CEN/CEN WS XXX

Date: 20XX -XX

Draft CWA XXXXX: XXXX

Workshop: XXX

Framework for Telehealth Adoption: Planning, Integration and Outcome Evaluation in Healthcare Systems

Einführendes Element — Haupt-Element — Ergänzendes Element

Élément introductif — Élément central — Élément complémentaire

ICS:

CCMC will prepare and attach the official title page.

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Foreword

This CEN Workshop Agreement (CWA XXXX:YYYY) has been developed in accordance with the CEN-CENELEC Guide 29 “CEN/CENELEC Workshop Agreements – A rapid way to standardization” and with the relevant provisions of CEN/CENELEC Internal Regulations - Part 2. It was approved by the Workshop [CEN and/or CENELEC “name of the Workshop”, the secretariat of which is held by “name of organization”] consisting of representatives of interested parties on YYYY-MM-DD, the constitution of which was supported by CEN following the public call for participation made on YYYY-MM-DD. However, this CEN Workshop Agreement does not necessarily include all relevant stakeholders.

The final text of this CEN Workshop Agreement was provided to CEN for publication on YYYY-MM-DD.

Results incorporated in this CWA received funding from the European Union’s Horizon EUROPE research and innovation programme under grant agreement No [Number].

The following organizations and individuals developed and approved this CEN Workshop Agreement:

— name organization and individual

— name organization and individual

— ...

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1 Scope

This document specifies the requirements for the evaluation, planning, and integration of telehealth services into existing healthcare delivery pathways. It establishes a structured assessment framework based on the Telehealth Evaluation Model (TEM), developed within the Horizon Project "Caring Nature".

The requirements set out in this document apply to healthcare organizations, healthcare professionals, and other stakeholders involved in the adoption and operationalisation of telehealth services.

This document:

- provides a harmonised set of criteria for determining whether, and under which conditions, telehealth services can be safely and effectively implemented;
- supports healthcare organizations in assessing contextual readiness, risks, and opportunities associated with telehealth adoption;
- promotes high quality, patient centred, safe, and sustainable remote care.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp/

— IEC Electropedia: available at http://www.electropedia.org/

No terms and definitions are listed in this document.

4 General

The telehealth services covered in this document are healthcare services provided using information and communication technologies (ICT) with or without medical devices.Such services primarily involve interactions between healthcare professionals and patients and/or their caregivers acting on behalf of patients, or between healthcare professionals involved in the assessment, diagnosis, treatment, monitoring, rehabilitation, or management of a patient.

The interactions may occur synchronously (real time) or asynchronously (delayed) and involve participants located at different sites.

The Telehealth Evaluation Model (TEM) is a pre-implementation decision-support framework designed to assess whether a defined clinical pathway can be safely and effectively transferred to, implemented through, or further developed as a telehealth model before significant time and resources are committed. The TEM is neither a maturity model nor a certification tool. It integrates Eligibility, Readiness and Sustainability assessments to support evidence-based and context-specific adoption decisions.

The TEM assessment begins with the definition of the Intended Use Case (IUC) and proceeds through three main assessment domains, as shown in Figure 1.

- Eligibility;
- Readiness; and
- Sustainability.

These domains provide the basis for interpreting the assessment results and supporting implementation decisions.

Ex-post evaluation is used to review the implemented telehealth model after application.

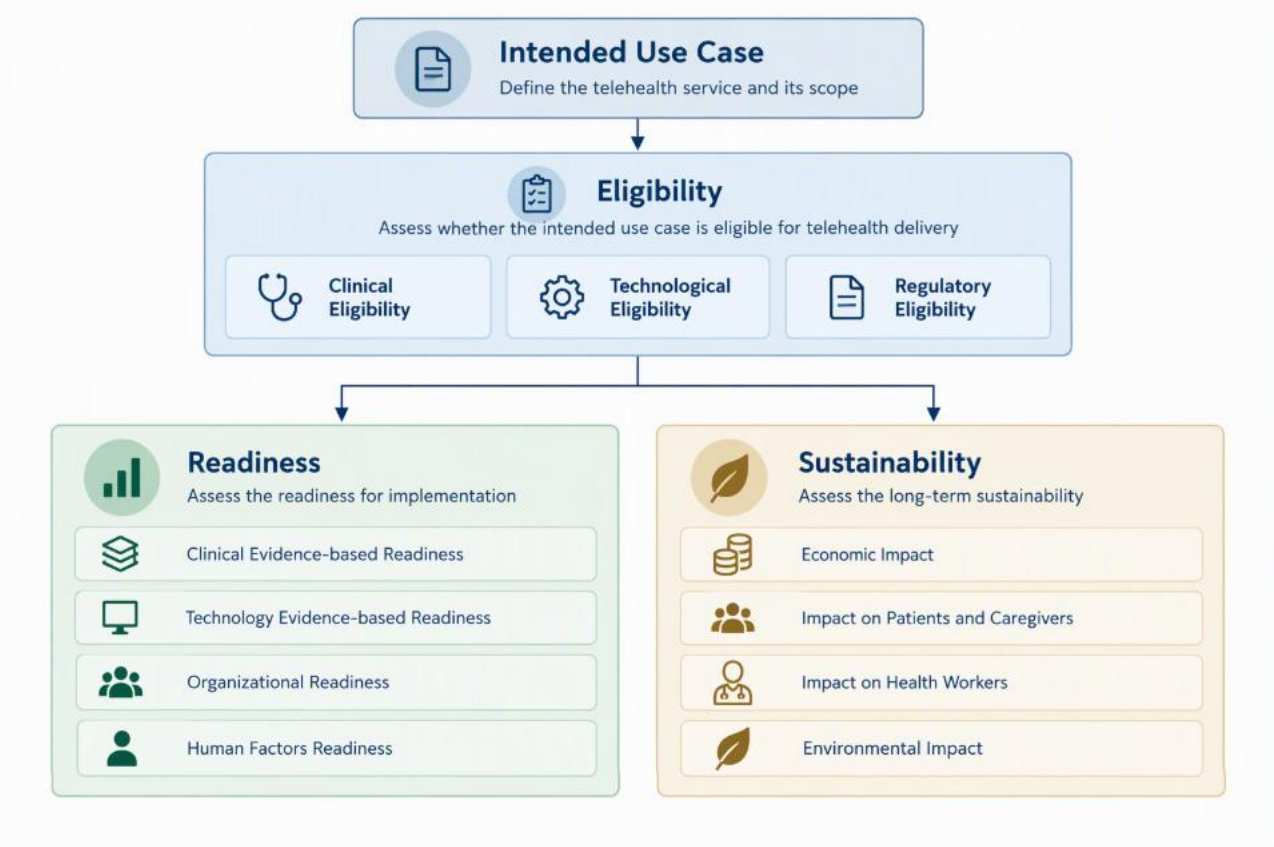


Figure 1 - Structure of the Telehealth Evaluation Model (TEM)

The TEM shall be applied to a defined Intended Use Case. The Intended Use Case defines the scope and common reference for the TEM assessment, including, as applicable, the medical action, target patient population, clinical pathway, target users, required technologies or medical equipment, implementation context, limitations and boundaries.

The TEM assessment results, including the calculated scores, are applicable only to the Intended Use Case as defined and assessed.

Where the Intended Use Case is modified, an assessment shall be made to determine whether amendments to the existing TEM evaluation are sufficient or whether a complete re-evaluation is required. Relevant modifications may include changes to the target patient population, clinical pathway, technologies, delivery model or implementation context.

The TEM does not replace clinical judgement, applicable legal or regulatory processes, conformity assessment, certification, or the responsibilities of competent authorities, manufacturers, healthcare organizations and other accountable actors.

The TEM can support telehealth adoption at different levels of maturity, including the Routine Pathway, the Implementation Pathway and the Innovation Pathway.

a) **The Routine Pathway** applies to telehealth models that have already demonstrated clinical safety, effectiveness and feasibility in the jurisdiction of use.

b) **The Implementation Pathway** applies to the transfer and implementation of a telehealth model established in another context or jurisdiction.

c) **The Innovation Pathway** applies to pilot, feasibility and early-adoption activities where further evidence and implementation experience still need to be generated.

The evaluation of the TEM should be performed by a multidisciplinary team possessing the expertise relevant to the Intended Use Case. Clinical expertise should form a central part of the assessment. Depending on the Intended Use Case and the stage of evaluation, relevant perspectives may also include healthcare management and finance, technology and information systems, legal and regulatory matters, compliance, risk management, organizational processes, and persons responsible for providing or interpreting the data required for the assessment. Different functions may contribute at different stages, while the final decision remains with the designated decision-making authority.

Consistent with its pre-implementation purpose, the TEM primarily uses information already available for the Intended Use Case, including applicable clinical guidelines and other authoritative clinical evidence, published scientific evidence, applicable legal and regulatory frameworks, and knowledge of the relevant healthcare and organizational context. The initial TEM assessment does not generally require patient surveys or new primary data collection. Identified evidence gaps shall be documented and may inform subsequent pilot, implementation, monitoring or evidence-generation activities.

The use of a telehealth service shall not delay or replace clinically indicated urgent in-person assessment or intervention. Where applicable, access to the established in-person care pathway and appropriate escalation procedures shall remain available. A remote assessment may precede an in-person assessment where this is clinically appropriate and consistent with the defined care pathway.

The TEM assessment process and its results shall be documented in sufficient detail to support review and decision-making by the designated decision-making authority. The documentation shall include the information and evidence considered, the assessment results, identified gaps and uncertainties, and the rationale for the resulting decision.

NOTE: A worked example illustrating the application of the TEM is available at [*LINK will be provided after commenting phase].*

5 Intended Use Case

Before starting the Telehealth Evaluation Model (TEM) assessment, the Intended Use Case (IUC) shall be defined with sufficient specificity to serve as the common reference for Eligibility, Readiness and Sustainability.

The IUC shall describe a specific and realistic telehealth scenario rather than a generic service concept, providing sufficient information on the target population, clinical activities, care delivery model, required clinical information and implementation context to support the subsequent TEM assessment.

Where information required to define the IUC is not yet available, assumptions may be used, provided that they are explicitly identified and documented for subsequent verification. The TEM is designed to enable an individual healthcare professional to prepare the IUC and conduct the assessment using readily accessible scientific, clinical and regulatory information, including online sources, and knowledge of the healthcare setting. The assessment should benefit from multidisciplinary expertise relevant to the IUC, with clinical expertise providing the central perspective.

The IUC shall describe the following elements, including the specified information where applicable to the Intended Use Case:

a) **Foreseen medical action**, including the clinical purpose, main medical activities, essential clinical information, relevant clinical decisions and expected benefits compared with conventional care;

EXAMPLE Post-discharge clinical monitoring during recovery from paediatric pneumonia.

b) **Intended patient population,** including age, sex, gender, clinical conditions, comorbidities, risk factors, inclusion and exclusion criteria and the estimated patient volume;

EXAMPLE Clinically stable children discharged following hospitalisation for pneumonia.

c) **Foreseen clinical pathway**, including the healthcare setting and conventional care pathway used as the reference, the starting and end points of the proposed pathway, remote and in-person activities, their expected frequency and duration, responsible actors, clinical decision points and escalation arrangements;

EXAMPLE Early supported discharge followed by short-term remote monitoring, with escalation to in-person care where predefined criteria for clinical deterioration are met.

d) **Foreseen target users**, including the healthcare professionals, patients, caregivers and other users involved, their roles and responsibilities, their interactions with the service and the essential competency, training and support requirements;

EXAMPLE Paediatric healthcare professionals and caregivers of children discharged following hospitalisation

e) **Foreseen medical equipment**, including the categories and clinical functions of the medical equipment required to obtain the relevant clinical information;

EXAMPLE Medical equipment used to obtain relevant clinical parameters and examination findings.

f) **Foreseen telehealth technologies**, including medical devices and non-medical technologies, where applicable, specifying their intended functions within the telehealth service. Commercial names may be specified, provided that the corresponding technological category and intended function are clearly identified;

EXAMPLE A remote consultation platform and connected examination or monitoring technology.

g) **Limitations and boundaries**, including relevant clinical, technological and operational limitations, exclusion conditions and circumstances requiring in-person or emergency assessment.

EXAMPLE The IUC is not intended for clinically unstable patients or as a substitute for urgent in-person or emergency assessment.

Any modification to the IUC shall be assessed to determine whether amendments to the existing TEM evaluation are sufficient. Where such amendments are insufficient, a complete re-evaluation shall be performed

6 Eligibility

6.1 Background

The Eligibility Assessment represents the first stage of the TEM. It comprises three assessment domains:

- Clinical Eligibility;
- Technological Eligibility; and
- Regulatory Eligibility.

Their combined assessment determines the eligibility of the proposed telehealth intended use case by evaluating:

- the clinical pathway, or one or more defined stages of the pathway; and
- the technologies proposed for its delivery.

The assessment is applicable regardless of whether the proposed telehealth service is driven by:

- an identified clinical need, such as improving access to care, reducing avoidable hospitalizations, reducing emergency department overcrowding, or ensuring continuity of care after discharge; or
- the availability of a technology considered for implementation, such as a remote patient-monitoring system, connected diagnostic equipment, a teleconsultation platform, or clinical decision-support software.

Eligibility is established when the proposed combination can support safe and effective telehealth delivery for a defined patient population.

6.2 Clinical Eligibility

Clinical Eligibility determines whether internationally recognized clinical criteria exist for the safe conventional management of the patient population defined in the Intended Use Case.

At this stage, the assessment concerns conventional in-person care and does not assess remote telehealth delivery.

The assessment shall be based on internationally recognized clinical guidelines, consensus statements or other authoritative scientific evidence.

Where internationally recognized guidance specifically addressing telehealth management already exists for the Intended Use Case, it should also be identified and considered as complementary evidence, without replacing the assessment of the underlying conventional clinical pathway.

NOTE: Telehealth-specific effectiveness and the maturity of the supporting scientific evidence are assessed subsequently under Readiness.

The applicable clinical guidelines, consensus statements or other authoritative scientific evidence shall specify:

a) diagnostic and therapeutic algorithms;

b) foreseeable clinical complications;

c) first-line and second-line treatments;

d) escalation of care; and

e) patient risk stratification.

The applicable clinical guidelines, consensus statements or other authoritative scientific evidence shall specify the essential clinical information required to meet these requirements, including:

f) signs and symptoms;

g) clinical parameters and thresholds;

h) required clinical examinations and tests;

i) monitoring parameters;

j) criteria for clinical improvement or deterioration;

k) criteria for discharge;

l) criteria for hospitalization;

m) criteria for escalation;

n) criteria for resolution of the clinical phase under consideration; and

o) short- and long-term follow-up requirements.

These essential elements shall provide the clinical basis for designing the telehealth clinical pathway, including patient inclusion and exclusion based on risk stratification, foreseeable clinical trajectories and complications, and the corresponding clinical actions.

They shall also define the clinical-data requirements for Technological Eligibility (see 6.3), including, as applicable, the signs, symptoms, clinical parameters, measurement requirements and decision thresholds necessary for remote clinical assessment, monitoring and decision-making. These requirements shall provide the basis for determining the technological functions and, where applicable, categories of devices required to support the telehealth pathway.

Before inclusion in the telehealth pathway, the patient shall meet criteria for inclusion, exclusion and safety defined for the Intended Use Case.

Red-flag criteria shall be defined, as applicable, for clinical deterioration or other safety-critical conditions, together with the corresponding escalation actions, including when remote management shall be discontinued and in-person or emergency assessment is required.

If the Clinical Eligibility requirements are met, the Intended Use Case shall be considered clinically eligible and may proceed to Technological Eligibility and Regulatory Eligibility.

If no internationally recognized clinical consensus exists for the conventional management of the intended patient population, the Intended Use Case shall not be considered clinically eligible or sufficiently safe for telehealth delivery, as the patient population, clinical-data requirements and corresponding clinical actions cannot be reliably defined. The Intended Use Case may be redesigned or narrowed to a patient population, clinical condition or stage of the clinical pathway for which the Clinical Eligibility requirements can be met and shall then undergo a new Clinical Eligibility assessment.

6.3 Technological Eligibility

Technological Eligibility determines whether the clinical-data requirements identified during Clinical Eligibility (see 6.2) can be reliably supported by available telehealth technologies. The required technologies shall be capable of acquiring, communicating and making available the clinical information necessary for the telehealth pathway and remote clinical decision-making.

The objective is to determine whether the proposed telehealth pathway can be supported by technology capable of providing the required clinical information. At this stage, the assessment shall focus on the required technological functions and capabilities, without selecting or assessing specific devices, products, brands, models or commercial solutions.

Integration with electronic medical record systems is not required at this stage but should preferably be supported.

Detailed cost analysis is not required now unless the technologies are clearly incompatible with realistic budget constraints.

Clinical information may be transmitted synchronously or asynchronously, depending on the requirements of the telehealth pathway.

The usability of the required technology for the intended users shall be assessed under Technological Evidence-based Readiness (see 7.5).

Where compatible with clinical and operational requirements, commonly available hardware solutions may be used.

If all technological requirements are fulfilled, Technological Eligibility is considered satisfied and the assessment shall proceed to Regulatory Eligibility (see 6.4). If no technology is available that can provide the essential clinical information required for clinical decision-making, the telehealth pathway shall not be considered technologically eligible.

6.4 Regulatory Eligibility

Regulatory Eligibility assesses whether applicable legal and regulatory frameworks affect the routine implementation of the Intended Use Case within the jurisdiction of use and whether any regulatory barriers to such implementation have been identified. It does not constitute a legal interpretation, conformity assessment or regulatory approval.

This document does not provide regulatory certification guidance and does not replace applicable legal, regulatory or conformity assessment processes. These aspects remain subject to the applicable legal and regulatory frameworks and to the responsibilities of the relevant competent authorities, manufacturers, healthcare organizations and other accountable actors.

The assessment shall consider the Intended Use Case as a whole, including the proposed healthcare delivery model and patient population and, where applicable, the regulatory status and intended purpose of the technologies involved Telehealth delivery does not necessarily require the use of medical devices or medical device software. Where technologies or functions are subject to specific regulatory requirements, these shall be considered within the assessment.

The identification of unresolved legal or regulatory barriers may indicate that routine implementation is not currently feasible under the applicable framework. Routine implementation can depend on the fulfilment of applicable legal and regulatory requirements.

Depending on the applicable legal and regulatory framework, pathways for experimental or pilot projects, clinical investigations or research can be available.

7 Readiness

7.1 Background

Readiness is the second decision level of the TEM Framework. It assesses the likelihood that an eligible telehealth service can be successfully implemented within a specific healthcare context.

Readiness shall be assessed using a numerical scoring system across two complementary and independent areas:

- **Extrinsic Readiness**, addressing scientific evidence and external factors relevant to implementation;
- **Intrinsic Readiness**, addressing organizational and human factors specific to the implementation context.

Readiness determines whether the eligible telehealth service can be successfully implemented in the Intended Use Case under existing conditions, whether specific precautions are required, or whether modifiable factors within the Intrinsic Readiness domains should be addressed to improve implementation readiness.

The results of all Readiness domains shall be documented before implementation planning.

7.2 Extrinsic Readiness

7.2.1 General

Extrinsic Readiness evaluates whether sufficient scientific evidence supports the proposed telehealth pathway and the technologies for the Intended Use Case.

It shall assess the maturity, quality, consistency and applicability of the available evidence across two complementary domains:

- Clinical Evidence-based Readiness (see 7.4); and
- Technology Evidence-based Readiness (see 7.5).

As primary outcomes, the assessment shall evaluate available evidence relating to:

a) clinical outcomes;

b) adverse events and patient safety; and

c) patient and caregiver satisfaction and perceived benefits, and, where available, healthcare professional satisfaction and perceived benefits.

Where available and relevant, secondary outcomes shall include:

d) healthcare access and service utilization;

e) impact on clinical workflow and care delivery;

f) equity, accessibility and potential barriers to use;

g) risk management;

h) resource requirements;

i) implementation effort; and

j) economic aspects and cost-effectiveness.

The assessment shall consider relevant evidence identified through peer-reviewed scientific literature and, where appropriate, shall be complemented by:

k) international evidence-based clinical guidelines;

l) Health Technology Assessment (HTA) reports;

m) publications issued by recognized organizations and competent authorities; or/and

n) documented implementation experience.

The assessment shall:

o) identify telehealth pathways addressing identical or comparable intended use cases;

p) identify the technologies used to support such pathways;

q) identify and collect relevant evidence from recognized sources;

r) critically appraise the quality, consistency and applicability of the available evidence;

s) determine the maturity of the evidence supporting the proposed telehealth implementation; and

t) identify evidence gaps, uncertainties and limitations that may affect implementation.

7.2.2 Extrinsic Readiness scoring

Each parameter of Clinical Evidence-based Readiness and Technology Evidence-based Readiness shall be assigned a score from 0 to 3 according to the defined assessment criteria (see 7.4 and 7.5), reflecting the strength and maturity of the available evidence supporting the proposed telehealth implementation.

A low score shall not, by itself, preclude further evaluation or implementation. It indicates greater uncertainty and therefore calls for increased caution, appropriate risk management and closer monitoring.

Where appropriate, the available evidence should also be used to identify whether the proposed Intended Use Case, could be adapted (e.g. patient population, clinical pathway, technology, or mode of delivery) to a configuration for which stronger scientific evidence is available.

If modifications to the Intended Use Case are made, the re-evaluation requirements specified in Clause 5 shall apply.

7.3 Intrinsic Readiness

7.3.1 General

Intrinsic Readiness evaluates whether the healthcare organization and its implementation context are prepared to implement the proposed telehealth service under the available conditions and resources.

It shall assess two complementary domains:

- Organizational Readiness (see 7.6); and
- Human Factors Readiness (see 7.7).

Intrinsic Readiness assesses the organizational and human factors that may facilitate or constrain the application of that evidence in routine clinical practice.

Successful implementation within the organization depends on:

a) the organizational capability to integrate the telehealth pathway into existing clinical, operational and technical processes, using the resources and infrastructure available in the intended setting; and

b) the ability of healthcare professionals, patients and caregivers, where applicable, to participate effectively in the proposed telehealth model.

The assessment shall identify modifiable factors that may affect implementation. It shall also determine which factors require improvement, adaptation or mitigation before deployment.

7.3.2 Intrinsic Readiness scoring

Organizational Readiness and Human Factors Readiness shall each be assessed and scored from 0 to 3 according to their respective assessment criteria.

The Intrinsic Readiness Score shall be the lower of the Organizational Readiness Score and the Human Factors Readiness Score. A higher score in one domain shall not compensate for a lower score in the other.

The lower-scoring domain shall identify the limiting Intrinsic Readiness dimension and guide the definition of appropriate corrective actions. Following the planning or implementation of such actions, the affected domain shall be reassessed and the Intrinsic Readiness Score recalculated.

If modifications to the Intended Use Case are made, the re-evaluation requirements specified in Clause 5 shall apply.

7.4 Clinical Evidence-based Readiness

7.4.1 General

Clinical Evidence-based Readiness assesses the strength and maturity of the scientific evidence supporting telehealth delivery for the clinical pathway and target patient population defined in the Intended Use Case, including the associated level of uncertainty Only Intended Use Cases that have met the Clinical Eligibility requirements (see 6.2) shall proceed to Clinical Evidence-based Readiness assessment.

Evidence of clinical effectiveness shall be available for the Intended Use Case.

Relevant evidence can include:

a) randomized controlled trials;

b) systematic reviews;

c) meta-analyses; or

d) well-designed real-world evidence studies.

The evidence shall address, as applicable:

e) effectiveness;

f) safety;

g) adherence; or

h) outcome equivalence compared with in-person care.

7.4.2 Determination of the Clinical Evidence-based Readiness Score

The Clinical Evidence-based Readiness Score shall be determined on the basis of the availability, quality and consistency of the scientific evidence supporting the intended population and clinical Intended Use Case, as specified in Table 1.

Table 1 — Determination of Clinical Evidence-based Readiness Score

Scoring criteria	Evidence	Score
No published scientific evidence identified	No published scientific evidence supporting the Intended Use Case has been identified.	0
Initial scientific evidence available	A limited number of publications supporting the Intended Use Case. The available evidence is of limited methodological quality and does not demonstrate sufficient consistency across studies.	1

Recognizable body of scientific evidence available	A broader body of scientific evidence supporting the Intended Use Case is available, including evidence of higher methodological quality. Higher-quality evidence shall include at least one well-designed randomized controlled trial. For example, multicentre, systematic review, meta-analysis or applicable evidence-based clinical guideline. Full consistency is not required; however, the available evidence shall demonstrate substantially concordant findings across independent studies, research groups or healthcare settings.	2
Sufficient body of scientific evidence to support a state-of-the-art assessment	A substantial body of high-quality scientific evidence directly supporting the Intended Use Case is available. The available evidence demonstrates a high degree of consistency across relevant studies and provides sufficient scientific support for a state-of-the-art assessment of the proposed telehealth pathway.	3

The score shall reflect the combined assessment of the availability, quality and consistency of the evidence. In all cases, the evidence shall be applicable to the Intended Use Case. Evidence relating to a different population or substantially different clinical intended use case shall not be considered equivalent without documented justification.

7.4.3 Interpretation and implications for implementation

A low Clinical Evidence-based Readiness Score shall not, by itself, preclude further evaluation or implementation. It indicates greater scientific uncertainty and therefore calls for increased caution, appropriate risk management and closer monitoring. Where stronger evidence supports a modified patient population, clinical pathway, monitoring strategy, escalation model or other component of the Intended Use Case, adaptation of the proposed Intended Use Case towards the configuration supported by the stronger evidence should be considered before implementation.

If modifications to the Intended Use Case are made, the re-evaluation requirements specified in Clause 5 shall apply.

7.5 Technology Evidence-based Readiness

7.5.1 General

Technology Evidence-based Readiness assesses the maturity, quality, consistency and applicability of the scientific evidence supporting the use of a telehealth technology for the Intended Use Case.

Only technologies that have fulfilled the applicable Technological and Regulatory Eligibility criteria for the Intended Use Case shall proceed to Technology Evidence-based Readiness assessment.

The scientific evidence shall be identified through a documented and reproducible literature search using appropriate scientific databases. The assessment shall consider evidence directly applicable to the technology for the Intended Use Case.

It shall not be interpreted as a regulatory conformity assessment, certification process or commercial product evaluation.

Where multiple technologies are compared, the comparison shall include only technologies intended to perform the same clinical function within the assessed telehealth pathway.

Technology Evidence-based Readiness may be applied to:

a) **assessment of a single technology;**

b) **comparative assessment of similar technologies** within the same technological category; or

c) **comparative assessment of alternative technologies** intended to perform the same clinical function.

The resulting assessment shall reflect the strength and maturity of the available scientific evidence and the associated level of uncertainty concerning the use of the technology for the intended clinical application.

7.5.2 Determination of Technology Evidence-based Readiness Score

The Technology Evidence-based Readiness Score shall be determined on the basis of the availability, quality and consistency of the scientific evidence supporting the technology, device or platform for its intended clinical function, as specified in Table 2.

Table 2 — Determination of Technology Evidence-based Readiness Score

Scoring criteria	Evidence	Score
No published scientific evidence identified	No published scientific evidence supporting the technology, device or platform for the Intended Use Case has been identified.	0
Initial scientific evidence available	A limited number of publications supporting the technology, device or platform for the Intended Use Case is available. The available evidence is of limited methodological quality and does not demonstrate sufficient consistency across studies.	1
Recognizable body of scientific evidence available	A broader body of scientific evidence supporting the technology, device or platform for the Intended Use Case is available, including evidence of higher methodological quality. Higher-quality evidence shall include at least one well-designed randomized controlled trial. For example, multicentre, systematic review, meta-analysis or applicable evidence-based clinical guideline. Full consistency is not required; however, the available evidence shall demonstrate substantially concordant findings across independent studies, research groups or healthcare settings.	2
Sufficient body of scientific evidence to support a state-of-the-art assessment	A substantial body of high-quality scientific evidence directly supporting the technology, device or platform for the Intended Use Case is available. The available evidence demonstrates a high degree of consistency across relevant studies and provides sufficient scientific support for a state-of-the-art assessment of the proposed technology.	3

The score shall reflect the combined assessment of the availability, methodological quality and consistency of the evidence. In all cases, the evidence shall be applicable to the technology, device or platform and the Intended Use Case. Evidence relating to a substantially different technology, technological configuration or clinical function shall not be considered equivalent without documented justification.

7.5.3 Interpretation and implications for implementation

A low Technology Evidence-based Readiness Score shall not, by itself, preclude further evaluation or implementation. It indicates greater scientific uncertainty and therefore calls for increased caution, appropriate risk management and closer monitoring. Where stronger scientific evidence supports an alternative technology, device, platform or technological configuration capable of performing the same intended clinical function, adoption or adaptation towards the configuration supported by the stronger evidence should be considered before implementation.

If modifications to the Intended Use Case are made, the re-evaluation requirements specified in Clause 5 shall apply.

7.6 Organizational Readiness

7.6.1 General

Organizational Context-specific Readiness assesses the extent to which a healthcare organization is prepared to implement and sustain a telehealth service within its specific clinical context and can be modified through planning, resource allocation, and organizational development. The resulting score reflects the level of confidence that the organization possesses the capability required to successfully implement and sustain the proposed telehealth service while minimizing organizational barriers and operational risks.

Organizational Context-specific Readiness shall assess the following domains for the Intended Use Case:

- **Governance and Leadership**, including strategic commitment, leadership support, accountability, implementation governance and organizational decision-making.
- **Clinical Workflow and Resource Planning**, including integration into routine clinical workflows, definition of operational procedures, allocation of human, technical and financial resources and availability of the resources required for routine service delivery.
- **Telehealth Infrastructure**, including hardware, software, network connectivity, interoperability, cybersecurity, technical support and the technological environment required for service delivery.
- **Risk Management, Quality Assurance and Performance Evaluation**, including **risk management procedures**, quality assurance processes, definition of **Key Performance Indicators** (KPIs), outcome monitoring, performance evaluation and continual improvement mechanisms.

A documented care pathway shall be established and include:

a) inclusion and exclusion criteria;

b) triage and monitoring processes;

c) red-flag thresholds for deterioration; and

d) escalation procedures to in-person or emergency care, where applicable.

Processes shall be established to ensure consistent interpretation and application of:

e) eligibility criteria;

f) stratification levels; and

g) escalation thresholds.

Telehealth processes shall be documented and include:

h) clinical workflows;

i) information flows; and

j) interfaces with in-person care.

Roles, responsibilities, authorities, and accountabilities of healthcare and supporting actors shall be defined and documented, including escalation authority.

Documented Standard Operating Procedures (SOPs) shall be available and address:

k) triage;

l) alert management;

m) escalation; and

n) exception handling.

Governance mechanisms shall be established to provide oversight of the telehealth service through medical boards, quality committees, or equivalent governance bodies.

Potential risks associated with the intended use of the technology, including usability and cybersecurity risks, shall be identified and assessed, taking into account the intended users and use environment. Appropriate risk mitigation measures shall be considered in accordance with applicable requirements.

The assessment may take into consideration relevant principles relating to organizational governance, process management, risk management and continual improvement.

For example, relevant standards can address:

a) quality management systems and processes (e.g. ISO 9001);

b) risk management practices (e.g. ISO 31000);

c) risk control related to connectivity failures (e.g. IEC 81001-1 and ISO 14971);

d) usability engineering of medical devices (e.g. IEC 62366-1);

e) health software security (e.g. IEC 81001-5-1);

f) risk management of IT networks incorporating medical devices (e.g. IEC 80001-1);

g) telehealth service planning (e.g. ISO 13131); and

h) interoperability and data transmission (e.g. ISO/IEEE 11073).

7.6.2 Determination of the Organizational Readiness Score

Organizational Context-specific Readiness shall assess the four domains specified in Clause 7.6.1 in relation to the Intended Use Case.

Each domain shall be assigned a score from 0 to 3 according to the common maturity scale defined in Table 3.

The overall score shall correspond to the lowest of the four domain scores.

Table 3 — Determination of Organizational Context-specific Readiness Score

Scoring criteria	Readiness	Score
Not established	Essential conditions are absent or unsupported by documented evidence	0
Initial	Activities have been initiated but remain informal, incomplete or insufficiently resourced	1
Partially established	Requirements are defined and partly operational, but relevant gaps or inconsistencies remain	2
Established and operational	Requirements are approved, resourced, implemented, documented and routinely monitored	3

The domain receiving the lowest score shall be identified as the limiting domain. Where two or more domains receive the same lowest score, all shall be reported as limiting domains.

A higher score in one domain shall not compensate for a significant limitation in another, as inadequate readiness in any of the four domains may compromise implementation. The limiting domain or domains shall guide corrective action. Following completion of these actions, the affected domains shall be reassessed and the overall score recalculated.

7.7 Human Factors Readiness

7.7.1 Background

Human Factors Readiness evaluates, whether healthcare professionals, patients, and caregivers, where applicable, possess the knowledge, skills, confidence, and engagement necessary to participate safely and effectively in the Intended Use Case.

The assessment shall consider the two groups directly involved in the delivery and use of the telehealth service:

a) **Healthcare Team Readiness**, assessing whether the healthcare professionals responsible for delivering the Intended Use Case have the required training, relevant practical experience and demonstrated competency; and

b) **Patient and Caregiver Readiness**, assessing whether the target patient population and, where applicable, caregivers are expected to have sufficient access, digital capability and engagement to participate effectively in the Intended Use Case.

The two domains shall be assessed separately and scored from 0 to 3 according to their respective criteria (see 7.7.2.2 and 7.7.3.2).

7.7.2 Healthcare Team Readiness

7.7.2.1 General

Healthcare Team Readiness evaluates whether the healthcare professionals responsible for delivering the Intended Use Case possess the competencies required to perform their roles safely and effectively.

The assessment shall be performed at team level and shall consider the healthcare professionals whose roles require the relevant competencies for the Intended Use Case. The assessment shall consider the specific clinical activities, professional roles and technologies involved.

The assessment addresses competencies related to telehealth technologies, clinical decision-making, communication, and compliance with applicable organizational and regulatory requirements.

The resulting score reflects the readiness of the healthcare team to support safe, effective, and reliable telehealth service delivery for the Intended Use Case within the organizational context.

The healthcare organization shall identify the healthcare professionals responsible for the Intended Use Case.

The assessment shall consider, as appropriate to the complexity of the service of the Intended Use Case:

- the availability of an appropriately qualified multidisciplinary healthcare team;
- telehealth-specific competencies relevant to each professional role;
- education, training, and practical experience relevant to telehealth practice;
- the safe integration of certified digital health technologies into clinical decision-making; and
- knowledge of the clinical, organizational, ethical, and regulatory requirements applicable to telehealth.

7.7.2.2 Determination of the Healthcare Team Readiness

Healthcare Team Readiness shall assess the following three criteria:

a) **Training** — whether the healthcare professionals whose roles require telehealth-specific competencies have completed structured training appropriate to the Intended Use Case. The training

shall address, as applicable, the fundamentals of telehealth, relevant legal, regulatory and ethical aspects, clinical and technological aspects, remote communication and patient engagement, and the hard and soft skills required for safe and effective telehealth delivery.

b) **Experience** — whether the healthcare professionals responsible for telehealth delivery have relevant practical experience in providing telehealth care applicable to the Intended Use Case.

c) **Demonstrated competency** — whether the relevant competencies of the healthcare professionals have been assessed and documented through a competency assessment, self-assessment programme, certification or another documented and verifiable method appropriate to the Intended Use Case.

Each criterion shall be assigned a binary score as described in Table 4.

Table 4 — Determination of Healthcare Team Readiness Score

Criterion	Score: 0	Score: 1
Training	Appropriate structured telehealth training has not been completed	Appropriate structured telehealth training has been completed
Experience	Relevant practical telehealth experience has not been demonstrated	Relevant practical telehealth experience has been demonstrated
Demonstrated competency	Relevant competency has not been assessed and documented	Required competency has been assessed, demonstrated to be adequate for the Intended Use Case, and documented.

The Healthcare Team Readiness Score shall be calculated as the sum of the individual scores assigned to the three criteria and shall range from 0 to 3.

The three criteria shall be assessed independently, since fulfilment of one criterion does not necessarily demonstrate fulfilment of the others. Practical telehealth experience does not necessarily demonstrate structured education in telehealth-specific legal, regulatory, ethical, or other relevant requirements, and demonstrated competency does not necessarily demonstrate relevant practical experience or knowledge of the applicable legal and regulatory requirements.

A score below 3 shall identify one or more specific areas that may require corrective action before implementation. Corrective actions may include structured telehealth training, supervised practical experience, competency assessment, self-assessment programmes or certification, as applicable.

The resulting score shall be interpreted as follows:

- 0 — Not Ready;
- 1 — Limited Readiness;
- 2 — Moderate Readiness; and
- 3 — High Readiness.

7.7.3 Patient and Caregiver Readiness

7.7.3.1 Background

Patient and Caregiver Readiness evaluates the extent to which the target patient population and, where applicable, caregivers are expected to possess the prerequisites required to participate safely and effectively in the Intended Use Case.

The assessment shall be performed at population level and shall reflect the characteristics expected for the majority of the target patient population, rather than those of individual patients. Where caregivers are expected to operate the technology or otherwise participate in the telehealth pathway, their characteristics shall be considered as applicable.

Insufficient patient and caregiver readiness may reduce service uptake, increase drop-out rates, compromise adherence to remote care, and limit the effectiveness and sustainability of telehealth services.

IEC 62366-1 provides relevant guidance on the consideration of user characteristics. In the context of Patient and Caregiver Readiness, digital exclusion, low health literacy and insufficient caregiver support should be considered as potential factors contributing to non-adherence, miscommunication and adverse outcomes in telehealth services.

Patient and Caregiver Readiness shall assess the following three criteria:

a) **Access** — whether the majority of the target patient population and/or caregivers, where applicable, are expected to have access to the essential connectivity and basic digital technology required to access the telehealth service, such as a reliable internet connection, smartphone, tablet or computer, where requested. Additional devices shall be considered under this criterion only where the Intended Use Case explicitly requires patients or caregivers to have access to them.

b) **Digital capability** — whether the digital capability of the majority of the target patient population, or of their caregivers where applicable, is expected to be sufficient to use the technology or technologies they are required to operate within the Intended Use Case. The assessment shall take into account the type, number and complexity of such technologies.

c) **Expected engagement** — whether the majority of the target patient population and/or caregivers, where applicable, are expected to be willing and able to engage with and remain engaged in the activities required by the Intended Use Case for the expected duration of the telehealth pathway.

The resulting score shall reflect the expected readiness of the target patient population prior to implementation of the telehealth service.

7.7.3.2 Determination of Patient and Caregiver Readiness Score

Each criterion shall be assigned a binary score based on whether it is expected to be met by the majority of the target patient population and/or caregivers, where applicable, as described in Table 5.

Table 5 — Determination of Patient and Caregiver Readiness Score

Criterion	Score: 0	Score: 1
Access	Sufficient access to essential connectivity and basic digital technology is not expected	Sufficient access to essential connectivity and basic digital technology is expected
Digital capability	Sufficient capability to use the required technology or technologies is not expected	Sufficient capability to use the required technology or technologies is expected
Engagement	Sustained engagement for the expected duration of the telehealth pathway is not expected	Sustained engagement for the expected duration of the telehealth pathway is expected

The Patient and Caregiver Readiness Score shall be calculated as the sum of the scores assigned to the three criteria and shall range from 0 to 3.

The score shall reflect the expected readiness of the target patient population and, where applicable, caregivers to participate in the Intended Use Case.

The resulting score shall be interpreted as follows:

- 0 — Not Ready;
- 1 — Limited Readiness;
- 2 — Moderate Readiness; and
- 3 — High Readiness.

A score below 3 shall identify one or more specific factors that may require corrective action before implementation.

Actions to improve Patient and Caregiver Readiness may include, as applicable:

a) provision of connectivity or required access technology;

b) patient or caregiver training;

c) technical assistance;

d) caregiver support;

e) adaptation or simplification of the technologies or telehealth pathway; or

f) refinement of the Intended Use Case.

Following the planning or implementation of corrective actions, the affected criteria shall be reassessed and the Patient and Caregiver Readiness Score recalculated.

7.7.4 Determination of the Human Factors Readiness score

The Human Factors Readiness Score shall be the lower of the Healthcare Team Readiness Score and the Patient and Caregiver Readiness Score. A higher score in one domain shall not compensate for a lower score in the other. The lower-scoring domain shall identify the limiting Human Factors dimension and guide the definition of appropriate corrective actions. Following the planning or implementation of such actions, the affected domain shall be reassessed and the Human Factors Readiness Score recalculated.

7.8 Determination of Total Readiness Score

The total readiness score is the sum of all four criteria (Clinical Evidence-based Readiness (7.4.2), Technology Evidence-based Readiness (7.5.2), Organizational Readiness (7.6.2), Human Factors Readiness (7.7.4) for the Intended Use Case, with a maximum possible score of 12.

The Total Readiness Score shall be calculated as the sum of the four Readiness domain scores for the Intended Use Case, with a maximum possible score of 12:

Total Readiness Score = [Clinical Evidence-based Readiness Score] + [Technology Evidence-based Readiness Score] + [Organizational Readiness Score] + [Human Factors Readiness Score]

8 Sustainability

8.1 General

Sustainability evaluates ability of the Telehealth Evaluation Model (TEM) to provide measurable benefits to the patients and caregivers, to the health workers, and to the environment, and to be economically affordable from the adopting organization's perspective.

Sustainability is evaluated along four domains:

a) Economic impact;

b) Impact on patients and Caregivers;

c) Impact on health Workers;

d) Environmental Impact.

In the TEM, sustainability is evaluated by comparing telehealth delivery with in-person delivery and assessing the relative improvement achieved (or expected to be achieved if the TEM is applied before a pilot).

The scoring model assumes equal relevance of the four domains. In the final interpretation step the relative relevance of the four domains may be taken into account, considering that it depends on the actual Intended Use Case, the decision-maker perspective, applicable national or local goals, the deployment context, and the objective stated in the value proposition of the Intended Use Case.

The interpretation of the results should also consider the magnitude of the improvement.

This depends primarily on the number of eligible patients targeted by the telehealth and the proportion of patients that will be treated in the telehealth mode.

Once the telehealth delivery mode is deemed suitable, the inclusion of each patient remains subject to clinical judgment, digital readiness of the patient–caregiver dyad, home environment constraints, and patient/caregiver preferences. The resulting care model will be hybrid, where some patients are monitored remotely while others continue with in-person visits.

This volume aspect is taken into consideration in the interpretation of the final results.

The results of all sustainability domains shall be documented before implementation planning.

8.2 Environmental Impact Score

8.2.1 Background

The Environmental Impact Score describes the environmental impact of the Intended Use Case by assessing the impact of used medical devices, patient travel, Information and Communication Technology (ICT) infrastructures.

8.2.2 Determination of the Environmental Impact Score

The assessment shall identify which of the following sources of environmental impact are applicable to the Intended Use Case and shall consider the applicable sources:

- patient travel;
- medical devices (production and initial transportation, delivery-related transportation, and energy consumption);
- ICT operations for data storage, transmission and processing, including the use of Artificial Intelligence (AI), where applicable; and

- consumables and materials (production, transport for procurement, waste transport and treatment) used in the Intended Use Case.

The following factors may be excluded where the impacts are negligible or equivalent across scenarios:

- building-level HVAC and lighting in the healthcare provider organization and at patient's premises, and
- common background ICT infrastructure (e.g. for electronic health record (HER) management)

The functional unit (e.g. per patient, per visit) shall be defined consistently for the in-person and telehealth scenarios.

A complete environmental evaluation may be based on Life Cycle Assessment (LCA) in accordance with ISO 14040 and ISO 14044, referring to a cradle-to-grave system boundary.

This implies the calculation in both scenarios for all sources of environmental impact; the value of multiple impact categories selected in line with ISO 14044 and regarding:

- resource depletion (consumption and reduction of natural resources, e.g. water);
- human health (pollutants, and hazardous substances on human well-being and health);
- ecosystem (e.g. biodiversity loss); and
- a mix of them (e.g. greenhouse gas (GHG) emissions concern both human health and ecosystems).

In a pre-implementation evaluation, avoided travel-related GHG emissions (kg CO_2e) can be used as a key indicator of the environmental benefit of telehealth. Travel-related emissions include emissions from travel by patients or healthcare professionals and from the transport of medical devices intended for use by patients.

NOTE: The main driver is the average distance from the patient's home to the in-person care delivery location.

Where the decision to proceed with implementation depends significantly on the environmental sustainability assessment, the more comprehensive LCA approach can be applied after calculation of the overall TEM score.

The remaining sources of impact are considered as correction factors, as shown in Table 6. The person performing the assessment can define a threshold, for classifying the travel-related GHG emissions are high or low. The threshold may be established with reference to the environmental impact reduction objectives of the healthcare provider organization.

EXAMPLE An indicator for assessing relevance can be the lifetime CO_2e saved per euro invested. If this value is higher than a predefined threshold (e.g. 2 kg CO_2e/€), then the saved emissions due to travel are high.

Table 6 — Determination of Environmental Impact Score

Reduction Medical Device used	AI not used	Reduction of Consumables	Score if saved travel emissions are…	
			High	Low
Yes	Yes	Yes	3	2
All other cases (at least one positive condition is fulfilled)			2	1
No	No	No	1	0

The travel emissions due to the transport back to the provider of the medical device, once the care sessions end, are included in the calculation of the saved travel emissions.

The presence of the medical device in the telehealth delivery may contribute additional environmental impacts including embodied emissions, and energy consumption.

If software based on AI is used in the telehealth delivery, the energy to use it can significantly contribute to the environmental impact.

Where consumables are used in the in-person delivery scenario, their environmental impacts may include embodied emissions arising from production, transport, waste transport and waste treatment.

8.3 Social Impact-Patients and caregivers

8.3.1 Background

The purpose of this clause is to evaluate the social sustainability from the perspective of patients and caregivers.

The evaluation considers the potential benefits of the Intended Use Case with regard to:

a) equitable and timely access to appropriate healthcare services;

b) reduction of the physical, emotional, time-related and economic burden associated with care;

c) improved continuity of care;

d) improved adherence to therapeutic and follow-up pathways; and

e) community-level benefits arising from the appropriate use, accessibility and capacity of healthcare services.

8.3.2 Determination of the Social Impact-Patients and caregivers

The following social sustainability impact categories shall be included in the evaluation framework:

- **Access to healthcare:** Extent to which telehealth facilitates equitable and timely access to appropriate healthcare services, particularly by reducing geographical, mobility, time, organisational, or other barriers that may limit patients' and caregivers' ability to obtain care when needed.
- **Patient and caregiver burden**: Extent to which telehealth reduces the physical, emotional, time-related, organisational, and economic burden associated with accessing and receiving care, including travel, waiting time, absence from work or other activities, caregiving effort, and out-of-pocket expenses.
- **Compliance**: Extent to which telehealth supports patients and caregivers in maintaining continuity of care and adherence to the prescribed therapeutic and follow-up pathway, by facilitating regular interactions with healthcare professionals, monitoring, timely follow-up, and access to support when needed.
- **Community-level impacts**: Extent to which telehealth generates broader benefits for patients and the community by promoting more appropriate use of healthcare services, reducing avoidable hospital visits and congestion, improving the allocation of healthcare resources and capacity, and enhancing the overall availability and responsiveness of healthcare services.

In a pre-implementation evaluation, objective and readily available parameters can be used to indicate the estimated level of impact.

a) **Access to healthcare:** Distance and time required to access the in-person delivery location, including travel, admission, waiting and consultation time.

b) **Patient and caregiver burden**: Time away from work for the patient, the need for a caregiver to accompany the patient to an in-person visit, and expenses related to travel and parking.

c) **Compliance:** Number of care sessions per patient.

d) **Community-level impacts**: Reduction in hospital length of stay where post-discharge care is delivered through telehealth, and reduction in waiting lists.

The person performing the evaluation can define thresholds that are appropriate for the intended operational context to determine whether an improvement is present.

These indicators should be reviewed periodically and used to adapt service design.

EXAMPLE Average distance ≥ 10 km or number of care sessions per patient ≥ 3 as YES/NO evaluation.

Table 7 shows how the score follows the evaluation against the four criteria.

Table 7 — Determination of Social Impact-Patients and caregivers Score

Level of social benefit for the patient and caregivers	Description	Score
Very low	The Intended Use Case improves no category	0
Low	The Intended Use Case improves one category	1
Moderate	The Intended Use Case improves two or three categories	2
High	The Intended Use Case improves all the categories	3

8.4 Social impact-Health Workers

8.4.1 Background

The Social impact-Health Workers describes the social sustainability from the healthcare worker's perspective, with regard to the potential benefits of telehealth in terms of the quality and meaningful use of working time, the ability to perform professional tasks effectively, protection from occupational health and safety risks, and the ability to manage workload and organise care activities efficiently.

8.4.2 Determination

Workers' sustainability impact categories shall be included in the evaluation framework, such as:

- **Work-time quality:** Extent to which telehealth of the Intended Use Case improves the use and perceived quality of working time by reducing time spent on administrative, repetitive, or low-value tasks and enabling greater focus on meaningful and satisfying tasks.
- **Work effectiveness:** Extent to which telehealth of the Intended Use Case enables workers to perform their tasks more effectively and deliver better care through improved access to information, patient monitoring, data recording, and collaboration with colleagues.

- **Occupational health and safety:** Extent to which telehealth of the Intended Use Case contributes to protecting healthcare workers' health and safety by reducing exposure to occupational hazards, such as infectious agents, physical risks, and potentially unsafe working conditions.
- **Workload:** Extent to which telehealth reduces or does not increase the healthcare workload, enabling working time and effort to be allocated more effectively according to patients' needs and workload priorities.

In a pre-implementation evaluation, objective and readily available parameters can be used to provide an indication of the expected level of impact

- **Work-time quality**: Administrative or low-value time avoided per care session. Examples are use of paper or manual documentation.
- **Work effectiveness**: Examples of clinically useful data that telehealth enables workers to access analyse or share more easily.
- **Occupational health and safety**: Potentially hazardous in-person contacts avoided. Examples of avoided risks, considering their frequency and severity.
- **Workload**: Reduction of the time per care session

The person performing the evaluation shall use the objective parameters as evidence to express agreement in a YES/NO evaluation for each category of impact.

These indicators should be periodically reviewed and used to adapt service design.

EXAMPLE A potential yes/no question could be: "Does the telehealth in the Intended Use Case improves the Work-time quality."

Table 8 shows how the score follows the evaluation against the four criteria in the Intended Use Case.

Table 8 — Determination of Social impact-Health Workers Score

Level of social benefit, for the health workers	Description	Score
Very low	The Intended Use Case improves no category	0
Low	The Intended Use Case improves one category	1
Moderate	The Intended Use Case improves two or three categories	2
High	The Intended Use Case improves all the categories	3

8.5 Economic

8.5.1 Background

The Economic Score describes the economic sustainability of the Intended Use Case from the perspective of the adopting organization, taking into account revenues and costs that cease, or change when telehealth delivery is introduced for the intended medical action and target patients population.

8.5.2 Determination of Economic

The economic evaluation shall be conducted from a clearly defined perspective appropriate to the Intended Use Case and the decision-making context. This may include the perspective of the healthcare organization, payer, healthcare system or society, as applicable.

EXAMPLE If the decisionmaker is a for-profit healthcare provider organization, external economic impact is not considered and, for instance, the lower costs of travel with personal care of the patient or of the caregivers are considered in the social impact evaluation.

The economic benefit depends on revenues and the total cost of ownership over the lifecycle of the assets and resources involved.

Revenues, investment and recurrent operational expenses (OPEX) depend on the volume of activity (e.g. number of visits) and on the delivery model (e.g. for how much time the device is allocated to the patient) and its impact on the overall health delivery (e.g. possibility to serve larger number of patients).

The economic evaluation shall consider the following cost categories, where applicable:

- Initial Investment (e.g. acquisition of medical devices);
- Installation and Activation costs (e.g. training, integration in the organization's information system);
- Operational Costs (e.g. licences, service delivery workflow and logistics management);
- Maintenance and Repair Costs;
- Risk management costs (e.g. insurances); and
- End-of-Life Costs (e.g. decommissioning of medical devices).

The categories of revenues to be considered include:

- Service fees; and
- Additional revenues generated by reduced length of stay, freeing bed capacity and increasing the hospitalization capacity

Revenues and costs are influenced by factors including:

- Pricing model of the devices. For example, devices are typically purchased, whereas software is commonly provided under recurring licence fees;
- Number of eligible patients targeted by the telehealth;
- Average number of care sessions per patient; and
- Target level of service (this influences the size of the device fleet to ensure availability when needed).

A pre-implementation assessment is subject to uncertainty, including:

- Percentage of patients that will be treated in the Intended Use Case;
- Percentage of the additional capacity (freed bed-days) that will be used; and
- Variation of the demand during the year and the duration of the time is allocated to the patient.

In general, the economic evaluation can be summarized in indicators that are relevant for the decision maker, consistent with the value proposition of the intended use case and applicable to the economic profile of the investment (e.g. presence/absence of investment or revenues).

EXAMPLE A for-profit healthcare provider can consider essential to achieve an acceptable economic benefit, assessed through indicators such as Payback period (PBP, time to fully recover the investment) and Lifecycle Financial Balance (LCFB) increase ($LCFB_{Telehealth}/LCFB_{in\text{-}person}$-1*100). The reference value for PBP is the maximum value normally accepted in the organization (PBP_{max} , e.g. 5 years).

If there is a meaningful investment, then the PBP can be used. If there is no significant investment, then the LCFB increase can be used, for example where devices are provided under a lease or licence agreement, or where training represents the main investment.

The person doing the evaluation shall select the applicable indicator and define thresholds that are appropriate to the decision-maker's operational context in order to assign a score on the 0 to 3 scale.

Table 9 provides an example of the scoring approach when the Payback Period (PBP) is used as the selected indicator.

Table 9 — Example for the determination of Economic score

Score	Level of economic benefit	Description (Example)
0	Low	PBP > 5 years or Negative LCFB
1	Limited	5 years ≥ PBP > 4 years
2	Moderate	4 years ≥ PBP > 2 years
3	High	PBP ≤ 2 years

The final score is obtained by comparing the value of the selected indicator with the thresholds defined by the person performing the evaluation.

8.6 Determination of Sustainability Score

The total Sustainability Score is the sum of all four criteria (Environmental Impact (see 8.2.2), Social Impact-Patients and Caregivers (see 8.3.2), Social Impact-Health Workers (see 8.4.2) and Economic (see 8.5.2) and can be a maximum of 12.

9 Determination and Interpretation of Telehealth Evaluation Model (TEM) score

The final TEM score is determined as the sum of the Readiness (see 7.8) and the Sustainability score (see 8.6) and can be maximum 24.

10 Implementation

The TEM final score shall be interpreted as follows:

a) **8 or lower:** implementation of telehealth for the Intended Use Case is not recommended;

b) **9 to 14:** strengthening actions shall be implemented before proceeding to a pilot;

c) **15 to 21:** a pilot should be conducted before full-scale implementation;

d) **22 to 24:** full-scale implementation may proceed, subject to appropriate monitoring.

If the TEM score is between 9 and 14, the identified gaps with the evaluation should be addressed before proceeding to a pilot. The actions depend on the type of gap. For instance:

- If it regards extrinsic readiness, appropriate mitigation measures shall be designed and implemented.

- If it regards intrinsic readiness, actions should be implemented to increase the readiness (e.g. train the staff, prepare appropriate communication or assistance protocols to help patients that are expected to have problems with using the medical device).
- If it regards economic sustainability, measures should be explored to increase the economic benefit, e.g. negotiating a lower price of the medical device.

If the TEM score is between 15 and 21 any key weaknesses that could compromise the success of the pilot shall be addressed beforehand.

The pilot should be structured making sure that:

- It confirms (or not) the assumptions done in the evaluation process, e.g. about percentage of eligible patients accessing the telemedicine mode, percentage of travels done by car, patients' readiness
- It provides indications on how to cope with the weaknesses spotted by the evaluation process, e.g. collecting signals about the risk for safety, defining fallback pathway to be followed in case of failure, assess the ability of healthcare professionals, patients and caregivers to use the telehealth service in practice.

If the TEM Score is 22 or higher, full-scale implementation may proceed. However, a monitoring process should be established to identify needs for refinement or improvement of the care delivery model.

The implementation of the telehealth service for the Intended Use Case should also consider the lowest scoring of the different factors of the Readiness Score. Table 10 provides implementation recommendations based on the lowest Readiness domain score.

Table 10 — Implementation recommendation of the lowest Readiness domain score

If the lowest score is …	Then, …
0	The implementation should generally be limited to exploratory or pilot research with comprehensive outcome collection, enhanced monitoring and rigorous risk management.
1	Implementation should be performed only with a cautious implementation strategy, clearly defined eligibility criteria and prospective evaluation of clinical outcomes.
2	Implementation is performed following the indications for the total score range, but with focused monitoring and periodic reassessment of the evidence for the weak factor(s)
3	Implementation is performed following the indications for the total score range. Continue routine monitoring, quality assurance and periodic review of newly published evidence body of scientific evidence available to support a state-of-the-art assessment

Bibliography