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

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.

Artificial intelligence tools refer to computer systems capable of performing complex tasks that historically only a human could do, such as reasoning, making decisions, or solving problems.

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.

Automated decision making means any technology enabled decision that is constructed based on the information it consumed, such is utilised to provide assistance or support to the health practitioner.

Act means the Health Professions Act, 1974 (Act No. 56 of 1974

Computer vision is 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.

Continuous learning systems refers to the ability of AI systems to acquire new knowledge, improve their performance, and adapt to changing conditions over time. It is an aspect of AI development and deployment that allows AI models to evolve and enhance their capabilities through ongoing learning and refinement.

Data mining means an 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.

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

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 Health Professions Council of South Africa (HPCSA) supports innovation that improves healthcare delivery, while ensuring and promoting safe practice in the health professions.

2.2 The HPCSA does not regulate nor 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 recognises that AI brings significant ethical, legal, and professional challenges that accompany its use, including over-reliance on it.

2.3 This guideline is intended to provide advice to assist health practitioners on matters relating to AI use. 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.[1]

2.4 AI's potential in healthcare is vast, and it is accompanied by risks such as discrimination due to historical data and automation biases, and the potential erosion of clinical skills amongst health practitioners.

2.5 AI systems rely on large datasets and this may compromise patient confidential record from where most of the information is drawn.

2.6 Multiple AI applications have been around for many years, with some already entrenched in daily healthcare service delivery. Common

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

examples include: computer vision systems to analyze medical 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 capable of building upon advances in complex algorithms, advance data analytics and machine learning.

2.7 The management of digital health records, for example, 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 These guidelines must further be read in conjunction with other ethical guidelines of the HPCSA, which include but are not limited to:

a) Booklet 1: General Ethical Guidelines for Healthcare Professions.
b) Booklet 2: Ethical and Professional Rules of Conduct.
c) Booklet 4: Seeking Patients' Informed Consent: The Ethical Considerations
d) Booklet 5: Confidentiality: Protecting and providing information.
e) Booklet 10: Guidelines for the practice of Telehealth.

3. ETHICAL PRINCIPLES

3.1 Health practitioners have a responsibility to ensure that, while using AI technology and related systems, the patient's best interests shall remain the primary concern. Patient's confidentiality, privacy, choice and dignity should always be respected.

3.2 The use of AI in healthcare should be patient-centered for the benefit of the patient's health and well-being and to improve health outcomes. The interest of patients and the wider community shall be the primary and guiding focus of all AI applications in healthcare.

3.3 AI serve as a tool to support and enhance clinical decision-making rather than replace it. It can aid the healthcare practitioner 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 complement the expertise of health practitioners, enhance efficiency and effectiveness in healthcare delivery while simultaneously ensuring that human judgment remains central to patient care.

3.5 The use of AI in healthcare shall not undermine the rights of patients to make informed decisions about their health and services provided to them. It shall respect and preserve the clinical independence and professional autonomy of health practitioners. Health practitioners shall always make the final decision on patient care, maintaining accountability and oversight. AI in healthcare must only occur with appropriate ethical oversight.[2]

3.6 Automated decision-making 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 individualised 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

[2] 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]

defined. Health practitioners shall always make the final decision on patient care, maintaining accountability and oversight in clinical settings.

3.8 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 practitioners should 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. It should be explainable to patients, including on limitations thereon, with potential risks, if any, indicated upfront.

4.2 Only an apparatus or health technology which proves upon investigation to be capable of fulfilling the claims made about its use 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 training data should be made to the patient as such learner algorithm automatically adjust the machine learning model based on the training data.[3]

4.4 Health practitioners should 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

[3] World Medical Association

to the “locked learners” that do not automatically update the model with new data.[4]

4.5 It is important for the health practitioners to be informed about the above to ensure better understanding of the output regarding the 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 is incorporated onto a medical device or equipment, then it should comply with the requirements of the South Africa Health Products regulatory Authority (SAHPRA).

4.7 Only AI that has been validated for reliability and cultural appropriateness should be utilised in healthcare.

5. ACCOUNTABILITY

5.1 The AI tools used must be guided by healthcare requirements and used by health practitioners to create positive and transparent interactions that instill trust in healthcare environment.

5.2 Application of AI should be consistent with the prevailing national 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 undue harms that flow from its use.[5] 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.

[4] World Medical Association

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

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 or confirm clinical care, not to replace.

5.4 Health practitioners must 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.

6. EQUITY AND TRANSPARENCY IN AI APPLICATION

6.1 The use of AI must be applied in a way that does not exacerbate disparities in healthcare, including but not limited to, those related to race, gender or socio-economic status. Health practitioners are 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). The patients who decline the use of AI may not be disadvantaged or refused access to health services.

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, on request.

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

health practitioner and patient.[6] 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 appraised about their diagnosis and treatment options, the risks and benefits involved, and reasonable alternatives.

6.6 Lack of transparency regarding the role that AI plays in the delivery of care and the inadequate communication between the health practitioner and the patient can undermine trust.

6.7 Transparency and disclosure of an AI tool in use should be done prior to its use, and it shall include:

a) capabilities and limitations of the tool.

b) safeguards that have been put in place to manage bias and ensure validity and reliability.

c) an independent explanation of components of diagnosis and treatment options available to the patient.

7. SAFETY AND QUALITY OF CARE

7.1 All interventions must take place under appropriate conditions and surroundings and no practitioner may embark upon an intervention unless 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 AII AI systems must be transparent, reproducible and must produce evidence-based data that can be shared with both health practitioners and patients. Usability of AI should be tested by participants who reflect similar contextual needs and practice patterns of the end user, and systems must work effectively with people[7].

6 World Medical Association
7 World Medical Association

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 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.[8]

9. CLINICAL DECISION MAKING

9.1 The responsibility for decision making on patient care must 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 should be effectively protected against improper disclosures at all times. Patient's health information

[8] World Medical Association

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 The regulatory tools for AI in South Africa are currently in development. The regulatory framework for AI, including but not limited to government statutes, industry guidance, and professional opinion, shall continually evolve as key players such as those in the legislative, governmental and non-governmental sectors explore the extent of their authority over AI systems.[9]

11.2 Adaptive regulatory frameworks are necessary, but not in a manner that imposes additional burdens of compliance on the profession. They should ensure that participants (including health practitioners and patients) feel safe in the application of AI.[10]

11.3 Regulating AI in healthcare in South Africa involves multiple relevant role-players, particularly, regulators with specific mandates, such as for example i) those regulating health practitioners including the HPCSA ii) the Office of Healthcare Standards and Compliance whose objectives are to protect and promote the health and safety of users of health services by monitoring and enforcing compliance by health establishments through norms and standards iii) South African Health Products Regulatory Authority whose purpose is to regulate 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 and the

9 Federation of State Medical Boards. (2024). Navigating the Responsible and Ethical Incorporation of Artificial Intelligence into Clinical Practice

10 Australian Medical Association. (2023). Position Statement: Artificial intelligence in healthcare

Information Regulator (IR) whose 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.

11.4 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.

11.5 These regulatory collective mandates should ensure that AI tools neither undermines healthcare delivery nor trust in the system.[11]

12. PILLARS OF AI

The pillars of AI 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 that relevant role players, including 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 respect for patient autonomy, privacy, and confidentiality etc., see par 3 above.

12.2 LEGAL

Platforms operating in the Republic of South Africa should be required to meet certain legal standards in line with the applicable legislation, including the Protection of Personal Information Act, Promotion of Access to Information Act and others.

12.3 TECHNICAL

[11] Australian Medical Association

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.

13. OPPORTUNITIES

13.1 AI can offer a transformative set of tools to health practitioners 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 and mental health education, training simulations, learning assistance, and 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 remains the responsibility of the health practitioner to be decisive in the correct AI Tool.

14.2 The effective use of AI may be hampered by laggard regulatory oversight to ensure safety and clinical efficacy, and sometimes lack of widely accepted standards, liability issues, lack of clear laws and regulations

governing data uses, and lack of shared understanding and applications.[12]

14.3 AI systems sometimes lack proper disclosure on its limitations, and scope of appropriate use of such systems. In turn, health practitioners are required to understand AI methods and systems in order to rely upon as an aid for clinical recommendations.

14.4 Anonymisation 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[13].

14.5 Viable technical solutions must be understood adequately 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 marginalised populations may be disadvantaged because there is less data available about their population dynamics and characteristics in the platform.

14.8 How a model is evaluated for accuracy involves careful analysis of the training data set and its relationship to the data set used to evaluate the algorithms may be an issue.

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 application.

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12 World Medical Association

13 World Medical Association

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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.***
Booklet 20:	***Ethical Guidelines on the use of Artificial Intelligence.***