Policy · AI-POL-001 · Version 1.1 · Approved by the ASF Expert Committee

Supports: 2D.4

At a glance

- No AI system supports diagnosis, triage or care decisions without an assessment against WHO AI governance guidance (E-011).
- Each AI system has a named clinical owner and a human oversight rule.
- Record each assessment on AI-FRM-001.
- Review every AI system each year.
- Stop and get help straight away if: an AI system is used in clinical decisions with no assessment or no named owner.

1. Purpose

To make sure AI systems used in diagnosis, triage or care decisions are introduced and governed in line with WHO guidance on the ethics and governance of AI for health [E-011].

2. Scope

Applies to	Clinical leads, IT lead, chief executive, ethics or governing body
Locations	All clinical areas at the facility
When	Before introduction, at each change, and yearly
Does not apply to	Simple non-clinical automation such as scheduling, unless it affects clinical decisions

3. Definitions

Term	Meaning
AI system	Software that uses machine learning or similar methods to produce outputs such as diagnoses, risk scores or recommendations

Human oversight	A named clinician who can review, change or reject an AI output before a care decision

4. Background

AI can help clinicians, but it can also be wrong in ways that are hard to see. WHO’s 2021 guidance sets principles such as protecting autonomy, promoting well-being and safety, transparency, accountability, equity and sustainability [E-011]. Criterion 2D.4 asks each system to be introduced in line with that guidance.

5. Responsibilities

Role	Responsibility	Competence
Chief executive	Approves the policy and high-impact systems	Executive
Clinical lead for each AI system	Owns the system and the oversight rule	Clinical
IT lead	Assesses data and technical risk	Health informatics (EC)
Ethics or governing body	Reviews high-impact systems	Ethics and governance (EC)

6. Materials and equipment

Item	Requirement	Condition
AI system assessment (AI-FRM-001)	Current	One per system
WHO guidance (E-011)	Current copy	Available to leads

7. Safety

- AI outputs are advice, not orders. A clinician makes and records the final decision.
- Do not use an AI system outside the population or setting it was validated for.

8. Before you start

- Check the system is on the register of AI systems.

9. Procedure

Step 1. Register the system.

- List each AI system in use: purpose, vendor, version, data used, and the clinical owner.

Key point: An unregistered system cannot be governed.

Step 2. Assess against WHO guidance.

- Complete AI-FRM-001 for each system against the WHO principles: autonomy, safety, transparency, accountability, equity and sustainability.
- Record the evidence for each principle.

Key point: The assessment must show how each principle is met, not only that it is claimed.

Step 3. Set human oversight.

- Write who reviews each output, when, and what they may do with it.
- Record the rule on AI-FRM-001.

Key point: Oversight must be real. A rubber stamp is not oversight.

Step 4. Decide and introduce.

- The approver decides on the basis of the assessment.
- Introduce with training and monitoring (AI-SOP-001).

Key point: The decision and its reasons are the evidence.

Step 5. Review yearly.

- Review each system yearly against the assessment and the monitoring results.

Key point: Models and data change over time.

10. Decision points

- If the assessment cannot show equity or safety for the patient group, the system is not used for that group.

11. Special situations

Situation	Action
Vendor update changes the model	Repeat the assessment before the update is used clinically.

12. Escalation

- Any AI-related safety concern goes to the chief executive and INC-POL-001 at once.

13. Monitoring

Measure	Target	Frequency	Owner	If not met
AI systems registered with assessment	100%	Yearly	IT lead	Stop use until assessed
Named oversight rule per system	100%	Yearly	Clinical leads	Escalate
Assessments reviewed yearly	100%	Yearly	Chief executive	Escalate to governing body

14. Records

Record	Kept in	Retention
AI system register and AI-FRM-001 assessments	Governance file	the period set by the facility’s records policy years after the system is retired

15. Training

- Clinical users are trained on each AI system and its oversight rule before use (EC).

16. Related documents

ID	Title	Use
AI-FRM-001	AI System Assessment	Used in step 2
AI-SOP-001	AI Performance and Safety Monitoring	Monitoring after introduction
SOP-N28	Responsible Use of AI Policy (generic)	Basis
DIG-SOP-002	Digital Care System Assessment	Overall digital assessment

17. Evidence

Reference	Note
E-011	WHO (2021), Ethics and governance of artificial intelligence for health. Used as the basis for AI governance. Link and wording to verify before publication.
E-009	ASF Expert Committee consensus. Assessment criteria and high-impact thresholds to be set by the committee.

18. Change history

Version	Date	What changed	Approval
1.0	the date of approval	First version	Approved by the ASF Expert Committee
1.1	the date of approval	Internal quality review: corrected cross-references, status wording and document control	Approved by the ASF Expert Committee

E-learning for this document

- **Artificial Intelligence in Healthcare Safety** (AI-001)
- Artificial Intelligence Systems for Care (TELE-10)

References

- World Health Organization (2021). Ethics and governance of artificial intelligence for health: WHO guidance. Geneva: WHO. **Open source** (E-011)
- Accréditation Sans Frontières (2026). ASF Expert Committee consensus on Standard 1. (E-009)

Download this document as PDF

Download this document as an editable Word file