

Responsible Use of AI in Care Policy

Policy | AI-POL-001

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Title	Responsible Use of AI in Care Policy
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Prepared by	{{roles.quality_lead.name}}, Quality lead
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Effective date	{{document.effective_date}}
Next review	{{document.review_date}} (12 months, or sooner after any incident or change)
Replaces	Adapts SOP-N28 (Responsible Use of Artificial Intelligence Policy, generic)
Standards and criteria supported	Standard 2D, criterion 2D.4
Evidence basis	E-011, E-009
Status of this document	Recommended best-practice model. A hospital may adopt, adapt or replace it with an equivalent that meets the same criteria.

At a glance: what to do

1. No AI system supports diagnosis, triage or care decisions without an assessment against WHO AI governance guidance (E-011).
2. Each AI system has a named clinical owner and a human oversight rule.
3. Record each assessment on AI-FRM-001.
4. 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 {{facility.legal_name}}
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 and abbreviations

Term	Meaning in this SOP
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 and rationale

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	Duties in this SOP	Competence needed
Chief executive	Approves the policy and high-impact systems	Executive
Clinical lead for each AI system	Owens 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. Equipment, materials and resources

Item	Specification or standard	Check before use
AI system assessment (AI-FRM-001)	Current	One per system
WHO guidance (E-011)	Current copy	Available to leads

7. Safety and infection prevention

- 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

Follow the steps in order. Where a step says "If", take the action for the case that applies. Do not skip a step. If a step cannot be done, use section 11 and section 12.

Step	Action	How to do it	Key point
1	Register the system.	List each AI system in use: purpose, vendor, version, data used, and the clinical owner.	An unregistered system cannot be governed.
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.	The assessment must show how each principle is met, not only that it is claimed.
3	Set human oversight.	- Write who reviews each output, when, and what they may do with it. - Record the rule on AI-FRM-001.	Oversight must be real. A rubber stamp is not oversight.
4	Decide and introduce.	- The approver decides on the basis of the assessment. - Introduce with training and monitoring (AI-SOP-001).	The decision and its reasons are the evidence.
5	Review yearly.	Review each system yearly against the assessment and the monitoring results.	Models and data change over time.

Decision points

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

10. Special situations

Situation	What to do
Vendor update changes the model	Repeat the assessment before the update is used clinically.

11. Problems and escalation

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

12. Monitoring and compliance

What is checked	Target	How often	Who	If the target is missed
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

13. Records

Record	Where it is kept	Kept for
AI system register and AI-FRM-001 assessments	Governance file	{{facility.records_retention_years}} years after the system is retired

14. Training and competence

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

15. Related documents

ID	Title	Relationship
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

16. Evidence

ID	Source and status
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.

EC = ASF Expert Committee consensus. Items marked EC are reviewed by the Committee each year.

17. Change history

Version	Date	What changed	Approver and signature
1.0	{{document.effective_date}}	First version	Approved by the ASF Expert Committee
1.1	{{document.effective_date}}	Internal quality review: corrected cross-references, status wording and document control	Approved by the ASF Expert Committee