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The Frontiers of Artificial Intelligence in Internal Medicine: Ethical and Regulatory Aspects

Andrea Fontanella

Past President of FADOI Foundation. President Emeritus of FADOI Campania, Italy

***Corresponding author**
Andrea Fontanella, Past President of FADOI Foundation. President Emeritus of FADOI Campania, Italy.

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Artificial intelligence (AI) undoubtedly represents one of the most significant innovations in modern medicine. From early diagnosis to personalized treatment, from decision support to management of continuity of care, its applications extend to all phases of the clinical journey. However, in the context of Internal Medicine, reflection on the adoption of AI cannot ignore a critical and multidimensional assessment, encompassing not only technological and operational aspects, but also, and above all, ethical, relational, and educational aspects.

The transformation of healthcare is the product of a shared vision among a broad range of stakeholders to establish the future of care delivery and develop new patient-centered and evidence-based models, in which value is rewarded by the volume of data and its heterogeneity, quality, and completeness. Key to this transformation are innovations based on recently developed and rapidly evolving technology. These include: digital health with wearables, smartphones, and sensor-based technologies; big data, which includes the aggregation of vast amounts of structured and unstructured health information; and sophisticated analytics using artificial intelligence, machine learning, and natural language processing; as well as precision health approaches to identify individual-level risk and the determinants of well-being and pathogenicity.

Internists are, by definition, physicians of complexity. Their work takes place at the intersection of multiple pathologies, concomitant therapies, clinical and social fragilities, changing scenarios, and decision-making uncertainty. Their most valuable tool is not only medical knowledge, but also the ability to synthesize, clinical judgment, empathy, the ability to listen, and a holistic view of the patient. In this context, artificial intelligence can act as a powerful ally, but never as a substitute.

As is well known, AI excels at analyzing large amounts of data, recognizing complex patterns, and formulating differential diagnoses based on statistical correlations. It can improve diagnostic efficiency, suggest therapeutic strategies, facilitate the prevention of exacerbations in chronic patients, optimize polypharmacy, and remotely monitor vulnerable patients. However, it remains completely inadequate at grasping nuance, context, and experiences. AI cannot smell insecticide or alcohol, cannot recognize anxiety in a patient's eyes, and cannot perceive the inappropriateness of a prescription given social fragility. Doctor-patient communication, in fact, is not just a process of verbal content. Mahatma Gandhi said: "Communication means transferring information, emotions, and feelings to others through verbal and nonverbal messages." Communication, therefore, is not just about "what" I say but also, and above all, "how" I say it; that is, observing the patient's reaction and understanding whether I need to modify the message. Therefore, communication is certainly made up of a declared content, which is the intentional action, then by: gestures, facial expression, spatiality, pauses and tone of voice, and finally by the entire nonverbal component: facial expressions, posture, rhythm, eye movements, breathing. This communicative limit, unattainable with AI, is not contingent, it is structural: it is the boundary between calculation and consciousness.

Internal medicine is the medicine of relationships, of long-term care, of narrative. Artificial intelligence cannot (and should not) replicate the empathy, trust, and profound communication that are at the heart of care. In this sense, algorithms can support, but never replace, the doctor-patient relationship. Indeed, the efficiency that AI can introduce into the management of bureaucratic and repetitive tasks should be reinvested in time spent listening, reflecting, and building a meaningful therapeutic relationship.

The ethical aspect is central and cannot be relegated to the end of the discussion. Every clinical decision mediated by an algorithm requires transparency, explainability, and human oversight. The "black box" problem of deep learning systems raises questions about responsibility, trust, and security. How can we accept a diagnosis being proposed without being able to understand the rationale behind its formulation? How can a doctor rely on a technology that, while high-performance, cannot be interrogated or justified in its inferential processes?

One aspect that, in clinical practice, can represent an obstacle to entrusting the diagnostic and therapeutic process to AI alone is the fact that medicine is not an exact science. Indeed, dealing with biological phenomena, it is not a Cartesian science.

The great internist William Osler, one of the Fathers of Modern Medicine (1849-1919), stated that "Variability is the law of life,

and just as no two faces are alike, so no two bodies are alike, nor two individuals who react and behave in the same way under the abnormal conditions of disease." He then went on to state that "Medicine is the science of uncertainty and the art of probability." Note that he used the term "Art" for a reason, implying imagination, creativity, and unpredictability—all qualities that, at present, are not yet qualities of AI but the exclusive prerogative of the human mind. In the field of exact sciences, starting from certain principles, controlled deductions can be made, but in medicine there are only biomedical data and apparent information, somehow linked and "with a certain tendency" to verify. The method of knowledge used by doctors is therefore necessarily forced to be based on uncertainty, or rather, on its mathematical counterpart, which is probability. In medicine, classical, binary logic, true-false, does not exist. There is no dividing line between health and disease, and the same clinical picture is never found. Another great internist, Vito Cagli, stated that this abundance of constantly changing variants must be mentally mastered because this is the cognitive task of medicine. Overcoming, or rather, rationally controlling, uncertainty and appropriateness—that is, the when, how, and how much of every action and every decision must be based on methodological reasoning. Reasoning that comes from knowledge, experience, and logic does not necessarily have to conform to any guidelines, but rather chooses the best path for the individual patient.

Therefore, the rigorous application of EBM would only imply a mechanistic approach based on algorithms, similar to the primitive pre-artificial intelligence computer programs of the past. In this approach, the physician views the patient as a statistic rather than an individual. This type of medicine could be practiced by administrators.

Clinical appropriateness, a topic so dear to Internal Medicine, cannot ignore these questions. Appropriateness isn't merely technically correct; it's appropriateness is what's right for that patient, at that moment, in their biographical, social, and psychological context. Clinical practice isn't just a technical exercise; it's an ethical act. The internist, with his or her global vision and critical problem-solving skills, remains the irreplaceable figure for maintaining this dimension of justice, proportionality, and humanity.

Another crucial aspect is training. We can't imagine a doctor of the future who isn't familiar with artificial intelligence, who doesn't know how to question it, evaluate it, and critically integrate it. A new digital literacy is needed for clinicians, one that goes beyond uncritical enthusiasm or prejudicial rejection. Just as in the past, doctors had to learn to read a CT scan or interpret a prognostic algorithm, today doctors must be able to interact with predictive models, understand the fundamentals of machine learning, interpret complex outputs, and assess the validity of incoming data. But, above all, it must maintain the capacity for clinical thinking, which cannot be delegated to any machine.

Finally, an institutional effort is needed. Technologies must be regulated, clinically validated, and integrated interoperably into healthcare systems. Models must be checked for bias, guaranteed for data security, and monitored for their real-world impact. Artificial intelligence cannot be adopted without ethical, professional, and organizational governance.

Finally, from an ethical perspective, there are three other fundamental issues in the adoption of AI in the diagnostic, care, and therapeutic, as well as prognostic, pathway: 1. ensuring patient privacy; 2. regulating informed consent; 3. the issue of medical-professional liability. The first issue concerns the effects of the application of AI models on the doctor-patient relationship. In this context, a first obstacle to overcome concerns privacy and data protection regulations, which can hinder the collection and sharing of healthcare data. Artificial intelligence in medicine requires data to train the machine, which is the basic building block for building algorithms and mathematical models. The availability of healthcare data (clinical data and parameters, images, laboratory data, etc.), their quality, and their interoperability, are key elements for the application of AI. In this context, privacy protection is considered an obstacle to its development. For AI to truly develop and support physicians in their daily clinical decisions, it is necessary to have ever-increasing amounts of data that transcend national boundaries. Its long-term preservation (imaging, etc.) is equally important. The availability of large amounts of data allows for the adequate training of algorithms, which would otherwise be unable to function. Clinical data, medical images, biological parameters, and genetic data fall within the category of personal data. Article 13 of the GDPR defines this data as "personal data." Article 4 of the GDPR (General Data Protection Regulation), the EU's governing data management and protection legislation, defines personal data as "any information relating to an identified or identifiable natural person." To avoid being prevented from using health data due to the risk of privacy breaches, AI technology is attempting to address this issue through the use of so-called synthetic data.

Regarding the second point, we know that decision-making autonomy is a fundamental principle in the doctor-patient relationship, aimed at the right to life, health, dignity, and, above all, self-determination. However, for autonomy to be real, a fundamental prerequisite is informed consent aimed at fully understanding and correctly assessing the risks and benefits of proposed diagnostic and therapeutic procedures. For doctors, who often encounter difficulties in informing patients about "ordinary" procedures, it is even more challenging to inform them about procedures that use AI models. Explaining complicated terms to the patient is also challenging because the doctor must explain a model that, essentially, isn't completely transparent. The patient learns terms from the doctor he or she had never imagined before, and therefore, it's likely that at the end of the conversation, the patient's consent will be based more on trust in the doctor than on a genuine understanding of the procedure itself.

Finally, the third point: medical-legal liability. The question that arises is: if the machine was programmed or used incorrectly, should the responsibility for (erroneous) decisions resulting from an AI system be attributed to the person who designed the machine, the owner of the machine, the person who trained the machine, or the person who uses it (in the latter case, the doctor)? Precisely because the author of the algorithms, the manufacturer of the system, the marketer, and finally the user are different actors, the problem of defining the responsibilities of each of them arises. Precisely because of the complexity of the structural model, it is not possible to attribute responsibility for any eventual harm to the patient, or whether this responsibility is solely due to the physician. Even if the command of the action remains with the physician (whether or not he or she uses the AI model), the physician himself or herself does not always directly carry out the action; in many cases, he or she assumes a marginal role. Precisely because of these different types of liability, new regulations will need to be enacted or, alternatively, existing ones will need to be revised and reinterpreted. For this to happen, discussion and more

effective collaboration between the medical and legal professions is essential to define the potential multiple medical responsibilities associated with AI. Updating regulations to reduce the medico-legal barriers to the adoption of AI in healthcare will allow the opportunities offered to be realized without compromising patient rights, physician responsibilities, and, last but not least, the quality of care.

Let's move on to the ethical and philosophical conclusions.

In a splendid treatise from the 1950s, Portraits from Memory and Other Essays (London: G. Allen & Unwin, 1956), in his essay "Knowledge and Wisdom," the great philosopher Bertrand Russell stated: "With every increase in knowledge and technique, wisdom becomes more necessary, for each such increase increases our capacity to achieve our purposes, and therefore increases our capacity to do harm, if our purposes are unwise."

In conclusion, the future of Internal Medicine will not be determined by a choice between man and machine, but by humans' ability to integrate the machine without losing themselves. AI should not be considered a threat to the role of the internist, but rather a tool that, if well understood and managed, can strengthen their mission. While it is true that no algorithm can replace a careful clinical approach, it is also true that no clinician today can afford to ignore the most advanced tools science has to offer.

The limitations of the internist's clinical method, specifically operating within the context of complexity, are structural and inherent to the method itself. To overcome them, today it seems inevitable to combine the clinical process with the totems of modernity, intertwining the threads of digitalization, big data, robotics, and algorithms, which would be capable of formulating diagnoses or therapies with greater potential than that of the human brain alone. Uncertainty and the resulting actions can be supported by the new potential offered by systems based on the use of Artificial Intelligence (AI).

AI could be an important tool in managing uncertainty, reducing diagnosis times and the risk of errors, thus making clinical practice as objective as possible.

AI could effectively integrate with the subjectivism based on the intuitive heuristic approach and the logic of Bayesian theory. The synergy between AI and medicine will become increasingly powerful as knowledge of the composition and structure of human neural networks develops. In the fluidity and uncertainty of the situations that internists experience, a point of reference to be taken as a compass is the indissolubility of human life and biological life, which contains within itself the rationale for warding off the "objectification" of humanity.

The more sophisticated the technological aspect, the greater the physician's responsibility toward the people who entrust themselves to him.

The challenge is open, and ethics will be the compass. An internal medicine that combines scientific rigor and human depth, technological innovation and critical discernment, will be not only more effective, but also more equitable. Because, ultimately, the ultimate goal is not efficiency, but the patient's well-being, and AI certainly guides us toward the most correct decisions, but the most technically correct choices are not always the wisest for the patient's well-being.

As I concluded in a 2014 special issue of the IJM Journals: "Yesterday, we had behaviors dictated by clinical wisdom, but less knowledge and less technical support. Today, we have much more knowledge and disproportionate technical development, but less wisdom in managing them. If we want to secure tomorrow's future, we must return to the ways of yesterday with the knowledge and technology of today."