Standard operating procedure (SOP) · AI-SOP-003 · Version 1.1 · Approved by the ASF Expert Committee

Supports: 2D.8

At a glance

- Tell each patient when an aspect of their care involves an AI system.
- Use plain language, on the patient information notice (AI-FRM-003).
- Record the disclosure in the patient file.
- Answer questions and offer a non-AI option where appropriate and possible.
- Stop and get help straight away if: a patient is not told about AI involvement in a decision that matters to their care.

1. Purpose

To make sure patients know when AI is part of their care, in words they understand, and can ask questions about it [E-011, EC].

2. Scope

Applies to	Clinicians and staff who explain care to patients
Locations	All clinical areas using AI systems at the facility
When	Before or at the point of care involving AI; the notice reviewed yearly
Does not apply to	General consent forms, which follow the consent standard (SOP-118, generic)

3. Definitions

Term	Meaning
Disclosure	Telling a patient that an AI system has supported an aspect of their care
Plain language	Words a patient understands on first reading

4. Background

Patients may assume every decision was made by a clinician alone. Disclosure is part of informed care, and it helps patients trust the care they receive. Criterion 2D.8 asks for disclosure as standard, not optional [E-011].

5. Responsibilities

Role	Responsibility	Competence
Treating clinician	Tells the patient and records it	Clinical communication
Clinical lead	Approves the patient notice	Clinical
Patient information lead	Keeps the notice current and in the needed languages	Communications

6. Materials and equipment

Item	Requirement	Condition
Patient notice on AI use (AI-FRM-003)	Current, plain language	Posted and given on request
Disclosure record in the patient file	Current	Held with the record

7. Safety

- Disclosure must never delay urgent care.

8. Before you start

- Check the notice is current and available in the patient’s language.

9. Procedure

Step 1. Tell the patient.

- Before or at the point of care, tell the patient that an AI system supported part of their care, and what it was used for.

- Explain that a clinician made the final decision.

Key point: The clinician is the one who decides. Say so.

Step 2. Use the notice.

- Give the patient AI-FRM-003, in plain language and in the language they use.

Key point: A plain notice is what most patients will read.

Step 3. Answer questions.

- Answer the patient's questions. Offer a non-AI route where it is clinically appropriate and possible.

Key point: Patients who ask deserve a clear answer, not a referral.

Step 4. Record.

- Record in the patient file that the patient was told and what was said.

Key point: The record is the evidence for the criterion.

Step 5. Review the notice.

- Review the notice yearly and after any change in AI systems.
- Ask a sample of patients whether they understood it.

Key point: Patients are the best test of plain language.

10. Decision points

- If a patient declines AI involvement, the clinician decides whether the non-AI route is clinically possible, and records the decision.

11. Special situations

Situation	Action
Emergency care	Give the care first, then inform the patient as soon as it is safe, and record it.

12. Escalation

- Complaints about disclosure go to INC-POL-002.

13. Monitoring

Measure	Target	Frequency	Owner	If not met
Patients told (sample of 10 records per quarter)	100%	Quarterly	Clinical lead	Re-brief clinicians
Notice current and available in patient languages	Yes	Yearly	Patient information lead	Update within 30 days
Patients who can confirm they were told (sample)	At least 80% (EC)	Yearly	Clinical lead	Review notice

14. Records

Record	Kept in	Retention
Disclosure entry in the patient record	Patient file	As the patient record (EC)
AI-FRM-003 Notice (current and superseded)	Patient information file	the period set by the facility’s records policy years

15. Training

- Clinicians are trained in disclosure and in plain-language explanation at induction (EC).

16. Related documents

ID	Title	Use
AI-FRM-003	Patient Information on AI-Supported Care	Notice used in step 2
AI-POL-001	Responsible Use of AI in Care Policy	Parent policy
CON-SOP-001	Informed Consent (Standard 1)	Consent process

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 patient languages 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)

Download this document as PDF

Download this document as an editable Word file