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

Data Justice in One Digital Health

7-8 December 2023
Hong Kong & ZOOM

This meeting seeks to consider current trends in the digitalisation of One Health initiatives, particularly those directed at mitigating harms relating to antimicrobial resistance (AMR), and their implications on data justice (using Linnet Taylor's conception as a general reference point). Sub-themes that we hope to address in this conference includes: (1) Different conceptions of data justice in international law and global health ethics; (2) Barriers (technical and non-technical) to the effective use of digital tools (including artificial intelligence) in addressing AMR concerns; and (3) Policy and other measures that may be considered in response to the aforementioned barriers.

Thursday 7 December 2023

9:30-12:45: One Digital Health: Ethics & Law

14:00-18:30: One Digital Health & Antimicrobial Resistance

Friday 8 December 2023

9:00-13:15: AI & Big Data in One Digital Health

Thursday 7 December – AM
One Digital Health: Ethics & Law

11th Floor, Cheng Yu Tung Tower, HKU Centennial Campus

09:30-10:00 **Welcome and Introductory Presentation**

Calvin W.L. Ho。何維倫
Centre for Medical Ethics and Law, Faculties of Law & Medicine, The University of Hong Kong

Zohar Lederman
Li Ka Shing Faculty of Medicine, The University of Hong Kong

10:00-10:30 **Social License is a Problem for one Digital Health**
Mike King
Bioethics Centre, School of Medicine, University of Otago, Dunedin

10:30-11:00 **Digital One Health should First be about One Health**
Zohar Lederman
Li Ka Shing Faculty of Medicine, The University of Hong Kong

11:00-11:15 **Intermission**

11:15-11:45 **Big Data Research Ethics**
Ji Ping。吉萍
Clinical Research Institute, Shenzhen-PKU-HKUST-Medical Center, Shenzhen

11:45-12:15 **Antimicrobial Resistance, One Health, Law and Policies**
Claire Lajaunie
French Institute of Health and Medical Research INSERM

12:15-12:45 **Analysing Antimicrobial Resistance as a Series of Interdependent Collective Action Problems**
Isaac Weldon
Centre for Law, Medicine, and Life Sciences at the Faculty of Law, University of Cambridge

12:45-14:00 **Lunch**

Thursday 7 December – PM
One Digital Health & Antimicrobial Resistance

Seminar Room 8.24, 8th Floor, Cheng Yu Tung Tower, HKU Centennial Campus

14:00-14:30 **Challenges in Establishing a Nationwide Antimicrobial and Antimicrobial Resistance Monitoring System in New Zealand's Companion Animal Sector: Insights from Stakeholder Interviews**
Nic Liebergreen
Bioethics Centre, School of Medicine, University of Otago, Dunedin

14:30-15:00 **Microbiome Research and Antibiotic Resistance: Help, Hope, and Hype**
Yonghui Ma。马永慧
Center for Bioethics, School of Medicine, Xiamen University

15:00-15:30 **Data Justice in Pathogen Genomics Surveillance**
Elyssa Liu
Centre for Outbreak Preparedness (COP), Duke-NUS Medical School, Singapore

15:30-15:45 **Intermission**

15:45-16:15 **Studying Antimicrobial Resistance at the Human–Animal Interface: Lessons Gained from Field Studies**
Serge Morand
HealthDEEP, at CNRS, Mahidol University, and Kasetsart University, Bangkok

16:15-16:45 **Competing Sectoral Goods, Zoonotic Antimicrobial Resistance and the Datafication of Agriculture**
Chris Degeling
Australian Centre for Engagement, Evidence and Values, University of Wollongong, Sydney

16:45-17:15 **Understanding the Risk of Spillover Across Landscapes**
Alice C. Hughes
School of Biological Science, The University of Hong Kong

17:15-17:30 **Intermission**

17:30-18:00 **Data Justice for Human Research Participants: Perspectives from the African Continent**
Edith Madela-Mntla
Department of Family Medicine, School of Medicine, University of Pretoria

18:00-18:30 **Public Engagement towards Data Justice: Embedding Participatory Governance into a One Digital Health Framework for Addressing Antimicrobial Resistance**
Kalina Kamenova
Canadian Institute for Genomics and Society, Toronto

19:00 **Dinner**

Friday 8 December 2023
AI & Big Data in One Digital Health

11th Floor, Cheng Yu Tung Tower, HKU Centennial Campus

09:00-9:30 **The Promise and Risks of Using Artificial Intelligence to Develop and Deliver New Antibiotics**
Rohit Malpani
Global Antibiotics Research and Development Partnership & World Health Organization, Geneva

9:30-10:00 **Can We Leverage Electronic Health Records to Improve Antimicrobial Resistance Surveillance System in Hong Kong?**
Celine S.L. Chui
School of Nursing & School of Public Health, LKS Faculty of Medicine, University of Hong Kong

10:00-10:30 **One Health & AI: Legal Paradigms in Research**
Barry Solaiman
College of Law, Hamad Bin Khalifa University, Doha

10:30-11:00 **Barriers to The Effective Use of Digital Tools in Addressing AMR Concerns: Perspective from Responsibility**
Yali Cong
Department of Medical Ethics and Health Law, Health Science Center, Peking University, Beijing

11:00-11:15 **Intermission**

11:15-11:45 **Global Governance of Benefit Sharing in "One Digital Health"**
Calvin W.L. Ho。何維倫
Centre for Medical Ethics and Law, The University of Hong Kong
Karel Caals
Centre for Biomedical Ethics, YLL School of Medicine, National University of Singapore

11:45-12:15 **Laws on Human Genetic Resources in China: Potential Impact on the Use of Human Genetic Data**
Li Du
Faculty of Law, University of Macau

12:15-12:45 **Respect for Persons & the Use of Biological Materials and Data in Research**
Jerry Menikoff
Centre for Biomedical Ethics, YLL School of Medicine, National University of Singapore

12:45-13:15 **Discussion & Closing Remarks**

Social License is a Problem for One Digital Health

One digital health requires the use of a range of digital technologies extant and emerging. It also likely requires the collection, sharing and use of information at scale. Use will likely include both public and private health measures. By the lights of one health there is a significant collective interest in achieving this, to the extent that health contributes to well-being, as well as personal benefit for all subjects of welfare (i.e. most people and many animals at least). However, most people have some interest in determining what information about them is collected, how it is collected, how it is used, and by whom. For these to work well and benefits to be realised, social license is needed. Social licence is the ongoing acceptance toward an activity and those conducting it. Social license may be difficult to achieve in digital one health due to its scale, the variety of stakeholders, the variety of technologies, and epistemic uncertainty, especially associated with use of AI. This is a problem for one digital health.

Mike King

Senior Lecturer & Head of Department, Bioethics Centre, School of Medicine, University of Otago, Dunedin

I am and senior lecturer at the Bioethics Centre. My research draws on my early academic experience in animal science as well as in moral and political philosophy. I lead a responsible research and innovation project within a broader project developing novel antimicrobials. I do research on the welfare and ethical treatment of animals in a range of contexts. Another strand is ethical treatment or use of 'novel beings', which can include artificial intelligence and robots. Past research includes regulation of reproductive and enhancement technologies, the treatment of human cadavers, and the ethics of facilitated aid in dying.

Digital One Health should First be about One Health

This paper argues that the field of Digital One Health (DOH) has started on the wrong foot, and if it wants to salvage itself, it should first understand and adopt the real normative core of OH, which is the ethical imperative to benefit humans, animals, and the environment. In making my case, I will first articulate what OH is all about. I will then critically review the literature on DOH, demonstrating that it has focused on the multi- or transdisciplinary aspect of OH while neglecting the ethical part.

Zohar Lederman

Postdoctoral Fellow, Medical Ethics and Humanities Unit, LKS Faculty of Medicine, University of Hong Kong

Zohar Lederman is an emergency medicine physician with a PhD in bioethics from the National University of Singapore and formal undergraduate training in the humanities with a focus on philosophy. He is currently a postdoctoral fellow at the Unit. Whenever not hiking or running, Zohar researches several topics in bioethics including loneliness and One Health Ethics. His work has been published in the top bioethics journals including the Journal of Medical Ethics, Bioethics, and Public Health Ethics.

Big Data Research Ethics

Abstract forthcoming

Ji Ping。吉萍

Deputy Director, Clinical Research Institute, Shenzhen-Peking University-The Hong Kong University of Science and Technology Medical Center, Shenzhen

Dr Ping Ji began her clinical research career as medical writer and monitor for industry in China after obtaining her PhD in 2006 at Cardiff University, UK. She developed her interests in medical research ethical review and human subjects protection since 2010. She took the role as director of Quality Assurance Office in Peking University Human Research Protection Program by 2016. Since 2016, she moved to Shenzhen for building clinical research support and supervision platforms for education & training, technological support, ethical review, and policy development with the support from the local health authority. Together with her colleagues, her team has made great achievements on developing regional clinical research infrastructure.

Antimicrobial Resistance, One Health, Law and Policies

International and regional organisations are developing strategies and action plans integrating the One Health approach to combat the antimicrobial resistance (AMR). We will present the different policies and how they are linked to the One Health Joint Plan of Action (2022–2026) of the Quadripartite (FAO, UNEP, WHO, WOAH) and to which extent they are aligned to the OHHLEP's Theory of Change. We will show how data are crucial for an effective implementation of a legislative framework in relation to AMR and why it is important to start from the field instead of starting from the existing legislation to develop enforceable rules, that will have an impact. We will also examine the ethical principles at stake when it comes to AMR and how they relate to the idea of justice.

Claire Lajaunie

Researcher, French Institute of Health and Medical Research INSERM

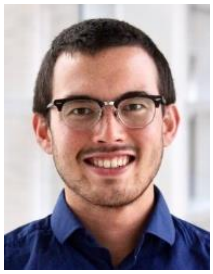
Claire Lajaunie, researcher in environmental law investigates the inter-linkages between biodiversity and health and their evolution due to global changes through the study on Global Environmental Law (at the different levels of decision-making, global to local level), governance and the associated ethical issues. Her research projects are based in Southeast Asia. She is working for the French National Institute of Health and Medical Research at the LPED, Marseille, France. She is Affiliate Researcher at the Strathclyde Centre for Environmental Law and Governance. Claire is in the roster of experts for the FAO as a Specialist of One Health. She is co-investigator on the project One Ocean Hub (UKRI, GCRF) and works on the One Health approach in relation to the ocean. She co-authored several publications and notably a book on "Biodiversity and Health: Linking Life, Ecosystems and Societies", 2017 Iste Press-Elsevier, co-edited a book on Biodiversity Conservation in Southeast Asia (Routledge, 2017) and a book on Law, public policies and complex systems: networks in action (Springer, 2019). Interested in the translation of scientific knowledge into policies, she is involved in the expert

working group on Biodiversity and pandemics for Eklipse, the European science-policy network for biodiversity and ecosystem services.

Analysing Antimicrobial Resistance as a Series of Interdependent Collective Action Problems

Antimicrobial resistance (AMR) causes over 1.27 million deaths annually, making it one of today's most urgent health threats. Given its urgency, there are calls for large-scale global initiatives to address AMR. However, collective action theory has yet to be applied to the problem in a systematic and coherent manner. Fuller engagement with collective action theory is necessary to avoid the risks of incorrectly characterizing the kinds of challenges that AMR presents; simplifying the problem by reducing it to a single type of collective action problem while ignoring others; and overstating the ability of collective action theory to formulate effective solutions. This paper relies on an analytical framework for collective action problems concerning public goods (i.e., goods that are non-excludable and non-rivalrous) and common goods (i.e., goods that are non-excludable and rivalrous). When analyzed with this framework, we find that the governance of AMR poses eight distinct collective action problems. This more granular framing of AMR provides, in our view, a better basis to develop policy solutions to address different aspects of AMR as a governance problem. We conclude with proposals for future research.

Isaac Weldon



Senior Research Associate, Centre for Law, Medicine, and Life Sciences, Faculty of Law, University of Cambridge

Isaac Weldon is a PhD Candidate in Political Science at York University, Toronto. He holds a Master of Science in International Health Policy (with Distinction) from the London School of Economics and Political Science as well as a Bachelor of Arts (First Class Honours) in History, Political Studies, and Economics from the University of Manitoba. Isaac's research uses political and social science methods to reveal novel ideas, innovative strategies, and transformative approaches for addressing global and planetary health challenges. He leverages interdisciplinary perspectives to investigate topics spanning the politics of global health governance, evidence use, nutrition policy, tobacco control, emerging health threats such as antimicrobial resistance (AMR), collective action, and Canadian foreign policy. His research has been featured in journals such as *The Lancet*, *American Journal of Public Health*, *Nutrition Reviews*, *International Journal, Global Public Health*, *Health Care Analysis*, and *Journal of Law, Medicine, and Ethics*, with a forthcoming manuscript in *Perspectives on Politics.*

Challenges in Establishing a Nationwide Antimicrobial and Antimicrobial Resistance Monitoring System in New Zealand's Companion Animal Sector: Insights from Stakeholder Interviews

Antimicrobial resistance (AMR) is a complex issue requiring a multisectoral One Health approach. While New Zealand has established systems for monitoring and understanding AMR and antimicrobial usage within the human healthcare context, a similar level of scrutiny is yet to be applied to the companion animal sector, despite the nation's high prevalence of pet ownership. While the human health sector enjoys accessible antimicrobial dispensing data and ongoing

surveillance of critical clinical AMR pathogens, the companion animal sector remains underexplored and under-monitored. Recent calls to establish a comprehensive monitoring system for companion animals have yet to translate into concrete action. This presentation draws upon interviews conducted with stakeholders in the companion animal sector in New Zealand. It aims to uncover the barriers and challenges that have hindered the development of a nationwide monitoring system for antimicrobial usage and AMR in companion animals and contributes valuable insights into the complexities surrounding AMR monitoring in this sector in New Zealand. It underscores the need for a coordinated effort to address this critical issue, but also draws attention to the potential tensions that may arise. This research serves as a foundation for future discussions and actions aimed at enhancing AMR monitoring in the companion animal sector and promoting health within a One Health paradigm.

Nicola Liebergreen

Assistant Research Fellow, Bioethics Centre, School of Medicine, University of Otago, Dunedin

A sociologist by trade, I work in the Bioethics Centre exploring societal and stakeholder attitudes towards novel antimicrobial development. My research is focused on the use of qualitative methodologies to inform policy and practice. I also work as a Senior Advisor Ethics for the New Zealand Ministry of Health. I have also conducted research into a variety of health and law topics, including the prevention of sexual abuse, patient attitudes towards drug tapering, reviewing the NZ Family Court 2014 reforms and experiences of relationship property division.

Microbiome Research and Antibiotic Resistance: Help, Hope, and Hype

The Emergence of Multi-Drug Resistant Organisms (MDROs) has become a serious public health problem. One standard approach to limit the spread of antimicrobial resistance is to reduce the unnecessary use of antibiotics, especially antibiotics that are the last line of defense against MDROs infections. Based on the new knowledge generated from human microbiome research, microbiome has increasingly been proposed as a tool and a target in the effort to address antimicrobial resistance, including strategies involving manipulation of the microbiome to deplete antibiotic resistance organisms or to enhance immune responses to vaccines may prove valuable, for example as fecal microbiota transplantation for recurrent and refractory C. difficile infections. This paper describes the intersections of microbiome science and antimicrobial stewardship, and ethics for the control and management of antimicrobial resistance. There are many considerations when evaluating microbiome intervention as a tool for antimicrobial stewardship programs to reduce antibiotic use as the potential benefits must be weighed against the known/unknown risks and long-term effects which for the patient and community.

Yonghui Ma。马永慧

Associate Professor, Center for Bioethics, School of Medicine, Xiamen University

Yonghui Ma is now Associate Professor on medical ethics/bioethics and also the Director of the Interdisciplinary Center for Bioethics at Medical School, Xiamen University. She had a bachelor degree on Medicine from Southeast University, MA from Peking Union Medical College, and obtained her PhD on bioethics from the University of Manchester in the

UK on 2013 (under full scholarship and supervised by Prof. John Harris). She is also member of International Association of Bioethics (IAB), member of Chinese Bioethics Association, editorial committee member of Nursing Ethics, Accountability in Research, Medicine and Philosophy, and Chinese Medical Ethics Journal. She serves as Institutional Review Board member (IRB, or Ethics consultants) in many tertiary hospitals in Xiamen as well as some other academic Institutions. Dr Ma's research interests focus on genetic ethics, clinical ethics, ethics of new biomedical technology, cross-cultural bioethics. She has published more than 35 peer-reviewed academic papers on American Journal of Bioethics (Target Article), BMC Medical Ethics, Nursing Ethics, Bioethics, Cambridge Quarterly of Healthcare Ethics, Journal of Bioethical Inquiry, Asian Bioethics Review, Experimental Dermatology, Protein & cell, as well as Chinese journals, e.g., Chinese Medical Ethics, Medicine and Philosophy, Chinese Medical Journal.

Data Justice in Pathogen Genomics Surveillance

In the last decade, and particularly since the COVID-19 pandemic, there has been global consensus on the importance of genomic pathogen surveillance in pandemic preparedness and response. Countries are increasingly utilising pathogen genomics to enhance surveillance and epidemiological investigations. Given the many legal and ethical issues around pathogen genomics surveillance, for example: the procurement and analysis of data, and issues around the sharing and storage of data, strong legal and regulatory frameworks are essential. The Asian Pathogen Genomics Initiative (APGI), hosted within the Centre for Outbreak Preparedness (COP) at Duke-NUS Medical School, Singapore, was established in late 2021, with the support of the Bill & Melinda Gates Foundation, to leverage scientific and technical partnerships in Singapore and across Asia to build the necessary capacities in the region. Our aim is to accelerate the application of pathogen genomic sequencing for early disease detection in Asia through four key objectives – Partnerships, Capacity Development, Enabling Environment and Monitoring & Research.

Elyssa Liu

Legal and Regulatory Specialist, Centre for Outbreak Preparedness (COP), Duke-NUS Medical School

Elyssa Liu, LL.M., LL.B. (Hons), is a Legal and Regulatory Specialist at the Centre for Outbreak Preparedness (COP) at the Duke-NUS Medical School in Singapore. With the Centre for International Law at NUS, Elyssa leads the legal pillar for COP's work on pathogen genomics surveillance and provides support to national and regional planning for pathogen genomics. She also leads the Centre's supply chain and procurement research and capacity development efforts. Elyssa has a decade of experience in global health, with previous roles at WHO, UNICEF, GOARN and other NGOs on health law and ethics, public health emergencies, preparedness and response, COVAX and ACT-A, bioethics and human rights. Elyssa has a Master of Laws in Global Health Law, a Bachelor of Laws with Honours, and is expecting a Master of Public Health in 2025.

Studying Antimicrobial Resistance at the Human–Animal Interface: Lessons Gained from Field Studies

We present the outcomes of several projects conducted in Southeast Asia to better understand the emergence and spread of antimicrobial resistance (AMR) at the interface between humans and animals (either domestic or wildlife). These projects raised several questions concerning study

design, implementation, ethics, information and samples collected, data management and potential policy impacts. Retrospective analysis highlight the need to better save all data collected during the preparation and realization of each project. These data are either qualitative, such as questionnaires, interviews, pictures, or quantitative, such as ecological, epidemiological and molecular data. Project proposals, methods, permits, ethics and individual consents need also to be preserved.

Serge Morand

Research Director, Health, Disease Ecology, Environment, and Policy (HealthDEEP), at the Centre National de la Recherche Scientifique (CNRS), Mahidol University, and Kasetsart University, Bangkok

Serge Morand is a disease ecologist with a background in evolutionary ecology and zoology. He is leading projects on the impacts of planetary changes (climate, land use, urbanization) on the links between biodiversity, health and societies in Southeast Asia. Researcher at the CNRS, he is the Director of the new International Research Unit "HealthDEEP" (Health, Disease Ecology, Environment and Policy) joining CNRS, Kasetsart University and Mahidol University in Thailand. He is a member of the One Health High Level Expert Panel (OHHLEP) of the One Health quadripartite (WHO, WOAH, FAO, UNEP).

Competing Sectoral Goods, Zoonotic Antimicrobial Resistance and the Datafication of Agriculture

Historically, efforts to increase the scale and efficiency in livestock production mainly rely on the datafication and standardisation of animals and farming systems. As global agriculture becomes increasingly financialised and bio-capitalised, production systems are becoming highly integrated (vertically and horizontally) such as to organise and control all aspects of the industry including medicines and pathogen surveillance systems. These structures and systems are explicitly oriented to maximise productivity, profitability and protect commercial interests. The One Health approach to antimicrobial resistance requires stakeholders to contribute to cross-sectoral efforts to minimise antibiotic use. Pathogenomic data and integrated human and animal surveillance systems show great promise in attenuating AMR risk to human and animal health but One Health policy implementation is challenging in livestock farming. As AMR emerged as a global health threat, antibiotic preservation and attempts to establish inter-species pathogen surveillance have come into tension with the organising logic of bio-capitalised agricultural intensification and the infrastructural role of antibiotics in production systems. Drawing on the example of interactions between poultry producers, commercial interests and food safety regimes, in this talk I will explore some of the value conflicts and regulatory hurdles inherent to instantiating digital One Health in large integrated agricultural systems.

Chris Degeling

Associate Professor, Australian Centre for Engagement, Evidence and Values, University of Wollongong, Sydney

Associate Professor Chris Degeling is Principal Fellow at the Australian Centre for Engagement, Evidence and Values at the University of Wollongong, Australia. As a social scientist with a background in veterinary medicine – and expertise in

qualitative and deliberative methodologies – Chris' research focuses on the intersection of public health ethics, public health policy and emerging issues at the human-animal-ecosystem interface.

Understanding the Risk of Spillover across Landscapes

In recent years the importance of OneHealth approaches have begun to be noted. However, whilst OneHealth in the context of captive wildlife and trade, and to some degree various domesticated animals has begun to be noted, understanding OneHealth from a landscape structure and management context is largely limited to case-specific examples and case-studies. Here we review not only the importance of OneHealth from a landscape context, but the importance of including ecophysiological and ecological considerations of into our understanding of species health in the landscape context. However, given persistent data-gaps requires using a wealth of data, including online databases, and predictive models. Using bats as a case-study we briefly review the various dimensions of OneHealth that need to be considered at a population level, the importance of species demography and habitat health in determining the risk of pathogen exposure, vulnerability and shedding, and how these relate to landscape structure. We review the intersectional research needs on bat taxonomy and systematics, as well as demographic and ecophysiological research needs, and how we can work better to ensure that data is shared digitally (based on consistent standards) so we can better integrate data to understand these systems, rather than looking at elements in isolation. Following from this we highlight current knowledge gaps, and future areas for research, as well as basic precautions for landscape management including agriculture, mining, forest management and recreation, and how seasonal considerations due to both resource availability and other ecological stressors are key to minimising the risk of spillover events going into the future.

Alice C. Hughes

Associate Professor, School of Biological Sciences, University of Hong Kong

Some of my primary research on the distribution of species, drivers of loss, and the development of mechanisms to reduce biodiversity loss, reduce spillover risk through OneHealth approaches, and the development of frameworks to manage landscapes and species to enable a more sustainable future. This research has been of pivotal importance in understanding the origins of Covid, and will hopefully facilitate better policy to minimise fugure risks. I and my team utilise diverse data to enable the development of new approaches, then integrate this into policy and practice through my roles on various NGOs, IGOs and through UN meetings such as the CBD and CITES where our data has enabled the uplisting of various species for more effective conservation. By providing a bridge between science and filling key data gaps we hope to enable a transition to a more sustainable, and biosecure future, thus I, and my team aim to continue to grow, develop and disseminate this research to maximise the impact of the work we do.

Data Justice for Human Research Participants: Perspectives from the African Continent

The United Nations first expressed the term "Data revolution' in 2014, acknowledging the transformative actions needed for responding to the demands of a complex development agenda

and improvements in data production and usage; closing data gaps to prevent discrimination; building capacity and data literacy; modernizing systems of data collection; liberating data to promote transparency and accountability; and developing new targets and indicators. The concept of data justice had long gained significant attention globally, emphasizing fairness, equity, and ethical considerations in the collection, processing, and utilization of data. However, discussions on data justice often overlook the diverse and unique perspectives of human participants. This abstract explores the notions of data justice concerning human participants from African perspectives, acknowledging the region's unique sociocultural, economic, and historical dynamics, but also cognisant of the differences between countries. In Africa, data justice intersects with multifaceted challenges, including colonial legacies, economic disparities, cultural diversity, and limited infrastructure. Here, human participants often face issues of agency, consent, and representation in data collection processes conducted by both domestic and international entities. Furthermore, the extraction of data from African communities without proper acknowledgment or benefit-sharing exacerbates concerns related to data exploitation and neo-colonial practices.

Edith Madela-Mntla

Senior Lecturer, Department of Family Medicine; Community Engagement coordinator and member, Health Sciences Faculty Research Ethics Committee, School of Medicine, University of Pretoria

Edith is an academic and researcher on transdisciplinary research with a diverse background. She holds a Doctorate in Mental Health Nursing and a year course in Research Methodology from the University of Johannesburg; a Certificate in Advanced Health Management from the University of Pretoria; a Diploma in Health Outcomes Research (Clinical Trials) and a Certificate in Ethical Issues of Clinical Research, from the Vienna School of Clinical Research; and a Senior Management Development Programme certificate from the Stellenbosch University. She works at the University of Pretoria; is Coordinator for Community Engagement in the School of Medicine; serves in the Health Research Ethics Committee and is the new Director of the Community-Oriented Primary Care Research Unit. Has served in (and chaired) various structures of the National Department of Health and the South African Health Products Regulatory Authority. She is a peer reviewer of journals and has been involved in the UN's Africa's SDG processes since 2011.

Public Engagement towards Data Justice: Embedding Participatory Governance into a One Digital Health Framework for Addressing Antimicrobial Resistance

Antimicrobial resistance (AMR) has emerged as a complex One Health issue that requires the application of a holistic approach, including multidisciplinary strategies and participation of diverse stakeholders and publics at the local, national, and global levels. As recent advances in AI, digital analytics and whole genome sequencing have provided strong capabilities for predicting antibiotic resistance in pathogens and effective surveillance of antimicrobials use across the human, animal, and environmental sectors, there is a growing concern about how to ensure fair access to data and distribution of knowledge, skills, and resources. In this presentation, I outline some considerations about the normative desirability of participatory governance for advancing fair and equitable data-driven solutions to address key AMR drivers, including political challenges, socioeconomic factors, and global health disparities. Specifically, I examine opportunities and challenges associated with

bottom-up citizen engagement vis-à-vis expert-led engagement initiatives that currently dominate public and policy deliberations on justice frameworks in health data governance.

Kalina Kamenova

Founder and Research Director, Canadian Institute for Genomics and Society, Toronto

Dr Kalina Kamenova's research is situated at the intersections of bioethics, science policy, health law, science communication, participatory governance, and science and technology studies. She is the Founder and Research Director of the Canadian Institute for Genomics and Society (Genomics4S), an independent think tank whose mission is to advance research on the ethical and policy issues of emerging biotechnologies and promote responsible innovation in genomic medicine. Dr Kamenova has previously held an Assistant Professor appointment in the Interdisciplinary Bachelor of Arts and Science (BAS) Program at Trent University in Peterborough, Ontario and has also served as the Inaugural Research Director of the Center for Public Involvement (CPI) at the University of Alberta, a community-university partnership for excellence in research on deliberative democracy and public participation.

The Promise and Risks of using Artificial Intelligence to Develop and Deliver new Antibiotics

A fast-growing use of AI has been its application for the discovery, development and delivery of medicines and vaccines. AI is used in most steps of pharmaceutical development. Eventually nearly all pharmaceutical products will be "touched" by AI at some point in their development, approval or marketing. While there are promising uses of AI to advance public health and address unmet medical needs, including the development of new antibiotics, the current focus of AI in pharmaceutical development is to generate commercial benefits. Thus, AI may only reinforce the neglect of developing treatments against drug-resistant infections, or only address drug-resistant infections relevant to adult populations in high-income countries. Furthermore, there are other risks associated with the use of AI in drug development, both those that exacerbate existing ethical challenges with pharmaceutical research and development, and several broader ethical challenges with the use of AI for health, including bias, privacy, transparency, and explainability. Addressing these ethical challenges will require new approaches to governance, and concerted efforts by the public, private, and not-for-profit sector to proactively apply AI to address priority bacterial pathogens.

Rohit Malpani

Senior Policy Advisor, Global Antibiotics Research and Development Partnership; Consultant, World Health Organization, Geneva

Rohit Malpani is an independent consultant, based in Paris. He is currently a Senior Policy Advisor to the Global Antibiotic Research and Development Partnership, and a consultant to the World Health Organization - for the latter he focuses on the ethics and governance of artificial i ntelligence in health. Previously, he was a Board Member to Unitaid representing non-governmental organizations, the Director of Policy for the Medecins Sans Frontieres Access Campaign, a Special Advisor at Oxfam, and an intellectual property

attorney for the law firm Wilson, Sonsini in Palo Alto, California. He has a Doctorate of Jurisprudence from the New York University School of Law.

Can We Leverage Electronic Health Records to Improve Antimicrobial Resistance Surveillance System in Hong Kong?

Antimicrobial resistance (AMR) is one of the global public health concerns. The emergence of AMR has led to challenges in the management of even common infections. Surveillance will provide evidence to quickly identify risk factors for AMR carriage which can potentially increases the risk of AMR infection. By leveraging the considerable amount of data accumulated through the local surveillance programme, this presentation demonstrated an example of using locally available electronic health records for AMR research in Hong Kong.

Carbapenemase-producing Enterobacteriales (CPE) are resistant to carbapenem, one of the "last resort" antibiotic classes that is reserved for use when other antibiotic treatments have failed. They are also one of the three bacteria-antibiotic pairs on the World Health Organization critical priority threat list published in 2017. CRE surveillance has been implemented since the end of 2010 in Hong Kong public hospitals managed by the Hospital Authority. This study aimed to demonstrate the feasibility of using routinely collected electronic health records to study the monthly incidence and risk factors for CPE carriage in Hong Kong.

From 1st January 2008 to 31st December 2019, 8,588 patients received CPE genotyping tests, and 2,353 had at least one positive result. Class B carbapenemase was the predominant enzyme in the samples (78.6%). The incidence rate increased from 0.04 in 2015 to 1.62 in 2019 per 10,000 person-year. In the nested case-control study, 1709 cases and 6664 controls were matched. Previous use of any beta-lactam antibiotics [Odds ratio:1.37 (1.22-1.53), p<.001] was found as an independent risk factor for carriage of CPE.

The carriage of CPE was found with an increasing trend in Hong Kong. Previous use of any beta-lactam antibiotics is a risk factor for CPE. We demonstrated the benefit of using such rich data sources to study the epidemiology of CRE, supporting the feasibility of developing an automated surveillance system using electronic health records to help combat AMR.

Celine S.L. Chui

Assistant Professor, School of Nursing & School of Public Health, LKS Faculty of Medicine, University of Hong Kong

Dr Chui is an Assistant Professor jointly appointed by the School of Nursing and School of Public Health at HKU. She is an epidemiologist by training and is specialized in applying new observational study design in medication safety research with the use of Big Data. Dr Chui aims to utilize Big Data from multi-regional/national large healthcare databases and that collected in the community to improve public health through implementation science. Her current research focuses on improving cardiovascular disease management and services through machine-learning (ML) driven risk prediction, Big Data for antimicrobial resistance surveillance, and improving care of people living with dementia. She has published more than 110 articles in peer-reviewed journals such as The Lancet Infectious Disease, JAMA Internal Medicine, BMJ, Journal of the American College of Cardiology, and Neurology.

One Health & AI: Legal Paradigms in Research

One Health has emerged as an encapsulating paradigm for human, animal and environmental health. Artificial intelligence (AI) will interconnect with these pathways in multifaceted and complex ways. There is much promise in using AI for the early detection of disease in humans, predicting the spread of pathogens from animals to people, and monitoring environmental parameters to identify risks to health. However, achieving robust technology requires proper research and development that accounts for the risks of AI. This requires clear guidelines and data processing rules. To explore these factors, this presentation examines the Arabian Gulf countries of Qatar, the United Arab Emirates and Saudi Arabia as case studies. These countries are among the forerunners in developing AI governance mechanisms in health, but they also demonstrate a disparity in approach to data processing. Those developments can either help or hinder AI in the One Health space. Learning from these approaches can inform developments in other countries.

Barry Solaiman

Assistant Professor & Assistant Dean, College of Law, Hamad Bin Khalifa University, Doha

Barry Solaiman is an expert on regulating AI in healthcare. He completed his PhD in law at the University of Cambridge, and holds a Fellowship in Bioethics from Harvard Medical School. In Qatar, he is the Lead Principal Investigator for a research project at HBKU and Project Investigator on another, both examining AI in healthcare. In addition to his journal publications in this space, he is co-editing a major book on 'Health, AI and the Law' to be released in 2024.

Ethical Governance of Medical AI R&D and Antimicrobial Resistance

In the context of antimicrobial stewardship programmes (ASP), digital tools have played a significant role in various aspects of the governance process. Here is a breakdown of their roles and expected contributions:

1. Data collection and processing: Digital tools are used to collect and process information related to antibacterial drug use. This could include data on the types of antibiotics prescribed, dosages, durations, and patient demographics. These tools help in efficiently gathering and organizing this data.

2. Data synthesis and calculation: Digital tools enable comprehensive analysis of antimicrobial drug use information from multiple sources. They can synthesize data from different healthcare settings, such as hospitals, clinics, and pharmacies, to provide a holistic view of antibiotic usage patterns. This allows for a better understanding of the overall antimicrobial landscape.

3. Data analysis and suggestions: Through advanced data analysis techniques, digital tools can provide rationalization and optimal suggestions for the rational use of antibiotics. These tools can identify trends, patterns, and potential areas for improvement in antibiotic prescribing practices. They can also generate recommendations for healthcare providers to optimize antibiotic use.

4. Assisted regulation and intervention: Digital tools can support the implementation of antibiotic

use regulatory systems. These tools can help monitor and enforce adherence to guidelines and policies related to antibiotic prescribing. They can provide real-time feedback to healthcare professionals and assist in interventions to improve prescribing practices.

However, it is important to acknowledge that the use of digital tools in combating antimicrobial resistance (AMR) is not without limitations. The boundary of digital tools should be considered, particularly in addressing local contexts. For example, while digital tools can be effective in data collection and analysis, they may not fully capture the nuances and complexities of antibiotic use in specific regions or cultural contexts.

In some cases, addressing AMR may require additional approaches beyond digital tools. For instance, public education and awareness campaigns can play a crucial role in promoting responsible antibiotic use, particularly in countries like China where cultural factors may influence prescribing practices. These campaigns can help educate the general public about the risks of antibiotic misuse and the importance of appropriate antibiotic use.

In summary, while digital tools have made significant contributions to the governance process of antimicrobial stewardship programmes, it is important to consider local contexts and supplement digital approaches with other strategies, such as public education, to effectively combat AMR.

Yali Cong

Professor, Department of Medical Ethics and Health Law, Peking University Health Science Center, Beijing

Yali Cong is a Professor in the Department of Medical Ethics and Health Law, Peking University Health Science Center, and Chair of the Medical Ethics Division of the Chinese Medical Association. She was trained on biology and got her PhD degree in Philosophy of Science and Technology in 1995. She joined Peking University Health Science Center in 1995 and has been teaching medical ethics. Prof. Cong took her position as PKU IRB Chair between 2010 to 2020. She has a wide range of research interest in Research Ethics, Global Public Health Ethics and Medical Professionalism. She has published about 100 papers in both English and Chinese in the field of Bioethics and works actively as PIs in the areas of medical professionalism, human subject protection and medical ethics education.

Global Governance of Benefit Sharing in One Digital Health

Data-driven genomic studies directed at addressing One Health concerns draw on biological materials and related data from human and non-human organisms. Where non-human genetic materials are concerned, the Nagoya Protocol to the Convention on Biological Diversity (CBD) sets out a system of access and benefit sharing (ABS) to support the fair distribution of benefits between the providers of these materials and their users. There is no such system that applies to the provision and use of human genetic materials and related data, although the notion of benefit sharing is discussed in a number of UNESCO documents, and is more generally encapsulated under the right to science (in human rights) and the principle of justice in health-related research guidelines and regulations. Research governance and related mechanisms may include requirements of data localisation, and have helped to safeguard the wellbeing of research participants. However, they have been less effective in ensuring the fair and just sharing of potential benefits of genomic research with underrepresented populations (notably in the lack of diversity in human genomic

studies). With focus on the digital aspects of OH genomic studies (or "One Digital Health"), I submit that a global governance framework should be established to enable benefit sharing in furtherance of the global solidarity and justice. While such a framework could be part of the proposed pandemic preparedness treaty, I highlight how the ABS system may be adapted to reflect the Manhattan and Berlin principles of the OH Initiative, as well as the core values of Health for All, and scaled up to encapsulate both human and non-human genetic materials and data.

Calvin W.L. Ho・何維倫

Associate Professor of Law & Co-Director, Centre for Medical Ethics and Law, Faculties of Law and Medicine, The University of Hong Kong

Dr Calvin Ho's research is on global health law and ethics, and the governance of health and biomedical technologies (with focus on health technologies based on Artificial Intelligence and data analytics). He is Co-Chair of the Expert Group on the Ethics of Social Listening and Infodemic Management, as well as a member of the COVID-19 Ethics & Governance Working Group of the World Health Organization (WHO). Calvin is also an Ethics Board member of Médecins Sans Frontières (Doctors Without Borders), and a member of the Regulation and Ethics Work Stream of the Global Alliance for Genomics & Health. He was one of the contributing authors of the WHO's Guidelines on Ethical Issues in Public Health Surveillance that was published in 2017.

Karel Caals

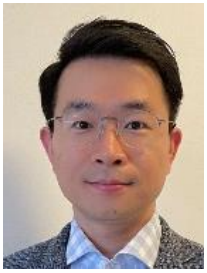
Research Fellow, Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore;
Assistant Editor, Asian Bioethics Review

Karel obtained a PhD in Health Geography, after qualitative field research on the training of healthcare professionals in Timor-Leste to establish the concept of the 'More-thanNational Health System'. As part of his interest in health systems, he researches the digitalisation of health, working on topics such as the ethics of artificial intelligence in healthcare and digital health surveillance. Additional interests include various topics in the field of research ethics, as well as stakeholder engagement.

Laws on Human Genetic Resources in China: Potential Impact on the Use of Human Genetic Data

Human genetic resources, which include genetic data, hold substantial potential for contributing to advancements in biomedicine, public health, and forensic science. The regulatory framework in China supervises not only conventional biological samples but also covers research findings derived from processing and analyzing genetic resources, including genomic sequencing data. In this presentation, I will examine the Chinese laws relating to human genetic resources, focusing on the potential legal challenges they might pose to Chinese and international collaborative projects on genetic research and development. Moreover, I will present the findings of our latest study that investigates public debate on social media in respect to the publication of Chinese gene sequencing data in a prestigious scientific journal.

Li Du



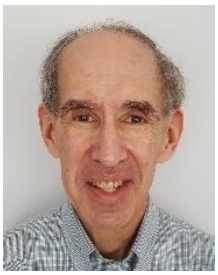
Associate Professor, Faculty of Law, University of Macau

Prof Du holds dual bachelor's degrees in both clinical medicine and law (Wuhan University, China) and a PhD. in law (University of Alberta, Canada). His teaching and research interests include international law, food law, biotechnology law and policy, and privacy law. Prof Du Li has led many research projects on legal and ethical implications of novel and emerging biotechnologies, e.g., genetic testing, stem cells, synthetic biotechnology, etc. He frequently shares his research findings at international conferences frequently and publishes articles in leading academic journals.

Respect for Persons & the Use of Biological Materials and Data in Research

Linnet Taylor posits the following as "[p]erhaps the central question raised by the concept of data justice": "how to balance and integrate the need to be seen and represented appropriately with the needs for autonomy and integrity. What are the implications of letting people opt out of data collection?" This raises interesting issues with regard to how the protection of autonomy interests should play out in various circumstances, such as One Health initiatives (including in the context of dealing with the antimicrobial resistance problem). In particular, how might one decide between a default policy of including data, with a subsequent method for then eliminating use of some of the data (based on autonomy interests), versus a default of excluding data, and only adding it to the research data set after resolving the autonomy interests (such as requiring some type of consent)? This issue will be explored through a discussion of recent developments in the United States rules relating to the secondary research use of biospecimens and data.

Jerry Menikoff



Professor, Centre for Biomedical Ethics, Yong Loo Lin School of Medicine,
National University of Singapore

Before this year joining the faculty of the NUS Centre for Biomedical Ethics as a Professor of Bioethics, and becoming a senior fellow of the Faculty of Law, Jerry Menikoff was for 14 years the director of the main U.S. regulatory agency protecting research subjects in federally funded research (OHRP). He oversaw the multi-year process of successfully revising the "Common Rule," with many of the changes reflecting proposals he promoted for years (particularly improving consent forms, making consent forms public, and requiring a single IRB for review of multi-centered research). He also played a lead role in creating the debate over determining the risk level in comparative effectiveness research (most notably, relating to issues raised in the SUPPORT trial of oxygen supplementation in premature infants). Prior to this, he was in charge of the intramural research protections program at the National Institutes of Health. He has been a faculty member of medical or law schools at the University of Kansas and the University of Chicago, among other schools. He is the author of the textbook Law and Bioethics: An Introduction (Georgetown University Press) and of What the Doctor Didn't Say: The Hidden Truth about Medical Research (Oxford University Press).

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10 ANNIVERSARY

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 digital health and emergent technologies, mental health and capacity, and population and global health.

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, Faculty of Law, The University of Hong Kong

Address: Office 9.21, 9th Floor, Cheng Yu Tung Tower, Centennial Campus, The University of Hong Kong

Email: cmel@hku.hk
Tel: (852) 3917 1845
Fax: (852) 2549 8495

Website: https://cmel.hku.hk
Twitter: @HKUCMEL
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