

LIABILITY IN AI-DRIVEN HEALTHCARE



SUMMARY

This joint opinion drafted by the **National Council of Ethics for the Life Sciences (Portugal)**, the **Spanish Bioethics Committee**, and the **Italian Committee for Bioethics**, examines legal and ethical liability in AI-driven healthcare and warns that AI must not create gaps in responsibility; it argues that AI should be a supportive tool while the final clinical decision remains human.

KEY POINTS

- ✓ **Liability and oversight** in AI healthcare are often unclear, so responsibility must be better defined and human supervision must be active, not merely formal
- ✓ **Legal frameworks** are still not fully adapted to the complexity of AI in clinical practice and need updating
- ✓ **Patient protection** should remain central, through transparency, informed consent, non-discrimination, and safety-focused design

RECOMMENDATIONS

Keep human decision-making central, with AI used only as a support tool.

Ensure AI used in clinical care is validated, transparent, and explainable.

Provide mandatory training and institutional safeguards to reduce automation bias.

Clarify liability rules and insurance, compensation mechanisms, and risk-based regulatory testing.

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