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FADOI official position on artificial intelligence in internal medicine

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Abstract

Artificial intelligence (AI) is rapidly reshaping clinical practice, healthcare organization, and medical decision-making. Internal medicine, characterized by multimorbidity, clinical uncertainty, and the need for integrated care across hospital and community settings, represents a particularly relevant context for the responsible implementation of AI technologies. The Federation of Associations of Hospital Internists (FADOI) developed this official position paper to provide a clinically grounded and operational framework for the integration of AI into internal medicine practice.

FADOI identifies the Human-in-the-Loop model as the core operational standard, whereby AI functions strictly as a decision-support tool while full diagnostic and therapeutic responsibility remains with the physician. Potential applications include clinical documentation, decision support systems, multidimensional data integration, continuity of care, pharmacovigilance, and optimization of patient flow and chronic disease management. Expected benefits include reduction of administrative workload, improved diagnostic safety, enhanced care coordination, and greater sustainability of medical practice.

The document emphasizes regulatory compliance, data protection, transparency, and mandatory human oversight, while addressing risks such as automation bias and oversimplification of complex clinical scenarios. FADOI further proposes internal medicine as a real-world environment for pragmatic evaluation, training, and validation of AI as a complex healthcare intervention.

This position paper translates international ethical and regulatory principles into practical guidance for the safe, accountable, and clinically governed adoption of AI in internal medicine.

Introduction

The Federation of Associations of Hospital Internists (FADOI), as the national scientific society representing Italian physicians in internal medicine, acknowledges that artificial intelligence (AI) is becoming increasingly central to the evolution of healthcare systems and clinical practice, as well as a strategic domain for research, education, and organizational innovation.[1-4]

Internal medicine—characterized by high clinical complexity, management of multimorbidity and frailty, and the constant need for multidisciplinary integration—represents a field particularly sensitive to the introduction of advanced tools supporting both clinical and organizational processes.[5-8]

Within this context, FADOI maintains that AI may play a meaningful role as a support tool for the internist, provided that its integration occurs in accordance with ethical principles, clinical responsibility, patient safety, and robust scientific evidence.[1,2,4,9-12]

In the absence of shared operational criteria for the routine use of AI in internal medicine, this manifesto seeks to move beyond a purely theoretical, ethical, or value-based framework. Without duplicating existing scientific position statements, the present document aims to translate general principles into professional, organizational, and decision-making criteria specific to Italian internal medicine.[4,13-15]

For the internist, AI is neither a neutral nor merely experimental technology. It may become a concrete instrument for governing clinical and organizational complexity, applicable in real hospital and community settings.[7,16-18] FADOI therefore commits to defining a clinical–operational governance framework for AI, oriented toward everyday bedside practice and aligned with international standards of accountability and risk management.[4,19-21]

Foundational principles: Human-in-the-Loop as the FADOI operational standard

Centrality of the physician and clinical responsibility

AI must be conceived exclusively as a support tool for the clinical and organizational activities of the internist. Responsibility for diagnostic, therapeutic, and clinical decisions always remain fully with the physician, who retains complete decision-making autonomy.[22,23]

Human-in-the-Loop: from ethical principle to operational rule

FADOI formally adopts and strengthens the Human-in-the-Loop model, moving beyond a merely declarative interpretation. Human supervision must be effective, verifiable, and governed.[3,4,24]

This includes: i) mandatory clinical validation checkpoints; ii) the ability to challenge and override algorithmic outputs; iii) explicit awareness of system limitations, uncertainty, and potential biases.[25,26]

Patient centrality and the care relationship

The use of AI must contribute to improving the quality of care and to restoring time and attention to the physician–patient relationship, without reducing the person to a collection of variables or computational patterns.[7,8]

Specificity of internal medicine: why a dedicated approach is required

Multimorbidity and clinical complexity

Internal medicine manages patients with multiple chronic conditions, frailty, and non-linear clinical trajectories. AI models trained on narrowly defined specialist tasks or highly selected populations may fail to capture this real-world complexity.[5,6,8] Longitudinal, contextual, and cross-domain data integration is therefore essential.

Risk of undue simplification

The principal risk of AI adoption in hospital wards is not limited to technical error. A major concern is the oversimplification of complex clinical pictures, potentially leading to automation bias or uncritical reliance on algorithmic outputs if not properly governed.[3,4,25]

Hospital-community integration

In alignment with Italian Ministerial Decree (DM) 77, FADOI regards AI as a strategic enabler of continuity of care, chronic disease management, and integration between hospital services, community care, and intermediate care settings.

Similar principles of integrated and coordinated care have been endorsed internationally. The World Health Organization has promoted Integrated, People-Centered Health Services,[17] while Integrated Care Systems within the United Kingdom National Health Service represent systemic efforts to align hospital and community care.[27] In the United States, value-based healthcare models and Accountable Care Organizations have reinforced coordinated, outcome-oriented care delivery.[28]

Within this global transformation toward digitally enabled and interoperable healthcare ecosystems, AI may act as a structural facilitator of continuity, information sharing, and coordinated responsibility across care transitions.[16,17,27,28]

Areas of artificial intelligence application in internal medicine

Clinical documentation

AI may assist in drafting clinical notes, discharge summaries, and reports, as well as structured synthesis of longitudinal clinical information.[7,20] Voice recognition and automated coding according to international standards may further enhance documentation processes.[1,29]

Expected impact: i) reduction of documentation time and administrative burden; ii) improved completeness and consistency of clinical records; iii) enhanced traceability of clinical reasoning; iv) reduced risk of omissions.

Clinical decision support

AI systems may provide alert mechanisms based on clinical and laboratory trends and offer evidence-based diagnostic and therapeutic support.[16,30-32] Decision-support tools must remain embedded within workflows and subject to mandatory human validation (Table 1).[4,33]

Expected impact: i) earlier identification of clinical deterioration; ii) improved adherence to guidelines; iii) reduction of unwarranted variability; iv) strengthened diagnostic safety.

Clinical data integration

Integrated analysis of structured and unstructured data—including texts, imaging, and physiological parameters—may enhance holistic assessment of complex patients.[5,6,30]

Expected impact: i) improved multidimensional understanding; ii) reduced fragmentation of information; iii) enhanced longitudinal continuity of assessment.

Continuity of care

AI may support follow-up planning, care transitions, and personalization of care pathways.[16,17,27]

Expected impact: i) smoother transitions between hospital and community; ii) reduced information loss; iii) improved personalization of follow-up strategies.

Admission appropriateness and patient flow

AI may assist in evaluating admission appropriateness and identifying alternatives to standard hospitalization, supporting optimized bed utilization and emergency department-ward flow.[18-34]

Pharmacovigilance and therapeutic safety
Automated detection of drug-drug interactions, prediction of adverse drug events, and support for medication reconciliation may improve patient safety and clinical governance.[29,30]

Chronic disease management and proactive medicine
AI models may help predict clinical decompensation and identify high resource-utilization patients, supporting proactive care approaches.[6,28]

Expected benefits
- Reduction of administrative burden.[7]
- Improved quality and traceability of clinical decisions.[3,4]
- Enhanced interdisciplinary communication and continuity.[16,17]
- Improved professional sustainability and reduced burnout risk.[8]

Ethics, regulation, and legal compliance
FADOI considers compliance with the European and national regulatory framework indispensable, including Regulation (EU) 2016/679 (GDPR), Regulation (EU) 2024/1689 (AI Act), and legislation governing medical devices and healthcare software.[11-13]
Beyond the European regulatory framework, governance models for medical AI are evolving globally. In the United States, the Food and Drug Administration has developed guidance for AI/Machine Learning-based Software as a Medical Device, introducing lifecycle-based oversight and post-market monitoring principles.[30,33] In parallel, the National Institute of Standards and Technology has issued an AI Risk Management Framework aimed at promoting trustworthy, transparent, and accountable AI systems across sectors, including healthcare.[19]
These transnational regulatory developments demonstrate a shared global concern: ensuring that AI systems integrated into clinical workflows remain human-supervised, ethically grounded, safe, and auditable.[1,2,4,19,23,35-37] Therefore, the FADOI governance model is aligned not only with European legislation but also with emerging international standards of AI accountability and risk management.[19,38,39]

Data protection
Minimum requirements include legal basis, purpose limitation, data minimization, security safeguards, and Data Protection Impact Assessments.[23]

Risk classification and oversight
Clinical decision-support systems generally qualify as high-risk AI under the AI Act.[35] Requirements include robustness, transparency, traceability, and effective human oversight.[4,19,40]

Limits of use
The use of non-certified consumer tools for processing identifiable health data is incompatible with regulatory requirements.[16,30] Outputs must be critically verified, and physician-responsible acts cannot be delegated to AI without final human validation.[9,41]

Physician centrality
The internist remains the final decision-maker. Human supervision must be substantive, with explicit allocation of responsibilities and override mechanisms.[3,4]

Research, training, and field validation

FADOI proposes to serve as a national laboratory for pragmatic evaluation of AI in Internal Medicine, treating AI as a complex clinical intervention.[9-12,42]

Evaluation should include: i) real-world clinical and organizational endpoints; ii) multicenter pragmatic studies; iii) metrics of effectiveness, equity, and sustainability.[4,8,25]

Training programs must address clinical, ethical, regulatory, and professional liability dimensions.[22,24,43]

Conclusions

AI, when properly governed and rigorously validated, can become a strategic lever for sustaining medical work, reducing burnout, and improving care pathways.[7,8]

The FADOI position aligns Italian Internal Medicine with global regulatory and governance standards, contributing to the international dialogue on the safe and sustainable integration of AI into complex clinical environments,[1,4,19] in continuity with recent contributions published in the Italian Journal of Medicine addressing both generative AI and its clinical applications in internal medicine.[44,45]

FADOI therefore proposes a model of AI integration grounded in clinical governance of complexity, professional responsibility, and healthcare system sustainability, translating general AI principles into operational rules applicable to daily practice (Figure 1).

References

1. European Parliament and Council of the European Union. Regulation (EU) 2016/679 (General Data Protection Regulation). In: Official Journal, L119/1, 4/05/2016.
2. European Parliament and Council of the European Union. Regulation (EU) 2024/1689 (Artificial Intelligence Act). In: Official Journal, L series, 12/07/2024.
3. European Parliament and Council of the European Union. Regulation (EU) 2017/745 on medical devices (Medical Device Regulation). In: Official Journal, L 117/1, 5/05/2017.
4. European Commission High-Level Expert Group on Artificial Intelligence. Ethics guidelines for trustworthy artificial intelligence. Brussels: European Commission; 2019.
5. European Commission. Proposal for a Directive on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive). Brussels: European Commission; 2022.
6. World Health Organization. Ethics and governance of artificial intelligence for health. 2021. Available from: https://www.who.int/publications/i/item/9789240029200
7. World Health Organization. Regulatory considerations on artificial intelligence for health. 2023. Available from: https://www.who.int/publications/i/item/9789240078871
8. Lyu G. Data-driven decision making in patient management: a systematic review. BMC Med Inform Decis Mak 2025;25:239.
9. Agenas. Digital health and artificial intelligence guidance documents. Rome: Agenas; 2023.
10. Palmieri S, Robertson CT, Cohen IG. New guidance on responsible use of AI. JAMA 2026;335:207-8.
11. Pencina MJ, Silcox C, Economou-Zavlanos N et al. Bridging the gap between developers and implementers in health AI. JAMA Health Forum 2025;6:e251692.
12. Dhingra LS, Aminorroaya A, Pedroso AF, et al. Artificial intelligence–enabled prediction of heart failure risk from single-lead electrocardiograms. JAMA Cardiol 2025;10:574-84.
13. Tirotta D, Nardi R. Le frontiere dell'intelligenza artificiale in medicina interna. Ital J Med 2025;19:2-8.
14. World Health Organization. Framework on integrated, people-centred health services. 2016. Available from: https://apps.who.int/gb/ebwha/pdf_files/wha69/a69_39-en.pdf
15. NHS England. Integrated care systems: design framework. London: NHS England; 2021.

16. International Medical Device Regulators Forum (IMDRF). Software as a medical device (SaMD): clinical evaluation. IMDRF; 2017. Available from: https://www.imdrf.org/documents/software-medical-device-samd-clinical-evaluation
17. U.S. Food and Drug Administration. Clinical decision support software: guidance for industry and Food and Drug Administration staff. 2022. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software
18. Centers for Medicare & Medicaid Services. Accountable care organizations and value-based care models. 2023. Available from: https://www.cms.gov/priorities-innovation-key-concepts-accountable-care-accountable-care-organizations
19. World Health Organization. Ethics and governance of artificial intelligence for health: guidance on large multimodal models. 2024. Available from: https://www.who.int/publications/i/item/9789240084759
20. Phi NTT, Montori VM, Kunneman M, et al. Cumulative burden of digital health technologies for patients with multimorbidity: a systematic review. JAMA Netw Open 2025;8:e257288.
21. World Health Organization. Mapping the application of artificial intelligence in traditional medicine: technical brief. 2025. Available from: https://www.who.int/publications/i/item/9789240107663
22. EUnetHTA. Health technology assessment of artificial intelligence-based medical technologies. EUnetHTA; 2021.
23. Topol EJ. High-performance medicine: the convergence of human and artificial intelligence. Nat Med 2019;25:44-56.
24. Pierfranceschi MG. Embracing artificial intelligence in internal medicine: a tool for physicians and patients. Ital J Med 2025;19:1791.
25. Bressman E, Shachar C, Stern AD, Mehrotra A. Software as a medical practitioner—licensing artificial intelligence? JAMA Intern Med 2026;186:5-6.
26. McDermott KW, Jiang HJ. Characteristics and costs of potentially preventable inpatient stays. Rockville (MD): Agency for Healthcare Research and Quality; 2019.
27. The White House. Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. Washington, DC; 2023.
28. National Institute of Standards and Technology. Artificial intelligence risk management framework (AI RMF 1.0). Gaithersburg (MD): NIST; 2023.
29. Bates DW, Saria S, Ohno-Machado L, et al. Big data in health care: using analytics to identify and manage high-risk and high-cost patients. Health Aff 2014;33:1123-31.
30. Vasey B, Nagendran M, Campbell B, et al. DECIDE-AI: reporting guidelines for early-stage clinical evaluation of artificial intelligence-driven decision support systems. Nat Med 2022;28:924-33.
31. Abdulnour RE, Gin B, Boscardin CK. Educational strategies for clinical supervision of artificial intelligence use. N Engl J Med 2025;393:786-97.
32. Balsano C, Cabitza F, Cicco S, et al. Artificial intelligence in medicine: a position paper by the Italian Society of Internal Medicine. Intern Emerg Med 2026:21:1-14.
33. Lekadir K, Frangi AF, Porras AR, et al. FUTURE-AI: international consensus guideline for trustworthy and deployable artificial intelligence in healthcare. Lancet Digit Health 2023;5:e477-87.
34. Food and Drug Administration. Artificial intelligence and machine learning (AI/ML) software as a medical device (SaMD) action plan. 2021. Available from: https://www.fda.gov/media/145022/download
35. Sendak MP, D'Arcy J, Kashyap S, et al. A path for translation of machine learning products into healthcare delivery. EMJ Innov 2020;4:54-60.
36. Liu X, Rivera SC, Moher D, et al. Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: CONSORT-AI extension. BMJ 2020;370:m3164.

37. Rajkomar A, Dean J, Kohane I. Machine learning in medicine. N Engl J Med 2019;380:1347-58.
38. Rivera SC, Liu X, Chan AW, et al. Guidelines for clinical trial protocols for interventions involving artificial intelligence: SPIRIT-AI extension. Nat Med 2020;26:1351-63.
39. Collins GS, Moons KGM. Reporting of artificial intelligence prediction models. Lancet 2019;393:1577-9.
40. Rajkomar A, Hardt M, Howell MD, et al. Ensuring fairness in machine learning to advance health equity. Ann Intern Med 2018;169:866-72.
41. Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri (FNOMCeO). Code of medical ethics. Rome: FNOMCeO.
42. Angus DC, Khera R, Lieu TA, et al. Artificial intelligence and the future of health care: the JAMA 2025;334:1650-64.
43. World Health Organization. Recommendations on digital interventions for health system strengthening. 2019. Available from: https://www.who.int/publications/i/item/9789241550505
44. Di Micco P, Bernardi Futura F, Fusco GM, Perrella A. How artificial intelligence during the pandemic modified the role of a biomarker as d-dimer. Ital J Med 2023;18:1656.
45. Ouanes K. Generative artificial intelligence in healthcare: current status and future directions. Ital J Med 2024;18:1782.

Table 1. Scope of use of artificial intelligence.

Area of use	Permitted	Conditional	Prohibited
Clinical record summarization	✓		
Diagnostic support (second opinion)		✓ (mandatory clinical validation)	
Identification of drug interactions	✓		
Automatic prescription of medications			✗
Use of non-certified "consumer" tools			✗

Figure 1. FADOI model of artificial intelligence integration grounded in clinical governance of complexity, professional responsibility, and healthcare system sustainability.