requesting and assisting HCPs shall have knowledge on available equipment, and expertise at requesting and requested facilities.
  ◦ All patients are ineligible for TLA provided that:
    ▪ Requesting HCP needs further assistance.
    ▪ Assisting HCP can provide the requested assistance.
    ▪ Such assistance does not exist at the bedside unless in case of capacity issues.
  ◦ The following shall not be considered a reason for TLA request:
    ▪ Second opinion or tele-expertise requests.
    ▪ Transfer of care requests is not a service used mainly for the purpose of transferring the case to another hospital.
    ▪ Patient or family requests.
    ▪ Requested for social reasons.
• Patient experience and patient rights:
  • Patients shall be informed of the result of the TLA request, the requested HCP details and credentials.
  • Patients shall not be subject to ‘first experience’ interventions where the requesting HCP is taking remote instructions on how to perform a procedure or an intervention that he is not trained on. An exception can be made with complete informed consent of the patient or their representative in extreme circumstances where it is the only way to save a life or prevent permanent damage.
• Technical:
  • Some of the tools and devices used during an encounter might be subjected to certification.
Tele-expertise:

Definition:
The use of telecommunications technology to facilitate the remote expert medical opinion provided by an expert HCP to a requesting HCP relying on store-and-forward (24).

Description:
Utilizing telecommunications capabilities to upload patient clinical information (store-and-forward) which may include filling specific forms, detailed clinical reports, multimedia content, investigation results and details about previous course of treatment and receive from the expert practitioners or centers an official recommendations or second opinion that may include diagnosis, suggested treatment.

Examples:
Tele-dermatology: A HCP or a patient asks a dermatologist an expert advice on the patient’s medical situation with a relevant clinical information and pictures of lesions and the level of urgency. The expert replies with the diagnosis, a potential treatment and if the patient needs further investigations or to be referred to the dermatologist.

Tele-second opinion: Utilizing telecommunications capabilities by HCPs or patients to upload patient clinical information which may include specific forms, clinical reports, multimedia content, investigation results and details about previous course of treatment and receive an official recommendations or second opinion that may include diagnosis, suggested treatment from expert practitioner or center.
Minimum requirements of:

• Medico-Legal:
  ◦ If the patient need to be examined by the expert physically, a referral should be advised.
  ◦ The medical report should be written to include all the information regarding the patient case.
  ◦ The medical questions or requests should be defined precisely
  ◦ all uploaded clinical information should be sent in a clear and easy way to read
  ◦ The medical report should be maintained unchanged during transfer or storage.
  ◦ The medical report should be labeled with patient and facility demography.
  ◦ the degree of emergency of the request should be defined
  ◦ the request should be related to the expert specialty
  ◦ Tele-expertise may not be suitable for emergency cases which needs urgent intervention
  ◦ All legal requirements applied to a HCP in the Kingdom of Saudi Arabia shall be applied to the practice of tele-expertise.
  ◦ The remote HCP should provide a service under a registered remote healthcare facility that have an official legally bounded agreement with a registered local healthcare facility. The HCP should be licensed and registered based on SCFHS and other the local policies in KSA.

• Setup:
  ◦ Tele-expertise requests are non-scheduled telehealth activities. The expert HCP may however schedule a dedicated time to reply to the requests or answer one by one based on his own agenda, availability, and urgency.
  ◦ The professional should receive training on the devices used in the evaluation process.
• Personnel:
  ◦ The professional should receive the required report about the case to perform proper evaluation.
  ◦ HCPs shall be trained on telehealth before practicing tele-expertise.
  ◦ The HCP should gather all relevant administrative and medical information.
  ◦ During a tele-expertise, both HCPs shall engage their responsibility based on their individual contribution.
  ◦ HCPs practicing tele-expertise should respect their obligations and ethical responsibilities

• Patient experience and patient rights:
  ◦ The medical report and patient details should be stored and transferred using technology that provide the required privacy and confidentiality.
  ◦ Patient consent should be taken
  ◦ A patient approval is required before any third-party participation in evaluating patient reports.
  ◦ Patients may refuse and/or cancel any participation to a tele-expertise activity, at any time, without the need to provide justification.

• Technical:
  ◦ The request form should be automated, tagged in a way to notify the urgency level of the case and the specialty needed.
Tele-education:

**Definition:**
Tele-education represents health education on distance, using Information Communication Technologies (ICT), as well as continuous education of a health system beneficiaries and use of electronic libraries, databases or electronic data with databases of knowledge (60).

**Description:**
A healthcare professional may convey health promotion and disease prevention messages. These could be related to diet, physical activity, and cessation of smoking, contagious infections. Similarly, he/ she may give advice on immunizations, exercises, hygiene practices.

A healthcare professional may have an access to a continuous educational materials, electronic libraries, databases, and live educational sessions.

**Examples:**
- General diseases education (Diabetes Mellitus, Hypertension, Bronchial Asthma, etc.)
- Using Interactive videoconferencing.
- Tele-mentoring and other forms of individual teaching (personalized education), (coaching).
- Lectures delivered through satellite broadcasts to multiple sites.
- Nudging in order to motivate people to adopt healthy behaviors without incentives or deterrent.

**Applications:**
- Provides high-quality surgery to medically underserved locations such as rural areas, battlefields, spacecraft, and peripheral hospitals.
- Allows for surgical collaboration amongst surgeons at different medical centers in real-time.
- Training and mentoring new surgeons.

**Minimum requirements of:**
- **Medico-Legal:**
  - Licensure requirements and regulatory regimes of both the jurisdiction where they practice and where their patients are located should be granted.
  - If the surgeon truly does not believe that these procedures will benefit his or her patients then traditional methods should be retained.
  - Full approval from the ethical/institutional review boards of both parties (remote and local site) involved must be obtained prior to initiating the surgery and Responsibilities must be clearly delineated.
  - All details such as medical privileges and reimbursement for the surgeons and insurance coverage for the patient should be completed prior to undertaking this type of operations.
  - The remote surgeon, in addition to the local surgeon, would have to accept liability for the perioperative welfare of patients.
  - Measures to evaluate the quality of medical services must be in place, in order to ensure the highest standard diagnostic and treatment services are offered to patients.
  - In case of critical incidents such as intra-operative complication or even patient death, the responsibility of the owner of the robot should be also investigated.

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**Telehealth Application Guidelines**

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Minimum requirements of:

- Medico-Legal:
  - Being aware of legislation, professional, and regulatory and licensing requirements that influence the delivery of educational information.
  - In organizations providing educational information, there should be senior management accountability for such information, including the supervision of all persons directly responsible for developing, coordinating, and operating Tele-education services.
  - Organizations providing Tele-education services must have policies and procedures in place to protect the data and confidentiality of information. Tele-education security policy and procedures should be integrated with those for electronic health records, whenever possible.
  - There should be policies and procedures for documentation, storage and retrieval of patient records that respect the confidentiality of the information.
  - Tele-education consultation should not be anonymous: both patient and the healthcare professional need to know each other’s identity (61).
  - Healthcare professional should obtain informed consent, which may be implied or expressed before starting any service or intervention following principles and processes similar to standard practice for the particular healthcare service.
  - Explicit consent should be obtained from the patient for medical acts that would normally require explicit consent in the traditional health care setting (e.g. video or audio recording of the sessions, use of data for research or educational purposes) (62).
  - Healthcare professional should share relevant information with the patient and caregiver, as appropriate, before the beginning of any Tele-education interaction. This information includes informing the patient of the objective of the Tele-education interaction, the role and responsibility of the provider and the patient during the Tele-education interaction, other people participating in this interaction.
• Setup:
  ◦ Platform and sessions for patient education should fulfil the required privacy and confidentiality measures in the kingdom.
• Patient experience and patient rights:
  ◦ Education material provided should be created and reviewed by subject matter experts in the field of the content provided and documenting the approving body.
  ◦ Education material should be maintained up to date and each content should have an expiry date when it is going to be subject for review.
  ◦ The evaluation parameters for the educational content are as follows: patient outcomes and satisfactions, provider satisfaction, quality of illustration content, clarity of the content and consumer completion of the content
  ◦ HCPs ethical conduct should not be compromised in all telehealth educational sessions.
  ◦ Patients’ rights and confidentiality should strictly preserved in all telehealth educational sessions.
• Technical:
  ◦ Technical requirements must be appropriate and fit for purpose to effectively transfer audio and visual data in real time and any interactions between the Provider-end and the Receiver-end during the tele-educational session.
  ◦ Software and hardware capability and suitability for the use of a tele-education setting for different purposes and scenarios may require a compatibility between the software and the different hardware tools such as computers, smartphones, laptops, tablets.
  ◦ Adopt a process of continuous monitoring and testing the used tele-education solutions, networks and devices in a frequency that prevent any failures during the real-time session and proactively discover and provide the support for any troubleshooting required instantly.
Cross-border access:

Definition:
Cross-border tele-health is the provision of healthcare services involves medical practice and information and communications technology. Cross border tele-health allows healthcare to be provided at distance, opening the door for healthcare services to be provided by a health professional who lives in a country other than the patient’s (63).

Description:
• When a patient is requesting a consultation from a healthcare professional who is located outside Saudi Arabia, whether using a synchronous (video consultation, tele-triaging, tele-education, tele-management, RPM) or asynchronous, store-and-forward (tele-expertise, tele-education)
• When a HCP requesting a service from another HCP who is located outside Saudi Arabia and vice versa, whether using a synchronous (tele-assistance, tele-management, tele-surgery, tele-education) or asynchronous, store-and-forward (tele-expertise, tele-diagnosis).
• The use of telehealth technical solutions and emerging technologies such as artificial intelligence (augmentation in screening) located in different countries.
Examples:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Synchronous / asynchronous</th>
<th>Beneficiary with cross-border provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tele-consultation</td>
<td>Synchronous</td>
<td>Patient with HCP</td>
</tr>
<tr>
<td>Tele-expertise</td>
<td>Asynchronous</td>
<td>Patient or HCP with HCP</td>
</tr>
<tr>
<td>Tele-assistance</td>
<td>Synchronous</td>
<td>HCP with HCP</td>
</tr>
<tr>
<td>Remote patient monitoring</td>
<td>Synchronous</td>
<td>Patient with HCP</td>
</tr>
<tr>
<td>Tele-surgery</td>
<td>Synchronous</td>
<td>Patient and HCP with HCP</td>
</tr>
<tr>
<td>Tele-diagnosis</td>
<td>Asynchronous</td>
<td>HCP with HCP</td>
</tr>
<tr>
<td>Tele-management</td>
<td>Synchronous</td>
<td>Patient and HCP with HCP</td>
</tr>
<tr>
<td>Emerging technology (AI, mobile, block chain...)</td>
<td>Both</td>
<td>Patient and/or HCP with technology provider</td>
</tr>
<tr>
<td>Tele-education</td>
<td>Both</td>
<td>Patient or HCP with education provider</td>
</tr>
</tbody>
</table>

Minimum requirements:

- Organizational:
  - Telehealth services should only be provided by healthcare facilities that are licensed and complied with laws and regulations issued by relevant authority.
  - The healthcare facility must provide the minimum requirements of healthcare practitioners, equipment, devices and technologies to provide telehealth services according to the relevant authority licensing guidelines for medical facilities.
  - The healthcare facility must have a formal agreement in place with the other healthcare facility.
  - The healthcare facility shall be responsible to ensure that the partnering health facility, which is not subject to the relevant jurisdiction, is made aware of all the applicable laws and regulations for telehealth services and assure compliance across both jurisdictions.
• Healthcare Professional:
  ◦ The remote HCPs are required to be licensed and registered based on SCFHS and other local policies in KSA
  ◦ Liability issues should be discussed and settled before engaging in any telehealth activity.
  ◦ The health professional who provides telehealth services should be affiliated with licensed healthcare facility.
  ◦ The licensed remote HCP should provide a service under a registered remote healthcare facility that have an official legally bounded agreement with a registered local healthcare facility.
  ◦ KSA HCP must be licensed or registered with the regulator in the patient’s jurisdiction if required.
  ◦ The healthcare professional must be aware about the approach, law and culture of the country receiving service.

The healthcare professional must complete training requirements.

• Information and technology:
  ◦ Healthcare professionals shall have access to all relevant patient records relevant to the practice of cross border telehealth services.
  ◦ Healthcare facilities shall provide secure, private and confidential workspace to safeguard patient privacy and during patient information exchange.
  ◦ Cross-border telehealth services shall be compliant with health information exchange policy, including all relevant data security, privacy requirements and level of sensitivity.
  ◦ Each healthcare facility is responsible for the availability and completeness of data when expected and needed.
  ◦ The healthcare facility should comply with the patient’s country set of principles and processes in applying telehealth services.
  ◦ The healthcare facility should comply with the patient’s country personal data protection laws.
  ◦ The healthcare professional should follow patient documentation rules as agreed between two healthcare facilities, fulfilling safety and clinical best practice.
  ◦ There are many international standards for privacy information management and information security management systems such as HIPAA, ISO/IEC 27701, ISO/IEC 27001 and ISO/IEC 27002, facilities from both countries should agree on implementing any of these international standards.
  ◦ Emerging technology in cross-border may require additional measures in privacy and confidentiality that enforce exchanging de-identified (anonymized) clinical information in line with the data protection law requirements.
• Legal:

◦ In tortious claims jurisdiction is decided on the basis of the place where harm occurred as a result of the tort (that is to say, a result of a negligent act or failure to act). The applicable law will normally be the law of the jurisdiction in which the tort was committed.

◦ The healthcare facility shall ensure malpractice insurance for healthcare professionals is in place throughout the duration of the telehealth service.

◦ Healthcare professionals shall be responsible based on their individual contribution.

◦ The physicians have the right to refuse a case if the quality and the quantity of the data provided in the patient record are not sufficient to give a complete and accurate medical opinion or if the quality of the images is insufficient.

◦ The patient has to give informed consent for the exchange of his patient file and medical data.

◦ Patient consent should cover the possibility of having a HCP present outside Saudi Arabia.

◦ Patients are entitled to a written or electronic medical record of their treatment, and access to at least a copy of this record.

◦ The local healthcare facility involved in cross-border telehealth activities should guarantee that there is no abuse, malpractice nor ethical issues during cross-border telehealth practice.

◦ The local healthcare facility involved in cross-border telehealth activities should have a bounding agreement that hold both parties committed and accountable to the national requirements and regulations in a constant manner.

◦ A translator should be present in case of language barrier to avoid misinterpretations during the consultation session between the HCP and the patient.
Emerging Technologies in Telehealth:

**Definition:**
- The use of new and novel telecommunications and information technology to provide access to health assessment, screening, diagnosis, intervention, collaboration, consultation, supervision, coaching and information across distance.

**Description:**
- In addition to virtual visits using telemedicine, there are several emerging technologies including wearable technology (e.g., to monitor activity and vital signs), RPM (e.g., environmental exposures and medication adherence) as well as electronic medical records augmented with clinical decision support (64).
- The artificial intelligence introduced augmentation to multiple clinical services such as patient online tele-triaging to guide him to the appropriate service and giving the required safe recommendations, also, it is used in screening imaging of the retina of the patients and give a detailed medical report about many retinal problems. In addition, it is used to screen other images such as histopathology, chest x-rays, mammogram and other diagnostic imaging to screen for specific diseases or general augmentation for radiologists.
- Augmented reality and virtual reality is used in tele-education and potentially can be used in other purposes.
- Social media for mass education and nudging.

**Examples:**
- Artificial intelligence
- Augmented reality (AR) and virtual reality (VR)
- Tele-robots
- The Internet of Things (IoT)
- Nanotechnology
- Mobile
- Block chain
- Cloud computing
Minimum requirements of:

- **Medico-Legal:**
  - All novel technologies should be registered either the SFDA or any other medical devices registration authorities.
  - Healthcare professionals should obtain informed consent from the patient for the use of these emerging technologies.

- **Setup:**
  - The Healthcare facilities must apply their safety procedures and protocols to Telemedicine services, when using all novel technologies.

- **Technical:**
  - The novel technology use should be secured by design.
  - Privacy and confidentiality measures should be maintained.

- **Personnel:**
  - Healthcare professionals providing Telemedicine services using novel technologies should have the necessary education, training/orientation and ongoing professional development needed for the safe provision of quality health services.
  - Each healthcare facility should be aware of best practices relating to Telemedicine and adapt and change processes as such practices evolve.

- **Patient experience and patient rights:**
  - Some evaluation parameters may include patient outcomes and satisfaction, provider satisfaction; technical quality of service; quality of communication; performance metrics; costs; utilization; and improved access to care.
  - HCPs ethical conduct should not be compromised in the use of any of the novel telehealth solutions.
  - Patients’ rights, privacy and confidentiality should strictly preserved in all novel telehealth solutions.
Appendix:

Appendix A:
Privacy and confidentiality of health information:
The Saudi personal data protection law, which is based on the following principles (14):

- **Principle 1- Accountability:** Data Controller’s privacy policies and procedures shall be identified, documented and approved by the head of entity (or his designee) and circulated to all concerned parties.

- **Principle 2- Transparency:** A notice of Data Controller’s privacy policies and procedures – Privacy Notice – shall be drawn up indicating the purposes for which personal data will be collected in a clear, easy to understand language.

- **Principle 3- Choice and Consent:** The purpose for collection of any personally identifying data shall be made clear to Data Subject and their (implicit / explicit) approval shall be obtained regarding collection, use and/or disclosure of personal data before collection.

- **Principle 4- Limiting Data Collection:** Collection of any personal data shall be limited to minimum data that enables fulfillment of purposes provided for in Privacy Notice.

- **Principle 5- Use, Retention and Destruction:** Personal data usage shall be restricted to purposes provided for in Privacy Notice, which the Data Subject has implicitly or explicitly approved. Moreover, Data shall be retained as long as necessary to achieve their intended purposes or as required by laws and regulations. Furthermore, data shall be destroyed it in a safe manner that prevents leakage, loss, theft, misuse or unauthorized access.

- **Principle 6- Access to Data:** Entities shall provide a means by which any Data Subject can review, update and correct their personal data.

- **Principle 7- Data Disclosure Limitation:** Disclosure of personal data to third parties shall be restricted to the purposes provided for in Privacy Notice, which was approved by Data Subject.

- **Principle 8- Data Security:** Personal data shall be protected from leakage, damage, loss, theft, misuse, modification, or unauthorized access – according to the controls issued by the National Cybersecurity Authority and the relevant authorities.

- **Principle 9- Data Quality:** Personal data shall be maintained after verification of its accuracy, completeness and timeliness, and such data shall be directly relevant to purposes provided for in Privacy Notice.

- **Principle 10- Monitoring and Compliance:** Compliance with Data Controller’s privacy policies and procedures shall be monitored, and any privacy-related inquiries, complaints, and disputes shall be addressed.
Appendix B:

Telehealth Patient Consent Form

I (name).........................................................
agree to receive a Telehealth service. I understand that
healthcare practitioner(name).................................
my be located in another facility.
A Telehealth service means that my visit with a
practitioner at the
distant site will happen by using special audiovisual
equipment.
This consent is valid for six months for follow-up
Telehealth
services with the healthcare provider.

I also understand that:
• I hereby authorize healthcare services to use the
telehealth practice platform for telecommunication
for evaluating, testing and diagnosing my medical
condition.
• I can decline the Telehealth service at any time
without affecting my right to future care or
treatment.
• If I decline the Telehealth services, the other
options/alternatives available for me is in-person
services.
• I will be informed of all people who will be present
during my Telehealth service.
• I may see an employee in-person immediately after
the
Telehealth service if an urgent need arises OR I will
be told ahead of time that this is not available.
• I agree that my medical records on telehealth can be
kept for
• further evaluation, analysis and documentation, and
in all of these, my information will be kept private.
• I will have access to all medical information resulting
from the Telehealth service as provided by law.
• The information from the Telehealth service (images
that can be identified as mine or other medical
information from the Telehealth service) cannot be
released to researchers or anyone else without my
additional written consent.
• I understand that technical difficulties may occur
before or during the telehealth sessions and my
encounter might not go as intended.
• I accept that the professionals can contact interactive
sessions with video call via robots; however, I am
informed that the sessions can be conducted via
regular voice communication if the technical
requirements such as internet speed cannot be met.

Nama: .........................................................
Tanggal lahir: ........................................
Jenis kelamin: ........................................
Tempat: ...................................................
Tanggal: ...................................................
Signature: ...................................................

Nama fasilitas kesehatan: ........................................
Nomor surat kabar: ........................................
Tanggal: .....................................................
Signature: .....................................................
References

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• When a patient is requesting a consultation from a healthcare professional who is located outside Saudi Arabia, whether using a synchronous (video consultation, tele-triaging, tele-education, tele-management, RPM) or asynchronous, store-and-forward (tele-expertise, tele-education)

• When a HCP requesting a service from another HCP who is located outside Saudi Arabia and vice versa, whether using a synchronous (tele-assistance, tele-management, tele-surgery, tele-education) or asynchronous, store-and-forward (tele-expertise, tele-diagnosis).

• The use of telehealth technical solutions and emerging technologies such as artificial intelligence (augmentation in screening) located in different countries.

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• Legal:

◦ In tortious claims jurisdiction is decided on the basis of the place where harm occurred as a result of the tort (that is to say, a result of a negligent act or failure to act). The applicable law will normally be the law of the jurisdiction in which the tort was committed.

◦ The healthcare facility shall ensure malpractice insurance for healthcare professionals is in place throughout the duration of the telehealth service.

◦ Healthcare professionals shall be responsible based on their individual contribution.

◦ The physicians have the right to refuse a case if the quality and the quantity of the data provided in the patient record are not sufficient to give a complete and accurate medical opinion or if the quality of the images is insufficient.

◦ The patient has to give informed consent for the exchange of his patient file and medical data.

◦ Patient consent should cover the possibility of having a HCP present outside Saudi Arabia.

◦ Patients are entitled to a written or electronic medical record of their treatment, and access to at least a copy of this record.

◦ The local healthcare facility involved in cross-border telehealth activities should guarantee that there is no abuse, malpractice nor ethical issues during cross-border telehealth practice.

◦ The local healthcare facility involved in cross-border telehealth activities should have a bounding agreement that hold both parties committed and accountable to the national requirements and regulations in a constant manner.

◦ A translator should be present in case of language barrier to avoid misinterpretations during the consultation session between the HCP and the patient.


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