ACCRÉDITATION SANS FRONTIÈRES (ASF)
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ASF Health Standards Version 11

Standard 5: Digital Care and AI

Core standard · applicability by facility type shown for each criterion

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REVISION HISTORY

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01	10 November 2026	First issue of the paper standard. Adapted from the web version of Standard 5 in ASF Health Standards Version 11.	Prof. Giorgi Pkhakadze

APPROVAL

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Date: 10 November 2026

Complete on its own, without internet access. References are listed in section 11. The current revision is at france-asf.fr.

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1 Introduction

This document is Standard 5 of ASF Health Standards. It sets out how a facility introduces and manages digital care and artificial intelligence safely and fairly: how digital care systems are assessed before use, how patients who cannot use digital care are still cared for well, how technical expertise supports the systems, and how AI systems are governed, monitored and explained to staff and patients, with clear accountability for the care they support.

A standard is a set of numbered criteria. Each criterion says what must be in place (the criterion statement), how it is rated for each setting, what the assessor will check and what evidence the facility must show. The guidance in this document explains what each criterion means in practice, so that a reader who has only this paper can understand and meet it.

Purpose of this document. Standard 5 makes sure that new technology improves care for every patient, and does not leave anyone behind or make decisions that no one is accountable for.

Who should read it. Members of the governing body, the chief executive, clinical leads, the information and digital lead, staff who use digital or AI systems, patient information staff, and the assessors who verify the facility. Each criterion names the positions responsible for it (section 8.2).

The standard is a tool to improve care, not a list of paperwork. Templates and forms named in this document are reference drafts. You may adapt them, replace them with your own, or upload your own documents, provided they meet the same criterion.

2 About ASF and this standard

Accréditation Sans Frontières (ASF) is a non-governmental, non-profit accreditation body. It was legally established in Paris in 2020. ASF develops health standards that are practical, affordable and open to all facilities, including those working with limited resources, in crisis, or in transition.

ASF believes accreditation should be accessible in every sense: geographically, so that facilities in remote areas can take part; financially, so that cost is not a barrier; and in language and format, so that staff can read and use the standard in their own working environment.

Each standard is an independent document. Standard 5 has been written so that it can be read and used on its own. It repeats the definitions, abbreviations and references it needs. A reader who has only this document can understand every criterion in it.

3 How to use this standard

If you are a facility manager or a member of the facilities team, read section 4 to confirm which criteria apply to your facility type, then section 5 to find the rating for your setting. Read each criterion from 2-4.1 to 2-4.8, paying attention to the rating, the guidance and the evidence. Prepare the evidence named in each criterion, covering the period stated.

If you are an assessor, use the sample and the checks in each criterion. The pass rule and the immediate-fail rule decide each criterion. A criterion is met only when all its checks are passed and no immediate-fail event is found.

Reading a criterion. Each criterion has: the criterion statement; the three ratings (humanitarian, transition and fragile, standard); the rating rule; the guidance; what good looks like; common mistakes; why it matters; the sample; the checks, with method, evidence and pass condition; the immediate-fail event; the documents with who writes, approves and checks them; the positions responsible; and the references.

Document codes. Each document has a code made of a topic prefix, a type and a number, for example ENV-SOP-001 (environment, procedure, 001). The type is one of FRM (form, a record kept as evidence), REG (register), PLN (plan),

POL (policy), SOP (standard operating procedure) or GDL (guide). The codes identify documents only. The full list is in section 12.

4 Scope

Standard 5 covers the assessment and management of digital care systems, the alternative route for patients who cannot use digital care, the technical expertise that supports these systems, and the introduction, monitoring, staff consultation, accountability and patient information for AI systems used in care.

The standard applies in three settings. The rating for each criterion is given for each setting, and the facility uses the rating for its own setting: **humanitarian settings** (emergency or crisis, very limited resources), **transition and fragile settings** (a health system in change or under strain), and **standard settings** (full resources).

WHERE STANDARD 5 APPLIES

Standard 5 applies to every facility type. Every criterion applies to all nine facility types, so no criterion is marked N/A. The applicability of all 70 standards is in **Annex 1: Applicability of ASF Health Standards by facility type** (ASF-HS11-ANX01), published on france-asf.fr.

Criterion	Applies to
2-4.1 Digital Care Systems Follow an Assessment and Management Process	all nine facility types
2-4.2 Digital Care Never Disadvantages a Patient Who Cannot Use It	all nine facility types
2-4.3 Technical Expertise Supports Digital Care Systems	all nine facility types
2-4.4 AI Systems Are Introduced in Line With WHO AI Governance Guidance	all nine facility types
2-4.5 AI Systems Are Monitored for Unintended Consequences	all nine facility types
2-4.6 Staff Are Consulted Before an AI System Is Introduced	all nine facility types
2-4.7 Accountability for AI-Assisted Care Is Explicitly Defined	all nine facility types
2-4.8 Patients Are Informed When Their Care Involves AI	all nine facility types

5 Ratings and colours

Rating	Colour	Meaning
Must		Required in every setting. Criteria that can directly affect a patient's life are always Must, and no setting lowers them.
Medium		Required, adapted to what a transition setting can realistically do.

Rating	Colour	Meaning
Minimum		The lowest acceptable level in a humanitarian setting, where resources are very limited.

In standard settings every criterion is Must.

TRAINING LEVELS

Level	Colour	Meaning
Essential		Must be completed by the people named in the role table.
Recommended		Good practice. Not checked as a requirement.
Optional		May be used for development.

6 Abbreviations

Abbreviation	Meaning
AI	Artificial intelligence
ASF	Accréditation Sans Frontières (Accreditation Without Borders), a non-governmental, non-profit accreditation body
FRM	Form. A record that is filled in and kept as evidence
GDL	Guide. Reference guidance for staff
ISCO-08	International Standard Classification of Occupations, 2008 edition (International Labour Organization)
PLN	Plan. A written plan with aims, owners and dates
POL	Policy. A written statement of what the facility will do and why
REG	Register. A running record of entries, such as monitoring results or complaints
SOP	Standard operating procedure. A step-by-step description of how a task is done
WHO	World Health Organization

DOCUMENT CODE PREFIXES

Prefix	Topic
AI	Artificial intelligence documents
DIG	Digital care and information documents

7 Terms and definitions

Term	Definition
Artificial intelligence system	Software that performs a task that normally needs human judgement, such as reading an image, sorting patients by urgency or suggesting a diagnosis.
Criterion	One numbered requirement in a standard, for example 2-4.1. Each criterion has its own rating, pass rule and immediate-fail rule.
Digital care system	Any electronic system used to deliver or support care, such as a telehealth platform, a remote monitoring tool or a patient-facing app.
Evidence	The records, documents and observations that show a criterion is met.
Immediate fail	One event that means a criterion is not met, whatever else is in place.
Interoperability	The ability of two systems to exchange and use information without manual re-entry.
Must, Medium, Minimum	The three ratings of a criterion. Must is required in every setting; Medium is required, adapted to what a transition setting can realistically do; Minimum is the lowest acceptable level in a humanitarian setting. See section 5.
Over-diagnosis and under-diagnosis	Over-diagnosis is a finding of a condition that is not present. Under-diagnosis is a failure to detect a condition that is present.
Pass rule	The condition that shows a criterion is met, given as a number, a percentage or a yes/no test.
Sample	The set of records, systems or patients that the assessor checks for a criterion. The sample is stated for each criterion.
Setting	The context in which a facility works: humanitarian, transition and fragile, or standard. Each criterion is rated for each setting.
Standard setting	A facility with full resources. Every criterion is Must in standard settings.
Transition and fragile setting	A facility in a health system that is changing or under strain, able to meet part of the standard at Medium level.
Verified micro-credential	A training credential that can be checked against the issuer's record, such as one held in the GMJ Academy micro-credential portfolio.

8 Standard 5 at a glance

Standard 5: Digital Care and AI is a core standard of ASF Health Standards. It applies to every facility type. It covers how digital care systems and artificial intelligence are assessed, introduced, monitored and explained, and who is accountable for the care they support.

The standard has eight criteria. Each is shown below and explained on its own page in section 9.

8.1 CRITERIA AND RATINGS

No.	Criterion	Humanitarian	Transition	Standard
2-4.1	Digital Care Systems Follow an Assessment and Management Process	Minimum	Medium	Must
2-4.2	Digital Care Never Disadvantages a Patient Who Cannot Use It	Minimum	Medium	Must
2-4.3	Technical Expertise Supports Digital Care Systems	Minimum	Medium	Must
2-4.4	AI Systems Are Introduced in Line With WHO AI Governance Guidance	Minimum	Medium	Must
2-4.5	AI Systems Are Monitored for Unintended Consequences	Minimum	Medium	Must
2-4.6	Staff Are Consulted Before an AI System Is Introduced	Minimum	Medium	Must
2-4.7	Accountability for AI-Assisted Care Is Explicitly Defined	Minimum	Medium	Must
2-4.8	Patients Are Informed When Their Care Involves AI	Minimum	Medium	Must

8.2 RESPONSIBILITIES

Each criterion names the positions responsible for it. The facility sets its own reporting lines, and each position should have written terms of reference. ISCO-08 codes are shown for each role and are recorded in the staff register.

No.	Criterion	Positions responsible or involved
2-4.1	Digital Care Systems Follow an Assessment and Management Process	Manager (ISCO 1342) · Secretary (ISCO 3344)
2-4.2	Digital Care Never Disadvantages a Patient Who Cannot Use It	Manager (ISCO 1342) · Secretary (ISCO 3344)
2-4.3	Technical Expertise Supports Digital Care Systems	Manager (ISCO 1342)
2-4.4	AI Systems Are Introduced in Line With WHO AI Governance Guidance	Chief executive (ISCO 1120) · Manager (ISCO 1342) · Nurse (ISCO 2221)
2-4.5	AI Systems Are Monitored for Unintended Consequences	Manager (ISCO 1342) · Nurse (ISCO 2221)

No.	Criterion	Positions responsible or involved
2-4.6	Staff Are Consulted Before an AI System Is Introduced	Manager (ISCO 1342) · Nurse (ISCO 2221)
2-4.7	Accountability for AI-Assisted Care Is Explicitly Defined	Chief executive (ISCO 1120) · Manager (ISCO 1342) · Nurse (ISCO 2221)
2-4.8	Patients Are Informed When Their Care Involves AI	Manager (ISCO 1342) · Nurse (ISCO 2221)

8.3 TRAINING FOR STANDARD 5

Training is shown by course. Essential training must be completed by the people named. Recommended training is good practice. The colours follow section 5.

Course	Essential for	Recommended for	Criteria	Status
Technology Platform Reliability & Security	Manager	Secretary	2-4.1	In development
Artificial Intelligence in Healthcare Safety	Chief executive, Manager, Nurse	Nurse	2-4.4, 2-4.5, 2-4.6, 2-4.7, 2-4.8	In development
Artificial Intelligence Systems for Care	Manager	Nurse	2-4.4	In development

Evidence of training may be a verified micro-credential in the GMJ Academy micro-credential portfolio, or a training certificate kept in the staff file.

2-4.1 Digital Care Systems Follow an Assessment and Management Process

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** Before any digital care system — telehealth platform, remote monitoring tool, patient-facing app — is introduced, the facility assesses its costs and benefits, manages its implementation, and continues to manage it afterwards — not adopted because a vendor made a compelling pitch, with no internal evaluation.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: every digital care system assessed for cost, benefit, interoperability and unintended consequences before it is introduced.

GUIDANCE

Before a digital care system is introduced, the facility assesses it. This covers telehealth platforms, remote monitoring tools and patient-facing apps. The assessment (DIG-SOP-002) weighs the costs against the expected benefits, checks that the system can exchange information with the facility's other records, and considers in advance what could go wrong, such as errors in data, loss of records or delays in care. The assessment is recorded on the assessment form (DIG-FRM-002).

A system that has been bought or installed without this assessment does not meet the criterion, even if it works well. The assessment is repeated when the system changes in a way that affects patients.

WHAT GOOD LOOKS LIKE

- A written assessment (DIG-SOP-002) covering cost, benefit, interoperability and unintended consequences.
- A completed assessment form (DIG-FRM-002) before implementation.
- A check that the system exchanges information with the facility's records.
- A repeat assessment when the system changes.

COMMON MISTAKES

- Buying a system and assessing it only afterwards.
- Assuming a system works with existing records without checking.
- Considering only the benefits, not the risks.
- Introducing a patient-facing app with no alternative for patients without a phone.

> **Why it matters.** A digital tool introduced into care without a check can slow care down, expose data, or fail when most needed. Assessing a tool before it is used, and managing it afterwards, protects the patient and the service.

WHAT THE ASSESSOR CHECKS

Sample. Review the assessment for each digital care system in use.

1 A cost/benefit analysis is done before implementation.

Method. Check the assessment record dated before the go-live date.

Evidence to show. DIG-FRM-002 Digital Tool Assessment Template; DIG-SOP-002 Digital Care System Assessment and Management.

Pass when. The analysis is dated before go-live.

2 Interoperability is assessed.

Method. Check that the assessment covers integration with existing clinical systems.

Evidence to show. DIG-FRM-002 Digital Tool Assessment Template.

Pass when. Interoperability and its risks are recorded.

3 Unintended consequences are considered in advance.

Method. Check the record for an identified risk list and its mitigations.

Evidence to show. DIG-FRM-002 Digital Tool Assessment Template.

Pass when. The risk list is complete and each risk has a mitigation.

Pass. The criterion is met when every check above is passed.

Immediate fail. A digital care system is introduced with no cost/benefit analysis and no interoperability check. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIG-SOP-002	Digital Care System Assessment and Management	Manager	Chief executive	Chief executive
DIG-FRM-002	Digital Tool Assessment Template	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the facility process this criterion measures	Technology Platform Reliability & Security Essential in all settings
Secretary (ISCO 3344)	Front desk and records support	Technology Platform Reliability & Security Humanitarian: Recommended; Transition: Recommended; Standard: Recommended

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Recommendations on digital interventions for health system strengthening. https://news.gmj.ge/guideline/recommendations-on-digital-interventions-for-health-system-strengthening/

2-4.2 Digital Care Never Disadvantages a Patient Who Cannot Use It

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** A process ensures that patients who cannot use digital devices, lack internet access, or are otherwise unable to engage with digital approaches are never disadvantaged by the facility's use of digital care — not digital convenience for most patients purchased at the cost of access for the patients least able to adapt.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: a defined alternative route for patients who cannot use digital care, with equivalent care.

GUIDANCE

Digital care must never be the only way a patient can receive care. A patient who cannot use a device, has no internet access, or is otherwise unable to take part in a digital approach has a defined alternative route, set out in the procedure (DIG-SOP-003). The alternative provides equivalent care, not a reduced service.

Before the service goes live, it is pre-tested with people who might struggle with it, such as older patients, people with limited literacy and people without a phone or internet access. The test and its results are recorded on DIG-FRM-003.

WHAT GOOD LOOKS LIKE

- A written alternative route (DIG-SOP-003) for patients who cannot use digital care.
- Equivalent care delivered through the alternative, recorded in the same way.
- Pre-testing with people who might struggle (DIG-FRM-003).
- Staff who know how to offer the alternative without judgement.

COMMON MISTAKES

- Digital care as the only option.
- An alternative that gives a shorter visit or less information.
- No test with patients who are less confident with technology.
- Patients who are turned away because they cannot use the app.

> **Why it matters.** Some patients cannot use a phone app, do not have internet, or find video calls hard. A service that moves everything online without an alternative leaves those patients without care.

WHAT THE ASSESSOR CHECKS

Sample. Select the digital care services in use and the records of patients who used the alternative route.

1 A defined alternative exists.

Method. Check the procedure for the alternative route.

Evidence to show. DIG-SOP-003 Digital Care Access and Alternatives.

Pass when. The alternative is defined and available.

2 The service was pre-tested with people who might struggle.

Method. Check the test record for a group of potential users.

Evidence to show. DIG-FRM-003 Digital Alternative Record.

Pass when. A pre-test with those users is recorded.

3 Patients using the alternative receive equivalent care.

Method. Select records of patients who used the alternative and compare the service they received.

Evidence to show. DIG-FRM-003 Digital Alternative Record.

Pass when. The service received is equivalent.

Pass. The criterion is met when every check above is passed.

Immediate fail. A patient who cannot use digital care has no alternative route, and receives reduced service. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIG-SOP-003	Digital Care Access and Alternatives	Manager	Chief executive	Chief executive
DIG-FRM-003	Digital Alternative Record	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the facility process this criterion measures	— Essential in all settings
Secretary (ISCO 3344)	Front desk and records support	— Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2024). Implementation toolkit for accessible telehealth services. https://news.gmj.ge/guideline/implementation-toolkit-for-accessible-telehealth-services/

2-4.3 Technical Expertise Supports Digital Care Systems

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** The facility has access to technical expertise — in-house, vendor-provided, or contracted — to support the effective use of its digital care systems, including testing and quality checks before full implementation, not digital systems left running with no technical support behind them.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: technical expertise available for digital care systems, and testing before full use.

GUIDANCE

Digital care systems need people who understand them. The facility has access to technical expertise, in-house, from the vendor or under contract, to support the effective use of each system. The support route is written in the implementation plan (DIG-PLN-001), and staff know how to reach it.

Testing takes place before full use. The test is recorded on the implementation form (DIG-FRM-004). A system that was switched on for all patients without a test does not meet the criterion.

WHAT GOOD LOOKS LIKE

- A named route for technical support, in-house, vendor or contracted (DIG-PLN-001).
- A test recorded on the implementation form (DIG-FRM-004) before full use.
- Staff who know how to contact support.
- A support record showing problems raised and resolved.

COMMON MISTAKES

- A system with no one to call when it fails.
- Switching on for all patients on the first day with no test.
- Support that exists only in the vendor's contract, unknown to staff.
- Problems fixed by staff with no record.

> **Why it matters.** A digital system that no one can support when it fails leaves staff stuck and patients unseen. Access to technical expertise, in-house or from a vendor, keeps the system working when it matters.

WHAT THE ASSESSOR CHECKS

Sample. Review the testing records and the support log for each digital care system.

1 Technical expertise is available.

Method. Check the support arrangement, in-house or contracted.

Evidence to show. DIG-PLN-001 Technical Support and Testing Arrangement.

Pass when. A named route to expertise exists.

2 Testing is done before full implementation.

Method. Check the test record dated before full use.

Evidence to show. DIG-FRM-004 Digital System Test and Support Record.

Pass when. Testing is recorded before full use.

3 Staff know the support route.

Method. Ask staff how they would get technical help for a digital system.

Evidence to show. DIG-PLN-001.

Pass when. Staff describe the route correctly.

Pass. The criterion is met when every check above is passed.

Immediate fail. A digital care system has no technical support route and was not tested before full use. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
DIG-FRM-004	Digital System Test and Support Record	Manager	Chief executive	Manager
DIG-PLN-001	Technical Support and Testing Arrangement	Chief executive	Governing body members	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the facility process this criterion measures	— Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2022). Consolidated telemedicine implementation guide. https://news.gmj.ge/guideline/consolidated-telemedicine-implementation-guide/

2-4.4 AI Systems Are Introduced in Line With WHO AI Governance Guidance

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** Any artificial intelligence system used to support diagnosis, triage, or care decisions is introduced and managed in accordance with WHO's Ethics and governance of artificial intelligence for health (2021). No such system is adopted without reference to this standard of responsible use.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: AI systems introduced in line with WHO guidance on the ethics and governance of AI for health.

GUIDANCE

Any AI system used to support diagnosis, triage or care decisions must be introduced and managed in line with WHO's guidance on the ethics and governance of artificial intelligence for health. The facility assesses the system before introduction (AI-FRM-001) and sets out a responsible-use policy (AI-POL-001) that says what the system is for, what it must not be used for, and who may use it.

The facility can name the governance basis it used. Where local law or national guidance applies, that is named too. An AI system in clinical use with no assessment and no governance basis does not meet this criterion.

WHAT GOOD LOOKS LIKE

- An AI assessment (AI-FRM-001) completed before introduction.
- A responsible-use policy (AI-POL-001) stating the purpose and the limits of use.
- A named governance basis, drawn from WHO guidance and any local rules.
- A list of the staff who are allowed to use the system.

COMMON MISTAKES

- A tool bought for clinical use with no assessment.
- Use of a general-purpose AI tool for patient decisions with no policy.
- A policy copied from elsewhere without adapting it to the facility.
- No record of who approved introduction.

> **Why it matters.** Artificial intelligence can help with diagnosis and triage, but it can also make errors that look confident. WHO's guidance on AI in health asks for safety, transparency and human oversight, and a facility that introduces AI must follow it.

WHAT THE ASSESSOR CHECKS

Sample. Review the assessment and policy for each AI system in clinical use.

1 An assessment is made before introduction.

Method. Check the assessment against WHO guidance on the ethics and governance of AI for health.

Evidence to show. AI-FRM-001 AI System Assessment.

Pass when. Each system has an assessment that cites the guidance.

2 A responsible-use policy is in force.

Method. Check that the policy is approved and covers each system in use.

Evidence to show. AI-POL-001 Responsible Use of AI in Care Policy.

Pass when. The policy is approved and covers each system.

3 The facility can name its governance basis.

Method. Ask the responsible person for the governance basis of one named system.

Evidence to show. AI-FRM-001 AI System Assessment.

Pass when. The basis is named and recorded.

Pass. The criterion is met when every check above is passed.

Immediate fail. An AI system is in clinical use with no assessment and no governance basis. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
AI-FRM-001	AI System Assessment	Manager	Chief executive	Manager
AI-POL-001	Responsible Use of AI in Care Policy	Chief executive	Governing body members	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Chief executive (ISCO 1120)	Carries accountability to the governing body	Artificial Intelligence in Healthcare Safety Essential in all settings
Manager (ISCO 1342)	Runs the facility process this criterion measures	Artificial Intelligence in Healthcare Safety; Artificial Intelligence Systems for Care Essential in all settings
Nurse (ISCO 2221)	Uses or checks the equipment and falls controls at the bedside	Artificial Intelligence Systems for Care Humanitarian: Recommended; Transition: Recommended; Standard: Recommended

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Ethics and governance of artificial intelligence for health. https://news.gmj.ge/guideline/ethics-and-governance-of-artificial-intelligence-for-health/

2-4.5 AI Systems Are Monitored for Unintended Consequences

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** The facility monitors and evaluates its AI systems — auditing results for over-diagnosis or missed diagnosis, tracking patient complaints related to AI-assisted care, and checking for other unintended consequences — not deploying an AI tool and assuming it works as intended with no ongoing scrutiny.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: AI output audited for over- and under-diagnosis, with a recorded response to any finding.

GUIDANCE

AI systems are monitored after introduction. The facility audits the output (AI-SOP-001) for over-diagnosis, where the system flags a condition that is not present, and under-diagnosis, where it misses one. The audit results are recorded in the AI monitoring register (AI-REG-001).

Complaints that relate to AI-assisted care are tracked, and each monitoring finding leads to a recorded response, such as retraining the staff, changing the threshold or stopping use. A known performance problem with no response does not meet this criterion.

WHAT GOOD LOOKS LIKE

- An audit procedure (AI-SOP-001) that checks for over- and under-diagnosis.
- A monitoring register (AI-REG-001) with the results and the date.
- A complaints log that shows AI-related complaints separately.
- A recorded response to each monitoring finding.

COMMON MISTAKES

- Checking the system only when someone complains.
- Results recorded but never reviewed.
- A known error with no change made.
- Monitoring that stops after the first month.

> **Why it matters.** An AI system can work well at first and then drift, missing diagnoses or over-diagnosing as the patients change. Auditing its results regularly is the only way to notice.

WHAT THE ASSESSOR CHECKS

Sample. Review the monitoring register for each AI system in use over the last 12 months.

1 AI output is audited for over- and under-diagnosis.

Method. Check the audit record for a sample of AI-assisted decisions.

Evidence to show. AI-SOP-001 AI Performance and Safety Monitoring.

Pass when. Audits are recorded for each system.

2 AI-related complaints are tracked.

Method. Check the complaints log for AI-related entries and their review.

Evidence to show. AI-REG-001 AI Monitoring Register.

Pass when. AI-related complaints are logged and reviewed.

3 A monitoring finding led to a response.

Method. Ask for one recorded case where monitoring found a problem and check the response.

Evidence to show. AI-REG-001 AI Monitoring Register.

Pass when. A recorded case shows a finding and a response.

Pass. The criterion is met when every check above is passed.

Immediate fail. An AI system's output is not checked, and a known performance problem has no recorded response. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
AI-SOP-001	AI Performance and Safety Monitoring	Manager	Chief executive	Chief executive
AI-REG-001	AI Monitoring Register	Secretary	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the facility process this criterion measures	Artificial Intelligence in Healthcare Safety Essential in all settings
Nurse (ISCO 2221)	Uses or checks the equipment and falls controls at the bedside	Artificial Intelligence in Healthcare Safety Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Ethics and governance of artificial intelligence for health. https://news.gmj.ge/guideline/ethics-and-governance-of-artificial-intelligence-for-health/

2-4.6 Staff Are Consulted Before an AI System Is Introduced

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** Staff who will deliver care using a new AI system are consulted before it is introduced, to understand the practical implications and identify training needs — not an AI tool rolled out to clinical staff with no engagement beyond a brief notification that it now exists.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: staff consulted before an AI system is introduced, with training needs met before go-live.

GUIDANCE

The staff who will deliver care with a new AI system are consulted before the decision to introduce it is final. The consultation (AI-SOP-002) covers the practical effect on their work, the risks they see and the training they will need. Its outcome is recorded on the consultation form (AI-FRM-002).

Training needs identified in the consultation are met before go-live. A system that goes live before staff have been consulted does not meet the criterion, even if it is later accepted by the team.

WHAT GOOD LOOKS LIKE

- A recorded consultation (AI-SOP-002) with the staff who will use the system.
- A consultation form (AI-FRM-002) showing the views and the training needs.
- Training completed before go-live.
- Staff able to describe what was discussed.

COMMON MISTAKES

- A decision made by managers and then announced.
- A consultation held after the system is live.
- No record of the staff who were consulted.
- Training planned but not delivered before go-live.

> **Why it matters.** Staff who will use an AI system every day know the practical problems that a manager may not. Consulting them before it is introduced finds those problems early.

WHAT THE ASSESSOR CHECKS

Sample. Review the consultation record for each AI system introduced in the last 12 months.

1 Staff are consulted before introduction.

Method. Check the consultation record dated before the decision was final.

Evidence to show. AI-FRM-002 Staff Consultation Record.

Pass when. Consultation is recorded before the decision.

2 Training needs are identified and met before go-live.

Method. Check that the consultation identified training needs and that training was recorded before go-live.

Evidence to show. AI-SOP-002 Staff Consultation Before AI Introduction.

Pass when. Identified training was completed before go-live.

3 Staff can describe the consultation.

Method. Ask staff who use a recent AI system whether they were consulted.

Evidence to show. AI-FRM-002 Staff Consultation Record.

Pass when. Staff confirm the consultation took place.

Pass. The criterion is met when every check above is passed.

Immediate fail. An AI system goes live with no staff consultation before the decision was final. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
AI-SOP-002	Staff Consultation Before AI Introduction	Manager	Chief executive	Chief executive
AI-FRM-002	Staff Consultation Record	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the facility process this criterion measures	Artificial Intelligence in Healthcare Safety Essential in all settings
Nurse (ISCO 2221)	Uses or checks the equipment and falls controls at the bedside	Artificial Intelligence in Healthcare Safety Humanitarian: Recommended; Transition: Recommended; Standard: Recommended

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Ethics and governance of artificial intelligence for health. https://news.gmj.ge/guideline/ethics-and-governance-of-artificial-intelligence-for-health/

2-4.7 Accountability for AI-Assisted Care Is Explicitly Defined

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** The facility has considered and documented accountability arrangements for care and treatment delivered with AI support — who is responsible when an AI-assisted decision is wrong — not leaving this as an unexamined question until the first time it matters.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: accountability for AI-assisted care documented, understood by clinicians and reviewed after incidents.

GUIDANCE

When care is delivered with AI support, someone must be accountable for each decision. The accountability arrangements are documented in the AI accountability policy (AI-POL-002). The policy says who is responsible when an AI-assisted decision is wrong, and it is not left between the clinician and the system.

Clinicians understand their own accountability and can describe it. Accountability is reviewed after any AI-related safety incident, and the review is recorded.

WHAT GOOD LOOKS LIKE

- An AI accountability policy (AI-POL-002) that names who is responsible for each type of decision.
- Clinicians who can describe their own accountability.
- A review recorded after any AI-related incident.
- A clear route for escalation when the AI output is doubted.

COMMON MISTAKES

- Accountability left unclear between the clinician and the vendor.
- A clinician who is asked to sign off decisions they cannot check.
- No review after an incident.
- A policy that no clinician has read.

> **Why it matters.** When an AI system contributes to a wrong decision, it is not clear who is responsible: the clinician, the vendor or the facility. A documented accountability arrangement answers that question before there is an incident.

WHAT THE ASSESSOR CHECKS

Sample. Review the accountability policy and the records of AI-assisted decisions in the last 12 months.

1 Accountability is explicitly documented.

Method. Check the policy and a sample of AI-assisted decision records.

Evidence to show. AI-POL-002 Accountability for AI-Assisted Care.

Pass when. Clinical accountability is stated in the policy and the records.

2 Clinicians understand their accountability.

Method. Ask clinicians who use AI-supported tools to describe their accountability for the final decision.

Evidence to show. AI-POL-002 Accountability for AI-Assisted Care.

Pass when. Clinicians describe it correctly.

3 Accountability is reviewed after an incident.

Method. Check the process for any AI-related safety incident.

Evidence to show. AI-POL-002 Accountability for AI-Assisted Care; INC-SOP-001 Root Cause Analysis of Serious Incidents.

Pass when. A review of accountability follows any such incident.

Pass. The criterion is met when every check above is passed.

Immediate fail. Accountability for an AI-assisted decision is not documented, and no review follows an AI-related safety incident. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
AI-POL-002	Accountability for AI-Assisted Care	Chief executive	Governing body members	Chief executive

Other records in the criterion: INC-SOP-001 Root Cause Analysis of Serious Incidents

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Chief executive (ISCO 1120)	Carries accountability to the governing body	Artificial Intelligence in Healthcare Safety Essential in all settings
Manager (ISCO 1342)	Runs the facility process this criterion measures	Artificial Intelligence in Healthcare Safety Essential in all settings
Nurse (ISCO 2221)	Uses or checks the equipment and falls controls at the bedside	Artificial Intelligence in Healthcare Safety Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Ethics and governance of artificial intelligence for health. https://news.gmj.ge/guideline/ethics-and-governance-of-artificial-intelligence-for-health/

2-4.8 Patients Are Informed When Their Care Involves AI

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: all nine facility types. Each setting shows its rating above.

> **Criterion.** A patient whose care involves an aspect delivered with AI system support is informed of this — not left to assume every decision was made by a human clinician alone, with disclosure treated as optional rather than a standard part of informed care.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: patients told in understandable language when their care involves an AI system.

GUIDANCE

A patient whose care involves an AI system is told so, in language they can understand. The information is given under the patient information procedure (AI-SOP-003), and it is not buried in a general consent form. It says what the AI does in their care and that a clinician remains involved.

The information is recorded on the patient information form (AI-FRM-003), and the record shows that the patient was told. Staff check that patients understood, and confirm it on the record.

WHAT GOOD LOOKS LIKE

- Patient information (AI-SOP-003) in understandable language, given before the care.
- An information form (AI-FRM-003) recorded in the patient file.
- A statement that a clinician remains involved in the decision.
- A check that the patient understood the information.

COMMON MISTAKES

- Mentioning AI only in a long general consent form.
- Using technical words the patient cannot follow.
- Not telling patients when AI has supported their care.
- Recording the information but never checking understanding.

> **Why it matters.** A patient who is treated with the help of AI has a right to know. Telling them, rather than leaving them to assume, is part of informed consent and trust.

WHAT THE ASSESSOR CHECKS

Sample. Review the patient information and the records of AI-supported care for the last 12 months.

1 Patients are informed when AI supports their care.

Method. Check the information given and the record of disclosure.

Evidence to show. AI-SOP-003 Informing Patients About AI-Supported Care.

Pass when. Disclosure is recorded for AI-supported care.

2 The information is understandable.

Method. Read the patient information for plain language and check it is not buried in a general consent form.

Evidence to show. AI-FRM-003 Patient Information on AI-Supported Care (template).

Pass when. The information is written in plain language and given separately.

3 Patients confirm they were told.

Method. Ask a sample of patients whether they were told AI was involved.

Evidence to show. AI-FRM-003 Patient Information on AI-Supported Care (template).

Pass when. Patients confirm they were informed.

Pass. The criterion is met when every check above is passed.

Immediate fail. A patient is not informed that AI supported their care, and no information is available. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
AI-SOP-003	Informing Patients About AI-Supported Care	Manager	Chief executive	Chief executive
AI-FRM-003	Patient Information on AI-Supported Care (template)	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Runs the facility process this criterion measures	Artificial Intelligence in Healthcare Safety Essential in all settings
Nurse (ISCO 2221)	Uses or checks the equipment and falls controls at the bedside	Artificial Intelligence in Healthcare Safety Essential in all settings

REFERENCES FOR THIS CRITERION

- World Health Organization (2021). Ethics and governance of artificial intelligence for health. https://news.gmj.ge/guideline/ethics-and-governance-of-artificial-intelligence-for-health/

10 Questions and answers

Do I need to meet every criterion in Standard 5?
Yes, where the criterion applies to your facility. Each criterion has its own pass rule and immediate-fail rule, so each one must be met on its own. The rating shown on each criterion gives the rating for each setting.

What is an immediate fail?
An immediate fail is one event that means the criterion is not met, even if everything else passes. Each criterion lists its own immediate fail on its page.

Which documents do I submit?
The documents listed under each criterion, in the form stated there. Registers and records are kept as Excel files, with one row per record. Policies and procedures are signed PDFs showing the version, date, owner and approver. Submit them before the survey, covering the period stated in each criterion.

What do the colours mean?
Red means Must: required in every setting. Yellow means Medium: required, adapted to what a transition setting can realistically do. Green means Minimum: the lowest acceptable level in a humanitarian setting, where a facility cannot do everything. In standard settings, every criterion is Must.

Do we have to use your forms and policies?
No. Everything here is a reference draft. Use it as a starting point, adapt it to your facility, or write your own. The assessor checks whether the standard is met and whether your documents show how.

What does essential or recommended training mean for my staff?
Essential training must be completed by the people named in the role table. Recommended training is good practice and is not checked as a requirement.

Does digital care replace in-person care?
No. A patient who cannot or does not want to use digital care must have a defined alternative, and must receive equivalent service through it (criterion 2-4.2).

Who is accountable when AI supports a decision?
Clinical accountability for the decision must be documented, not left between the clinician and the system. Clinicians must understand their own accountability, and accountability is reviewed after any related safety incident (criterion 2-4.7).

Are patients told when AI is used in their care?
Yes. The patient is informed in understandable language, not buried in a general consent form (criterion 2-4.8).

The criterion text is the authority. These answers summarise it.

11 References

CITED FOR CRITERIA

1. World Health Organization (2021). Recommendations on digital interventions for health system strengthening. https://news.gmj.ge/guideline/recommendations-on-digital-interventions-for-health-system-strengthening/ (criterion 2-4.1)
2. World Health Organization (2024). Implementation toolkit for accessible telehealth services. https://news.gmj.ge/guideline/implementation-toolkit-for-accessible-telehealth-services/ (criterion 2-4.2)
3. World Health Organization (2022). Consolidated telemedicine implementation guide. https://news.gmj.ge/guideline/consolidated-telemedicine-implementation-guide/ (criterion 2-4.3)
4. World Health Organization (2021). Ethics and governance of artificial intelligence for health. https://news.gmj.ge/guideline/ethics-and-governance-of-artificial-intelligence-for-health/ (criterion 2-4.4, 2-4.5, 2-4.6, 2-4.7, 2-4.8)

INTERNATIONAL STANDARDS CITED

1. International Labour Organization (2008). International Standard Classification of Occupations, ISCO-08. Geneva: ILO.

12 Document register

Every document code used in Standard 5, with its type and the criteria that use it. The codes identify the documents; a facility may use its own document if it meets the same criterion.

Code	Document	Type	Criteria
AI-FRM-001	AI System Assessment	Form (record)	2-4.4
AI-FRM-002	Staff Consultation Record	Form (record)	2-4.6
AI-FRM-003	Patient Information on AI-Supported Care (template)	Form (record)	2-4.8
AI-POL-001	Responsible Use of AI in Care Policy	Policy	2-4.4
AI-POL-002	Accountability for AI-Assisted Care	Policy	2-4.7
AI-REG-001	AI Monitoring Register	Register	2-4.5
AI-SOP-001	AI Performance and Safety Monitoring	Procedure (SOP)	2-4.5
AI-SOP-002	Staff Consultation Before AI Introduction	Procedure (SOP)	2-4.6
AI-SOP-003	Informing Patients About AI-Supported Care	Procedure (SOP)	2-4.8
DIG-FRM-002	Digital Tool Assessment Template	Form (record)	2-4.1
DIG-FRM-003	Digital Alternative Record	Form (record)	2-4.2
DIG-FRM-004	Digital System Test and Support Record	Form (record)	2-4.3
DIG-PLN-001	Technical Support and Testing Arrangement	Plan	2-4.3
DIG-SOP-002	Digital Care System Assessment and Management	Procedure (SOP)	2-4.1
DIG-SOP-003	Digital Care Access and Alternatives	Procedure (SOP)	2-4.2
INC-SOP-001	Root Cause Analysis of Serious Incidents	Procedure (SOP)	2-4.7