DOH STANDARD FOR THE PROVISION OF TELE-MONITORING SERVICES IN THE EMIRATE OF ABU DHABI

Standard

Contents

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1. Purpose

This Standard aims to:

1.1. Define the minimum requirements for the provision of tele-monitoring to support the delivery of healthcare services to patients in the Emirate of Abu Dhabi.

1.2. Ensure the quality and safety of tele-monitoring services.

2. Scope

This standard applies to:

2.1. All DOH licensed healthcare facilities that have been authorized by DOH to provide tele-monitoring services.

2.2. All DOH licensed healthcare professionals employed in facilities authorized to provide tele-monitoring services.

2.3. All eligible outpatients determined by treating physician for which tele-monitoring is clinically indicated.

2.4. All devices and supporting systems used to automatically transmit signals from patients to a central station where abnormalities will trigger a response by healthcare professionals or those that support the monitoring data quality, utilization management review and risk management.

3. Definitions

3.1. **Tele-monitoring:** Refers to biomedical and other forms of data collection directly from patients (or through care givers) by remote systems, which are used by healthcare professionals for clinical purposes such as, but not limited to vital sign monitoring, remote chronic disease management and home monitoring.

3.2. **Tele-monitoring healthcare service providers:** A DOH licensed healthcare facility authorized by DOH to provide tele-monitoring services and/or healthcare professional employed by a DOH licensed healthcare facility authorized/privileged by their facility to provide tele-monitoring services. Patients may be located at their home, or temporarily in another location within the UAE.

3.3. **Electronic Medical Record (EMR):** A repository of patient data in digital form, stored and exchanged securely, and accessible by multiple authorized users. It contains retrospective, concurrent and scheduled information. Its primary purpose is to support the delivery of effective and efficient healthcare services, assure quality, safety and the provision of integrated healthcare services.

3.4. **Patients:** All eligible patients determined by the treating physician for which tele-monitoring is clinically indicated.

3.5. **Equipment:** Devices and supporting systems used to automatically transmit signals from patients to a central station where abnormalities will trigger a response by healthcare professionals or these that support the monitoring of data quality, utilization management review and risk management.

3.6. **Treating Physician:** A DOH licensed specialist or consultant who offers an opinion within his area of specialty and provides treatment to a patient for a specific condition.

4. Duties for Healthcare Providers

DOH licensed tele-monitoring healthcare service providers must:

4.1. Only provide the healthcare services in accordance with the requirements of this Standard;

4.2. Ensure that tele-monitoring services are accessible to eligible patients determined by the treating physician;

4.3. Ensure that tele-monitoring services are offered in at least Arabic and/or English languages in compliance with DOH Policy on Cultural Sensitivity and Awareness, available at http://www.haad.ae/haad/tabid/819/Default.aspx;

4.4. Coordinate with other healthcare providers to assure continuity of care;

4.5. Ensure that they procure and offer ICT technologies that meet Abu Dhabi Systems and Information Centre (ADSIC) available at [https://adsic.abudhabi.ae/adsic/faces/en/home?_adf.ctrl-state=9t3fb4qg1_49&_afrLoop=2992952698969950#!%40%40%3F_afrLoop%3D2992952698969950%26_adf.ctrl-state%3D1b962cpvvs_4], and DOH technical specifications and regulatory requirements, and that these technologies afford a high degree of interoperability. [https://www.haad.ae/haad/ar/tabid/36/Default.aspx];

4.6. Have Information and Communication Technology (ICT) policies, procedures and systems in place to assure safe and effective tele-monitoring and transmission of confidential personal and health information confidentially and securely and monitor, assess and assure their effectiveness regularly;

4.7. Develop and implement clinical and quality governance systems to ensure the quality and safety of tele-monitoring services, and protect the confidentiality and security of medical information during and after data transmission; and

4.8. Uphold the following principles of consent as per UAE laws and DOH regulation including:

    4.8.1. Medical record keeping;

    4.8.2. Monitoring and sharing of data;

    4.8.3. Surgical insertion of monitoring devices;

    4.8.4. The provision of transparent and clear information to the patient or their legal guardian (carer) on the nature and type of monitoring service to be provided via tele-monitoring, including information about the specific intervention(s), service details such, activities involved and risks;

    4.8.5. Comply with DOH requests to inspect and audit records and cooperate with DOH authorized auditors, as required for inspections and audits by DOH; and

    4.8.6. Document, report and update DOH on activities in support of achieving the objectives of this Standard, including submitting data to DOH, as per the reporting requirements detailed in Appendix 2.

5. Tele-monitoring Governance Framework

The facility may utilize tele-monitoring to support the delivery of high quality and safe healthcare services. The healthcare facility providing tele-monitoring services shall have in place:

5.1. Written documentation to describe the purpose(s) of tele-monitoring services scope and the service specification in accordance with evidence based practice;

5.2. Evidence to demonstrate DOH licensed staff are appropriately trained in the use of tele-monitoring devices and have adequate capacity to manage the desired frequency of monitoring and interaction of patients as indicated by the treating physician;

5.3. Written Policy and Standard Operating Procedures (SOP) to cover the following:

    5.3.1. Tele-monitoring Governance including Operational aspects (medical care and technical IT systems), quality and security of data for tele-monitoring services, in written governance and management protocols in accordance with the General Duties, Governance and Change of Control Chapter, Healthcare Provider Manual;

    5.3.2. Privileging staff;

    5.3.3. Roles and responsibilities of staff and accountabilities of the management team;

    5.3.4. Regular review and adoption of evidence based best practice;

    5.3.5. Patient referral to other healthcare providers as needed, including emergency cases and report these cases to DOH as indicated in Appendix 2; and

    5.3.6. Referral Agreements with other healthcare providers for continuity of care.

5.4. Ensure there is a policy and procedure for downloading and uploading patient data. Quality assurance and improvement framework including:

    5.4.1. Setting, monitoring and keeping records of performance against quality and safety metrics set by the facility;

    5.4.2. Maintaining comprehensive Electronic Medical Records;

    5.4.3. Implementing risk control and management processes for tele-monitoring services. This includes recording, monitoring and reporting of issues and their

resolution, auditing of activities and services provided and compliance with DOH requirements (clinical, financial, technological and environmental safety), providers' professional duties as set out in the Professional Duties Chapter, Healthcare Professionals Manual, in addition to management of conflicts of interest (inducements and the like).

6. Access

6.1. Access to tele-monitoring services must be available to all patients who are clinically eligible to receive the service as determined by the treating physician after a face-to-face assessment in the healthcare facility or direct through a tele-consultation session;

6.2. Healthcare facilities providing tele-monitoring may choose services availability timeframe in accordance to the identified needs and available workforce;

6.3. Tele-monitoring services shall:

6.3.1. Specify the number of times, type of control and the method of when and how the patient data is obtained and transferred;

6.3.2. Where infrastructure permits and patient location indicates, services should be available in rural and remote areas and customized to meet patient's needs;

6.3.3. Assure an agreement with respective providers is in place where a patient is placed in a remote area and needs to be seen immediately.

6.4. Patients are entitled to cease tele-monitoring services at any time;

6.4.1. Healthcare providers must ensure written notification is issued and signed by the patient and/or caregiver where discontinuation of the service places the patient at serious risk of deterioration or in case of being admitted to emergency services;

6.4.2. A discharge form must be documented at the end of the tele-monitoring period.

6.5. Policies and procedures regarding clinical documentation that originates from tele-monitoring shall be established in compliance with facility legal and risk management oversight requirements.

7. Clinical Care

Tele-monitoring service providers must provide tele-monitoring services as part of a structured and well-organized system of clinical care.

7.1. Healthcare providers shall:

7.1.1. Determine the clinical suitability of patients for the provision of tele-monitoring services;

7.1.2. Ensure all healthcare professionals involved in tele-monitoring uphold the standard of care to maintain patient safety;

7.1.3. Make use of healthcare management and referral protocols to ensure patients' needs are met in a timely manner;

7.1.4. Follow evidence based clinical care guidelines for tele-monitoring of patients;

7.1.5. Adopt a systematic approach for measuring quality and clinical outcomes.

7.1.6. Undertake a face-to-face evaluation prior to the commencement of tele-monitoring services; and

7.1.7. Ensure that the tele-monitoring generated data is reviewed by a nurse or physician and reported to the treating physician as per their request or on a periodic basis.

7.2. Provision of tele-monitoring service shall include:

    7.2.1.   Face-to-face follow up or direct tele-consultation sessions; and

    7.2.2.   Regular monitoring and maintenance of devices used.

7.3. Tele-monitoring should not be solely used to assess and determine the patient plan of care;

7.4. The duration and frequency of monitoring shall be adjusted in accordance with the expected timeframe for clinical review and patient's need;

7.5. All satisfactory alternatives and risks to tele-monitoring must have been considered; and

7.6. Treating physician must orient a tele-monitered patient on how to act in case of a medical emergency.

8. Communication, Education, Orientation and Training

Healthcare facilities providing tele-monitoring services must:

8.1. Ensure that appropriate, flexible, reliable and secure communication approaches are adopted;

8.2. Ensure that tele-monitoring services provided to eligible patients are secured and optimized;

8.3. Ensure that patients and/or their caregivers receive adequate communication and education to enable them to perform the necessary tasks to benefit from tele-monitoring services;

8.4. Communication and education must include:

    8.4.1.   A patient feedback loop on the approach and level of communication; and

    8.4.2.   Self-identification of a problem or error with the monitoring device and an emergency contact number.

8.5. Ensure that the responsible staff are oriented and trained to ensure that the provision of tele-monitoring services does not compromise patient safety, privacy and the expected quality of care;

8.6. Ensure staff are trained to use tele-monitoring equipment including but not limited to:

    8.6.1.   Actions to take if the technical and/or environmental factors disrupt the transmission of expected patient data to the facility;

    8.6.2.   Interpretation of monitoring data;

    8.6.3.   The limitations of the technology being used and actions to take in the event of sudden discontinuation of data and information; and

    8.6.4.   Develop a risk management plan in case of any emergency that include the escalation and management of a detected error, abnormal reading or patient /carer of patient reported emergency and necessary actions.

8.7. Depending on the scope of service, tailored communication protocols must be in place to ensure the minimum requirement for communication is met and any other factors are accounted for such as literacy, language, security and privacy.

9. Technology and Equipment

DOH licensed healthcare providers authorized by DOH to provide tele-monitoring services shall have in place criteria for procurement of tele-monitoring devices including but not limited to:

9.1.   Safety (including alert features during abnormal/unexpected behavior of device);

9.2.   Quality (monitoring and diagnostic);

9.3.   User compatibility and acceptability;

9.4.   Installation and portability;

9.5.   Means of communication and speed of monitoring;

9.6.   Accuracy and reliability;

9.7.   Durability;

9.8.   Conformity to Internationals Standards;

9.9.   Robustness;

9.10. Interoperability;

9.11. Security, data protection, patient and user authentication (including but not limited to inherent ability identify and restrict/prevent hack attempts, encrypt data during transmission and storage, authentication and authorization of access and privileges, ability to fix weakness (vulnerabilities) within device through controlled mechanism, ability of the device to not introduce new threat to the connected/integrated environment);

9.12. Reporting capability (for errors, investigation and analysis).Maintenance (testing features, network requirements, hardware and software maintenance, calibration and training);

9.13. Infection control; and

9.14. Compliance with UAE Laws.

10. Technical Standards

Healthcare facilities licensed and authorized by DOH to provide tele-monitoring services must:

10.1. Ensure there is a system to monitor the performance of the tele-monitoring devices that:

    10.1.1. Captures reliable and accurate monitoring data by date and time;

    10.1.2. Issues alerts for abnormal or disrupted patient data; and

    10.1.3. Issues reports of quality and safety performance measures.

10.2. Ensure there is evidence to demonstrate the request to install and activate tele-monitoring in the patients home;

10.3. The application/order of the service must be signed and dated by the treating physician and subject to patient consent/agreement;

10.4. Ensure Tele-monitoring data forms part of the Electronic Medical Record;

10.5. Develop protocols and procedures to manage "adverse events" or "system errors";

10.6. Establish response protocols for the use of an automated alert system;

10.7. Ensure that all devices used for remote monitoring are tested with the patient and all necessary checks have been undertaken;

10.8. Ensure the technology and equipment is incorporated into the normal workflow of clinical processes by the healthcare provider to maximize integration within the healthcare providers overall clinical governance and oversight of other clinical processes;

10.9. Ensure all monitoring equipment is maintained to a high standard as per the manufacturer's instructions and specifications; and

10.10. Report to DOH, as part of DOH Medical Device Post Market Surveillance Program:

10.10.1. Any safety issue with a medical device;

10.10.2. Any adverse event which has impacted either the patient, device operator or any other person which is attributed to or may be attributed to the use of a medical device;

10.10.3. Any quality or technical malfunctions which have or may have the potential to lead to an adverse event;

10.10.4. Reporting should be directly after an adverse event occurs and should be included on the annual report submitted as per Appendix 2; and

10.10.5. Report should be submitted via email to medicaldevices@doh.gov.ae or by fax: 02 419 3643, by downloading and filling the medical device incident report form found www.haad.ae/medicaldevices.

11. Tele-monitoring Licensing and Authorization

11.1. A healthcare provider may seek approval to provide tele-monitoring services through submitting a request for "adding service" under the existing DOH licensed facility;

11.2. Application and approval for tele-monitoring healthcare services is available only for the following types of facilities:

11.2.1. Hospitals;

11.2.2. Centers;

11.2.3. Provision of Health Services - Home healthcare; and

11.2.4. Telemedicine provider.

11.3. In addition to satisfying the DOH requirements for healthcare facility licensure [https://www.haad.ae/haad/tabid/857/Default.aspx]; applicants for authorization for tele-monitoring services must demonstrate the ability to satisfy the requirements detailed in Appendix 1.

12. Enforcement and Sanctions

12.1. DOH may impose sanctions in relation to any breach of requirements under this Standard in accordance with the Complaints, Investigations, Regulatory Action and Sanctions Chapter, Healthcare Regulator Manual.

13. Appendices:

Appendix 1: Requirements for DOH licensure and/or authorization to provide tele-monitoring services.

Dimension	Element	Requirement
A. General Considerations	1. Governance	i. Governance and management protocols defining roles and responsibilities (General Duties, Governance and Change of Control Policy, Chapter V, Healthcare Providers Policy Manual, Version 1.0). ii. Quality Committee (for facilities with ≥ 10 professionals). iii. Industry good practice Standard Operating Procedures for the following: a. Bio data monitoring. b. Escalation and Management protocols for tele-monitoring emergencies.
	2. Personal Identification and Data Management is assured by the healthcare provider	i. Patient identification and the recording of patient identifiers such as Emirate ID number (or passport number where an EID is not issued). ii. Patient legal guardian identification and establishing their status as legal guardian. A minimum of three identifiers are required including: Emirate ID number (or passport number where an EID is not issued) and document identity establishing relationship and legal authority as guardian. iii. Data security and protection protocols are compliant with DOH Data Standards, Procedures and Requirements https://www.haad.ae/haad/tabid/1500/Default.aspx. iv. Data confidentiality, privacy and patient consent protocols and applicable forms are compliant with DOH Standards. v. Risk management and disaster recovery protocols (data records and electronic files).
B. Technological Considerations	1. Information Technology (IT)	i. IT operations: adequate resources for planning, setting up operation and maintenance of information and communication infrastructure. ii. User support resources for employees and patients; iii. Quality control of medical device used for tele-monitoring.
	2. Communication	i. Network integrity including preventive business

		continuity plans including for: a. Adequate bandwidth. b. Alternative methods of communication between provider and user. c. Back-up power system. ii. Technologies and internet systems comply with UAE Information Assurance Standard's requirements https://www.abudhabi.ae/cs/groups/public/documents/attachment/mtmz/njg0/~edisp/adsic_nd_133684_en.pdf iii. Medical, including bio-monitoring devices, comply with MOH registration requirements http://www.mohap.gov.ae/en/services/Pages/380.aspx.
C. Service Operation Considerations	1. Infrastructure	i. Tele-monitoring workstation and room design to satisfy DOH Guidelines for Health Facilities Design. ii. Hardware, including for communication and internet access, with good industry standard servers, physical and logical security measures in compliance with requirements of UAE Information Assurance Standard . iii. Environmental and occupational health and safety is compliant EHSMS requirements. iv. Good industry standard tele-monitoring system including call recording and integration with patient management system, where possible. v. Case management through tele-monitoring system is suited to the type of services being offered by the provider.
	2. Quality assurance and measurement	i. Evidenced based - monitoring protocols. ii. Training and certification of an evidenced based training program for professionals and staff must be submitted to DOH on application for licensure or authorization, audit and inspection. Accreditation of such training programs may be obtained from internationally reputable bodies such as, but not limited to, the American Telemedicine Association. iii. Evidence of a system to monitor and report on quality and safety performance. Metrics for monitoring patient satisfaction and managing patient conditions may be considered.

Appendix 2: Tele-monitoring Related Activities Report

Annual Report: Tele-monitoring related activities	
Facility Details:	Name: Location: Contact: Type: ☐ Hospitals ☐ Centers ☐ Provision of Health Services - Home healthcare ☐ Telemedicine provider
Total number of cases who used the tele-monitoring devices during the previous year	
List of the identified clinical indications for which tele-monitoring services were prescribed	List of the most common five indications: 1. 2. 3. 4. 5.
Any safety issue with the tele-monitoring device.	☐ Yes ☐ No If yes, kindly identify: - Total number of the cases: ----------
Any adverse event which has impacted either the patient, device operator or any other person which is attributed to or may be attributed to the use of a tele-monitoring device.	☐ Yes ☐ No If yes, kindly identify: - Total number of the cases: ----------
Any quality or technical malfunctions in the tele-monitoring device and/or service, which have or may have the potential to lead to an adverse event.	☐ Yes ☐ No If yes, kindly identify: - Total number of the cases: ----------

Total number of tele-monitored patients referred to other healthcare providers whose vital signs showed abnormalities and/or triggered alerts indicating the need for referral.	Number of referred cases to obtain specialized care: ---------------- List of the most common five indications for referral: 1. 2. 3. 4. 5.	Number of emergency cases identified ---------------- List of the most common five indications for referral: 1. 2. 3. 4. 5.

Note: Healthcare facilities providing the tele-monitoring services are required to submit this report by Dec 30 of every year to email: hps@doh.gov.ae