Policy · AI-POL-002 · Version 1.1 · Approved by the ASF Expert Committee

Supports: 2D.7

At a glance

- The clinician who makes the final decision remains accountable for it.
- Write the accountability arrangement for each AI system, approved by the governing body.
- Review accountability after any AI-related safety incident.
- Make the arrangement known to every clinical user.
- Stop and get help straight away if: an AI-assisted decision is made where accountability is not written down for that system.

1. Purpose

To define, in writing and in advance, who is accountable when an AI-assisted care decision is wrong, so that the question is answered before it matters [E-011, EC].

2. Scope

Applies to	Clinicians, clinical leads, chief executive, governing body, legal adviser
Locations	All clinical areas using AI systems at the facility
When	Before each AI system is introduced; reviewed yearly and after incidents
Does not apply to	Accountability for decisions made without AI, covered by existing clinical governance

3. Definitions

Term	Meaning
Accountability	The duty to answer for a decision, and to put right harm caused by it
Final decision	The clinical decision that is communicated to the patient and recorded

4. Background

When an AI-supported decision goes wrong, the question “who is responsible” is often left open, which harms patients and staff. Criterion 2D.7 asks for it to be defined in advance and approved [E-011].

5. Responsibilities

Role	Responsibility	Competence
Governing body	Approves the arrangement	Governance
Chief executive	Keeps the arrangement current; leads reviews	Executive
Clinicians	Accept accountability for their final decision and understand the system limits	Clinical
Legal adviser	Advises on the legal position (EC)	Legal

6. Materials and equipment

Item	Requirement	Condition
Accountability arrangement per AI system	Written, approved by governing body	Current
Staff briefing on accountability	Plain language	Given at induction and when a system is introduced

7. Safety

- The arrangement must never discourage clinicians from overriding an AI output.

8. Before you start

- Confirm the arrangement for the system is approved.

9. Procedure

Step 1. Write the arrangement.

- For each AI system, write who makes the final decision, who is accountable for it, and how the system's limits are communicated.
- Include the process for patient harm and redress.

Key point: Write it before use, not after the first incident.

Step 2. Approve.

- The governing body approves the arrangement before the system is used.

Key point: Approval makes the arrangement binding on leaders as well as staff.

Step 3. Brief clinicians.

- Brief each clinical user on their accountability and on the limits of the system.
- Record the briefing.

Key point: Clinicians must understand their duty before they use the tool.

Step 4. Review after incidents.

- After any AI-related incident, review whether the arrangement was clear and worked.
- Update it and record the change.

Key point: Each incident tests the arrangement.

Step 5. Review yearly.

- Review each arrangement yearly, and after any change of system or law.

Key point: Law and systems change.

10. Decision points

- If accountability is unclear in an incident, the chief executive decides and records the reasons, then updates the arrangement.

11. Special situations

Situation	Action
Clinician overrides an AI output and harm follows	Review the decision under the incident process, not automatically as an AI fault.

12. Escalation

- AI-related incidents go to the chief executive and INC-POL-001 at once.

13. Monitoring

Measure	Target	Frequency	Owner	If not met
AI systems with approved arrangement	100%	Yearly	Chief executive	Stop use until approved
Clinicians briefed	100%	Yearly	Clinical leads	Brief within 30 days
Incidents reviewed against arrangement	100%	Each event	Chief executive	Escalate to governing body

14. Records

Record	Kept in	Retention
AI accountability arrangement and briefing records	Governance file	the period set by the facility’s records policy years

15. Training

- Clinicians are briefed at induction and when a system is introduced (EC).

16. Related documents

ID	Title	Use
AI-POL-001	Responsible Use of AI in Care Policy	Parent policy
INC-POL-001	Incident Reporting and Management	Incident route

INC-SOP-001	Root Cause Analysis of Serious Incidents	Review of serious incidents

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. Legal position set by the ASF Expert 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)

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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