

Informing Patients About AI-Supported Care

Standard operating procedure (SOP) | AI-SOP-003

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Title	Informing Patients About AI-Supported Care
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Replaces	None (new document)
Standards and criteria supported	Standard 2D, criterion 2D.8
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. Tell each patient when an aspect of their care involves an AI system.
2. Use plain language, on the patient information notice (AI-FRM-003).
3. Record the disclosure in the patient file.
4. 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 {{facility.legal_name}}
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 and abbreviations

Term	Meaning in this SOP
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 and rationale

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	Duties in this SOP	Competence needed
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. Equipment, materials and resources

Item	Specification or standard	Check before use
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 and infection prevention

- Disclosure must never delay urgent care.

8. Before you start

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

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	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.	The clinician is the one who decides. Say so.
2	Use the notice.	• Give the patient AI-FRM-003, in plain language and in the language they use.	A plain notice is what most patients will read.
3	Answer questions.	• Answer the patient's questions. Offer a non-AI route where it is clinically appropriate and possible.	Patients who ask deserve a clear answer, not a referral.
4	Record.	• Record in the patient file that the patient was told and what was said.	The record is the evidence for the criterion.
5	Review the notice.	• Review the notice yearly and after any change in AI systems. • Ask a sample of patients whether they understood it.	Patients are the best test of plain language.

Decision points

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

10. Special situations

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

11. Problems and escalation

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

12. Monitoring and compliance

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

13. Records

Record	Where it is kept	Kept for
Disclosure entry in the patient record	Patient file	As the patient record (EC)
AI-FRM-003 Notice (current and superseded)	Patient information file	{{facility.records_retention_years}} years

14. Training and competence

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

15. Related documents

ID	Title	Relationship
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

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. Sample size and patient languages to be agreed.

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