



#AMCOA2024

11 - 15 AUGUST 2024

AVANI RESORT, LIVINGSTONE

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THE ETHICS AND REGULATION OF AI AND OTHER ADVANCED TOOLS IN HEALTHCARE

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Outline



Why AI is
Ethically
Unsettling?



Ethical and
Regulatory
Focus

Ethical Focus

Regulatory Focus



Looking
Forward



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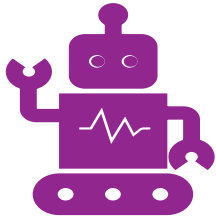
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...why AI is ethically unsettling?

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Technologies behind Generative Artificial Intelligence (GenAI)

- are part of the family of **AI technologies** called **Machine Learning** (ML)
- uses **algorithms** to enable it to **continuously** and **automatically** improve its performance from data



The recent advances are by a type of ML called **Artificial Neural Networks** (ANNs) (eg. the use of AI for facial recognition) is inspired by

how the human brain works and its synaptic connections between neurons.

*There are many types of ANNs (**both text and image**)*

ChatGPT- for instance, uses a Generative Pre-trained Transformer (GPT),

while **image GenAI** typically uses what are known as **Generative Adversarial Networks** (GANs)

Alpaca- meta & standford; **Bard**- Google, real time up-to-date info; **Jasper**



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...why AI is ethically unsettling?

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Health Admin - useful tool in minimising fraud thro smart audits; stock supplies, etc.

Public health/medical research- AI used to analyse large health data for population level predictions;

- **Elicit- AI Research Assistant-** automates parts of researchers' workflows, identifying relevant papers and summarising key information

Medical Education and Training

- **AI Tutor** providing AI-based virtual patients to facilitate virtual and remote training; telemedicine, telehealth, etc.



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...why AI is ethically unsettling?

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Medical Professional Support

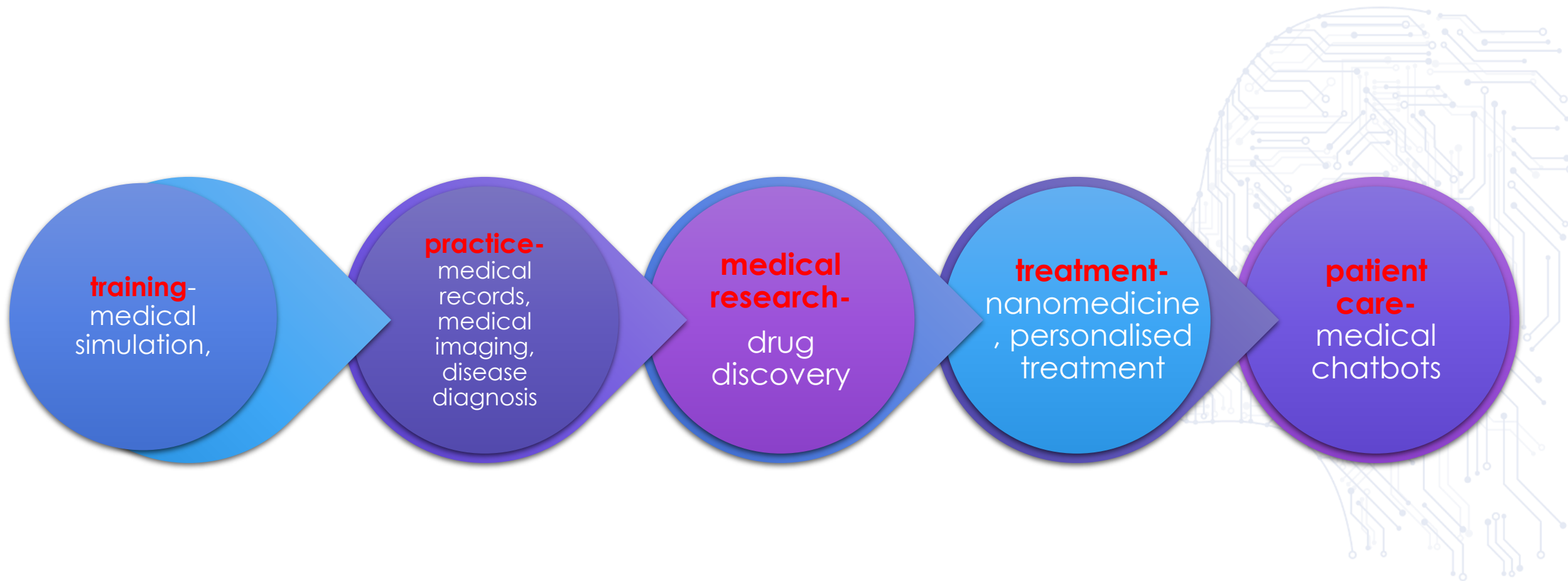
- **GenAI**-identify high risk patients requiring ICU for example,
- **Jasper**- can be trained to write in a user's preferred style and generate images,etc.;
- **AI robots (Moxie)** proactively determines what nurses require- supplies, assistance with test logistics, etc.
- **Surgical systems**
 - **Da Vinci surgical system** (approved by USA FDA 2000)- minimally invasive cardiac, colorectal, gynaecological, head & neck, thoracic, urological and general surgeries
 - **ION by Intuitive surgical system** (approved by USA FDA 2019)- robotic catheter
 - **Mako by Strkyer surgical system** (approved 2013)- partial knee, total hip and total knee operations
 - **NAVIO by Smith & Nephew** (approved 2018)- used by practising surgeons and residents who are learning the robotics-assisted procedure and involves clinically supported virtual reality (VR) simulations of the procedure
 - **Monarch by Auris Health** (approved 2018)- flexible robotic endoscope, etc...
- **Medicine**
 - **Nanomedicine**- personalised medicine using nanotechnology

Patient Engagement

- **AI Chabots**, faster info, locate hospitals, book appointments, describe needs;
- **AI Lirio**, provides personalised nudges and precision (pateint-tailored) prompts to seek visit

...why AI is ethically unsettling?

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....ethical and regulatory focus.....

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GenAI – is revolutionalising the training and practice of healthcare professions.

But **weighty ethical and legal issues emerge**- requiring careful consideration to ensure responsible use.



Focus (Ethical & Regulatory)

...towards a human-centred approach to harnessing the healthcare potential of GenAI technologies, etc.



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....ethical focus....

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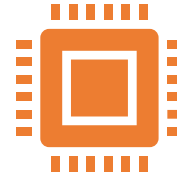


Human Autonomy/Agency

Most of the **LLMs** are continually improved and more and more mirror human actions or behaviours with person sounding algorithms such as (certainly, I am sorry, what can I do for you, I know this is hard on you, I feel your pain/frustration,etc)

real danger of **undermining**

- **human agency**, usurping human thinking in the care environment
- and **distorting** the doctor-patient relationship



Data Ownership and Related Issues

Data security and privacy- vast amounts of health datasets are involved. GenAI systems require access to paradigmatically personal and sensitive health information, raising serious questions about **medical confidentiality and privacy**- Ensuring that patient information is adequately protected is central to maintaining TRUST between doctors and their patients.

Constitution 1992 art 18 (2); Public Health Act, 2012, Act 851; HPRBA, 2013, Act 857; Data Protection Act, etc.



Care without Informed Consent

Patients have the **right to be informed** about how GenAI technologies work in their care and should have the option to consent or refuse AI-driven care (diagnoses, treatment, follow-up advice, etc). Ensuring that, where appropriate, **ALL patients understand the role of GenAI technologies in their care is an ethical imperative.**



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....ethical focus....

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Discrimination and Unfairness

Most of the **GenAI LLMs algorithms** may generate responses by relying on inherent biases from historical health related datasets potentially contributing to widening disparities in diagnosis and treatment. (**garbage in, garbage out**).

Addressing algorithmic bias and historical injustices are crucial to **ensuring equity , inclusiveness, cultural diversity (pluralism) health outcomes for all patients.**

Transparency and accountability

A vast majority of users are **ignorant** about the algorithms the LLMs run on. **The black box** nature of the algorithms of some of these GenAI technologies make it extremely challenging to understand how decisions are reached. Accordingly, patients and doctors (healthcare managers/providers) may be **unable to hold AI systems accountable** when errors, mistakes, or biased decisions are made.

Mis/Dis-information & Manipulation/Deepfake

COVID-19 and Infodemic; **professional integrity** is an ethical imperative.

Willful stupidity- callow indifference to facts or logic; shows a stubborn devotion to uninformed opinions ignoring contrary ideas, opinions, or data.

Knowledgeable ignorance, insightful ignorance or perceptive ignorance- a condition of knowledge; the absence of facts, understanding, insight, or clarity about something; it is normally not due to an individual but a community gap in knowledge

Regulators punish wilful stupidity because wilful stupidity harms, kills.



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....mis-/dis-information kills...

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.....regulatory focus.....

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Quality Assurance and Safety Standards

- **Develop regulatory competencies**
- Defining, enforcing and tracking/monitoring quality and safety standards for GenAI technologies in healthcare is essential to achieving our regulatory policy goals of guiding the professions, protecting the public health, safety and well-being, etc.

Credentialling and Licensure

- As health systems rely more and more on GenAI technologies in making care decisions, legitimate questions arise as to the credentialling and licensure of GenAI systems and their developers- HeFRA, Professional Regulators, Tech Regulator- NITA???
- **hmmmm Is the robot a professional, a service, a facility, a product, device, an implement????? aye jue syndrome**



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.....regulatory focus.....

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Liability obligations

- When GenAI technologies make **harmful decisions, or make errors, or mistakes** in patient care who takes responsibility for these? Who pays the compensation? etc.
- Regulatory/ legal frameworks must as a matter of **necessity and urgency help bring clarity** to these situations so healthcare professionals and providers are not left scratching their heads when these materialize.



Regulatory compliance

Ensuring that healthcare GenAI technologies **adhere to regulatory requirements** is an important part to **assuring patient safety and healthcare quality**.



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.....looking forward.....

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❑ Addressing the ethical & legal concerns; **some thoughts**

❑ Human Autonomy

- ❑ **build capacity of professionals and healthcare providers**
- ❑ **build GenAI technology systems competencies anchored on human-centred ethical and professional values- while technology changes, and changes really fast, our obligations to patients do not change; are not diminished.**

Our ethical and professional obligations remain the same regardless of the medium or technology used.

❑ Discrimination and Unfairness

- ❑ **build locally relevant application models and build a bank of cumulative local evidence-base to enhance inclusiveness, cultural diversity, equity and improve health outcomes.**

❑ **The AFRICAN context is COMMUNITARIAN in nature underpinned by the principle of collective solidarity.**



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❑ Data Ownership and Related Issues

- ❑ **Adjust or enforce** regulation in respect of access to, and use of, local health data. In **Ghana** (*Constitutional/statutory rights issues; Patient's Charter section 167 of Act 851; Data Protection Act; Cybersecurity Act; RTI Act; etc*)

- ❑ We are in the ERA of **DATA/DIGITAL ECONOMY** (National (Bio)Ethics Agencies is now a MUST for **ALL COUNTRIES**)



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Transparency and Accountability

Regulatory regimes / frameworks must provide clear lines of accountability in cases of GenAI technology related harm, or error, or mistake.



Quality Assurance and Safety Standards

Regulators must develop patient-centric guidelines for the use of GenAI technologies in health with the anchored on transparency & accountability, safety and fairness among others.



Patient Empowerment

Regulatory frameworks must prioritise patient education and participation in policy decision making about how GenAI technologies are deployed in their care. Informed consent, privacy and confidentiality must be emphasised!



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However developed and deployed in healthcare GenAI technologies

- must be based on **human-centred values**
- **cannot replace** professionals (may reduce their number)
- **must respect** patient rights, data security and privacy, fairness- must address existing biases and inequities not worsen them, etc.
- **should improve** service efficiency and health outcomes for ALL



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- ❑ A human-centred approach to developing and deploying AI technologies including nanotechnologies (**nanomedicine**) should be premised on the grounds that these technologies help to **expand, improve, or augment**
 - ❑ human abilities,
 - ❑ **technical competence, professional practice standards and conduct, and social skills including responsive communication**and not undermine them, conflict with them, or usurp them altogether
- ❑ **AND YES!!....a professional cannot say; BLAME THE ROBOT!!!!**



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- ❑ Regulating risks associated with innovation, technology, - **standards require continuous refinement**,
- ❑ Precautionary approach to regulating these must be informed by principles of –

- ❑ **Proportionality**

- ❑ Regulators should only intervene when necessary, the regulatory responses should reflect the potential risks and harm posed, while costs of the regulatory intervention are identified and kept to the minimum.

- ❑ **Accountability**

- ❑ Regulators should be able to justify their decisions and the decisionmaking should be subject to external scrutiny

- ❑ **Consistency**

- ❑ Gov't rules and standards should not contradict each other, and they should reflect wider ethical, legal and regulatory approaches

- ❑ **Transparency**

- ❑ Regulatory standards should be simple and user-friendly, that is, easy to understand

- ❑ **Targeting**

- ❑ Regulatory intervention should be focused on the problem, and minimise side effects.



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☐ **Creative Compliance**

- ☐ those regulated avoid having to break the rules and do so by circumventing the scope of a rule while still breaking the spirit of the rule

☐ **Inclusiveness**

- ☐ rules if ill-formulated may be over inclusive or under inclusive

☐ **Dear Regulator beware of these regulatory PITFALLS**

- ☐ **The AFRICAN context is COMMUNITARIAN in nature underpinned by the principle of collective solidarity. Though doing it alone may seem a daunting task, WHEN WE DO IT TOGETHER WE DO IT BETTER- YES, TOGETHER WE CAN- AN AFRICA WIDE GUIDANCE ON AI IS AN URGENT NECESSITY.**

- ☐ **TIME IS NOT OUR FRIEND, MY FRIENDS!!!!**

THANK YOU!



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