SMU
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2024 MacKay International Medical Education Conference

Medical Innovations Through the Legal Lens: Social Ethics and Humanistic Challenges (26 Oct 2024)

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Introduction

1. Recent medical/technological advances

2. Laws and regulations as well as ethics and human-centred principles

3. The legal position in Singapore (mainly) and relevant non-binding ethics and industry guidelines

Contents

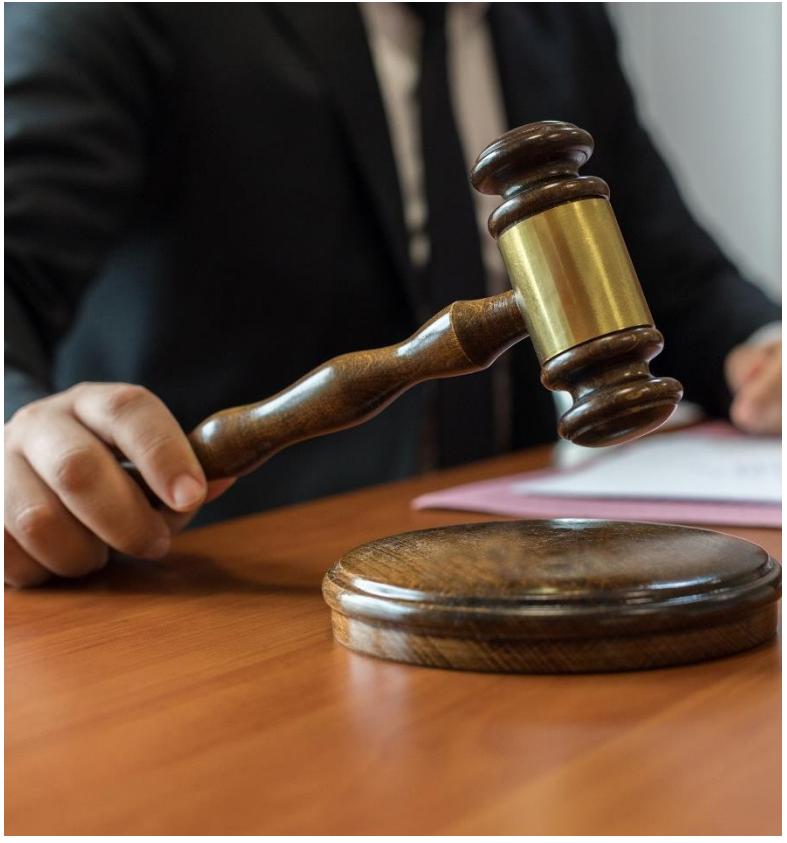
Innovative treatments and untested practices

Innovative treatments are regulated through:

1. Medical disciplinary cases – sanctions against errant doctors e.g. deregistration, suspension, fines, reprimand

2. Civil claims against medical doctors in tort of negligence – see novel surgical procedures in *Rathanamalah d/o Shunmugam v Chia Kok Hoong* 2018)

3. Institutional Review Boards (IRBs) and ethics committees



Innovative treatments and untested practices

General Approach:

Doctors must treat patients according to **generally accepted practices**, per the SMC Ethical Code and Ethical Guidelines 2016

Factors determining "generally accepted practice":

- Peer-reviewed studies, replication and reproducibility, randomized controlled trials
- assessment of risks and benefits must be acceptable to medical community
  - *Gobinathan Devathasan v SMC* (2010): Therapeutic Ultrasound
  - *Pang Ah San v SMC* (2014): Loop Percutaneous Endoscopic Gastronomy Tube

If deviations from generally accepted practice:

- Doctor has to show no harm (and/or the benefits)

*The same general approach is used for Traditional Chinese Medicine, but based on generally accepted practice in TCM, not orthodox medicine:

- *Huang Danmin v TCM Practitioners Board (2010)*

Human Biomedical Research

To generate knowledge for public good in healthcare

Bioethics Advisory Committee, Singapore (est. 2000)

- Provides ethical guidance and recommendations
  - Ethics Guidelines for Human Biomedical Research (2015), based on international guidelines
- Emphasis on respect for persons, solidarity, justice, proportionality and sustainability (social ethics and humanistic concerns)
- Recommendations have been accepted by government and applied to enact laws

Singapore's Human Biomedical Research Act (HBRA)

- Regulated by Ministry of Health (MOH), Institutional Review Boards (IRBs)
- Protects safety, dignity and welfare of human research participants
- Imposes criminal sanctions for breaches (fine and imprisonment)

Regulatory mechanisms

Human Biomedical Research Act 2015

- Prohibits certain research (e.g. on human-animal combination embryos beyond 14 days)
- Restricts research, approval through IRB required (e.g. biomedical research involving human eggs and embryos)
- Protection of research participants
  - Seeks participant consent
  - Protects participant personal information
- Regulates human issues e.g. no commercial trading

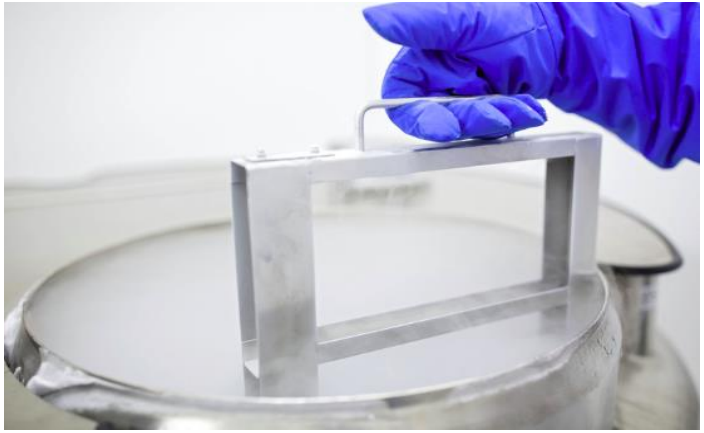
Human Cloning and Other Prohibited Practices Act, 2004

- Prohibits human embryo cloning in the body of a human or animal, commercial trading in human embryos, eggs and sperms, etc

Human tissues – the Cordlife issue

Cordlife → company that collects, processes, stores, and distributes cord blood.

Storage tanks were exposed to excessive temperatures → cord blood units of clients were damaged and rendered non-viable.



1. Refunds - compensation?
2. MOH Regulations – suspended operations in November 2023
   https://www.moh.gov.sg/news-highlights/details/investigation-of-cordlife-group-limited-for-suboptimal-storage-temperature-for-cryopreserved-cord-blood
3. Lost accreditation with Association for the Advancement of Blood and Biotherapies (AABB)
   Cordlife loses accreditation with international blood bank body – CAN (channelnewsasia.com)

Gene Editing

Reasons for gene editing :

1. Therapeutic editing of somatic (non-hereditary) cells

2. Research

Techniques:

CRISPR gene editing

Singapore scientists develop novel gene editor to correct disease (a-star.edu.sg)

Dangers of gene editing

Germline gene editing affects future generations → designer babies?

Gene editing – regulations and guidelines in Singapore

Non-heritable Gene Editing

Allowed for research purposes, subject to IRB approvals and participant consent.

Health Products (Cell, Tissue and Gene Therapy Products) Regulations 2021

Regulates:

- the manufacture, import, supply, etc of cell, tissue, and gene therapy products (CTGTP)
- Two classes of CTGTP depending on risk levels

Gene Editing in Germline Cells

Allowed for research purposes, in human embryos of not more than 14 days.

Human Biomedical Research (Restricted Research) Regulations 2017

- Only surplus embryos created in assisted reproduction treatment may be used for research
- Separate consent for use in research to be obtained

Gene editing – Designer Babies

BAC's Ethics Guidelines for Human Biomedical Research (2021 Revised):
"Research involving human germline modification for purposes other than the prevention or treatment of serious genetic conditions ***should not be allowed***… [such procedures] should be ***prohibited*** until there is adequate evidence from research that such clinical procedures are ***safe and effective***."

BAC 2005
Editing for enhancement could result in:

- Potential devaluation of those without the traits
- Social stratification
- Adverse effects on parent child relationships

BAC 2005 & MOH 2011

1. No sex selection for non-medical reasons
2. No sperm sorting (for sex selection).

Gene editing – other considerations

BAC Public Consultation on Ethical, Legal and Social Issues Arising from Human Nuclear Genome Editing (June to Aug 2024)

"… current state of the technology is largely in the nascent stage that is lacking in both safety and efficacy data. Therefore, the ***risks entailed largely outweigh the benefits perceived*** from the use of gene editing technologies, which ***compromise on the principle of proportionality***."

Legal considerations – see wrongful birth cases

e.g., IVF case (**ACB v Thomson Medical Centre (2017)** – loss of genetic affinity)

Neurotechnology in Healthcare

"Neurotechnology"
electronic devices to analyse, measure, or modify neural activity

Invasive

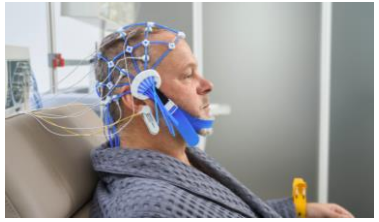
electrodes implants; cochlear implants, mind controlled neuroprosthetics

Examples:

1. Depression → deep brain stimulation
2. Alzheimer's Disease → electrical stimulation

Non-Invasive

1. Electroencephalography (EEG)
2. Functional Magnetic Resonance Imaging (fMRI)



EEG

fMRI

Neurotechnologies – Regulations & Recommendations

Function	Regulations/Recommendations
Neuroscience research	Regulation: • regulated via HBRA for the protection of research participants Recommendation • Re-seek informed consent in studies that might affect participants' personal identity or autonomy
Neurotechnology devices in clinical practice	Regulated by the Health Sciences Authority **as medical devices.**
Neuro-enhancements	Recommendations: Prior to research, researchers should conduct **risk-benefit assessments** based on the **principle of proportionality**

The case of *Guido Girardi v Emotiv*: Supreme Court of Chile

Facts:

- Insight – a wireless electroencephalography device that collects brain data to interpret emotions
- Users only have access to brain data if they purchase a 'Pro' license
- Girardi purchased a 'free' license – brain data remained in Emotiv's cloud servers cloud system even in the case of deleted accounts.

Held:

The state must "***directly protect human integrity in its entirety***, an issue that includes ***privacy and confidentiality*** as well as the rights to psychological integrity and integrity of individuals included in scientific experiments".

Therefore,

- Emotiv to delete Girardi's brain data
- Insight to be strictly strictly assessed by the National Customs Service and Public Health Institute of Chile before its commercialization and use in Chile

Protections from risks

"Neurosecurity"

"the *protection of the confidentiality, integrity and availability of neural devices* from malicious parties with the goal of *preserving the safety of a person's neural mechanisms*, *neural computation* and *free will*" (Denning *et. al*, 2009)

Neurorights

1. Right to mental privacy
2. Right to psychological continuity
3. right to mental integrity
4. right to cognitive freedom

Should human rights framework incorporate neurorights?

- Some existing human rights:
  - Freedom of thought and expression
  - Right of privacy
  - Right to life and liberty

Information Technology-related Innovations in Healthcare

Medical AI

Telemedicine and Telehealth Products

Mental health apps

Medical AI

Scope of medical AI use: Diagnosis, Treatment, Predictions of diseases and disorders, etc

Example: Singapore Eye Lesion Analyser (SELENA+) uses retinal images to detect diabetic eye disease, glaucoma and age-related macular degeneration

Challenges:
- novel technology and different medical opinions
- AI opacity and non-explainability

Ex ante regulations and guidelines

1. Heath Products Statute and subsidiary regulations

   Medical devices regulations and non-binding guidelines on software medical devices (2020)

2. Regulatory guidelines for Telehealth Products 2019 (see slide 27 below)

3. Regulatory Guidelines

   E.g. non-binding Singapore's Artificial Intelligence in Healthcare Guidelines (2021) – MOH, HSA, IHiS.

Tort of Negligence – common law approach

Ex post legal liability

Tests for the tort of negligence

1. **Duty of care:** Is there a legal duty of care?
2. **Standard of Care:** Has there been a Breach of Duty?
3. **Causation:** Has the Breach caused the injury?
4. **Remoteness:** Is the type of damage reasonably foreseeable?
5. **Defence of volenti to risks/consent?**

Artificial Intelligence in Healthcare Guidelines (2021) (AIHGLe)

Safe development and implementation of AI-MD and other AI in healthcare

Provides **recommended guidelines** for AI developers and AI Implementers (eg, hospitals and doctors)

Not legally binding – but consider indirect impact on application of legal principles in negligence

Negligence: Step 1: Duty of Care

Do AI developers/implementers owe any legal duty to injured patients?

Duty can arise when:

1. Foreseeability of harm
2. Legal proximity between AI developers/implementers and patients
3. Policy considerations

(scope: Design, Build and Test AI systems – AIHGLe)

[note: Hospitals and doctors generally owe duty of care to patients]

Negligence: Step 2: Standard of Care – AI Implementers

Have hospitals and medical doctors fallen below legal standards?

- What have they considered prior to implementing AI-MD?
  - intended purpose, safety, risks, regulatory approvals, etc (AIHGLe)
- Did they monitor AI performance & track deployment? (AIHGLe)
- Should they have relied on approving authorities?
- Did they omit to use medical AI that is reliable, accessible, affordable and superior to human performance?

Negligence: Step 2: Standard of Care – AI Implementers

Diagnosis and Treatment	Medical Advice

• **deference to medical peers**
• **whether medical peer opinion is logical**
• **how to apply SOC to novel medical technology such as AI**
  ▪ analogies to case precedents, general acceptance, risks and benefits
• **Blackbox medicine**
  ▪ focus on procedural steps to validate AI?
	Medical peer opinion with patient-centric approach (s 37 Civil Law Act):
	• Deference to and logic of medical opinion
	• requires doctors to disclose material information to patients
	e.g. risks and complications of surgery
	
	Must doctors disclose use of AI to patients? ("interact" with AI – AIHGLe)
	• to provide patient with **sufficient information** to make an **informed decision** whether to use an AI-MD/clinician

Telemedicine

Telemedicine Guidelines 2015

"the systemic provision of healthcare services over physically separate environments via information and communications technology"

4 domains of telemedicine

1. Tele-collaboration amongst healthcare professionals
2. Tele-treatment
3. Tele-monitoring
4. Tele-support for patients and caregivers

Regulations and guidelines

- Duty of care and standard of care are applicable: Telemedicine Guidelines 2015 and SMC Ethical Code and Ethical Guidelines 2016.
- Informed consent: SMC Ethical Code and Ethical Guidelines 2016
- Confidentiality and privacy of patient data (PDPA)

Recent case in the spotlight

An outpatient telemedicine service

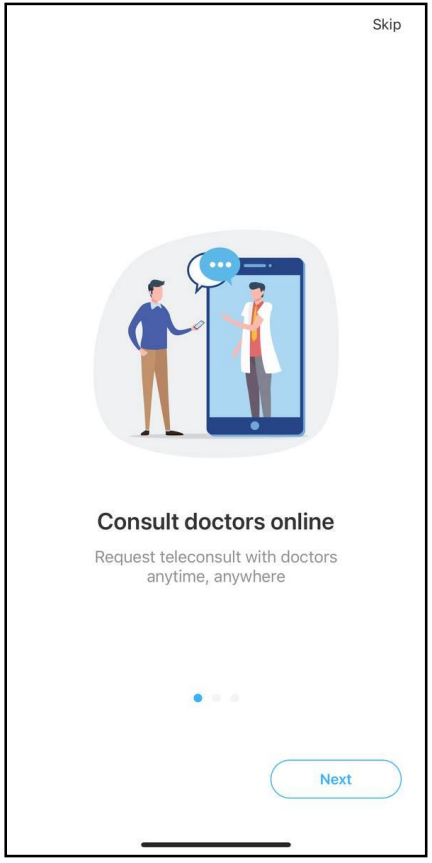
- Large number of patients had undergone very short teleconsultations, multiple medical certificates issued over a short period to the same patients.

Penalty:

- Suspension of outpatient telemedicine services, and subsequently licence revoked by MOH

Applicable Statutory Obligations (under Healthcare Services Act), Regulations, and Relevant Licensing Conditions:

- Licence Conditions for Remote Provision of Outpatient Medical services – only for direct doctor and/or dentist-led teleconsultations
- SMC's Ethical Code and Ethical Guidelines 2016



Home page of ManaDr's app

Telehealth products

Telehealth Products:

"Instrument, Apparatus, Machines and Software used for telemedicine"
(Regulatory Guidelines for Telehealth Products 2019)

categorisation of device is determined by its intended purpose (medical or non-medical e.g., wellness devices)	
Medical device Regulated through product registration and dealer's licensing 	Standalone mobile applications Regulated through product registration and dealer's licensing 

Mental Health Apps

Examples:
1. Mobile app to collect and measure the degree of tremor in patients with Parkinson's disease;
2. "reSET" app on CBT for substance use disorder

Concern 1: Safety
Can the mental health app cause harm? (see clinical standards and practices; chatbot errors)

Concern 2: Efficacy
Is the app as efficacious as psychotherapy to treat a mental disorder?
(RCTs; eg conversational agent Woebot for depression; mindfulness-based smartphone app, Headspace to reduce stress)

Concern 3: Privacy
Would the privacy and security of users' health data be protected?
(Encryption and privacy policy)

Are mental health apps trustworthy?

Trust = Lego-regulatory, ethical and technological

Laws and regulations:

1. **Medical Devices –** Health Sciences Authority
   a. Telehealth Guidelines 2019
   b. Standalone Mobile Applications - Immediate Registration Pathway (based on approvals by agencies in Australia, Canada, the European Union, Japan and the United States)
   c. Regulatory Guidelines for Software Medical Devices 2020

2. **Data protection**
   a. Personal Data Protection Commission and PDPA 2012

3. **Advertising:**
   a. Advertising Standards of Singapore and under the Health Products (Medical Devices) Regulations 2010 on verification and truthfulness

4. **Tort of negligence**
   a. The courts

Are mental health apps trustworthy?

Ethics & technological guidelines/standards/best practices:

1. **Medical professional guidelines**
   e.g. Canadian Medical Association's Guiding Principles for Physicians Recommending Mobile Health Applications to Patients (2015)

2. **National standards**
   e.g. mHabitat framework for the effectiveness evaluation of mobile (mental) health tools for app developers by National Institute of Health Research UK

3. **Certification by private organisations**
   e.g. Organisation for the Review of Care and Health Apps in the UK

4. **App stores' policy and guidelines**

Intersecting laws, regulations, ethics, guidelines, licensing conditions etc

Law and regulations
(e.g. HRBA, negligence, MOH 2021)

- pre-empt risks
- deter errant acts
- regulate medical innovations
- legal consequences for breach
  - criminal punishments,
  - compensation for victims
  - non-licensing of medical practices

Professional ethical codes
(e.g. SMC ECEG 2016 on innovative treatments)

- evidence of medical opinion
- Can lead to medical disciplinary sanctions (and indirectly, negligence lawsuits)

Ethics and industry guidance
(e.g. BAC guidance on gene editing and non-binding AIHGLe on medical AI)

- possible precursor to future laws and regulations

References

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Primary materials and reports

- Regulations: HRBA 2015, Human Cloning and other Prohibited Practices Act
- Ethics: BAC Ethical Guidelines 2015; National Medical Ethics Committee, Guidelines on Gene Technology (2001)
- Licensing conditions: Ministry of Health, *Licensing Terms and Conditions for Assisted Reproduction Centres*, 2011.
- Recommendation on Responsible Innovation in Neurotechnology, the Organisation for Economic Co-operation and Development (OECD) (2019)
- UNESCO, The Risks and Challenges of Neurotechnologies for Human Rights, 2023

Thank you for your attention!

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Acknowledgments: to research assistant Ms Janae Kwan, SMU law student, for assistance on the presentation slides

Questions?