



**HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA**

**GUIDELINES FOR GOOD PRACTICE IN THE HEALTH PROFESSIONS**

**ETHICAL GUIDELINES ON THE USE OF ARTIFICIAL  
INTELLIGENCE**

**BOOKLET 20**

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## ETHICAL AND PROFESSIONAL GUIDELINES

High quality clinical outcomes are only achieved if patients and health practitioners trust each other explicitly. Practice in the healthcare profession is therefore a moral enterprise and demands that health practitioners have a life-long commitment to sound, ethical professional practice and an unstinting dedication to the interests and wellbeing of society.

It is in this spirit, that the HPCSA formulates these ethical guidelines, to guide and direct the practice of health practitioners. They apply to all health practitioners registered with the HPCSA and are the standard against which professional conduct is evaluated.

[In these guidelines, health practitioner and health professional refers specifically to persons registered with the HPCSA.]

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# ETHICAL GUIDELINES ON THE USE OF ARTIFICIAL INTELLIGENCE

## 1. DEFINITIONS

**Artificial Intelligence (AI)** is a branch of computer science, statistics and engineering that uses algorithms or models to perform tasks and exhibit behaviour such as learning, making decisions and making predictions. The artificial intelligence in healthcare is primarily utilised in assistive role, emphasizing that its design enhances human intelligence rather than replaces it.

**Health practitioner** means a person providing health services, registered in terms of the Health Professions Act, 1974 (Act No. 56 of 1974).

**Automated decision making** means any technology that either assists or replaces the judgment of human decision-makers.

**Algorithm** means a set of detailed, ordered instructions that are followed by a computer to solve a mathematical problem or to complete a computer process.

**Computer vision** means an interdisciplinary scientific field that deals with how computers can be made to gain high level understanding from digital images or videos and seeks to automate tasks that the human visual system can do.

**Data mining** means a interdisciplinary subfield of computer science and statistics whose overall goal is to extract information (with intelligent methods) from a data set and transform the information into a comprehensible structure for further use.

**Machine learning** means the scientific study of algorithms and statistical models that computer systems use to effectively perform specific tasks with minimal human interaction and without using explicit instructions, by learning from data and identification of patterns.

**Natural language processing** means a subfield of computer science, information engineering, and artificial intelligence concerned with the interactions

between computers and human (natural) languages, in particular how to program computers to process and analyze large amounts of natural language data.

**Training data** means data that is used to train an algorithm; it generally consists of a certain percentage of an overall dataset along with a testing set. As a rule, the better the training data, the better the algorithm performs. Once an algorithm is trained on a training set, it's usually evaluated on a test set. The training set should be labelled or enriched to increase an algorithm's confidence and accuracy.

## 2. INTRODUCTION

- 2.1 The Health Professions Council of South Africa (HPCSA) supports innovation in healthcare delivery, while ensuring and promoting safe practice in the health professions.
- 2.2 The HPCSA does not regulate or approve new technologies or medical devices.
- 2.2 While the HPCSA acknowledges the enormous potential for Artificial intelligence (AI) to improve accessibility, enhance quality, and reduce administrative burden, it is also recognised that it brings significant ethical, legal, and professional challenges that accompany its use, including relating to over-reliance.
- 2.3 This guideline is intended to provide advice to assist health practitioners on matters relating to AI use and challenges. The use of AI in healthcare should minimize potential data-related harm and promote the equitable delivery of safe quality care and maintain the integrity of the practitioner/patient relationship<sup>1</sup>.
- 2.4 AI's potential in healthcare is vast, but it is accompanied by risks such as bias and discrimination due to historical data biases, automation bias, and the potential erosion of clinical skills amongst health practitioners.
- 2.5 Privacy concerns are significant as AI systems rely on large datasets that may compromise patient confidentiality.
- 2.6 Multiple AI applications have been around for many years, some continue to form part of daily use in healthcare. Some common examples of such applications include: computer vision systems to analyze medical

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<sup>1</sup> The College of Physicians & Surgeons of Manitoba. (2024). Advice to the profession: Responsible Use of Artificial Intelligence in the Practice of Medicine.

images, natural language processing to review clinical notes, predictive algorithms and advanced data analytics to forecast clinical trends, voice recognition to support clinical documentation, chatbots to provide patient education, dictation and speech recognition software, electronic medical record macros or templates, and automated decision making and pathways, protocols, and clinical scores, analysis of diagnostic information or identify pharmacological interactions and contraindications and more recent AI tools such as GenAI that is in its evolution technology capable of building upon advances in complex algorithms, advance data analytics and machine learning.

- 2.7 The transition to digital health records and the utilization of AI for diagnostics, such as in radiology and dermatology, have enhanced healthcare capabilities. New technologies have led to notable changes in the delivery of healthcare, with an increase in the use of virtual and remote care technologies.
- 2.8 At an inquiry, the professional board concerned shall be guided by the ethical rules, its annexures, ethical rulings or these guidelines, and policy statements which the board concerned, or Council makes from time to time.
- 2.9 The use of AI shall be sustainable to social, economic, environmental and human indicators.
- 2.10 These guidelines must further be read in conjunction with other ethical guidelines of the HPCSA, which include but are not limited to:
  - i. Booklet 1: General Ethical Guidelines for Healthcare Professions.
  - ii. Booklet 2: Ethical and Professional Rules of Conduct.
  - iii. Booklet 4: Seeking Patients' Informed Consent: The Ethical Considerations
  - iv. Booklet 5: Confidentiality: Protecting and providing information.
  - v. Booklet 10: Guidelines for the practice of Telehealth.



### **3. ETHICAL PRINCIPLES**

- 3.1 Health practitioners have a responsibility to ensure that the patient's best interests remain their primary concern; and patient's confidentiality, privacy, choices and dignity are always respected, and AI systems must always adhere to these values.
- 3.2 The use of AI in healthcare should be patient-centred for the benefit of the patients' health and well-being and to improve health outcomes. The interest of patients and the wider community should be the primary and guiding focus of all AI applications in healthcare.
- 3.3 AI should serve as a tool to support and enhance clinical decision-making rather than replace it. It can aid healthcare practitioners in making more informed decisions and further contribute to improving the quality of healthcare services, as well as optimizing clinical care processes.
- 3.4 Ultimately, AI should complement the expertise of health practitioner, ensuring that human judgment remains central to patient care while leveraging technology to achieve greater efficiency and effectiveness in healthcare delivery.
- 3.5 The use of AI in healthcare should not undermine the rights of patients to make informed decisions about their health and services provided to them in a way that respects and preserves the clinical independence and professional autonomy of health practitioners.
- 3.6 Automated decision-making AI tools must be used in a way that respects and preserves the clinical independence and professional autonomy of healthcare practitioners. This ensures that health practitioners exercise their professional judgment and discretion, while maintaining their ability to make individualized decisions in the best interests of their patients

- 3.7 The use of AI for treatment and diagnosis should include express accountability for any errors, ensuring that ultimate responsibility is defined. A health practitioner should always make the final decision on patient care, maintaining accountability and oversight in clinical settings.
- 3.8 Health practitioner should always make the final decision on patient care, maintaining accountability and oversight. AI in healthcare must only occur with appropriate ethical oversight<sup>2</sup>
- 3.9 The use of AI in healthcare must support the protection of patient health information privacy. Where unidentifiable data will serve the purpose, anonymized data should be used with full knowledge that no guarantee for complete privacy and confidentiality exist in digital space.

#### **4. DISCLOSURE**

- 4.1 Health practitioner shall only utilise a form of treatment, apparatus or health technology that is not a secret or claimed to be secret. In this regard, the health practitioner shall assess whether the AI tool suits its intended purpose, for example, that it is up-to-date, valid, and reliable, transparent respecting the data it is trained on, explainable to patients, including respecting limitations thereon, that it is capable of producing good and interpretable output and repeatable and it acknowledge the potential risks and the issues they could create.
- 4.2 Only an apparatus or health technology which proves upon investigation to be capable of fulfilling the claims made with regard to it may be considered and the health practitioner must understand it and be assured of its appropriateness.
- 4.3 A disclosure of whether an AI system utilizing machine learning employs an algorithm programmed to learn from data referred to as

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<sup>2</sup> World Medical Association. (2019). Statement on Augmented Intelligence in Medical Care. <https://www.wma.net/policies-post/wma-statement-on-augmented-intelligence-in-medical-care/> [Accessed on 18 September 2024].

training data should be made to the patient as such learner algorithm automatically adjust the machine learning model based on the training data<sup>3</sup>.

4.4 Health practitioner shall also understand and disclose to patients whether the tool is a “continuous learning system” that updates the model without human oversight as new data is presented, as opposed to the “locked learners” that do not automatically update the model with new data<sup>4</sup>.

4.5 It is important for the health practitioner is informed whether the learner algorithm is eventually locked or whether the learner algorithm continues to learn once deployed into clinical practice in order to assess the systems for quality, safety, and bias. Being able to trace the source of training data is critical to understanding the risk associated with applying a healthcare AI system to individuals whose personal characteristics are significantly different than those in the training data set.

4.6 If the AI tool fits or is incorporated onto a medical device, then it should comply with the requirements of South Africa Health Products regulatory Authority (SAHPRA).

## **5. ACCOUNTABILITY**

5.1 The AI tools that health practitioner’s use must be guided by health practitioners to create positive and transparent interactions that instill trust in healthcare environment.

5.2 AI use shall be consistent with the prevailing standards for any technology used in healthcare, as health practitioners are ultimately responsible for their use of AI tools and may be held accountable for any

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<sup>3</sup> *Ibid*

<sup>4</sup> *Ibid*

harms that flow from use<sup>5</sup>. The extent to which a health practitioner may be held professionally accountable for the use of an AI tool will depend on the relationship between the AI being used and the risk that it may either create patient harm or otherwise impact the professional obligations of the health practitioner.

- 5.3 Health practitioners should always reflect on their own clinical reasoning and professional judgment, even during the use of AI as such tools are only intended to assist and complement clinical care, not to replace.
- 5.4 Health practitioners should take steps to mitigate or avoid over-reliance on AI tools to such a degree that it jeopardizes independent professional judgement and vigilance.
- 5.5 The developers of the AI systems are also liable with the user of such systems for adverse events resulting from malfunction(s) or inaccuracy in output.

<b>6. EQUITY AND TRANSPARENCY IN AI APPLICATION</b>
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- 6.1 The use of AI technologies must be applied in a way that does not exacerbate disparities in healthcare, including but not limited to those related to race, gender or socioeconomic status. Health practitioner is expected to respect the dignity, diversity, cultural values, and rights of patients and colleagues, and avoid using AI to create or disseminate content that is discriminatory, offensive, or harmful.
- 6.2 Patients must be informed when a diagnosis or treatment recommendations were determined or assisted by an AI program or tool, how algorithms are used in clinical diagnosis and decision-making including the ethical and clinical criteria used to set decision-making parameters (including any inherent biases).

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<sup>5</sup> The College of Physicians & Surgeons of Manitoba. (2024). Advice to the profession: Responsible Use of Artificial Intelligence in the Practice of Medicine.

- 6.3 Information on how algorithms are used in clinical diagnosis and decision-making should be available to patients, including any biases and the associated risks.
- 6.4 Informed consent is not a list of AI-generated risks and benefits, but instead a meaningful dialogue and shared decision-making between the physician and patient<sup>6</sup>. The process of informed consent process is to ensure patient autonomy in clinical decision-making.
- 6.5 For informed consent to be valid, a patient must be adequately informed about their diagnosis and treatment options, the risks and benefits involved, and reasonable alternatives.
- 6.6 A lack of transparency regarding the role that AI has played in the delivery of care and the inadequate communication between the health practitioner and the patient can undermine trust and may serve to highlight the lack of understanding of the tool in use.
- 6.7 Transparency and disclosure of AI tool in use should be done prior to its use, and it should include:
- (i) discuss capabilities and limitations of the tool.
  - (ii) discuss safeguards that have been put in place to manage bias and ensure validity and reliability.
  - (iii) be able to independently explain components of diagnosis and treatment options to fulfill their professional responsibilities.

## **7. SAFETY AND QUALITY OF CARE**

- 7.1 All interventions must take place under appropriate conditions and surroundings no practitioner may embark upon an intervention unless

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<sup>6</sup> *Ibid*

he/she feels that it is in the patient's interest, and other than in a life or limb threatening emergency, that it is safe to do so.

- 7.2 All systems must be transparent, reproducible and be trusted by both health practitioners and patients. Usability should be tested by participants who reflect similar needs and practice patterns of the end user, and systems must work effectively with people<sup>7</sup>.

## **8. CONTINUING PROFESSIONAL DEVELOPMENT**

- 8.1 Health practitioners have a professional and ethical duty to maintain a requisite level of skill, knowledge and judgement to provide competent and safe care in their professional practice, including in the usage of AI tools.
- 8.2 As AI tools are increasingly incorporated into the delivery of healthcare, it is important that health practitioners follow significant developments within their field, update their skills and strive to understand how the technology works, its limitations, the benefits and risks, and its privacy implications.
- 8.3 The development in the promising use for AI systems include enhancing predictive analytics, precision medicine, diagnostic imaging of diseases, and clinical decision support, as such, health practitioners must also strive to be involved, learn or understand how AI is improving the healthcare delivery.
- 8.4 The development and application of AI to healthcare must be inclusive, undertaken (developed and tested) with appropriate consultation with the health professionals, patients and the wider community<sup>8</sup>.

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<sup>7</sup> World Medical Association. (2019). Statement on Augmented Intelligence in Medical Care. <https://www.wma.net/policies-post/wma-statement-on-augmented-intelligence-in-medical-care/>

<sup>8</sup> *Ibid*

## **9. CLINICAL DECISION MAKING**

- 9.1 The responsibility for decision making on patient care should always remain with the health practitioner, irrespective of the assistance or tool/s employed to support such decision-making process.
- 9.2 Health practitioners are accountable for clinical decisions and are held liable for their decisions. It is contrary to good practice for AI to be applied as the final decision maker as only a person registered in terms of the Act may partake in an act that consists of but not limited to diagnosis, treatment or giving advice in respect of an illness, treatment, deficiency or rehabilitation of any kind.

## **10. DATA PRIVACY AND PROTECTION**

- 10.1 The personal information about a patient be effectively protected against improper disclosures at all times. Patient's health information must not be given to others unless the patient provides their consent, or the healthcare practitioner can justify the disclosure.
- 10.2 Health practitioners have an obligation to safeguard patient health information against unauthorized access and inappropriate use.

## **11. REGULATION**

- 11.1 Regulating AI in healthcare in South Africa involves several regulators with specific mandates, such as:
- i) The HPCSA which regulates the health practitioner.
  - ii) the Office of Healthcare Standards and Compliance (OHSC) whose objects are to protect and promote the health and safety of users of health services by monitoring and enforcing compliance by health establishments with norms and standards.

- iii) The South African Health Product Regulatory Authority (SAHPRA) ensures that the regulation of health products intended for human and animal use through the licensing of manufacturers, wholesalers, and distributors of medicines and medical devices; radiation emitting devices and radioactive nuclides.
- iv) The Information Regulator (IR)'s mission is to regulate the processing of personal information and the promotion of access to information in accordance with the Constitution and the law to protect the rights of everyone.

11.2 The government has a crucial role to play in ensuring synergy between regulators of different components of the health system (amongst others) and in particular the application of AI in healthcare to ensure that it is used appropriately.

11.3 This regulatory environment collective mandates ensure that AI tools developed by companies do not undermine healthcare delivery nor trust in the system<sup>9</sup>.

11.4 The regulatory tools for AI in South Africa are currently underdeveloped. As the tools continue to develop, the regulatory framework for AI, including but not limited to government statutes, industry guidance, and professional opinion, should significantly, continually change as key players such as legislatures, government explore the extent of their authority over AI systems, and the legal and regulatory considerations<sup>10</sup>.

11.5 Adaptive regulation are necessary, not impose additional burdens of compliance on the profession, but to ensure that participants (health

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<sup>9</sup> *Ibid*

<sup>10</sup> Federation of State Medical Boards. (2024). Navigating the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice.



practitioners and patients) feel safe in the application of AI, promoting innovation and progress in this important field<sup>11</sup>.

## **12. PILLARS OF AI**

The pillars of AI tool are the fundamental components or key areas of focus that support and drive the successful implementation of the AI tool. Amongst the pillars of AI, the following are the most common pillars that the health practitioners should take note of:

### **12.1 ETHICS**

Health practitioners should always be mindful that AI tools should support ethical matters such as respects for patient autonomy, privacy, and confidentiality etc., see par 3 above.

### **12.2 LEGAL**

Any platforms operating in the Republic of South Africa is required to meet certain legal standards in line with the applicable legislation. For example, Protection of Personal Information Act, Promotion of Access to Information Act and others.

### **12.3 TECHNICAL**

Healthcare AI tool should have express and available defined criteria, features, functionalities, and capabilities, systems or software application that possess capability to meet intended objectives and fulfill health practitioner and patient's needs. AI applications should be safe, reliable, and sufficiently robust to meet the data quality management, interoperability, and cybersecurity standards.

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<sup>11</sup> Australian Medical Association. (2023). Position Statement: Artificial intelligence in healthcare.

## **13. OPPORTUNITIES**

- 13.1 AI can offer a transformative set of tools to physicians and patients and has the potential to make healthcare safer and more efficient by automating processes and increase productivity.
- 13.2 Data mining produce accurate useful data at the right time may improve electronic health records and access to relevant patient information. Results of data mining may also provide evidence to inform resource allocation and utilization decisions.
- 13.3 New insights into diagnosis and best practices for treatment may be produced because of analyzing all known data about a patient.
- 13.4 The potential also exists to improve the patient experience, patient safety, and treatment adherence.
- 13.5 Applications of AI to continuing medical education, training simulations, learning assistance, coaching for students may provide objective assessment tools to evaluate competencies.

## **14. CHALLENGES**

- 14.1 Some of the AI tools do not fall under the definition of a medical device requiring Regulator's approval as such, it is difficult to regulate them.
- 14.2 The effective use of AI may be hampered by evolving regulatory oversight to strengthen safety and clinical efficacy, lack of widely accepted standards, liability issues, need for clear laws and regulations governing data uses, and a lack of shared understanding of terminology and definitions<sup>12</sup>.
- 14.3 AI systems must ensure proper disclosure and note the benefits, limitations, and scope of appropriate use of such systems. In turn, health

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<sup>12</sup> World Medical Association. (2019). Statement on Augmented Intelligence in Medical Care. <https://www.wma.net/policies-post/wma-statement-on-augmented-intelligence-in-medical-care/>

practitioners are required to understand AI methods and systems in order to rely upon as an aid for clinical recommendations.

- 14.4 Note anonymization of data does not provide enough protection to a patient's information when machine-learning algorithms can identify an individual from among large complex data sets when provided with as few as three data points, which could put patient data privacy at risk<sup>13</sup>.
- 14.5 Viable technical solutions must be understood to mitigate these risks relating to confidentiality of the personal information are yet robust enough.
- 14.6 Data structure and integrity are major challenges that need to be addressed when designing healthcare AI systems. The data sets on which machine learning systems are trained are created by humans and may reflect bias and contain errors. As such, the data sets may 'normalize' errors and biases inherent in their data sets.
- 14.7 Minorities and marginalized populations may be disadvantaged because there is less data available about their populations.
- 14.8 How a model is evaluated for accuracy involves very careful analysis of the training data set and its relationship to the data set used to evaluate the algorithms.
- 14.9 There is currently limited research-based evidence to guide an approach to the use of advanced AI tools by health practitioners, though there are many studies underway.
- 14.10 Inadequate risk assessment may result in incorrect tool usage.

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<sup>13</sup> *Ibid*

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# Ethical guidelines for good practice in the health care professions

The following Booklets are separately available:

- Booklet 1:** *General ethical guidelines for health care professions.*
- Booklet 2:** *Ethical and professional rules of conduct.*
- Booklet 3:** *National Patients' Rights Charter.*
- Booklet 4:** *Seeking patients' informed consent: The ethical considerations.*
- Booklet 5:** *Confidentiality: Protecting and providing information.*
- Booklet 6:** *Guidelines for the management of chronic diseases.*
- Booklet 7:** *Guidelines withholding and withdrawing treatment.*
- Booklet 8:** *Guidelines on Reproductive Health management .*
- Booklet 9:** *Guidelines on Patient Records.*
- Booklet 10:** *Guidelines for the practice of Telehealth.*
- Booklet 11:** *Guidelines on over servicing, perverse incentives and related matters.*
- Booklet 12:** *Guidelines for the management of health care waste.*
- Booklet 13:** *General ethical guidelines for health researchers.*
- Booklet 14:** *Ethical Guidelines for Biotechnology Research in South Africa.*
- Booklet 15:** *Research, development and the use of the chemical, biological and nuclear weapons.*
- Booklet 16:** *Ethical Guidelines on Social Media.*
- Booklet 17:** *Ethical Guidelines on Palliative Care.*
- Booklet 19:** *Ethical Guidelines on Matters related to Billing Practices.*