Standard operating procedure (SOP) · AI-SOP-001 · Version 1.1 · Approved by the ASF Expert Committee

Supports: 2D.5

At a glance

- Audit a sample of AI-assisted decisions each quarter for over-diagnosis and missed diagnosis.
- Track every complaint or concern about AI-assisted care.
- Act on any finding: retrain, restrict use, or stop.
- Record each audit on AI-REG-001.
- Stop and get help straight away if: an audit shows harm or a pattern of error, and use continues without review.

1. Purpose

To monitor AI systems after introduction for over-diagnosis, missed diagnosis, complaints and other unintended effects, and to act on findings [E-011, EC].

2. Scope

Applies to	Clinical leads, quality lead, IT lead
Locations	All clinical areas using AI systems at the facility
When	Quarterly audit; continuous complaint tracking
Does not apply to	General clinical audit, covered by SOP-N26

3. Definitions

Term	Meaning
Over-diagnosis	A condition recorded or treated that would not otherwise have needed it
Missed diagnosis	A condition the AI system or its use failed to detect
Audit sample	A set of AI-assisted decisions selected for checking against the clinical outcome

4. Background

An AI tool can perform well in testing and poorly in use. Criterion 2D.5 requires ongoing checks for over-diagnosis, missed diagnosis and other unintended effects, not an assumption that the tool works as intended.

5. Responsibilities

Role	Responsibility	Competence
Clinical lead for each system	Runs the quarterly audit	Clinical
Quality lead	Reviews findings and trends	Quality (SOP-N26)
IT lead	Checks performance data and system changes	Health informatics (EC)

6. Materials and equipment

Item	Requirement	Condition
Audit sample list (random, 10 per quarter, EC)	Current	Generated each quarter
AI-REG-001 Monitoring Register	Current	Quality file

7. Safety

- Patients affected by a suspected error are reviewed clinically at once, not left until the next audit.

8. Before you start

- Confirm the system version and the audit period.

9. Procedure

Step 1. Select a sample.

- Select a random sample of AI-assisted decisions each quarter (EC size).
- Include decisions where the clinician agreed and where they overrode the AI output.

Key point: Cases where clinicians overrode the AI are a useful source of error.

Step 2. Check against outcome.

- For each case, compare the AI output with the clinical outcome or expert review.
- Record over-diagnosis, missed diagnosis, and other effects.

Key point: The outcome, not the agreement of the clinician, is the check.

Step 3. Track complaints.

- Record every complaint or concern about AI-assisted care on INC-POL-002, flagged as AI-related.
- Review each one with the clinical lead.

Key point: Patients often notice errors first.

Step 4. Act on findings.

- For each finding, decide: no action, retrain, add a check, restrict use, or stop use.
- Record the decision and its owner on AI-REG-001.

Key point: A finding with no action is a finding that repeats.

Step 5. Report.

- Report results each quarter to the quality committee, and to the governing body yearly.

Key point: Reporting keeps the monitoring visible.

10. Decision points

- If the audit shows a pattern of missed diagnosis, use is restricted at once while the cause is found.

11. Special situations

Situation	Action
Vendor update	Re-run the audit sample after the update before full use.

12. Escalation

- Patient harm linked to an AI system is reported as an incident at once (INC-POL-001).

13. Monitoring

Measure	Target	Frequency	Owner	If not met
Quarterly audit completed	100%	Quarterly	Clinical lead	Escalate to quality lead
AI complaints tracked and reviewed	100%	Quarterly	Quality lead	Escalate
Findings with decision recorded	100%	Quarterly	Quality lead	Escalate to chief executive

14. Records

Record	Kept in	Retention
AI-REG-001 AI Monitoring Register	Quality file	the period set by the facility’s records policy years

15. Training

- Clinical auditors are trained in the method at appointment (EC).

16. Related documents

ID	Title	Use
AI-REG-001	AI Monitoring Register	Used in steps 2 to 4
SOP-N26	Internal Audit, Quality Oversight and Learning Policy (generic)	General audit
AI-POL-001	Responsible Use of AI in Care Policy	Parent policy

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. Sample size and thresholds to be agreed.

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)

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)

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