Organiser

HKU LAW CMEL THE UNIVERSITY OF HONG KONG CENTRE FOR MEDICAL ETHICS AND LAW

Co-organisers

HONG KONG ACADEMY OF MEDICINE 香港醫學專科學院

PHG FOUNDATION

Roundtable: The Development of Regulation and Professional Guidance on Medical AI in Hong Kong Programme Booklet (Day 1)

The objectives of the roundtable are to explore:

(a) how best to regulate and govern medical AI (including, but not limited to, AI medical devices) in Hong Kong;

(b) the responsibilities of doctors in Hong Kong regarding their use of AI; and

(c) the provision of guidance in the form of guidelines to doctors on these responsibilities.

Organiser: Centre for Medical Ethics and Law (CMEL), The University of Hong Kong (HKU)

Co-organisers: PHG Foundation, The University of Cambridge
Hong Kong Academy of Medicine

Date: **18 – 19 September 2026 (Fri – Sat)**

Venue: **Academic Conference Room, 11/F, Cheng Yu Tung Tower, Centennial Campus, HKU**

Mode of Attendance: In person

The roundtable is not open to the public.
Attendance is by invitation only.

Notice

A meeting report by CMEL and the PHG Foundation of the University of Cambridge will emerge from this roundtable meeting. The report will not attribute anything said by anyone except for presentation summaries specifically approved.

Acknowledgement

CMEL and the PHG Foundation would like to express their sincere gratitude and appreciation to the WYNG Foundation for their support.

Programme

Day 1

Opportunities for Proportionate Regulation and Governance of Medical AI in Hong Kong

9:00 – 9:15	Arrival - Registration and Refreshments
9:15 – 9:20	**Welcome and Introduction** **Prof Gilberto Leung** Co-Director, Centre for Medical Ethics and Law, HKU Director of the School of Clinical Medicine, Clinical Professor and Tsang Wing Hing Professor in Clinical Neuroscience, LKS Faculty of Medicine, HKU Convenor, Task Force on Laws for Healthcare Practitioners, Professionalism and Ethics Committee, Hong Kong Academy of Medicine
Session 1: The Policy Context for Medical AI Regulation in Hong Kong **Moderator:** **Prof Gilberto Leung** Co-Director, Centre for Medical Ethics and Law, HKU Director of the School of Clinical Medicine, Clinical Professor and Tsang Wing Hing Professor in Clinical Neuroscience, LKS Faculty of Medicine, HKU Convenor, Task Force on Laws for Healthcare Practitioners, Professionalism and Ethics Committee, Hong Kong Academy of Medicine	
9:20 – 9:40	**Hong Kong's Overarching AI Policy and Governance** **Mr Brian Sun** Assistant Commissioner (Data Applications), Digital Policy Office, Government of the HKSAR
9:40 – 10:00	**Medical Innovation, R&D, Clinical Trials, Evidence Generation— and Where AI Sits within it** **Ms Joyce Kok** Deputy Secretary for Health, Health Bureau, Government of the HKSAR
10:00 – 10:20	**On-Going Developments in Medical Device Regulation in Hong Kong** **Mr Leo Wong** Chief Electronics Engineer (Medical Device), Department of Health, Government of the HKSAR
10:20 – 10:50	Roundtable Discussion
10:50 – 11:10	Intermission (Tea Break)
Session 2: Global Developments in the Regulation and Governance of Medical AI **Moderator:** **Prof Eric C. Ip** Co-Director and Research Fellow, Centre for Medical Ethics and Law, HKU Professor, Faculty of Law, HKU	

11:10 – 11:30	**Framing the Ethics of Medical AI with a Focus on Human Dignity and Physician Responsibility** **Prof Carl Hildebrand** Assistant Professor, Medical Ethics and Humanities Unit, School of Clinical Medicine, LKS Faculty of Medicine, HKU Research Fellow, Centre for Medical Ethics and Law, HKU
11:30 – 12:00	**A Global Overview on AI Governance and the Australian Experience on AI Regulation** **Ms Chelsea Gordon** Legal Lead - AI Advisory, MinterEllison, Sydney, Australia **Prof Gilberto Leung** Co-Director, Centre for Medical Ethics and Law, HKU Director of the School of Clinical Medicine, Clinical Professor and Tsang Wing Hing Professor in Clinical Neuroscience, LKS Faculty of Medicine, HKU Convenor, Task Force on Laws for Healthcare Practitioners, Professionalism and Ethics Committee, Hong Kong Academy of Medicine
12:00 – 12:20	**China's Medical AI Governance: An Overview** **Prof Chunyan Ding** Professor, School of Law, City University of Hong Kong
12:20 – 12:50	Roundtable Discussion
12:50 – 14:00	Lunch
Session 3: Clinical Perspectives and Real-World Applications **Moderator:** **Prof Neeraj Ramesh Mahboobani** Convenor of the Task Force on Artificial Intelligence, Professionalism and Ethics Committee, Hong Kong Academy of Medicine Clinical Assistant Professor, Department of Imaging and Interventional Radiology, Faculty of Medicine, The Chinese University of Hong Kong Honorary Consultant, Department of Imaging and Interventional Radiology, Prince of Wales Hospital	
14:00 – 14:20	**Safe and Effective AI Adoption: Current Practices and Strategic Directions in Hong Kong's Public Hospitals** **Dr Michael Lap-gate Wong** Director (Quality and Safety), Hospital Authority
14:20 – 14:40	**Frontline Experience of Implementing AI Augmented Clinical Workflows at Scale** **Prof Neeraj Ramesh Mahboobani** Convenor of the Task Force on Artificial Intelligence, Professionalism and Ethics Committee, Hong Kong Academy of Medicine Clinical Assistant Professor, Department of Imaging and Interventional Radiology, Faculty of Medicine, The Chinese University of Hong Kong Honorary Consultant, Department of Imaging and Interventional Radiology, Prince of Wales Hospital

14:40 – 15:00	**How the Industry Thinks About Medical AI** **Dr Alexander Ng** President of Tencent Healthcare Head of Tencent AI for Life Sciences Lab Head of Tencent Inclusive Health Lab Honorary Professor, HKU Honorary Professor, The Chinese University of Hong Kong
15:00 – 15:30	Roundtable Discussion
15:30 – 15:50	Intermission (Tea Break)
Session 4: Shaping Medical Device Regulation for AI Development **Moderator:** **Dr Pete Mills** Director, PHG Foundation, The University of Cambridge	
15:50 – 16:20	**Are Medical Device Regulations AI-ready? Insights into Key Issues and Emerging Approaches from Around the World** **Mr Jamie Hearing** Senior Policy Analyst, PHG Foundation, The University of Cambridge **Dr Chaitanya Erady** Policy Analyst, PHG Foundation, The University of Cambridge **Ms Julia Weiyao Han** PhD Candidate in Law, Faculty of Law, HKU Visiting Scholar, PHG Foundation, The University of Cambridge
16:20 – 16:50	Roundtable Discussion
16:50 – 16:55	**Closing Remarks** **Prof Gilberto Leung** Co-Director, Centre for Medical Ethics and Law, HKU Director of the School of Clinical Medicine, Clinical Professor and Tsang Wing Hing Professor in Clinical Neuroscience, LKS Faculty of Medicine, HKU Convenor, Task Force on Laws for Healthcare Practitioners, Professionalism and Ethics Committee, Hong Kong Academy of Medicine

Presentation Abstracts and Biographies of Presenters

Presentation Title: Hong Kong's Overarching AI Policy and Governance

Mr Brian Sun
Assistant Commissioner (Data Applications), Digital Policy Office, Government of the HKSAR

Abstract:

Artificial intelligence (AI) reshapes public administration and societal engagement. Balanced governance is essential to unlocking innovation while safeguarding public trust. In Hong Kong, the Digital Policy Office (DPO) has promulgated a practical baseline for responsible adoption through the Ethical AI Framework and the Hong Kong Generative AI Technical and Application Guideline. While several industry sectors have begun establishing proactive tailored guidelines, deploying AI across specialised domains requires continuous improvement in how we manage risk and scale innovation.

To ensure inclusive societal benefit, the Government promotes the "AI for All" inclusive programme, driving targeted training across different tiers from the public with basic digital literacy, youth to talent and professional to promote awareness and culture, professional empowerment and practical training tailed to AI-workplace scenarios for enhancing efficiency and competitiveness.

This presentation examines how overarching policy principles can be reconciled with domain-specific demands. Closing the governance gaps requires active co-creation among key stakeholders, including regulators, public authorities, industry providers, technology developers and users to forge trusted, sector-specific guidance that ensures safe and sustainable AI adoption across Hong Kong.

Biography:

As the Assistant Commissioner (Data Applications) of the Digital Policy Office, Mr Brian Sun is responsible for leading major AI initiatives including the pilot of generative AI tools in the Government, the establishment of the Hong Kong AI Research and Development Institute, managing various central AI platforms as well as guidelines on ethical use and adoption of AI. Besides, he also oversees the provision of "iAM Smart" as a single digital identity of Hong Kong residents for authentication in online transactions and as a single portal for online government services, and implementation of data-related initiatives, including data governance principles, the open data policy, and various central data platforms such as the Open Data Portal, Consented Data Exchange Gateway, etc.

Presentation Title: Medical Innovation, R&D, Clinical Trials, Evidence Generation— and Where AI Sits within it

Ms Joyce Kok
Deputy Secretary for Health, Health Bureau, Government of the HKSAR

Abstract:
This talk sets out how Hong Kong's Health Bureau is building a health and medical innovation hub, linking discovery, clinical trials, regulatory evaluation, public healthcare deployment, and real-world evidence into a closing loop, and where AI fits within it. Since 2023, foundational steps have included ICH observership, the "1+" registration mechanism, the Centre for Medical Products Regulation, and the Hetao GBAICTI and BAYTRIAL "one institute, one center" collaboration model, which has cut trial initiation timelines significantly. Hong Kong's longitudinal electronic health records and the eHealth+ plan provide the data foundation for AI, while the Real-World Study and Application Centre is developing AI tools for patient-matching and trial-eligibility alerts. Apart from medical innovation, this talk also briefly sets out where AI sits in public healthcare, and discusses the key challenges and guiding principle in relation to AI application.

Biography:

Ms Joyce Kok joined the Hong Kong Special Administrative Region Government's Administrative Service in 2005. She has served in various bureaux and departments including the Home Affairs Department, the former Food and Health Bureau and the Financial Services and the Treasury Bureau. She was the Assistant Director of the Housing Department (Private Housing) in 2015 and then the Principal Assistant Secretary for Transport and Housing (Transport) in 2020. Miss Kok assumed the position of the Deputy Secretary for Health in July 2026. She is responsible for healthcare manpower planning, training and professional development of healthcare professionals, university teaching facilities related to healthcare manpower training, regulation of private healthcare facilities and regulation of pharmaceutical products.

Presentation Title: On-Going Developments in Medical Device Regulation in Hong Kong

Mr Leo Wong
Chief Electronics Engineer (Medical Device), Department of Health, Government of the HKSAR

Abstract:

With the vision of becoming an international health and medical innovation hub, Hong Kong, China, is advancing towards a new era of medical device regulation. Since 2004, the Department of Health (DH) has been implementing and enhancing the voluntary Medical Device Administrative Control System (MDACS) with a view to developing a statutory regulatory framework. Developed in line with international regulatory harmonisation principles, the MDACS adopts a risk-based approach to ensure that medical devices supplied locally meet recognised standards of safety, quality, and performance.

This presentation outlines Hong Kong's recent progress toward establishing a comprehensive and agile regulatory regime for medical devices. It highlights the latest measures to address the rapidly evolving landscape of medical technologies, including the challenges and opportunities presented by AI medical devices. It also provides an update on the DH's on-going efforts to facilitate the approval of eligible innovative medical devices and to foster a vibrant local medical technology ecosystem, with a view to advancing clinical excellence and improving patient outcomes.

Biography:

Mr Leo Wong is a seasoned electronics engineer with a distinguished career dedicated to public service in Hong Kong. He earned his degree from the Chinese University of Hong Kong in 2004 and achieved Corporate Membership with the Hong Kong Institution of Engineers (HKIE) in 2011.

Since joining the HKSAR Government as an Electronics Engineer in 2012, Mr WONG has taken on a series of critical projects directly impacting the community. His portfolio includes project design and management of control systems for sewage treatment works, implementation of radio and dispatch systems for the Fire Services Department, and regulation of lift and escalator safety.

In 2025, Mr WONG joined the Medical Device Division of the Department of Health, where he now serves as Chief Electronics Engineer (Medical Device). In this capacity, he leads the team responsible for drafting the upcoming legislation to regulate medical devices in Hong Kong. He also oversees education and promotional initiatives to ensure a smooth transition to the new regulatory framework, preparing stakeholders for this significant change.

Presentation Title: Framing the Ethics of Medical AI with a Focus on Human Dignity and Physician Responsibility

Prof Carl Hildebrand
Assistant Professor, Medical Ethics and Humanities Unit, School of Clinical Medicine, LKS Faculty of Medicine, HKU
Research Fellow, Centre for Medical Ethics and Law, HKU

Abstract:

Framing the Ethics of Medical AI with a Focus on Human Dignity and Physician Responsibility

This paper addresses two concerns in the ethics of medical artificial intelligence (AI). The first is algorithmic bias and the role of normative, or value-based judgment implicit in algorithmic decision making. The second is the nature of physician's role and authority alongside AI. A question running through each point is how to get the most from powerful AI systems, enabling optimal health outcomes, while respecting the dignity and unique value of each patient (an ethical question). A related question is how to engage these systems when we cannot wholly understand how they work (an epistemic question). In what follows, I argue that the value judgments in algorithmic design are unavoidable and should be made explicitly, and that medicine has good reason to make them in favor of the individual patient. I then argue that the physician is best understood as a responsible guarantor who vouches for machine outputs and is answerable to the patient for them. Two cases will be discussed to support this argument, one from criminal justice and one from nephrology, with a view to framing constructive and appropriately open-ended ethical deliberation moving forward.

Beginning with the first point, an early example of value judgment that is built in, regardless of intention, is the algorithmic risk-assessment tool COMPAS (Correctional Offender Management Profiling for Alternative Sanctions). This tool was developed by Northpointe to aid parole boards in making decisions about parole and the sentencing of defendants. Controversy emerged when a study by investigative journalists (ProPublica) concluded it was biased against black defendants. In retrospect, the likelihood of a black defendant who did not reoffend being assigned a high risk score was close to twice that of a white defendant who did not reoffend.[1] Scores were based on items that included criminal history like previous arrests, histories of family and associates, neighborhood and residency, employment status, and education levels among other things. While the algorithm (which remains proprietary) is not *directly* biased against black defendants, the items on which its scores are based serve as unintentional proxies for race in this case, lending credibility to the argument that the tool is *indirectly* biased against black defendants.

A relevant question here is whether such an outcome counts as unlawful or unethical discrimination. Under UK law, for example, individuals are protected from both direct and indirect forms of discrimination where they are treated unfavorably because of a protected characteristic such

[1] Alexandra Chouldechova, "Fair Prediction with Disparate Impact: A Study of Bias in Recidivism Prediction Instruments" in *Big Data* 5:2 (2017): 153-163.

as age, sex, or race.[2] Assigning higher risk scores and lengthier sentences to black individuals because they are black would be a form of direct discrimination. Doing the same because an individual belongs to a racial group which has been deprived of access to education could constitute indirect discrimination.[3] However, indirect discrimination is often upheld as justifiable where it can be shown to be necessary in supporting a sufficiently important objective.[4] Sentencing criminals with a risk of reoffending is likely to be considered sufficiently important for purposes of public safety, so if a tool like COMPAS indirectly discriminates, its use is likely to be upheld in most jurisdictions.[5]

This is what happened in *State v. Loomis* where Eric Loomis, who pled guilty to attempting to flee a traffic officer and using a motor vehicle without the owner's consent, claimed COMPAS violated his due process rights. "Because COMPAS reports provide data relevant only to particular groups and because the methodology used to make the reports is a trade secret, Loomis asserted that the court's use of the COMPAS assessment infringed on both his right to an individualized sentence and his right to be sentenced on accurate information."[6] The courts denied this motion. They stressed both the importance of individualized sentencing and the tool's value as a statistical aid in decision-making the outcome of which (i.e., the final decision) remains the responsibility of a human judge.

This shines a spotlight on the ethical tension in this technology and algorithmic decision-making generally. We can observe a possible tradeoff in incommensurable normative priorities (or rankings of value), where application of the algorithm implies a judgment that has been made in advance about the values in question. This can be described broadly as a tension between dignity- or rights-based and aggregative (e.g., consequentialist) modes of ethical reasoning. For example, COMPAS provides risk assessments of individuals based on empirical data about recidivism risks for the group to which they belong. The predictive accuracy of these assessments may hold up when applied to the group, so that retrospectively the decision to use them is justified. This is insofar as the results are viewed in aggregate, something the consequentialist framework validates insofar as it prioritizes good consequences measured this way.

The shortcoming, or problem, is that this does not treat the individual as unique, judging them instead in virtue of social categories which in this case serve as a proxy for race. This is what John Rawls famously expressed in saying that utilitarianism, a form of consequentialism, "does not take seriously the distinction between persons."[7] This mode of thinking runs contrary to dignity-centered frameworks that emphasize the unique, equal, and independent value of each human being.[8] It should

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[2] *Equality Act*: https://www.legislation.gov.uk/ukpga/2010/15/section/19.
[3] Binesh Hass, "AI and Discriminatory Intent" in *AI Morality*, edited by David Edmonds (Oxford: Oxford University Press, 2024), 43.
[4] Tarunabh Khaitan, *A Theory of Discrimination Law* (Oxford: Oxford University Press, 2015), 75.
[5] Hass, "AI and Discriminatory Intent," 45. One response is to shift the basis of discrimination's directness away from intention and toward effects, arguing that discrimination can be direct even where unintentional provided its effects on the protected individual are significant enough (note the discussion of James v. Eastleigh Borough Council). Note also the availability of the but-for test: "but for the failure to debias for race, Amir would not have received, on account of the AI instrument's prediction of recidivism, a harsher sentence than Jeff" (Hass, 47).
[6] "State v. Loomis" in *Harvard Law Review* 130: 5 (2017): 1531.
[7] John Rawls, *A Theory of Justice revised edition* (Cambridge, MA: Harvard University Press, 1999), 24.
[8] This can be traced to Immanuel Kant's formula of humanity (see his *Groundwork of the Metaphysics of Morals revised edition* translated by Mary Gregor and Jens Timmermann (Cambridge: Cambridge University Press, 2012), 4:429) and finds expression in the UNESCO *Universal Declaration on Bioethics and Human Rights* and other documents. Where the

be obvious that justice and healthcare systems alike ought to treat individuals as individuals. But one might argue that the risk in prioritizing the unique value of persons is that empirically verifiable (in aggregate) data, a valuable resource, is forgone along with the transparency and efficiency it brings to the decision-making process. In *State v. Loomis*, the courts sought to endorse the value of both frameworks simultaneously and by requiring the tool to be subordinate to human judgment attempted to preserve the unique value (and rights) of individuals. This may not be so easy, however, as the apparent rationality and anchoring effect of empirical assessments on decisions is often hard to resist, creating concerns around bias of another kind.[9]

A different course was pursued by the medical community in response to bias in algorithms used to measure kidney function via estimated glomerular filtration rate (eGFR). Here, the algorithm had been adjusted for race, assigning black individuals higher eGFR values based on evidence that members of the black population release more creatinine into their blood at baseline due to greater muscle mass.[10] The problem, much like in the COMPAS case, is that this may be true in aggregate, i.e. at a population level, while it is not true for many individuals within the same population. While the intention is to provide more accurate assessments of kidney function, an approach which has been defended on ethical as well as medical grounds (a misdiagnosis of kidney disease could affect ability to attain life insurance), a result is that some black individuals will suffer delayed referral or transplantation because of an adjustment that does not reflect their individual case.[11] This could lead to poorer health or death. A further uncomfortable feature of this case is that, unlike COMPAS, the algorithm measuring eGFR targets race directly. This raises further reasonable concerns about the reinforcement of structural inequality and injustice (racism) in the healthcare system.[12]

Contrary to *State v. Loomis*, after deliberation a joint task force of the National Kidney Foundation and American Society of Nephrology recommended a race-free equation which was then widely adopted.[13] It is notable that this is a value-based decision.[14] While there were also good medical reasons to reject race-based correction in the algorithm, the decision was guided by a deeper desire to uphold the equal and independent value of persons, particularly those in need of protection from the effects of injustice for historical reasons. The point to land on here is that normative (value-based) decisions are inescapable where algorithmic assessments concern the human good, because letting the algorithm run without intervention or oversight prioritizes one form of good over another, which in this case can be interpreted as the good of the whole (consequentialist justification) over the good of

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term 'dignity' is not used, autonomy can very roughly be substituted given our purposes here (e.g. see the first ethical principle of the WHO's *Ethics and Governance of AI for Health*, viii-ix).

[9] "State v. Loomis," 1536.

[10] Vyas et al., "Hidden in Plain Sight – Reconsidering the Use of Race Correction in Clinical Algorithms" in *The New England Journal of Medicine* 383: 9 (2020): 875.

[11] For a defense of race adjustment on medical and ethical grounds, see Neil Powe, "Black Kidney Function Matters" in *JAMA* 324: 8 (2020): 738.

[12] Dorothy Roberts, "Abolish Race Correction" in *The Lancet* 397 (2021): 17-18.

[13] Cynthia Delgado et al., "A Unifying Approach for GFR Estimation: Recommendations of the NKF-ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Disease" in *Journal of American Society of Nephrology* 32 (2021): 3011.

[14] As evidenced in the purpose of the task force: the "rationale for the task force includes the following: race is a social and not a biologic construct, the problematic nature of applying race to clinical algorithms, and the need to advance health equity and social justice" (ibid., 2995).

the individual (dignity or rights-based justification). From an ethical and regulatory point of view, therefore, a decision needs to be made about which way to go, and why and in what manner to do so.

The above decision from the American medical community communicates that respect for the equal dignity of persons, and a level of care appropriate to that, is a deep feature of the medical profession. More than with other professions, medicine functions as a moral community, because of the unique vulnerability and therefore trust with which patients approach physicians and other members of the healthcare profession.[15] Informed consent, an ethical cornerstone of modern medicine, is a statement of the profession's fidelity to this trust and its fidelity to patients.[16] This is the ethical core of good medical practice, running deeper than a superficial application of the established (and otherwise sound) four principles.[17]

The moral-epistemic context is more complicated where Large Language Models (LLMs) are used instead of regression models, due to the black box that deep learning entails. However, the mechanism of the bias as observed, for example, in the regression models above does not change (nor does the ethical core of good medical practice). The difference is that similar biases may go undetected because whether and where they are in the model cannot be traced. Of greater concern here is the black box nature of decision-making generally in applications involving LLMs. For it is difficult to trust decisions the justification of which it is impossible to understand. Further to this, philosophers point out a "testimony gap" insofar as machines cannot assert claims (speech acts) because they cannot be held morally responsible for them, so a human is needed to fill the gap by vouching for the machine.[18] This implies a responsibility gap, too, which should also be filled by a human, unless we are comfortable with the idea that no one is responsible for machine outputs.[19]

In the medical profession, this gap is filled where physicians (a) vouch for machine outputs while (b) taking responsibility for the patients these outputs concern. In this sense, an AI can be thought of as a creative diagnostic partner, stimulating reflection and opening possibilities that might otherwise have been ignored. While it may be impossible to understand the reasoning behind a LLM's output, a competent physician can discern plausible diagnoses that might differ from their own diagnosis and articulate the reasoning behind them. While this is not the same as understanding the model's reasoning, it provides a justification the physician can stand behind and be held responsible for. In this way, the physician can act as a *guarantor* of correct medical knowledge, whether that knowledge is presented to them by a LLM directly or by a patient who has been consulting one in private. In the language of epistemology, the physician retains *epistemic authority*, because the patient can rationally take the

[15] Edmund Pellegrino and David Thomasma, *The Virtues in Medical Practice* (New York: Oxford University Press, 1993), 35-37.
[16] Paul Ramsey, *The Patient as Person* (New Haven: Yale University Press, 2002), 5.
[17] Though Beauchamp and Childress of course recognize the value of trust and trustworthiness in medicine (see Tom Beauchamp and James Childress, *Principles of Biomedical Ethics 9th edition* (Oxford: Oxford University Press, 2026), 43-44).
[18] Robert Sparrow and Gene Flenady, "The Testimony Gap: Machines and Reasons" in *Minds and Machines* 35: 12 (2025): 12.
[19] Responsibility rests on embodiment, membership in a sociocultural community, and susceptibility to the reactive attitudes (ibid.). See also Elizabeth Fricker, "On the Metaphysical and Epistemic Contrasts Between Human and AI Testimony" in *Inquiry* 69: 6 (2026): 2859-2884.

physician's judgment to preempt the outputs of a LLM or other AI.[20] This is grounded formally in their professional standing (more broadly based in social contract) and substantively in their understanding and medical expertise.

In this way, the physician assumes responsibility both for the knowledge they share, as embodied in the advice they give, and the patients with whom they share it. This is a feature of human communication and relationships that AI cannot replicate, and it is consistent with the ethical core of good medical practice mentioned above. If anything, this makes the physician's job more intellectually challenging and robust, as responsibility over AI should be well-based (even as deleterious forms of cognitive offloading are increasingly tempting, another puzzle for the profession to address in due course). In recent years, the medical community has signaled its commitment to prioritizing dignity-centered ethical reasoning over a general maximization of good consequences (perhaps in part to atone for its complicity in historical wrongs like Tuskegee). The argument here is that this is the right direction to go, and a good way to frame deliberation on medical applications of AI going forward. Trust and responsibility are at the core of good medical practice and AI does not change this. To warrant this trust, physicians and other healthcare professionals must treat the patient as an individual, vouching for machine outputs as their own and remaining answerable to the patient for them.

Biography:

Prof Carl Hildebrand is Assistant Professor at the Medical Ethics and Humanities Unit, School of Clinical Medicine, LKS Faculty of Medicine, University of Hong Kong, and Research Fellow at the Centre for Medical Ethics and Law. He holds a DPhil in Philosophy from the University of Oxford. His research sits at the intersection of bioethics, moral psychology, and the philosophy of medicine. He has published on the nature of empathy, moral character and emotion, and the ethical implications of artificial intelligence in healthcare, including work on LLMs and informed consent. Current research focuses on the evolving doctor-patient relationship in the age of clinical AI. Other projects engage philosophical questions related to forgiveness, moral trauma, and friendship among other things. Carl teaches medical ethics to MBBS students at The University of Hong Kong; he is the Coordinator of the Medical Ethics and Law curriculum for MBBS Year 1 and Graduate Entry Track programs.

[20] Following Linda Zagzebski and her adaptation of Raz in Zagzebski, *Epistemic Authority* (Oxford: Oxford University Press, 2012), 107.

Presentation Title: A Global Overview on AI Governance and the Australian Experience on AI Regulation

Ms Chelsea Gordon
Legal Lead - AI Advisory, MinterEllison, Sydney, Australia

Prof Gilberto Leung
Co-Director, Centre for Medical Ethics and Law, HKU
Director of the School of Clinical Medicine, Clinical Professor and Tsang Wing Hing Professor in Clinical Neuroscience, LKS Faculty of Medicine, HKU
Convenor, Task Force on Laws for Healthcare Practitioners, Professionalism and Ethics Committee, Hong Kong Academy of Medicine

Abstract:

Australia has not introduced an AI Act. Instead it is relying on pre-exiting laws to govern artificial intelligence, with specific uplifts. This legal framework is complimented by regulator guidance, with regulators playing an active role in shaping businesses' understanding of how existing legal frameworks apply to their procurement, deployment, and ongoing use of AI systems. Chelsea will explore the role of key regulators in healthcare in Australia, including the Therapeutic Goods Administration and Health Practitioner Regulation Agency. This presentation will explore Australia's approach to regulation of AI systems through:

· briefly considering the threshold questions around identifying AI systems and the new legal risks they create;
· outlining the regulatory landscape in Australia generally as it relates to AI systems, and specifically as it related to AI in context of Australian healthcare;
· focusing on regulation of medical devices in the context of healthcare tools which are increasingly initialising AI system capabilities; and
· discussing recent developments around regulation of AI systems in Australia.

Biographies:

Ms Chelsea Gordon
Ms Chelsea Gordon is the Legal Lead in MinterEllison’s AI Advisory team and excels in AI regulation, governance and Responsible AI. Chelsea enables clients to maximise AI opportunities while mitigating legal risks. She has deep expertise in health and life sciences, including health regulation, novel technology, health funding, service contracting, clinical trials, and therapeutic goods.

Chelsea is a strategic thinker, who advises organisations about how to implement AI and other emerging technologies to achieve legally sound, commercial and strategic outcomes.

As a Legal Lead in MinterEllison’s AI Advisory practice, Chelsea guides boards and executive teams on AI governance frameworks, Responsible AI implementation and regulatory compliance.

She supports clients in developing privacy and contract settings that protect personal information and intellectual property and align with AI risk management and ESG obligations. Chelsea advises ASX-listed companies and government across regulated sectors, including healthcare, education and financial services.

Chelsea also serves as the Australian Ambassador for the Global Council of Responsible AI, reflecting her leadership in shaping AI ethics, policy and best-practice governance.

Prof Gilberto Leung

Prof Gilberto Leung is a neurosurgeon, Clinical Professor, and Tsang Wing-Hing Professor in Clinical Neuroscience at the University of Hong Kong (HKU). He graduated from the University of London with M.B.B.S. in 1992 and joined HKU in 2005, where he later obtained his MS, PhD, and MD degrees. He currently serves as Director of the School of Clinical Medicine and Convenor of the Clinical Neuroscience Consortium at the HKU Faculty of Medicine. He is the Immediate-Past President and Honorary Fellow of the Hong Kong Academy of Medicine; Council Member of the Medical Council of Hong Kong; and Convenor of the Institute for Medical Advancement and Clinical Excellence (IMACE). He holds an LLB from the University of London and an LLM in Medical Law and Ethics with Distinction from the University of Edinburgh. He is Co-Director of the Centre for Medical Ethics and Law (CMEL) at HKU; Convenor of the Task Force for Laws for Healthcare Professionals at the Hong Kong Academy of Medicine; and Chairman of the Clinical Ethics Committee of the Hospital Authority Hong Kong Island Cluster.

Presentation Title: China's Medical AI Governance: An Overview

Prof Chunyan Ding
Professor, School of Law, City University of Hong Kong

Abstract:

This presentation provides an overview of China's governance framework for medical AI, covering AI-enabled tools used in diagnosis, medical image analysis, drug development, and other healthcare applications. China has not enacted dedicated legislation specifically for medical AI. Instead, it adopts a multi-layered regulatory approach that integrates formal laws, administrative regulations, technical guidelines, and industry consensus. The framework is built on four core principles: human-centred responsibility, with AI serving as an assistive tool; full-lifecycle governance; the prioritisation of data security and personal rights protection; and multi-stakeholder co-governance. In practice, China applies risk-based classification, market access controls combined with post-market surveillance, institutional oversight mechanisms, and a mix of hard and soft law instruments. Despite these measures, several challenges persist. These include ambiguous allocation of tort liability among multiple parties, unclear regulatory boundaries for general-purpose medical large models, limited enforceability of industry soft norms, and the absence of clear statutory standards for algorithmic fairness and explainability. Further refinement of targeted liability rules and specific regulations for large models is therefore needed.

Biography:

Prof Chunyan Ding is a Professor at the School of Law at the City University of Hong Kong. She obtained an LLB and LLM at Peking University, an LLM at University College London, and PhD at the University of Hong Kong. She became a qualified PRC lawyer in 2001. Before joining the City University of Hong Kong in 2010, Ding was a Fulbright research fellow at Harvard Law School, where she conducted research on comparative health law and tort law in 2008-09. She was an elected visiting scholar at the Max Planck Institute for Comparative and International Private Law in 2022-23. Her primary areas of research and teaching include tort law, health law, data protection and AI regulation, and Chinese and comparative civil law. She has authored *Medical Negligence Law in Transitional China* (2012) and co-edited *Chinese Ethical and Legal Perspectives on Automated Vehicles* (2025). She has published over fifty journal articles and book chapters in her research fields.

Presentation Title: Safe and Effective AI Adoption: Current Practices and Strategic Directions in Hong Kong's Public Hospitals

Dr Michael Lap-gate Wong
Director (Quality and Safety), Hospital Authority

Abstract:

Artificial intelligence (AI) is fundamentally reshaping healthcare delivery. In Hong Kong's public hospitals, the adoption of medical AI is driven by a commitment to enhancing clinical efficacy, patient safety, and operational resilience. This presentation explores the current practices of AI integration within the public healthcare system, highlighting active applications such as AI-assisted diagnostic imaging, predictive analytics for patient deterioration, and smart clinical triaging.

Crucially, the discussion will examine the strategic directions guiding this digital transformation. We will outline the robust governance frameworks required to safely transition AI tools from localized pilot phases to enterprise-wide deployment, emphasizing the necessity of rigorous clinical validation, localized data training, and continuous post-implementation monitoring. Furthermore, the presentation will address the evolving professional responsibilities of clinicians in an AI-augmented environment. By maintaining a strict "human-in-the-loop" paradigm, Hong Kong's public hospitals aim to foster clinical trust, ensure accountability, and pave the way for comprehensive professional guidelines in medical AI.

Biography:

Dr Michael Lap-gate Wong is currently the Director of Quality and Safety of the Hospital Authority (HA). Under his leaderships, the Quality & Safety Division oversees the quality standards, patient safety, clinical incident management, patient relations management, healthcare technology assessment, disasters response and infection control for the public hospitals under HA.

Dr Wong is a specialist in haematology & haematological oncology, and has also attained fellowship qualification in pathology. Prior to his current appointment, he has been the Chief Manager (Cluster Performance) in Head Office, Chief Manager of Kowloon West Cluster, Deputy Hospital Chief Executive of the North Lantau Hospital and Deputy Hospital Chief Executive (Operation) of Princess Margaret Hospital.

Presentation Title: Frontline Experience of Implementing AI Augmented Clinical Workflows at Scale

Prof Neeraj Ramesh Mahboobani
MBBS (HK), FRCR, FHKCR, FHKAM (Radiology)

Convenor of the Task Force on Artificial Intelligence, Professionalism and Ethics Committee, Hong Kong Academy of Medicine

Clinical Assistant Professor
Department of Imaging and Interventional Radiology, Faculty of Medicine
The Chinese University of Hong Kong

Honorary Consultant
Department of Imaging and Interventional Radiology, Prince of Wales Hospital

Abstract:

Artificial intelligence has the potential to significantly transform healthcare, the extent of this however hinges on the challenging topic of implementation science for successful integration with clinical workflows.

This presentation will discuss the frontline experience of implementing an automated AI augmented workflow for the screening and detection of intracranial haemorrhage in patients presenting to Accident & Emergency Departments of public hospitals in Hong Kong. It will describe the motivation to adopt AI for workflow augmentation starting in a single hospital, the process of validation, establishment of proof-of-concept, and workflow covering network infrastructure, data and cyber security, and user access control, with means and strategies adopted to subsequently scale up to cover 17 hospitals. It will cover important aspects around multidisciplinary collaboration, governance, and engagement of various stakeholders which are vital to successful implementation.

Biography:

Prof Neeraj Ramesh Mahboobani is a Clinical Assistant Professor in the Department of Imaging & Interventional Radiology, Faculty of Medicine, The Chinese University of Hong Kong and Honorary Consultant radiologist in the Department of Imaging & Interventional Radiology at Prince of Wales Hospital in Hong Kong SAR.

He obtained his fellowship in 2017, upon which he was awarded the Dr FL Chan medal by the Hong Kong College of Radiologists for his outstanding performance during his training. He was also awarded the Certificate of Excellence as a Distinguished Young Fellow by the Hong Kong Academy of Medicine in 2018, the Hospital Authority Young Achiever Award in 2023, and was recognized as one of the Ten Outstanding Young Persons of Hong Kong in 2023. He also received the Vocational Service Excellence Award from The Rotary Club of Kowloon Golden Mile in 2024.

He is an interventional neuroradiologist by clinical background and training. After joining CUHK in 2025, he is expanding his expertise to developing and testing new imaging biomarkers for various

cancer screenings and diagnosis. He is also developing AI and magnet-based needle guidance systems for image guided interventions.

He has been actively involved in the use and adoption of Artificial Intelligence in Radiology. He is the Convenor of the Task Force on Artificial Intelligence under the Hong Kong Academy of Medicine and the Chairman of the Artificial Intelligence Subcommittee of Hong Kong College of Radiologists. He played a central role in the implementation of AI for the detection of acute intracranial haemorrhage and midline shift on non-contrast CT brain scans in 17 public hospitals in Hong Kong.

Presentation Title: How the Industry Thinks About Medical AI

Dr Alexander Ng
President of Tencent Healthcare
Head of Tencent AI for Life Sciences Lab
Head of Tencent Inclusive Health Lab
Honorary Professor, HKU
Honorary Professor, The Chinese University of Hong Kong

Biography:

Dr Alexander Ng is President of Tencent Healthcare, and heads Tencent's AI for Life Sciences Lab and Inclusive Health Lab. He leads the development of integrated online-offline medical services, AI-powered self-care tools, and AI models for drug discovery and disease screening. Alex also severs as an Honorary Professor at the University of Hong Kong and The Chinese University of Hong Kong. Previously, he contributed to global health as a member of the World Health Organization's Digital Health Technical Advisory Group, where he provided expert consultation on ethical AI and digital health policies. Prior to Tencent, he was Deputy Director for Health Innovation at the Bill & Melinda Gates Foundation and an Associate Partner at McKinsey & Company. He holds a medical degree from the University of Auckland, a postgraduate diploma in health informatics from the University of Otago, and an MPH from Harvard.

Presentation Title: Are Medical Device Regulations AI-ready? Insights into Key Issues and Emerging Approaches from Around the World

Mr Jamie Hearing
Senior Policy Analyst, PHG Foundation, The University of Cambridge

Dr Chaitanya Erady
Policy Analyst, PHG Foundation, The University of Cambridge

Ms Julia Weiyao Han
PhD Candidate in Law, Faculty of Law, HKU
Visiting Scholar, PHG Foundation, The University of Cambridge

Abstract:

This presentation will share interim findings from a policy-focused research paper exploring opportunities for proportionate regulation and governance of medical AI in Hong Kong. It draws on issues encountered by medical device regulators in the USA, UK, EU, and China, among others, and their approaches to AI at different points in the regulatory pathway. Based on our analysis, we will present a series of considerations for medical device regulation. First, the questions of which AI applications qualify as a medical device and how to classify the different levels of risk they entail. Both are essential for determining the amount of regulatory scrutiny that is applied. In contrast to conventional medical devices, the potential for AI to adapt once it has been deployed raises additional considerations. Regulatory responses to this at both pre- and post-market stages, including requirements for post-market surveillance, will be discussed. Aside from these pathway considerations, a broader question asked of regulators about how to support innovation in AI without undermining patient safety will be explored. The presentation will conclude with prompts for discussion on the most relevant considerations in Hong Kong.

Biographies:

Dr Chaitanya Erady

Dr Chaitanya Erady is a Policy Analyst at PHG working on how emerging technologies, including AI, can help shape equitable, data-driven healthcare. At the PHG Foundation, she has evaluated large-scale international genome projects, conducted systematic reviews of novel biomarkers for cardiovascular disorders, and conducted market analyses for new rare disease therapies. She has contributed to consultations for the NHS and other UK-based organisations on the future of omics technologies and assessed the potential of AI and novel computing methods in accelerating healthcare delivery. Notably, she co-led a 25-delegate interdisciplinary stakeholder roundtable on AI and multiomics, as well as a 220-delegate workshop on wearables as part of the Cambridge Wearables Innovation Forum. More recently, she conducted research on global regulatory and legislative approaches to medical AI.

She holds a PhD in Psychiatric Genetics from the University of Cambridge for her machine-learning-based analysis of multiomic data from neuropsychiatric samples, and has supported market analysis and technology deployment in the UK and LMICs for charities and start-ups.

Mr Jamie Hearing

Mr Jamie Hearing is a senior policy analyst at the PHG Foundation, a not-for-profit consultancy based in Cambridge, UK. He works on ethical, regulatory and governance dimensions of health innovation, mainly in relation to genomics, data and AI. Via PHG's projects, he has collaborated with a range of people and organisations, including academics, clinicians, health system leaders, policy makers and regulators.

Ms Julia Weiyao Han

Ms Julia Weiyao Han is a PhD Candidate in Law at the University of Hong Kong. She was a Visiting Scholar at the PHG Foundation, University of Cambridge, in 2026, where she conducted research on the comparative regulation of AI-enabled medical devices.

Moderators

Prof Gilberto Leung
Co-Director, Centre for Medical Ethics and Law, HKU
Director of the School of Clinical Medicine, Clinical Professor and Tsang Wing Hing Professor in Clinical Neuroscience, LKS Faculty of Medicine, HKU
Convenor, Task Force on Laws for Healthcare Practitioners, Professionalism and Ethics Committee, Hong Kong Academy of Medicine

Prof Eric C. Ip
Co-Director and Research Fellow, Centre for Medical Ethics and Law, HKU
Professor, Faculty of Law, HKU

Prof Eric C. Ip (DPhil, University of Oxford) is a public health bioethicist and Professor at the Centre for Medical Ethics and Law, The University of Hong Kong (HKU).

His work on the law and ethics of population health has appeared in *The Lancet Public Health*, *The Lancet Planetary Health*, *American Journal of Public Health*, *Journal of Law and the Biosciences*, *Medical Law Review*, *Journal of Medical Ethics*, *Health Economics, Policy and Law*, and *Public Health Ethics*. He is pioneering a new paradigm of planetary health law, which helps to develop a more coherent legal regime that addresses, among other things, the implications of the climate crisis on health and human rights. He teaches global health law for the Li Ka Shing Faculty of Medicine at HKU.

Prior to joining HKU, Prof Ip taught at University College London (UCL) and the Chinese University of Hong Kong (CUHK), where he served as Assistant Dean of the Faculty of Law. He has received the Young Researcher Award (2014) and Research Excellence Award (2015) from CUHK, and the Faculty Research Output Prize (2017), Faculty Outstanding Teaching Award (2018), University Research Output Prize (2020), Faculty Research Output Prize (2021), and University Outstanding Young Researcher Award (2021) from HKU, in recognition of his achievements in research or teaching.

Prof Neeraj Ramesh Mahboobani
Convenor of the Task Force on Artificial Intelligence, Professionalism and Ethics Committee, Hong Kong Academy of Medicine
Clinical Assistant Professor, Department of Imaging and Interventional Radiology, Faculty of Medicine, The Chinese University of Hong Kong
Honorary Consultant, Department of Imaging and Interventional Radiology, Prince of Wales Hospital

Dr Pete Mills
Director, PHG Foundation, University of Cambridge

Pete Mills is the Director of the PHG Foundation, a not-for-profit consultancy specialising in 'making science work for health', and linked charity of the University of Cambridge. Originally trained in philosophy, Pete has worked for over 25 years at the intersection of emerging science, ethics and public policy, covering subjects including: assisted reproductive technologies and human embryo research, agricultural biotechnology, genomics and genomic medicine, genome editing, the use of data in healthcare and biomedical research, innovation

governance, human rights and public engagement. He has worked for the UK Government, in the regulatory sector (HFEA), and for an independent bioethical advisory body (the Nuffield Council on Bioethics), and served on many national and international committees and advisory groups. Pete's first degree was in Philosophy, Politics and Economics at the University of Oxford, and he has an MA and PhD in Philosophy from the University of Warwick.

About CMEL

CMEL
THE UNIVERSITY OF HONG KONG
CENTRE FOR MEDICAL ETHICS AND LAW

The Centre for Medical Ethics and Law (CMEL) develops new ideas and solutions in response to the big ethical, legal and policy questions of medicine and health. CMEL is the first cross-faculty interdisciplinary institution of its kind in the region. It was founded in 2012 by the LKS Faculty of Medicine and Faculty of Law at The University of Hong Kong as a joint inheritor of their vibrant intellectual traditions dating back to 1887 and 1969 respectively.

Today, CMEL brings together bioethicists, academic lawyers, medical scientists, and other scholars to conduct cutting edge bioethical and legal research and contribute to policy development in flagship areas like clinical care, population and global health, mental health and capacity, health technologies, and legal medicine and coroners' practice.

Research, teaching and knowledge exchange—CMEL's core initiatives—aim to ensure that developments in biomedicine and public health will be underpinned by ethical and legal considerations.

Centre for Medical Ethics and Law, The University of Hong Kong

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