Artificial Intelligence in General Practice

Position Paper of SIMG (Italian College of General Practitioners and Primary Care)

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Introduction

This document represents the position of the Italian College of General Practitioners and Primary Care (SIMG) on the use of Artificial Intelligence (AI) in healthcare, with particular reference to General Practice. The main goal is to ensure that the development and implementation of AI-based technologies are ethical, transparent, and patient-centered, while at the same time protecting physicians' professional autonomy and promoting equity and safety.

With the growing number of AI-enabled tools and healthcare systems, it is essential that these technologies are designed, developed, and implemented in an ethical, fair, responsible, and transparent manner. Considering the slow adoption of national governance policies or oversight mechanisms for AI, it is crucial that the medical community actively participates in shaping policies that support the education of physicians and patients, and guide interaction with these new technologies. It is also important that the medical community contributes to directing the development of these tools to best meet the needs of both doctors and patients, and defines its tolerance for risk, especially where AI has a direct impact on patient care.

In this document, when referring to risks associated with Artificial Intelligence, we mean the possibility that an AI-based system may produce undesirable or harmful effects for patients, physicians, or the healthcare system. Such risks may include diagnostic errors, non-transparent automated decisions, algorithmic discrimination, or impacts on the doctor–patient relationship. The European regulatory framework (AI Act) adopts a risk-based approach, in which AI systems are classified and regulated according to their potential negative impact. Understanding and correctly assessing risk is essential to promote safe, ethical, and responsible use of AI in General Practice.

SIMG believes that AI has extraordinary potential to improve clinical care and support the work of general practitioners and primary care physicians.

SIMG intends to provide valid support to physicians on how to best interact with new AI-based technologies, with the awareness that the development of such technology will continue to evolve rapidly in this field.

Oversight of Artificial Intelligence (AI) in Healthcare

At present, there is no national policy or governance structure guiding the development and adoption of AI technologies not tied to medical devices. Considering the future entry into force of the European AI regulation, the "AI Act," SIMG encourages an integrated Italian governmental approach, harmonized with the European one, to implement governance policies that mitigate, as much as possible, the overall and disparate risks for consumers and patients arising from AI.

Beyond government, healthcare institutions and professional societies also share responsibility for adequate oversight and governance of AI-enabled systems and technologies. They are in the best position to determine whether AI applications are of high quality, clinically appropriate, and valid. Clinical experts are best suited to validate the clinical knowledge, care pathways, and standards of care used in the design of AI tools, and to monitor their clinical validity as technology evolves over time.

Definitions

- **AI System**: An automated system designed to operate with varying levels of autonomy and potential adaptability after deployment, which, for explicit or implicit objectives, infers from the input it receives how to generate outputs such as predictions, content, recommendations, or decisions that may influence physical or virtual environments.
- **AI Risk**: The probability that an AI system may generate a negative effect on individuals or groups, compromising safety, health, fundamental rights, or fairness. Risk may arise from errors, algorithmic bias, lack of transparency, misuse, or unintended impact of the system. The level of risk determines the extent of supervision and control required to ensure safe and ethical use of AI.
- **AI-based Decision Support**: Technologies that assist human decision-makers while maintaining human oversight.
- **AI Language Models (LLMs)**: Advanced AI systems capable of generating convincing natural language texts after being trained on large volumes of data.
- **Machine Learning**: A methodology through which computers analyze large amounts of data to learn patterns and solutions without being explicitly programmed.
- **Healthcare Robotics**: The use of robots and automated systems in clinical contexts, including surgical interventions and other medical applications.

Key Principles for the Oversight and Use of AI in Healthcare

- **Ethics, equity, responsibility, and transparency**: AI in healthcare must be designed, developed, and implemented ethically, fairly, responsibly, and transparently.
- **National governance policies**: The adoption and use of AI in healthcare require clear national governance policies to regulate integration, ensure patient safety, and mitigate inequalities. Such policies should be developed with collaboration across government departments and agencies.
- **Mandatory compliance**: Compliance with national governance policies is necessary to develop AI ethically and responsibly, ensuring patient safety, quality, and continuous access to care. Voluntary agreements or voluntary compliance are not sufficient.
- **Risk-based approach**: AI in healthcare requires a proportional risk-based approach, where the level of oversight, validation, and control corresponds to the overall or disparate potential harm that an AI system could introduce.
- **Human intervention**: Clinical decisions influenced by AI must include specific points of human intervention during the decision-making process. As the risk of harm to the patient increases, the physician's intervention to interpret or act upon an AI recommendation must occur at earlier stages of the care plan.
- **Risk mitigation capacity**: Healthcare practices and institutions should not use AI systems or technologies that introduce overall or disparate risks that cannot be mitigated. Implementation and use of AI should avoid increasing physicians' workload and should be designed and integrated in harmony with clinical workflows.
- **Role of medical-scientific societies**: Specialty medical societies and clinical experts are the most qualified to identify the most appropriate uses of AI-enabled technologies in their fields, as well as to define standards of care and validation criteria for their integration into healthcare practice. Beyond this guidance role, scientific societies must take a primary role in training healthcare professionals, developing structured educational programs based on up-to-date scientific evidence.

In particular, they should:

- Design and promote certified training pathways on the use of AI in medicine, ensuring continuous updating and adequate preparation of physicians for interaction with these technologies.
- Provide clinical guidelines and protocols, ensuring that AI is used appropriately, safely, and ethically, with human supervision proportional to the associated risk.

- Collaborate with academic institutions and regulatory bodies to integrate AI education into university curricula and continuing medical education (CME) programs.
- Monitor the impact of AI on clinical practice, collecting data to assess its effectiveness, identify critical issues, and update implementation strategies.

Through these actions, medical-scientific societies act as guarantors of the proper integration of AI in healthcare, ensuring that technological innovation meets the highest standards of quality, safety, and equity for patients.

Ethical Principles for AI in Healthcare

The adoption of AI in healthcare must be guided by strong ethical principles, considering clinical, social, and legal implications. SIMG identifies the following fundamental principles:

- **Patient centrality**: AI must be designed and implemented to improve patient health and well-being, always prioritizing their needs and rights.
- **Professional autonomy**: The introduction of AI must in no way compromise physicians' clinical and decision-making independence.
- **Transparency**: All AI applications must be developed and implemented transparently, making decision-making processes understandable to both physicians and patients.
- **Accountability**: It must be clear who is responsible in the event of errors or malfunctions of AI-based tools.
- **Equity**: The use of AI must reduce, not amplify, inequalities in access to and outcomes of healthcare.
- **Privacy**: The protection of patient data must be ensured through rigorous security measures.

Principles of Development and Implementation

AI offers significant opportunities to improve the quality of healthcare. However, its use must be accompanied by strong governance and control measures:

- Each AI tool must be rigorously tested to ensure safety and effectiveness before being integrated into clinical practice.
- The design of AI tools must involve physicians, patients, and other relevant stakeholders to ensure practical and useful solutions.

- Healthcare systems must implement robust frameworks to manage AI-related risks, including protocols for data management and professional training.
- AI technologies must be periodically reviewed to ensure updates, compliance with ethical and clinical standards, and protection against cybersecurity vulnerabilities and unauthorized access.

Regulatory Principles

Regulation is essential to ensure the safe and effective use of AI in healthcare. SIMG identifies the following regulatory principles:

- Government must establish an evidence-based regulatory framework that promotes innovation and ensures patient safety.
- Every AI application must undergo regular reviews and independent audits to ensure quality and compliance.
- Accountability for errors or harm arising from the use of AI must be clearly defined.
- Regulation must include measures to prevent algorithmic discrimination and promote equity in access.

Conclusions

Artificial Intelligence represents an unprecedented opportunity to improve healthcare in General Practice. However, to realize this potential, its development and implementation must be guided by ethical principles, transparency, and patient centrality. SIMG, whose mission is to protect citizens' health through evidence-based and person-centered medicine, is committed to supporting the responsible integration of AI into the Italian healthcare system and into the daily practice of General Practice.