Pathogen Access and Benefit Sharing: Global and Regional Legal Perspectives

Monday, 20 January 2025

DukeNUS Medical School | Centre for Outbreak Preparedness

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Pathogen Access and Benefit Sharing: Global and Regional Legal Perspectives

Global Perspectives

SPEAKER

Suerie Moon

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Professor of Practice in International Relations & Political Science, Graduate Institute Geneva

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PATHOGEN ACCESS AND BENEFIT-SHARING (PABS)
A GLOBAL HEALTH GOVERNANCE CHALLENGE

PATHOGEN ACCESS AND BENEFIT SHARING: GLOBAL AND REGIONAL LEGAL PERSPECTIVES

CENTRE FOR OUTBREAK PREPAREDNESS (COP) & CENTRE FOR INTERNATIONAL LAW (CIL)
NATIONAL UNIVERSITY OF SINGAPORE

20 JANUARY 2025

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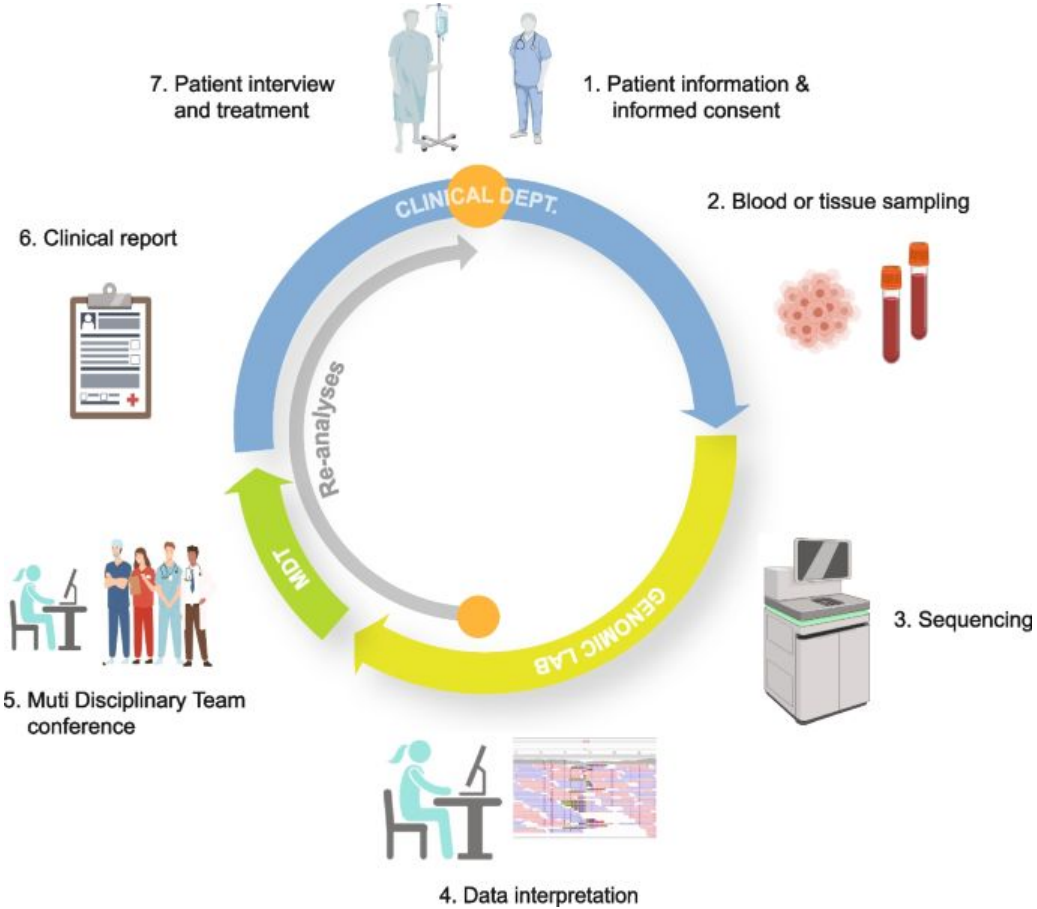
GENEVA GRADUATE INSTITUTE

OVERVIEW

1. Context: What is PABS, why does it matter?
2. History: How has PABS been governed internationally?
3. Covid-19: What happened?
4. Closing reflections: Politics and possibilities

WHAT IS A PATHOGEN (SAMPLE) & GENOMIC SEQUENCING DATA (GSD)?



Source: https://bmcmedgenomics.biomedcentral.com/articles/10.1186/s12920-024-01795-w

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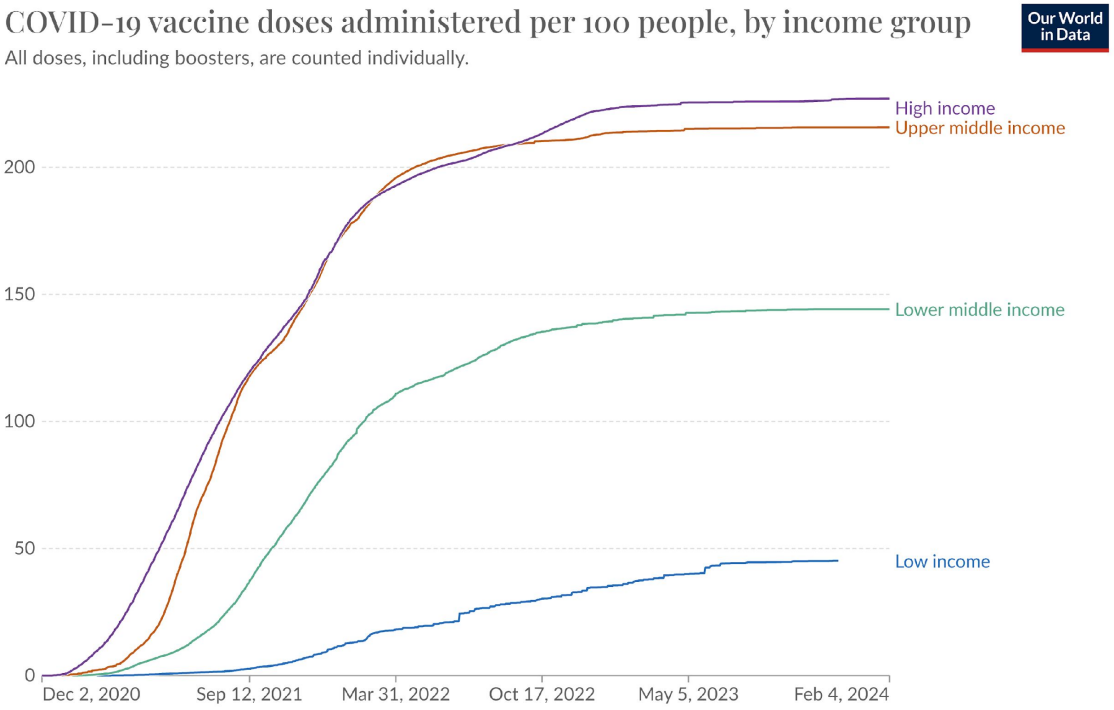
CONTEXT: WHY DOES PABS MATTER?

USES OF PATHOGEN SAMPLES AND GENOMIC SEQUENCING DATA (GSD)

- Identify pathogen
- Track pathogen transmission and spread
- Track pathogen evolution and resistance
- Test existing diagnostics, therapeutics and vaccines
- Develop novel diagnostics, therapeutics and vaccines

CONTEXT: WHY DOES PABS MATTER?
CHALLENGES ACCESSING BENEFITS



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BENEFIT-SHARING
WHAT'S A BENEFIT?

- *Academic benefits*: e.g. scientific collaboration, co-authorship, acknowledgement
- *Economic benefits*: e.g., shared ownership, access fees, licensing, joint ownership of IP, royalty rights
- *Outbreak-related benefits*: information sharing and access to medical countermeasures (vaccines, diagnostics, therapeutics)
- *Systems-strengthening benefits*: e.g. capacity building, technology transfer, infrastructure development

CURRENT PRACTICE & GOVERNANCE

Two kinds of pathogen sharing:

- **Routine** (e.g. seasonal influenza)
- **Outbreak-related** (e.g. COVID, Ebola, Zika, mpox)

Regular pathogen-sharing across borders is everyday practice of scientists, laboratories, governments and industry…

…with some grit in the wheels

Wanted: **Rapid, reliable, fair and equitable** sharing of pathogens and related benefits, especially for pathogens of pandemic potential

But…**insufficient international rules** to do so

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INDONESIA, H5N1 & PIP FRAMEWORK

- 2005-6: Indonesia: highest # of H5N1 influenza cases and fatalities
- 2007: refused to continue sharing H5N1 samples, citing 1992 Convention on Biological Diversity (CBD) principle of sovereignty over genetic resources
  - “The current unfair access to vaccines worsens the global inequality between the rich and the poor, between the North and the South—and I think that is more dangerous than a pandemic.”-Siti Fadilah Supari, Health Minister
- Resumed sharing & GISAID created for GSD
- 2007-2011: Intergovernmental negotiations towards PIP
  - WHO Pandemic Influenza Preparedness (PIP) Framework: “sovereignty over biological resources, virus and benefit sharing on an equal footing, and financing mechanisms for equitable access to benefits.”
  - Limited to influenza virus of pandemic potential
  - Vaccine donations and financing for sample-sharing system
  - Excludes provisions for GSD – no clear rules

WHAT ARE THE CBD AND NAGOYA PROTOCOL?

Convention on Biological Diversity (CBD) (1992) objectives

1. Conservation of biological diversity,
2. Sustainable use of its components and
3. Fair and equitable sharing of the benefits arising out of the utilization of genetic resources

Nagoya Protocol (2014)

- Developed for CBD objective 3
- Requires access to genetic resources be based on prior informed consent and on mutually-agreed terms – usually case-by-case negotiation

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- Recognizes specialized arrangements may be needed for public health, but does not prescribe what they are

CURRENT GOVERNANCE ARRANGEMENTS: PATCHWORK OF INTERNATIONAL NORMS AND RULES

- **Informal norms** of scientific cooperation
- Pandemic Influenza Preparedness Framework: **influenza samples** only
- For all other pathogen samples: CBD and Nagoya Protocol (implemented into some national laws)
- For GSD:
  - **Policies of digital platforms** (e.g. GISAID, GenBank/INSDC)
  - **WHO Guiding Principles** for Pathogen Genome Data Sharing (2022)
  - **CBD** Cali Fund for DSI

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KEY GSD MOMENTS DURING COVID-19 CRISIS

- 10 January 2020: Edward Holmes (University of Sydney, Australia) received first Covid-19 GSD from Zhang Yong-Zhen (Fudan University, Shanghai), posts to public website (virological.org)
- Scientists use this data to quickly develop diagnostic tests and start working towards a vaccine

- Jan 2020: GISAID, a database initially developed for sharing GSD on influenza, expands to include Covid-19. It seeks to protect “data ownership” by scientists and requires log-in and terms of use. It becomes the database with the largest number of countries and sequences on Covid-19.

- 25 Nov 2021: South Africa announces omicron variant of Covid-19, shares GSD on GISAID. Many countries respond with travel and trade bans, including on lab reagents required to continue sequencing.

CNN World Africa Americas Asia Australia China Europe India Middle East United Kingdom

The first cases of the Omicron variant identified around the world

By Rob Picheta, CNN

Updated 0959 GMT (1759 HKT) December 2, 2021

Expert explains how we'll know if vaccines work against Omicron variant 02:14

London (CNN) — *Editor's note: The Omicron coronavirus variant has now been identified in dozens of countries globally and this story will no longer be updated. Follow the latest updates on the spread of the variant here.*

https://edition.cnn.com/2021/11/29/world/covid-omicron-variant-countries-list-cmd-intl/index.html

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WHAT HAPPENED WITH GSD DURING COVID-19?

- 15 million sequences shared informal scientific norms for sharing
- Preference for data ownership protections (Table 1)
- Increased sequencing capacity, but more needed
- Inadequate arrangements for benefit-sharing
- No clear obligations for sharing pathogens, GSD or benefits
- Recent political/legal developments: CBD & BBNJ

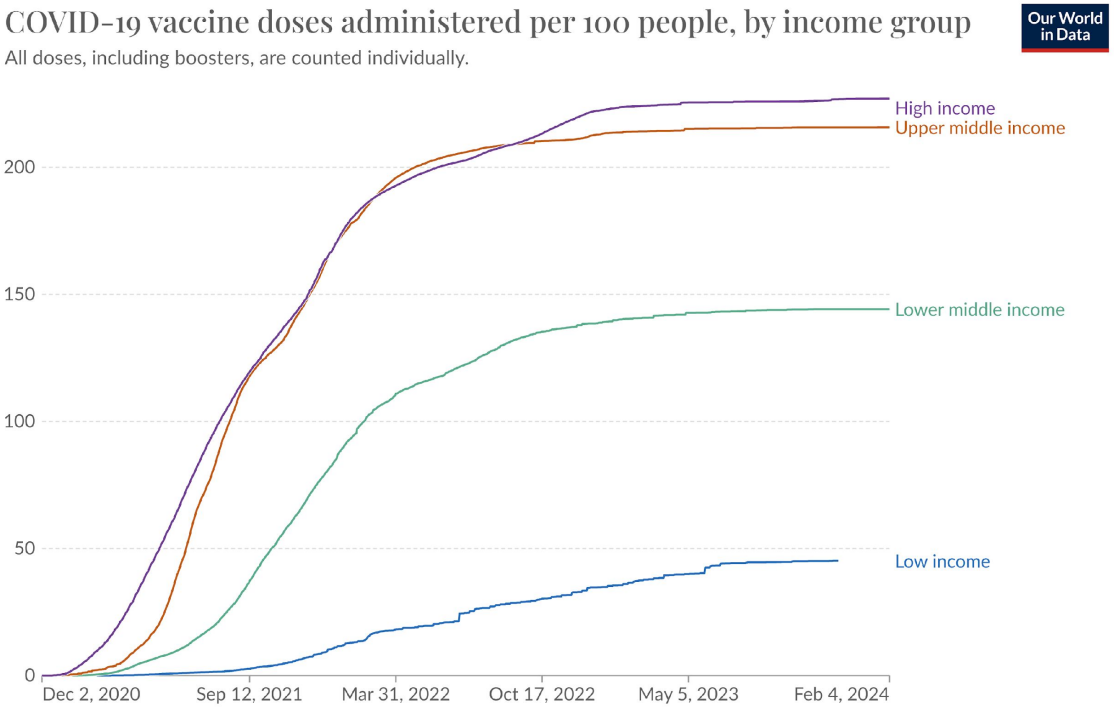
Table 1. Proportion of Countries within an Income Level Submitting any Sequences, January 1, 2020 – March 18, 2023

	GISAID	GenBank
Total	183/191 (95.81%)	110/191 (57.59%)
High Income	57/58 (98.27%)	42/58 (72.41%)
Upper Middle	50/53 (94.34%)	32/53 (60.38%)
Lower Middle	51/52 (98.08%)	25/49 (51.02%)
Low Income	25/28 (89.29%)	11/28 (39.29%)

Source: With thanks to Anna Bezruki (Georgetown University) for data & analysis

CONTEXT: WHY DOES PABS MATTER?

CHALLENGES ACCESSING BENEFITS



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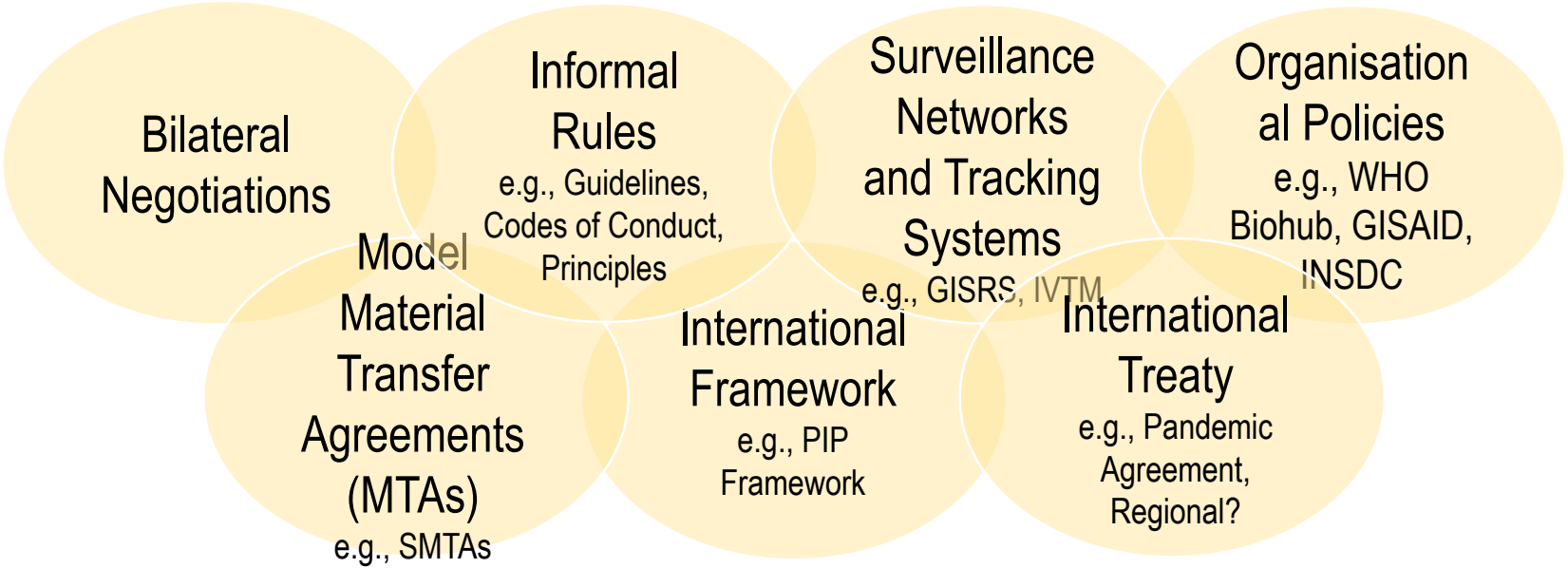
Potential Tools & Instruments to Strengthen PABS Governance



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CLOSING REFLECTIONS
POLITICS AND POSSIBILITIES

1. Technological change (GSD) challenging pre-existing international rules (e.g. PIP, CBD, Nagoya)

2. Lack of clear rules on PABS a global vulnerability

3. Global North-South negotiating camps on PABS, crux of political bargain in Pandemic Agreement

4. Technical complexity challenging, but strong political logic for a deal.

Once-in-a-generation opportunity needs to be seized

THANK YOU

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Pathogen Access and Benefit Sharing: Global and Regional Legal Perspectives

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Academic Adviser of its Global Health Centre

DukeNUS Medical School | Centre for Outbreak Preparedness

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INTERNATIONAL HEALTH REGULATIONS AMENDMENTS AND THE PANDEMIC TREATY

PATHOGEN ACCESS AND BENEFIT SHARING: GLOBAL AND REGIONAL LEGAL PERSPECTIVES

CENTRE FOR OUTBREAK PREPAREDNESS (COP) & CENTRE FOR INTERNATIONAL LAW (CIL)

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SENIOR VISITING PROFESSOR OF INTERNATIONAL LAW

GENEVA GRADUATE INSTITUTE

GENEVA GRADUATE INSTITUTE | GLOBAL HEALTH CENTRE

WHAT DOES INTERNATIONAL LAW TO DO WITH PATHOGEN AND BENEFIT SHARING?

- Encroachment of biodiversity law with existing practices and institutions
- Convention on Biological Diversity (CBD) adopted in 1992, quasi-global participation. Framework convention – two protocols: Cartagena on GMO and Nagoya (142 parties) on benefit-sharing
- Rationale: preservation of biodiversity, combating biopiracy, leverage for mega-diverse countries and indigenous people. Public health not part of original design
- Objectives (art. 1): "conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources"
- Principles (art. 15): sovereignty over genetic resources, no firm obligation to share, prior informed consent, mutually agreed terms

LINKAGES BETWEEN CBD AND PATHOGENS

- Indonesia's 2007 claim and subsequent growing consensus: pathogens fall under CBD
- Definitions (Art. 1 CBD): " "*Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity."*
- *"Genetic resources" means genetic material of actual or potential value"*
- CBD and Nagoya Protocol: transactional, bilateral approach and variety of national approaches unfit for public health and health crises – risk of chilling effects (influenza)
- WHO's Pandemic Influenza Preparedness (PIP) Framework as first multilateral reaction, WHO's stewardship role and global public good approach

PATHOGEN AND BENEFIT SHARING (PABS) IN THE PANDEMIC AGREEMENT

- Pandemic agreement (PA) negotiations: tensions between "security" and "equity".
- PABS as central issue in PA negotiations – last trench of "equity" and perception of leverage for global south. Mutual mistrust and current stalemate. Hollowing out of text and reliance on future instrument. Are the expectations by the Global South justified?
- Multiple layers of complexity and uncertainty of PA process outcome
- Complex interacions with the biodiversity regime

MAIN LEGAL ISSUES
1) CARVE OUT

- Creation of self-contained system carved out from CBD/Nagoya. Art. 4.4 Nagoya: "*Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument*"
- What criteria for an SII? Will PABS qualify? Who decides? What consequences from determination? What possible outcomes?

2) MANAGEMENT OF DIGITAL SEQUENCE INFORMATION (DSI)

- DSI/GSD not mentioned in CBD and PIP and no official position on inclusion in its scope
- Fundamental differences with physical samples, existing network of databases with own rules, ease of sharing, difficult to track and trace, difficult to link with jurisdiction. Increasing accessibility of technology and increased use by pharma – game changer and legal gap.
- Search for an ad hoc normative regime and influence on PABS:
- 1) CBD COP decision 15/9 (2022) on distinctive solution for benefit sharing, multilateral solution, no tracking and tracing, search for legal certainty
- 2) Decision 16/2 (2024) creating "Cali Fund" for DSI benefit sharing by benefitting sectors. Still work in progress. What implications for PABS?

MANY OPEN QUESTIONS…..

- Challenge of role of private sector: prescribe and regulate or encourage and urge
- How to adapt international law to technically complex and diffuse practices? Risk of chilling effects on science or ineffectiveness
- How to distribute obligations to provide benefits? How to create incentives for participation ? Is the Cali Fund the right answer?
- What are the possible models? FAO treaty on plant genetic resources for food and agriculture, PIP Framework, BBNJ
- What are the essential features of a future PABS?

A WEBINAR TO CLARIFY EVERYTHING…..

- **What does biodiversity have to do with public health? UN decisions on Digital Sequence Information and the Pandemic Agreement**
- *International Geneva Global Health Platform*
- 23 January 2025 , 13:00 - 14:15 CET
- Moderated by **Adam Strobeyko** | Swiss National Science Foundation Researcher, Global Health Centre, Geneva Graduate Institute
- Registration link here

Pathogen Access and Benefit Sharing: Global and Regional Legal Perspectives

Calvin Ho

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Just Transitions through Data Governance Frameworks in One Digital Health

Duke-NUS Medical School, 20 January 2025

Calvin Ho, JSD MSc LLM PCLT FRSPH

Calvin.Ho@Monash.edu

1. The research was supported by a grant awarded by the British Academy.

2. Grateful thanks to Centre for Outbreak Preparedness (COP) and the Centre for International Law (CIL) for the kind invitation.

3. All views and errors are mine

MONASH University

“Yugen” study: Issues

- What does “Just Transitions” mean in a data environment?
- Re-conceptualising AMR, especially in terms of the stakeholders
- Conceptual: “Justice” and “Transitions”
  - Re-defining inclusivenss
  - International Governance Framework
  - Norms-setting and mechanisms
- Data generation and applications

One Digital Health (not digital one health ☺)

- Operationalising One Health (OH) as One Digital Health
  - Note that WHO developed the WHONET software in 1989 for AMR surveillance
  - By 1996, 160 microbiology labs from 31 countries (including China) applied WHONET
- Key Domains:
  1. Humans
  2. Animals and Plants
  3. Climate and Ecosystems
- Digital Representation / Data Visualisation
  - For Domains (1) and (2)
    - Biochemical
    - Genomics (unique to domains of humans, animals and plants)
    - Politico-social Behaviour
  - For Domain (3)
    - General Regularly-distributed Information in Binary form (GRIB)
    - Network Common Data Form (netCDF)
    - Hierarchical Data Format (HDF)

HYPOTHESIS AND THEORY article

Front. Public Health, 03 May 2022
Sec. Planetary Health
Volume 10 - 2022 | https://doi.org/10.3389/fpubh.2022.768977

This article is part of the Research Topic
One Health Operationalization: Strategies for a More Integrative Approach to Biodiversity & Health
View all 5 Articles >

Operationalizing "One Health" as "One Digital Health" Through a Global Framework That Emphasizes Fair and Equitable Sharing of Benefits From the Use of Artificial Intelligence and Related Digital Technologies

Calvin Wai-Loon Ho*

Department of Law and Centre for Medical Ethics and Law, The University of Hong Kong, Pokfulam, Hong Kong SAR, China

The operationalization of One Health (OH) through digitalization is a means to deploy digital technologies (including Artificial Intelligence (AI), big data

Challenges to harnessing the potential of multi-omics & AI / ML

FAIR Principles Compliance

Findability

Resource and its metadata are easy to find by both, humans and computer systems. Basic machine readable descriptive metadata allows the discovery of interesting data sets and services.

- **F1**. Resource is uploaded to a public repository.
- **F2**. Metadata are assigned a globally unique and persistent identifier.

Accessibility

Resource and metadata are stored for the long term such that they can be easily accessed and downloaded or locally used by humans and ideally also machines using standard communication protocols.

- **A1**. Resource is accessible for download or manipulation by humans and is ideally also machine readable.
- **A2**. Publications and data repositories have contingency plans to assure that metadata remain accessible, even when the resource or the repository are no longer available.

Interoperability

Metadata should be ready to be exchanged, interpreted and combined in a (semi)automated way with other data sets by humans as well as computer systems.

- **I1**. Resource is uploaded to a repository that is interoperable with other platforms.
- **I2**. Repository meta- data schema maps to or implements the CG Core metadata schema.
- **I3**. Metadata use standard vocabularies and/or ontologies.

Reusability

Data and metadata are sufficiently well-described to allow data to be reused in future research, allowing for integration with other compatible data sources. Proper citation must be facilitated, and the conditions under which the data can be used should be clear to machines and humans.

- **R1.** Metadata are released with a clear and accessible usage license.
- **R2.** Metadata about data and datasets are richly described with a plurality of accurate and relevant attributes.

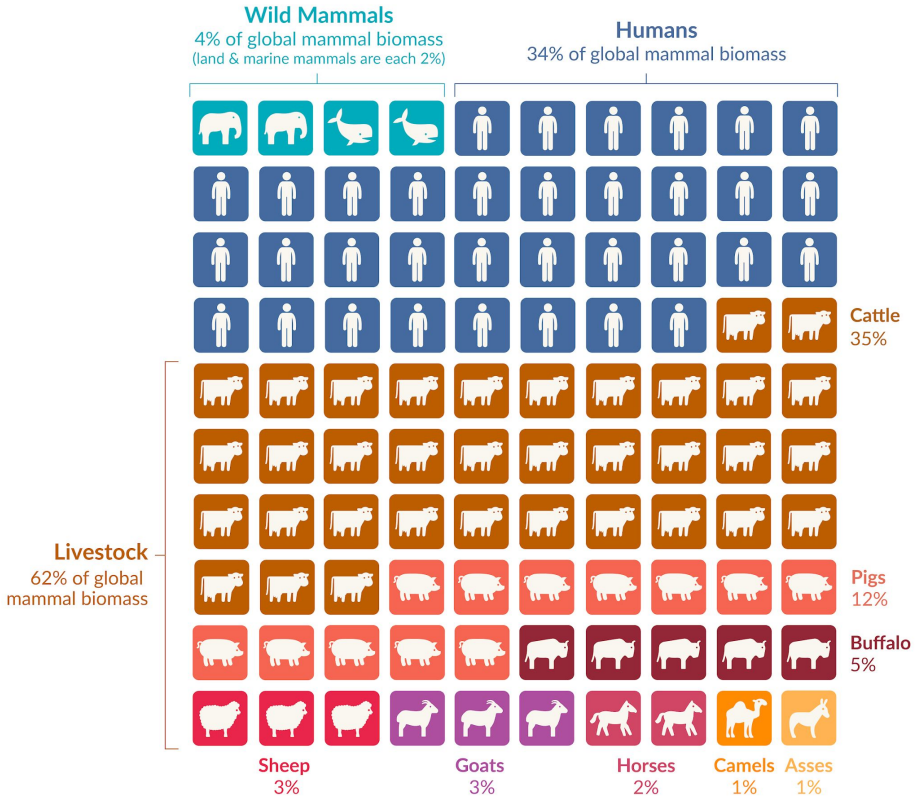
International Law Landscape

- **International Health Regulations**
- **Convention on Biological Diversity and related protocols + Post 2020 GBF**
- Paris Agreement under the UN Convention on Climate Change
- Framework Convention on Tobacco Control
- Sendai Framework for Disaster Risk Reduction
- UN Convention to Combat Desertification
- Convention on International Trade in Endangered Species of Wild Fauna and Flora
- Agreement on Sanitary and Phytosanitary (SPS) Measures

Distribution of mammals on Earth

Our World in Data

Mammal biomass is measured in tonnes of carbon, and is shown for the year 2015. Each square corresponds to 1% of global mammal biomass.



Note: An estimate for pets has been included in the total biomass figures, but is not shown on the visualization because it makes up less than 1% of the total.

Unknowns

- Proprietary data (“Planet Farm”)
- Earth science data (scalable and interoperable?)
- Environmental science data
- AI / analytics capabilities

Enhancing Effectiveness

The NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

AI IN MEDICINE

Jeffrey M. Drazen, M.D., *Editor*, Isaac S. Kohane, M.D., Ph.D., *Guest Editor*, and Tze-Yun Leong, Ph.D., *Guest Editor*

Advances in Artificial Intelligence for Infectious-Disease Surveillance

John S. Brownstein, Ph.D., Benjamin Rader, M.P.H., Christina M. Astley, M.D., Sc.D., and Huaiyu Tian, Ph.D.

FLORENCE NIGHTINGALE'S INNOVATIVE "ROSE DIAGRAM" OF PREVENTABLE deaths revolutionized data-driven disease surveillance.[1] Raw hospital mortality data collected during the Crimean War were transformed into a compelling, visual insight — poor sanitary conditions killed more people than battle wounds did. This act of synthesizing noisy, complex data into an elegant, effective message was the foundation for a royal commission to track morbidity and mortality and thus launched a new era in which analytic methods were used to better monitor and manage infectious disease. In the more than 160 years since the first publication of Nightingale's rose diagram, tools and technology for translating high-density data and uncovering hidden patterns to provide public health solutions have continued to evolve. Manual techniques are now complemented by machine-learning algorithms. Artificial intelligence (AI) tools can now identify intricate, previously invisible data structures, providing innovative solutions to old problems. Together, these advances are propelling infectious-disease surveillance forward.

The coronavirus disease 2019 (Covid-19) pandemic has highlighted the speed with which infections can spread and devastate the world — and the extreme importance of an equally nimble, expeditious, and clever armamentarium of public health tools to counter those effects. Throughout this crisis, we have witnessed a multitude of AI solutions deployed to play this role — some much more successful than others. As new pathogens emerge or old challenges return to command our attention, the incorporation of the lessons learned into our public health playbook is a priority. In this review article, we reflect on the effects of new and long-standing AI solutions for infectious-disease surveillance. AI applications have been shown to be successful for a diverse set of functions, including early-warning systems,[2,3] hotspot detection,[4,5] epidemiologic tracking and forecasting,[6,7] and resource allocation[8] (Fig. 1). We discuss a few recent examples.[9,11,12] We begin with how AI and machine learning can power early-warning tools and help distinguish among various circulating pathogens (e.g., severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] vs. influenza virus). We then discuss AI and machine-learning tools that can backtrack epidemics to their source and an algorithmic method that can direct an efficient response to an ongoing epidemic. Finally, we emphasize the critical limitations of AI and machine learning for public health surveillance and discuss salient considerations to improve implementation in the future.

From the Computational Epidemiology Laboratory (J.S.B., B.R., C.M.A.) and the Division of Endocrinology (C.M.A.), Boston Children's Hospital, Harvard Medical School (J.S.B., C.M.A.), and Boston University School of Public Health (B.R.), Boston, and the Broad Institute of MIT and Harvard, Cambridge (C.M.A.) — all in Massachusetts; and the State Key Laboratory of Remote Sensing Science and Center for Global Change and Public Health, Beijing Normal University, Beijing (H.T.). Dr. Brownstein can be contacted at john.brownstein@childrens.harvard.edu or at Boston Children's Hospital, 300 Longwood Ave., BCH3125 Bldg., Boston, MA 02115.

Dr. Brownstein and Mr. Rader contributed equally to this article.

N Engl J Med 2023;388:1597-607.
DOI: 10.1056/NEJMra2119215

Function	Examples
Early warning	• Natural-language processing of news sources to identify outbreaks (Freifeld et al., *JAMIA* 2008) • Unsupervised machine learning of social media data to detect unknown infections (Lim, Tucker, and Kumara, *J Biomed Inform* 2017)
Pathogen classification	• Convolutional neural network model for reading antibiograms (Pascucci et al., *Nat Commun* 2021) • Convolutional neural network model to automate malaria microscopy and diagnosis (Liang et al., *IEEE* 2016)
Risk assessment	• Reinforcement learning of Covid-19 positivity rates to target limited testing in Greece (Bastani et al., *Nature* 2021) • Machine-learning models including random forest and extreme gradient boosting to use syndromic surveillance for Covid-19 risk prediction (Dantas, *PLoS One* 2021)
Source identification	• Automated data mining of electronic medical records to uncover hidden routes of infection transmission (Sundermann et al., *Clin Infect Dis* 2021) • Supervised machine learning in combination with digital signal processing for genomic tracing of Covid-19 (Randhawa et al., *PLoS One* 2020)
Hotspot detection	• Neural computing engine to correlate sound from hospital waiting rooms with influenza spikes (Al Hossain et al., *Proc ACM Interact Mob Wearable Ubiquitous Technol* 2020) • Multilayer perceptron artificial neural network model to detect spatial clustering of tuberculosis (Mollalo et al., *Int J Environ Res Public Health* 2019)
Tracking and forecasting	• Real-time stacking of multiple models to improve forecasts of seasonal influenza (Reich et al., *PLoS Comput Biol* 2019) • Machine learning to combine new data sources for monitoring Covid-19 (Liu et al., *J Med Internet Res* 2020)

Figure 1. Various Functions of Artificial Intelligence (AI) for Infectious-Disease Surveillance.
Shown is a nonexhaustive list of functions of AI-aided infectious-disease surveillance and representative examples from the published literature.[2-13] Each example includes the type of AI algorithm, a brief description of its purpose, and the associated citation. Covid-19 denotes coronavirus disease 2019.

MONASH University

nature COMMUNICATIONS

ARTICLE

https://doi.org/10.1038/s41467-021-21187-3 OPEN

AI-based mobile application to fight antibiotic resistance

Marco Pascucci[1,2,3,12], Guilhem Royer[4,5,6,12], Jakub Adamek[7], Mai Al Asmar[8], David Aristizabal[7], Laetitia Blanche[1], Amine Bezzarga[1,9], Guillaume Boniface-Chang[7], Alex Brunner[7], Christian Curel[10], Gabriel Dulac-Arnold[11], Rasheed M. Fakhri[8], Nada Malou[1]✉, Clara Nordon[1], Vincent Runge[2], Franck Samson[2], Ellen Sebastian[7], Dena Soukieh[7], Jean-Philippe Vert[11], Christophe Ambroise[2,13]✉ & Mohammed-Amin Madoui[5,13]✉

Antimicrobial resistance is a major global health threat and its development is promoted by antibiotic misuse. While disk diffusion antibiotic susceptibility testing (AST, also called antibiogram) is broadly used to test for antibiotic resistance in bacterial infections, it faces strong criticism because of inter-operator variability and the complexity of interpretative reading. Automatic reading systems address these issues, but are not always adapted or available to resource-limited settings. We present an artificial intelligence (AI)-based, offline smartphone application for antibiogram analysis. The application captures images with the phone's camera, and the user is guided throughout the analysis on the same device by a user-friendly graphical interface. An embedded expert system validates the coherence of the antibiogram data and provides interpreted results. The fully automatic measurement procedure of our application's reading system achieves an overall agreement of 90% on susceptibility categorization against a hospital-standard automatic system and 98% against manual measurement (gold standard), with reduced inter-operator variability. The application's performance showed that the automatic reading of antibiotic resistance testing is entirely feasible on a smartphone. Moreover our application is suited for resource-limited settings, and therefore has the potential to significantly increase patients' access to AST worldwide.

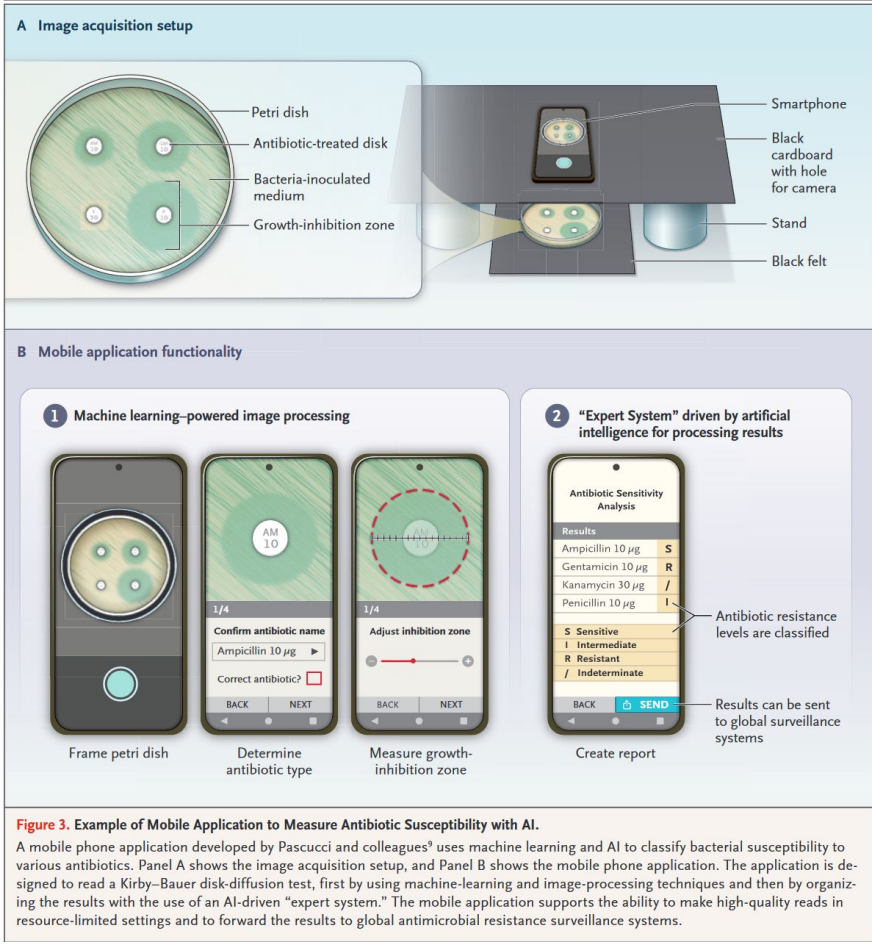


Figure 3. Example of Mobile Application to Measure Antibiotic Susceptibility with AI.
A mobile phone application developed by Pascucci and colleagues[9] uses machine learning and AI to classify bacterial susceptibility to various antibiotics. Panel A shows the image acquisition setup, and Panel B shows the mobile phone application. The application is designed to read a Kirby–Bauer disk-diffusion test, first by using machine-learning and image-processing techniques and then by organizing the results with the use of an AI-driven "expert system." The mobile application supports the ability to make high-quality reads in resource-limited settings and to forward the results to global antimicrobial resistance surveillance systems.

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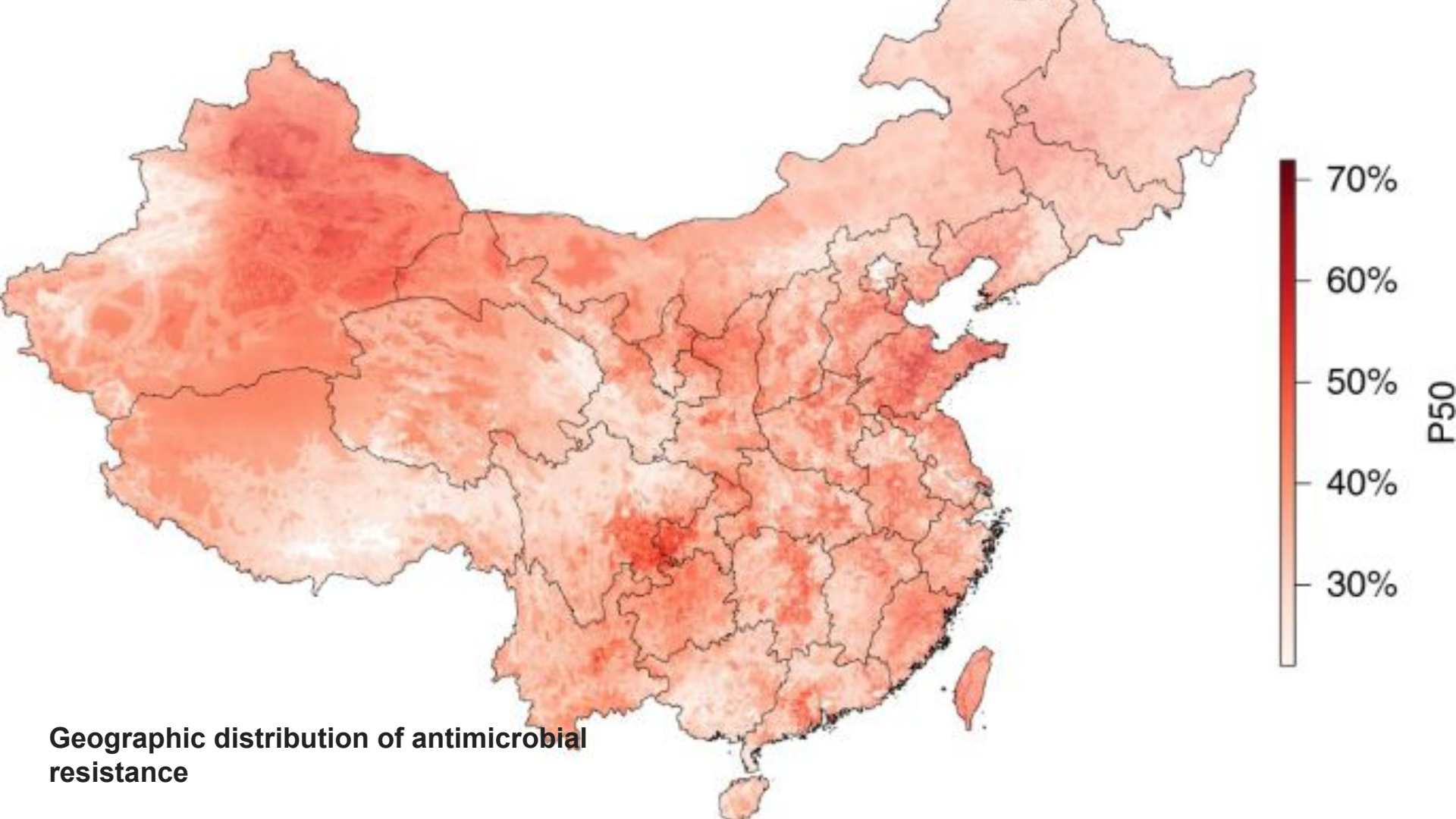
AMR Governance in China

- National Action Plan issued in 2016 for the period of 2016 to 2020
  - In response to GAP-AMR
  - But no systematic surveillance system for animal AMR or not publicly reported
- Clinical care: Stronger professional regulation since 2012; Raised attention over antibiotic use and bacterial resistance in children
  - Research team discovered mcr-1 transmissible polymyxin-resistant gene in 2013
  - National Health and Wellness Committee responsible for clinical AMR monitoring, but remit does not include public engagement, etc
- Agriculture:
  - Banned use of lomefloxacin, olaquindox and 6 other antibiotics between 2015-2017
  - Colistic sulfate banned for use as growth promoters in animals since April 2017
  - MoA issued surveillance plan in 2018, 2019 and 2021 to ensure safety of animals as food source
  - Lack of data in Aquaculture
- Environment: Few policies or actions
- Policies mainly initiated by the deputies of the NPC
- Query international data-sharing (note: China is not member of GLASS; could limit the quality of susceptibility testing across countries by WHO)



Geographic distribution of antimicrobial resistance

Data Justice (Linnet Taylor)

- Fairness in the way that people are made visible, represented and treated as a result of their production of digital data
  - Digital and biometric registration are becoming the new norm in even the poorest countries, and practices in international aid, development and humanitarian response
  - Vast amounts of digital data to map, sort and intervene on the mass scale in lower income regions
- A primary goal is to advance rule of law
  - Exponential rise in technology adoption worldwide
  - Globalisation of data analytics
- Greatest burden of dataveillance (surveillance using digital methods) has always been borne by the poor.
  - Law enforcement
  - Undocumented migrants are tracked more than higher income travellers

Data Justice - Taylor (Cont'd)

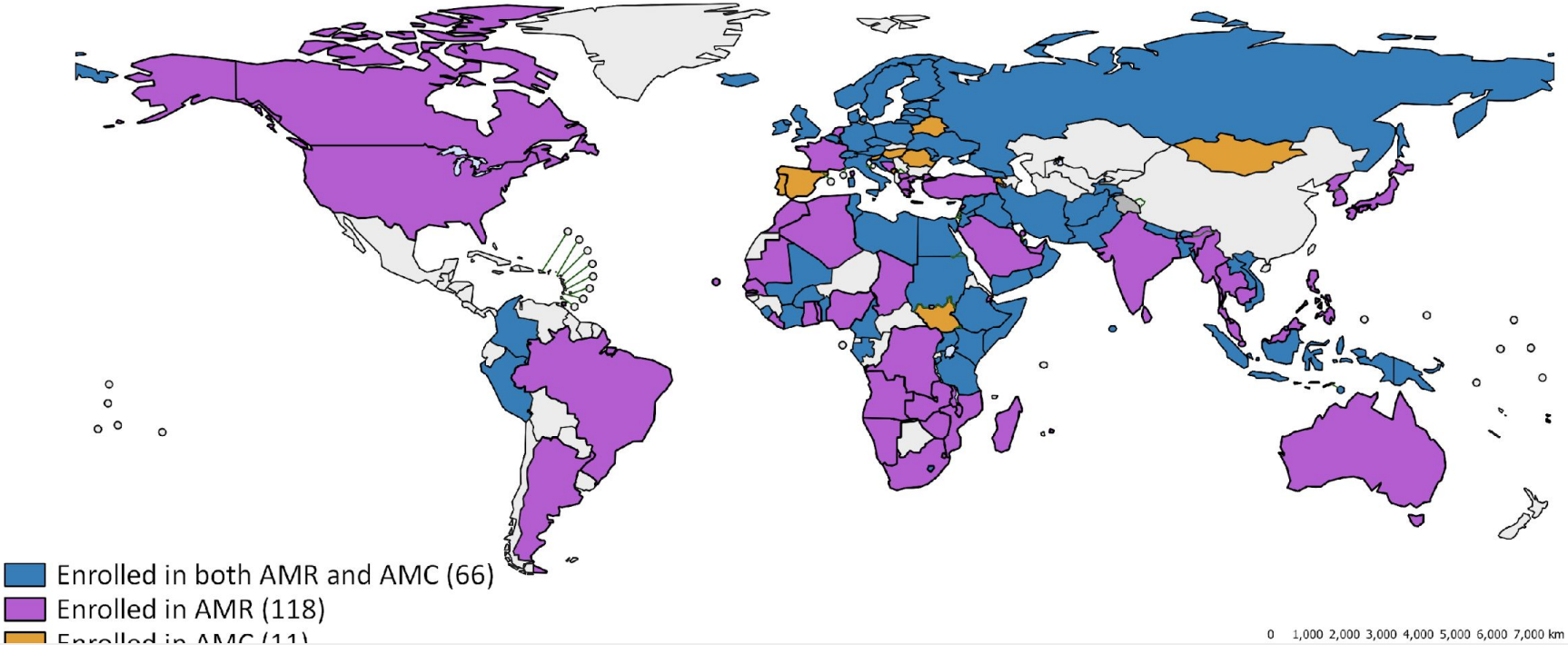
- Identifies three main approaches to conceptualise data justice
  - Ways in which data used for governance can support power asymmetries
  - Ways that technology can provide greater distributive justice through making the poor visible
  - Examining how practices of dataveillance can impact on the work of social justice organisations
- Taylor's concept: Three pillars to integrate positive with negative rights and freedoms
  - (In)visibility
  - (Dis)engagement with technology
  - Antidiscrimination
- Based on capabilities approach

Global Antimicrobial Resistance and Use Surveillance System (GLASS)

- ROUTINE SURVEILLANCE
    - **GLASS-AMR** provides a standardized approach to the collection, analysis and sharing of national AMR data in samples collected routinely for clinical purposes for a set of pathogens that cause common bacterial infections in human. **GLASS-AMC** provides a common and standardized set of methods for measuring and reporting antimicrobial consumption (AMC) at country, regional and global levels. Both technical modules collect data on the implementation of the respective national surveillance systems.
- FOCUSED SURVEILLANCE
    - **GLASS-EAR**, the emerging AMR reporting (EAR) module, supports the timely detection, reporting, risk assessment and monitoring of emerging resistance. **GLASS-FUNGI** focuses on the surveillance of invasive fungal bloodstream infections caused by *Candida* spp.
- SURVEYS AND STUDIES
    - **EGASP** offers an enhanced approach to sentinel gonorrhoea surveillance of men with urethral discharge and suspected urogenital infections. The **One Health** technical module offers an integrated multi-sector surveillance programme based on the extended-spectrum beta-lactamase (ESBL)-*Escherichia coli* (‘Tricycle’) project. **PPS-AMU** proposes a method for the conduct of point prevalence surveys (PPS) of antibiotic use (AMU) at the hospital level, and the **BURDEN** technical module presents studies estimating the public health impact of AMR

GLASS Enrolment Map June 2023

Number of countries enrolled in GLASS: 129



World Health Organization

Donate

Online public consultation: Attributes and principles for genomic data sharing platforms supporting surveillance of pathogens with epidemic and pandemic potential

Deadline for submission: 12 February 2025, 23:59 CET

Related Highlight

International Pathogen Surveillance Network (IPSN) ›

Published on 29.8.2024 in Vol 4 (2024)

Preprints (earlier versions) of this paper are available at https://preprints.jmir.org/preprint/56307, first published January 15, 2024.

Ethical Considerations in Infodemic Management: Systematic Scoping Review

Federico Germani[1]; Giovanni Spitale[1]; Sandra Varaidzo Machiri[2]; Calvin Wai Loon Ho[3]; Isabella Ballalai[4]; Nikola Biller-Andorno[1]; Andreas Alois Reis[5]

Abstract

Background:
During health emergencies, effective infodemic management has become a paramount challenge. A new era marked by a rapidly changing information ecosystem, combined with the widespread dissemination of misinformation and disinformation, has magnified the complexity of the issue. For infodemic management measures to be effective, acceptable, and trustworthy, a robust framework of ethical considerations is needed.

Objective:
This systematic scoping review aims to identify and analyze ethical considerations and procedural

Citation

Please cite as:

Germani F, Spitale G, Machiri SV, Ho CWL, Ballalai I, Biller-Andorno N, Reis AA Ethical Considerations in Infodemic Management: Systematic Scoping Review
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PMCID: 11393515

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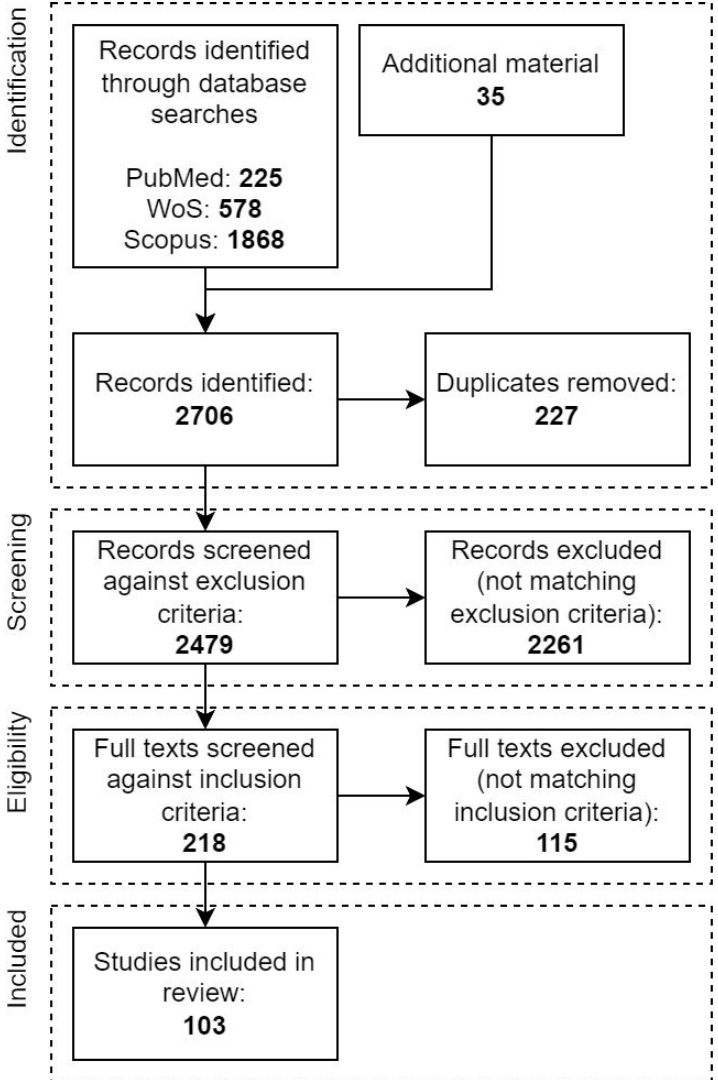
Reviews in Infodemiology (5)



Top 10 ethical issues in the literature includes (see Appendix 1 to Manuscript):

1. Right to be informed truthfully
2. Trust and mistrust
3. [Surveillance & Social Listening represented a composite of issues]
4. Vulnerability and inequality
5. Free speech vs. Regulation
6. Privacy
7. Lack of community engagement
8. Informing vs. Manipulating
9. Honesty vs. Conflicts of interest
10. Lack of education

Top 5 ethical aims of infodemic management includes (discussed in manuscript):

1. Truthful communication and outreach
2. (Responsible and effective) surveillance
3. Community Engagement
4. Trust
5. Transparency

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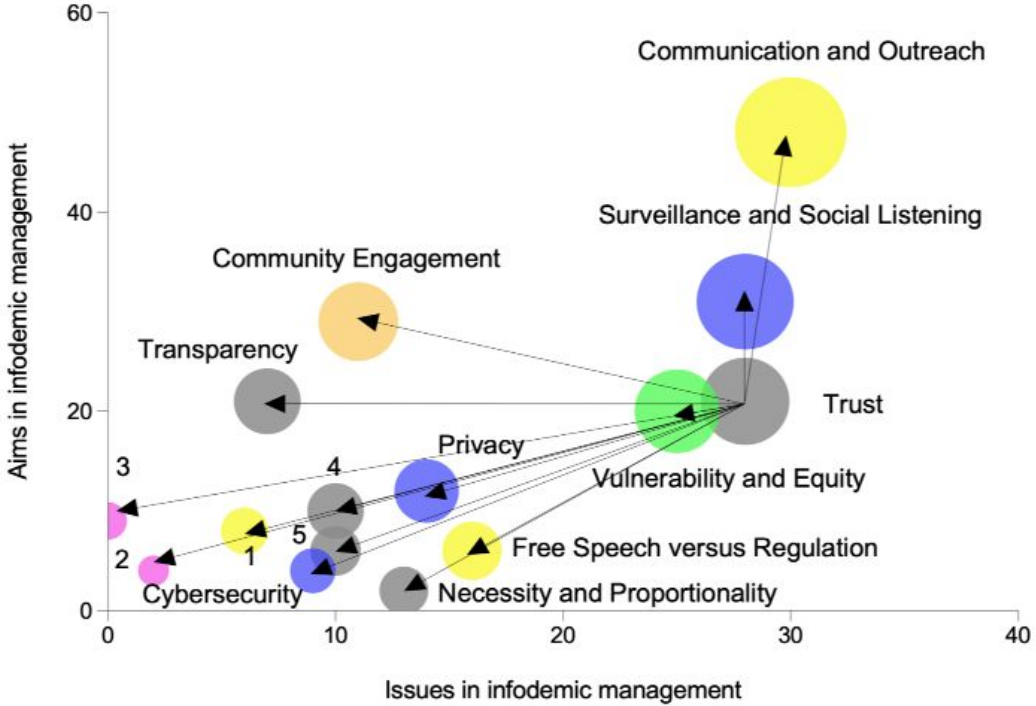
Trust and Mistrust



Category

- Communication, Media, and Information
- Privacy, Surveillance, and Data Ethics
- Ethics, Responsibility, and Governance
- Social Equity and Inclusivity
- Public Engagement and Education
- Other

1 Translation of Evidence into Public Health Practice
2 Research
3 Cooperation Between Institutions
4 Informing versus Manipulating Behavior
5 Honesty and Conflicts of Interest

How the EU AI Act Seeks to Establish an Epistemic Environment of Trust

Original Paper | Open access | Published: 24 June 2024

Volume 16, pages 345–372, (2024) Cite this article

Asian Bioethics Review

Aims and scope →

Submit manuscript →

Calvin Wai-Loon Ho & Karel Caals

Abstract

With focus on the development and use of artificial intelligence (AI) systems in the digital health context, we consider the following questions: How does the European Union (EU) seek to facilitate the development and uptake of trustworthy AI systems through the AI Act? What does trustworthiness and trust mean in the AI Act, and how are they linked to some of the ongoing discussions of these terms in bioethics, law, and philosophy? What are the normative components of trustworthiness? And how do the requirements of the AI Act relate to these components? We first explain how the EU seeks to create an epistemic environment of trust through the AI Act to facilitate the development and uptake of trustworthy AI systems. The legislation establishes a governance regime that operates as a socio-epistemological infrastructure of trust which enables a performative framing of trust and trustworthiness. The degree of success that performative acts of trust and trustworthiness have achieved in realising the legislative goals may then be assessed in terms of statutorily defined proxies of trustworthiness. We show that to be trustworthy, these performative acts should be consistent with the ethical principles endorsed by the legislation; these principles are also manifested in at least four key features of the governance regime. However, specified proxies of trustworthiness are not expected to be

European Commission

INDEPENDENT

HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE

SET UP BY THE EUROPEAN COMMISSION

ETHICS GUIDELINES FOR TRUSTWORTHY AI

Key Features

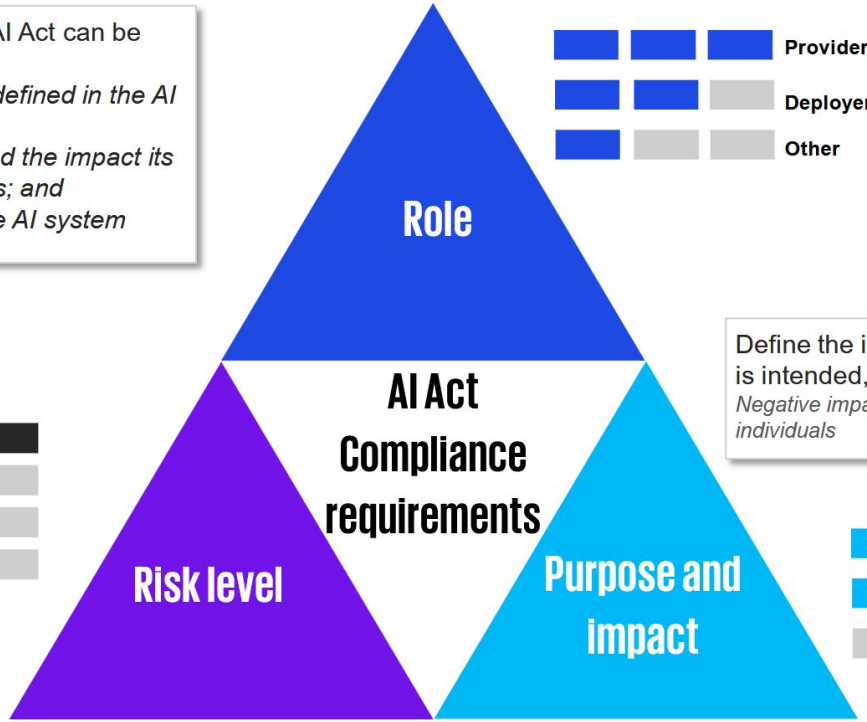
- The AI Act is the first horizontal legislation in the EU to regulate AI systems and takes the leading role in setting global standards on AI systems.
- Main Objectives:
  - Safeguarding fundamental rights and Union values, and ensures product safety
  - Cultivating innovation and competitive growth
- Risk-based approach: The AI Act introduces 4 risk categories and sets legal rules according to the level of risk.
- Providers vs. Deployers: Different actors in the AI value chain will assume distinct roles and responsibilities.
- Extraterritorial Scope: Govern AI systems developed by an EU provider; AI systems put on the EU market; AI systems developed and used outside of the EU, but where the output of the system is intended for use in the EU.

Aims & Penalties

- Aims to Promote Trust:
  - Regulations and compliance are expected to protect individuals for negative impact of AI.
  - The AI Act aims to ensure that AI systems are safe, respect fundamental rights, foster AI investment, improve governance, and encourage a harmonised single EU market for AI.
- Strengthened Code of Practice on Mis- and Disinformation.
- Penalties:
  - Prohibited AI violations: up to 7% of global annual turnover or 35 million euros.
  - Most other violations (providers and deployers): up to 3% of global annual turnover or 15 million euros.
  - Supplying incorrect information to authorities: up to 1% of global annual turnover or 7.5 million euros.

The degree of obligation under the AI Act can be derived from three main factors:

1. *The role of the organization, as defined in the AI Act*
2. *The purpose of the AI system and the impact its use with gave on natural persons; and*
3. *The risk level associated with the AI system*



Provider
Deployer
Other

Define the impact of the use for which the AI system is intended, it purposes, on individuals

Negative impact on security, safety and fundamental rights of individuals

Unacceptable
High
Limited
Minimal

Purpose negatively impacting individuals
Purpose impacting individuals
No to minimal impact in individuals

Existing and Emerging Capabilities in the Governance of Medical AI

Letter to the Editor | Published: 24 June 2024

Volume 16, pages 307–311, (2024) Cite this article

Asian Bioethics Review

Aims and scope →

Submit manuscript →

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Gilberto K. K. Leung, Yuechan Song & Calvin W. L. Ho

The Centre for Medical Ethics and Law of the University of Hong Kong (HKU) hosted an international conference from 9 to 11 May 2023 on 'Governance of Medical AI'. This event was held in collaboration with HKU's Clinical Trials Centre, the Medical Ethics and Humanities Unit of the LKS School of Medicine of HKU, and the Hong Kong Academy of Medicine. For the purposes of this conference, medical artificial intelligence (AI) was broadly understood as an algorithm, model or software developed with the intent for use in healthcare and in health-related research. Technology governance, as defined by the Organisation for Economic Co-operation and Development (OECD 2023), was adopted in the discussions so that 'governance' refers not only to regulation, but also to a multitude of institutional and normative requirements, standards and mechanisms that steer technological development.

Sections References

Health Policy Watch
Independent Global Health Reporting

Ho

Antimicrobial Resistance | Infectious Diseases | Pandemics & Emergencies | Non-Commu Diseases

Pandemic Agreement Talks Extended: One More Year to Resolve Critical Issues

Pandemics & Emergencies 02/07/2024 · Daniela Morich & Ava Greenup

Share this:

Ashley Bloomfield, co-chair of the Working Group on Amendments to the International Health Regulations and Precious Matsoso, co-chair of the Intergovernmental Negotiating Body (INB) on the eve of the World Health Assembly

Following the 77th World Health Assembly (WHA)'s endorsement of a delay of up to one year for finalizing a pandemic agreement, the Intergovernmental Negotiating Body (INB) is set to resume talks on 16-17 July 2024.

COMMENT · Online first, October 24, 2024

Equitable access to pandemic products demands stronger public governance

Adam Strobeyko [a] · Caesar A Atuire [b] · Ruth Faden [c] · Calvin W L Ho [d] · Vitor Ido [e] · Mohga Kamal-Yanni [f] · et al. Show more

Affiliations & Notes · Article Info

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Show Outline

The slow arrival of vaccines to the increasing number of countries ravaged by mpox shows that the COVID-19 pandemic did not result in the structural change needed to address global inequities. The absence of global arrangements to ensure access to health products during emergencies is a gap that governments are seeking to fill through recently agreed amendments to the International Health Regulations (IHR) and continuing negotiations towards a Pandemic Agreement. Pending the outcome of intergovernmental negotiations, WHO created the interim Medical Countermeasures Network (i-MCM-Net) as a temporary measure to coordinate the rapid development of and equitable access to pandemic products. As the global health community debates what longer-term mechanism should follow i-MCM-Net, substantial disagreement remains on governance, particularly the role of WHO. We argue that governments are primarily and collectively responsible for ensuring equitable access to essential health products and should mandate WHO with a more robust role in relation to states and non-state actors.

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Incorporating New Datasets like Genomics Requires New Regulatory Capabilities

nature genetics

Comment | Published: 09 September 2024

Defining and pursuing diversity in human genetic studies

Maili C. Raven-Adams, Tina Hernandez-Boussard, Yann Joly, Bartha Maria Knoppers, Subhashini Chandrasekharan, Adrian Thorogood, Judit Kumuthini, Calvin Wai Loon Ho, Ariana Gonzlez, Sarah C. Nelson, Yvonne Bombard, Donrich Thaldar, Hanshi Liu, Alessia Costa, Vijaytha Muralidharan, Sasha Henriques, Jamal Nasir, Aimé Lumaka, Beatrice Kaiser, Saumya Shekhar Jamuar & Anna C. F. Lewis

Nature Genetics (2024) | Cite this article

Calls for more diverse data in genetics studies typically fall short of offering further guidance. Here we summarize a policy framework from the Global Alliance for Genomics and Health designed to fill this gap. The framework prompts researchers to consider both what types of diversity are needed and why, and how aims can be achieved through choices made throughout the data life cycle.

Regulatory Capability Requires an Anticipatory Character

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Dedication

Contents

Figures

Tables

Contributors

Acknowledgements

Introduction

Part I Concepts, Tools, Processes

28 - When Learning Is Continuous

Bridging the Research-Therapy Divide in the Regulatory Governance of Artificial Intelligence as Medical Devices

from Section IIB - Widening the Lens

Published online by Cambridge University Press: 09 June 2021

By Calvin W. L. Ho

Edited by Graeme Laurie, Edward Dove, Agomoni Ganguli-Mitra, Catriona McMillan, Emily Postan, Nayha Sethi and Annie Sorbie

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Chapter Figures

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Summary

Artificial intelligence and machine learning (AI/ML) medical devices are able to optimise their performance by learning from past experience. In healthcare, such devices are already applied within controlled settings in image analysis systems to detect conditions like diabetic retinopathy, for instance. In examining the regulatory governance of AI/ML medical devices in the United States, it is argued that the development and application of these devices as a technical and social concern whether in research or in clinical care must proceed in tandem with their identities in regulation. In the light of emerging regulatory principles and approaches put forward by the International Medical Device Regulators Forum, and endorsed by the US Food and Drug Administration, conventional thinking about clinical research and clinical practice as distinct and separate domains needs to be reconsidered. The high connectivity of AI/ML medical devices that are capable of adapting to their digital environment in order to optimise performance suggest that the research agenda persist beyond what may be currently limited to the pilot or feasibility stages of medical device trials. If continuous risk-monitoring is required to support the use of software as medical devices in a learning healthcare system, more robust and responsive regulatory mechanisms are needed, not less.

The notion of anticipatory governance is especially relevant to reconciling data-driven learning health systems with a human right to science. **Anticipatory governance** may be understood as a broad-based capacity extended through society that can act on a variety of inputs to manage emerging knowledge-based technologies while such management is still possible (Knoppers 2018).

The possibility for anticipatory governance relies on continuous evolution, where the discovery engine is governed by policies for complex collective innovation, and the negotiation of co-designed innovation futures informed by earlier foresight generated with the inclusion of knowledge generators, end users and evidence (including uncertainty) to imagine the possible multiplex futures for innovations.

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Regulatory Governance should be Participatory

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Volume 10, Issue 2
July-December 2023
(In Progress)

Article Contents

Abstract
I. INTRODUCTION
II. HUMAN RIGHT TO SCIENCE
III. RISK-BASED REGULATION
IV. PARTIAL JUSTIFICATION OF RISK-BASED APPROACH IN HRS
V. 'SOFTWARE AS A MEDICAL DEVICE' AS A NEW REGULATED ENTITY
VI. PARTICIPATION IN REGULATION GOVERNANCE UNDER HRS
VII. CONCLUSION
ACKNOWLEDGEMENTS
Footnotes
Author notes

< Previous Next >

JOURNAL ARTICLE

Implementing the human right to science in the regulatory governance of artificial intelligence in healthcare

Calvin W L Ho ✉ Author Notes

Journal of Law and the Biosciences, Volume 10, Issue 2, July-December 2023, lsad026, https://doi.org/10.1093/jlb/lsad026

Published: 14 October 2023 **Article history** ▾

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Abstract

Artificial intelligence (AI) enables a medical device to optimize its performance through machine learning (ML), including the ability to learn from past experiences. In healthcare, ML is currently applied within controlled settings in devices to diagnose conditions like diabetic retinopathy without clinician input, for instance. In order to allow AI-based medical devices (AIMDs) to adapt actively to its data environment through ML, the current risk-based regulatory approaches are inadequate in facilitating this technological progression. Recent and innovative regulatory changes introduced to regulate AIMDs as a software, or 'software as a medical device' (SaMD), and the adoption of a total device/product-specific lifecycle approach (rather than one that is point-in-time) reflect a shift away from the strictly risk-based approach to one that is more collaborative and participatory in nature, and anticipatory in character. These features are better explained by a rights-based approach and consistent with the human right to science (HRS). With reference to the recent explication of the normative content of HRS by the Committee on Economic, Social and Cultural Rights of the United Nations, this paper explains why a rights-based approach that is centred on HRS could be a more effective response to the regulatory challenges posed by AIMDs. The paper also considers how such a rights-based approach could be implemented in the form of a regulatory network that draws on a 'common fund of knowledges' to formulate anticipatory responses to adaptive AIMDs. In essence, the HRS provides both the mandate and the obligation for states to ensure that regulatory governance

Key source of more specific rights and freedoms to which all humans are entitled in relation to scientific progress and its applications.

- Article 27 of the Universal Declaration of Human Rights (UDHR)
- Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)

At least three main components in implementation:

- The right of everyone to benefit from and contribute to scientific and technological progress (or HRS in the public interest sense)
- The right of scientists to do research and push forward science and technology (or HRS in a technical sense)
- Countries' duty to provide an enabling environment (or HRS in a governance sense). "right for people to have a legislative and policy framework adopted and implemented which aims at making the benefits of scientific progress available and accessible—both through encouraging new scientific discoveries and through removing barriers for existing scientific knowledge to be used for public benefit". [**Evolving capacity**]


THANK YOU!

Discussion

Discussion

Global Perspectives

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Suerie Moon

Visiting Professor, SingHealth Duke-NUS Global Health Institute

Professor of Practice in International Relations & Political Science, Graduate Institute Geneva

SPEAKER

Gian Luca Burci

Senior Visiting Professor, Graduate Institute Geneva

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Ayelet Berman

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DukeNUS Medical School | Centre for Outbreak Preparedness

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National University of Singapore

Pathogen Access and Benefit Sharing: Global and Regional Legal Perspectives

Regional Perspectives

SPEAKER

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Lead, initiatives in Asia, O'Neill Institute for National and Global Health Law

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Pathogen Access and Benefit Sharing: Global and Regional Legal Perspectives

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Law, Policy and Governance of Pathogen Genomics Surveillance and Data Sharing: Perspectives from India

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Visiting Scholar, Harvard Law School

20 January, 2025, Duke-NUS

Agenda

- Country Context: Why India?
- Legal, policy and governance landscape of pathogen genomic surveillance and data sharing in India
- Key Issues and Gaps
- Looking Ahead

Country Context: Why India?

- Most populous – diverse epidemiological profile – forefront of emerging infectious diseases
- Pharmacy of the World – central role in addressing health emergencies worldwide – home to major manufacturers – Eg. SII, BBIL
- COVID-19 Response – Global Vaccine Supply Chain Disruption
- Implementation of Global Frameworks Varies – Nagoya Protocol
- India's Approach – Case Study on how an Emerging Economy Balances Sovereign Rights v. Global Commitments to Equitable Access
- PABS Regulatory Landscape impacts a countries' ability to foster TT and build local manufacturing capacities

Law and Governance of Pathogen Genomics Surveillance and Data Sharing in India

- Public Health Surveillance
- Access and Benefit Sharing
- Storage and Sharing of Biological Data including International Data Sharing
- Data Protection and Security
- Consent
- Ethics
- Intellectual Property Rights
- Genetic Discrimination
- One Health
- Laws Facilitating Collaboration & Stakeholder Engagement

Public Health Surveillance

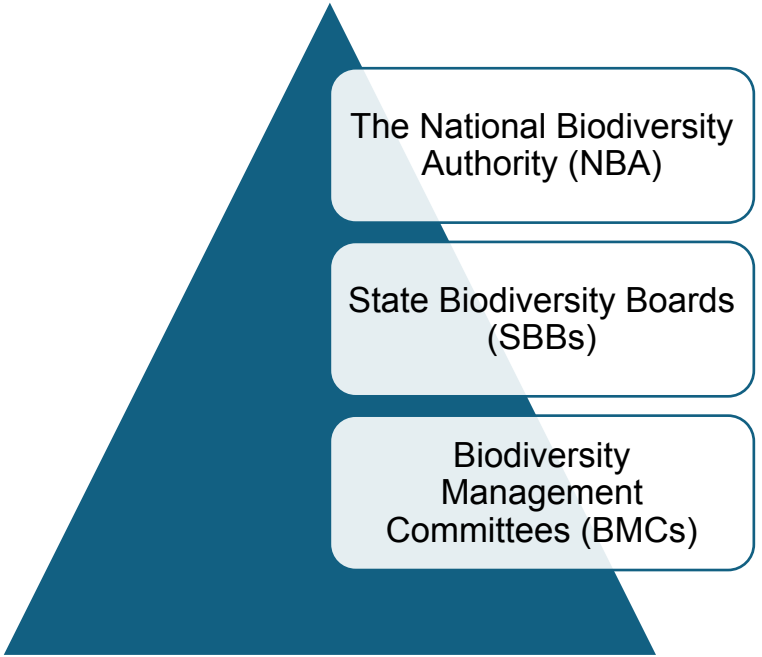
- **Integrated Disease Surveillance Programme (IDSP):**
  - Established in 2004 in 101 districts
  - Each district now has a surveillance unit and a rapid response team (RRT)
  - A Central Surveillance Unit (CSU) at Delhi, State Surveillance Units (SSU) at all State/UT headquarters and District Surveillance Units (DSU) at all Districts
- Key programme components of IDSP include:
  - Integration and decentralization of surveillance activities through establishment of surveillance units at Centre, State and District level
  - Human Resource Development – Trainings
  - Use of Information Communication Technology for collection, collation, compilation, analysis and dissemination of data.
  - Strengthening of public health laboratories - maintains decentralised laboratory
  - Inter sectoral co-ordination for zoonotic diseases.

Public Health Surveillance

- **Indian SARS-CoV-2 Genomics Consortium (INSACOG):**
  - To ascertain the status of Variants of Interest (VoI) and Variants of Concern (VoC) in the country;
  - To establish sentinel surveillance and surge surveillance mechanisms for early detection of genomic variants and assist in formulating effective public health response;
  - To determine the presence of genomic variants in samples collected during super-spreader events and in areas reporting increasing trend of cases/deaths etc.
- **Alliance for Pathogen Surveillance Innovations (APSI)-India**: multi-city consortium backed by the Rockefeller Foundation
- **GenomeIndia Project**: '10,000 genome project'
- In 2008, the **Indian Genome Variation (IGV) consortium** was one of the first such initiatives to develop a large-scale database of genomic diversity in India
- **Government Departments/Agencies:**
  - National Centre for Disease Control (NCDC)
  - Department of Biotechnology (DBT)
  - Indian Council of Medical Research (ICMR)
  - Council for Scientific & Industrial Research (CSIR)

Access and Benefit Sharing

- Biological Diversity Act, 2002 *(implementing CBD)*
- Rules 2004
- Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations (ABS Regulations), 2014 *(implementing Nagoya P)*
- Amendment, 2023



Access and Benefit Sharing

- The BDA regulates biological resources, which is defined as

"plants, animals, microorganisms, or parts of their genetic material and derivatives (excluding value-added products), with actual or potential use or value for humanity, but does not include human genetic material"

- The law specifically excludes human genetic material from its scope..

- *Microorganisms or pathogens (including vectors of human diseases) found in human body would still be considered as biological resources.*

Access and Benefit Sharing

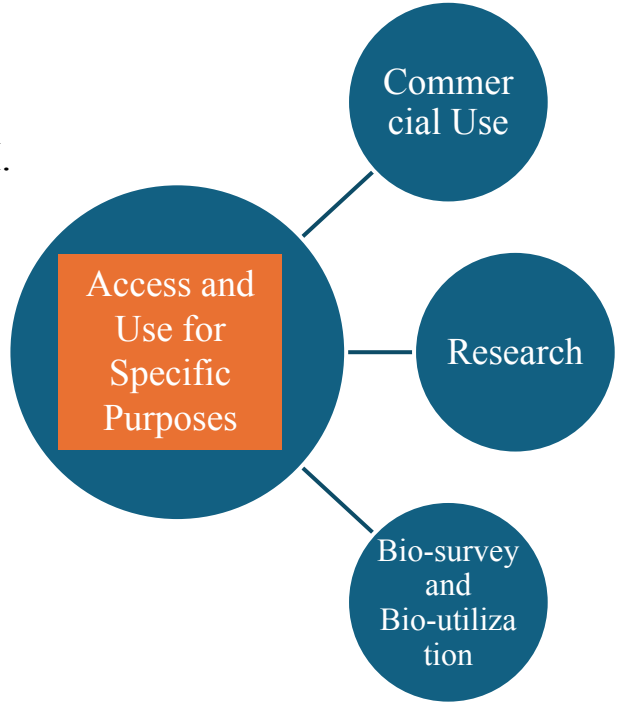
- While the BDA does not include explicit reference to Digital Sequence Information (DSI) or any such terminology, the relevant provisions in the Act can cover in their scope the utilization of DSI.

India's submission on Digital Sequence Information on Genetic Resources in response to CBD notification 2019-012 dated 5 February 2019 pursuant to decisions 14/20 and NP-3/12

a) To clarify the concept, including relevant terminology and scope, of digital sequence information on genetic resources and if and how domestic measures on access and benefit-sharing consider digital sequence information on genetic resources;

(b) On benefit-sharing arrangements from commercial and non-commercial use of digital sequence information on genetic resources.

- Legal Status of the person/entity: Indian and non-Indian



Access and Benefit Sharing

PHASE 1: Access by applicant: through approval (constituting PIC) from institutional structures

PHASE 2: Benefit sharing: through signing of MAT and actual sharing with competent authority

PHASE 3: Distribution of benefits: to benefit claimers by competent authority either directly or through biodiversiity funds

ABS Implementation in India

Access and Benefit Sharing

Phase 1: Access to Biological Resources

- Approvals to be sought by non-Indians for access – *irrespective of purpose!*
- Approvals to be sought by Indians for access for *commercial utilization*
- Approvals for international data sharing [transferring 'results of research']
- Approvals for seeking intellectual property rights

Unlike requirements for non-Indians, Indians are not required to seek any approvals for access to biological data for carrying out research or bio-survey/bio-utilization

Access and Benefit Sharing

Phase 2 and 3: Benefit Sharing Mechanisms

Fair and Equitable Sharing of Benefits:

- *Grant of joint ownership of intellectual property rights to NBA, or where benefit claimers are identified, to such benefit claimers*
- *Transfer of technology*
- *Location of production and R&D units in areas that would facilitate better living standards to the benefit claimers*
- *Association of Indian scientists, benefit claimers and local people with R&D in and bio-survey and bio-utilization*
- *Setting up of venture capital fund for aiding the cause of benefit claimers*
- *Payment of monetary compensation & non-monetary benefits to benefit claimers as suggested by NBA. The ABS Regulations 2014 lists the statutory options available for both monitory and non-monitory compensation.*

Access and Benefit Sharing

Phase 2 and 3: Benefit Sharing Mechanisms

Fair and Equitable Sharing of Benefits Options [Regulations, 2014]

Monetary benefits options:

(i). Up-front payment;
(ii). One-time payment;
(iii). Milestone payments;
(iv). Share of the royalties and benefits accrued;
(v). Share of the license fees;
(vi). Contribution to National, State or Local Biodiversity Funds;
(vii). Funding for research and development in India;
(viii). Joint ventures with Indian institutions and companies;
(ix). Joint ownership of relevant intellectual property rights.

Non-monetary benefits options:

(i). Providing institutional capacity building, including training on sustainable use practices, creating infrastructure and undertaking development of work related to conservation and sustainable use of biological resources;
(ii). Transfer of technology or sharing of research and development results with Indian institutions/ individuals/entities;
(iii). Strengthening of capacities for developing technologies and transfer of technology to India and/or collaborative research and development programmes with Indian institutions/ individuals/ entities;
(iv). Contribution/ collaboration related to education and training in India on conservation and sustainable use of biological resources;
(v). Location of production, research, and development units and measures for conservation and protection of species in the area from where biological resource has been accessed, contributions to the local economy and income generation for the local communities;
(vi). Sharing of scientific information relevant to conservation and sustainable use of biological diversity including biological inventories and taxonomic studies;
(vii). Conducting research directed towards priority needs in India including food, health and livelihood security focusing on biological resources;
(viii). Providing scholarships, bursaries and financial aid to Indian institutions/ individuals preferably to regions, tribes/ sects contributing to the delivery of biological resources and subsequent profitability if any;
(ix). Setting up of venture capital fund for aiding the cause of benefit claimers;
(x). Payment of monetary compensation and other non-monetary benefits to the benefit claimers as the NBA

Access and Benefit Sharing

Total Applications Received		8366
Approvals granted and Agreement Signed	Access to Bioresources for Research/ Commercial Purposes [Form I]	746
	Transfer of Research Results [Form II]	45
	Approval for obtaining IPRs [Form III]	4279
	Third Party Transfer [Form IV]	34
	Form B	189
	Total	5293

Storage and Sharing of Biological Data

- **The Indian Biological Data Centre (IBDC)** (also known as Data Repository or National Biological Knowledge, Information and Data Centre) set up in 2022 - *first life sciened data repository*

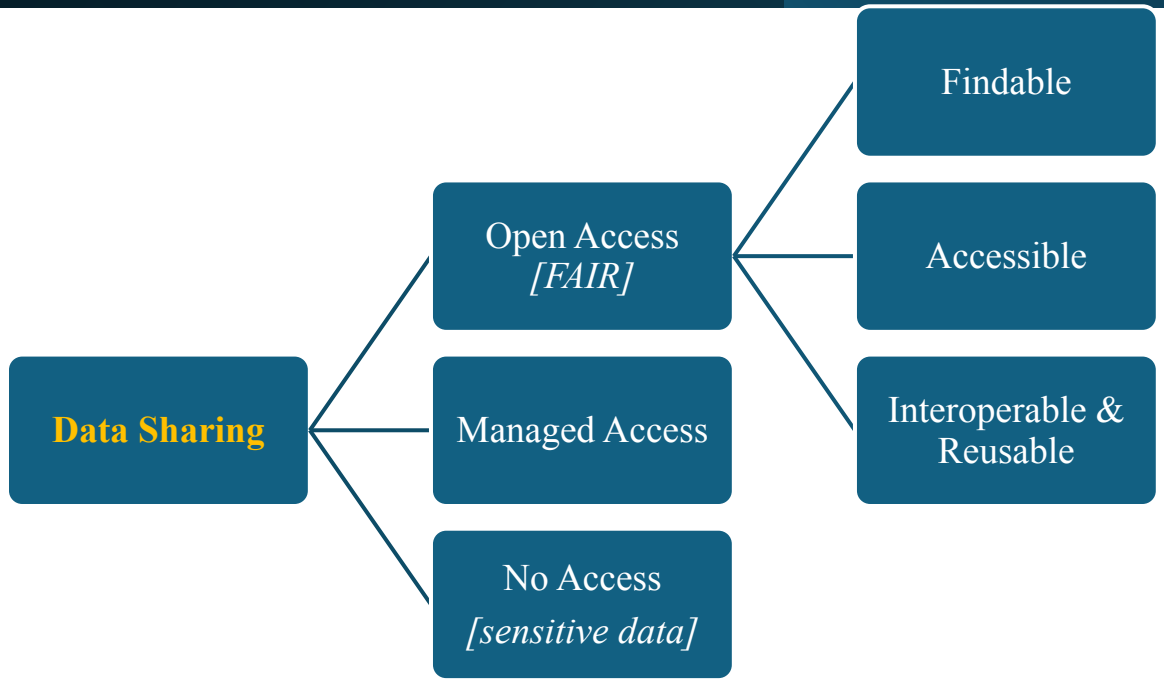
- **BIOTECH-PRIDE Guidelines (Promotion of Research and Innovation through Data Exchange), July 2021** to facilitate and enable sharing and exchange of biological knowledge, information and data generated through research *conducted within the country through public money/funds (either partly or in whole)*

Data in Digital Form

Type of Data	Data Deposit Timeline
Raw (level 1) Data	Within one year of data-generation
Reference Data Set	Within six months of data-generation
Processed (level 2) Data	Within two years of data-generation
Metadata	To be deposited concurrently with other types of data

Storage Timeline Requirement

Storage and Sharing of Biological Data



- Also permits the **withdraw** of data, provided the data so requested for withdrawal is identifiable in the database
- **Data User Agreement**: Guidelines mention detailed user terms

Key Issues and Gaps

1. **Pathogen Genomic Surveillance Infrastructure: Gaps, Strengths**
    a. Fragmented infrastructure, with concentrated efforts in urban centres
    b. Lack of integration with field-level surveillance programs – IDSP
    c. Decentralized approach is needed – with States given more autonomy
2. **Inter-agency Coordination**
    a. Lack of collaboration between agencies such as INSACOG, IDSP, NCDC, ICMR, NBA
    b. Centralized decision-making within INSACOG – critical issue
    c. Solution – Statutory body/agency (INSACOG model), but disease-agnostic, with clearer roles
3. **Access and Benefit Sharing (ABS): Policy and Legal Frameworks**
    a. Ambiguities in Legal Interpretation and Implementation – *pathogens? DSI?*
    b. Challenges in Applying ABS to Pathogens – *current framework does not account for the unique nature of pathogens and the urgent need for rapid information exchange during outbreaks*
    c. Transparency and Public Accountability in ABS Agreements
    d. Uncertainty Around Non-Monetary Benefits and Fair Benefit Sharing
4. **Data Storage and Sharing: Challenges**
    a. Lack of a clear definition for when the process of ‘data-generation’ is considered complete
    b. Inconsistencies in the timely deposition of data into national repositories

Way Ahead

1. **Enhancing Pathogen Genomic Surveillance Infrastructure**
    a. Develop a National Genomic Surveillance Strategy
    b. Decentralize Surveillance Capabilities
    c. Invest in Workforce Training
2. **Improved Inter-agency Coordination:** *establishing a statutory, disease-agnostic body!*
3. **Revisit Access and Benefit Sharing (ABS) ?**
    a. Clarify legal scope and applicability
    b. Develop tailored ABS frameworks for pathogens?
    c. Enhance transparency in ABS agreements – *terms and conditions, especially non-monitory?*
4. **Strengthen Data Storage and Sharing Mechanisms**
    a. Standardize Data Submission Timelines
    b. Enhance Computational Infrastructure
    c. Promote Local Data Control with Global Collaboration - need to enhance local data storage capabilities and ensuring domiciliary control over genomic data rather than relying *solely* on global platforms like GISAID

Thank you

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Pathogen Access and Benefit Sharing: Global and Regional Legal Perspectives

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Pathogen Genome Surveillance and Data Sharing in Indonesia

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January 20, 2025

Presentation Roadmap

- 1. Overview of Current Initiatives
- 2. PABS (Pathogen Access & Benefit Sharing) Foundations
- 3. IP Rights and Pathogen in Indonesia
- 4. Pathogen Sequencing Data (GSD) / Digital Sequences Information (DSI) and Data Protection in Indonesia
- 5. Conclusions and Q&A

Current Initiatives in Indonesia

Biomedical and Genome Science Initiative (BGSi) under MoH

- Laid groundwork for pathogen genomic surveillance
- Heavy reliance on external funding, raising questions of long-term viability

Network of Public Health Laboratories

- Collaboration with hospitals, research institutes, universities
- Fragmented infrastructure: ~51% utilization rate; capacity unevenly distributed

Decentralized Health Governance

- 38 provinces, 500+ districts inconsistent implementation
- Coordination challenges for rapid data sharing and outbreak response

Key Achievements & Challenges

- Achievements
  - **National Strategic Plan** integrating pathogen genomics (e.g., for TB, influenza, emerging viruses)
  - **Legal Basis**: New Health Law explicitly mentions genomics in health services
  - **Improving Lab Protocols**: Some labs accredited by international standards, albeit limited
- Challenges
  - **Funding Gap**: ~57% from donors; only ~32% from public funds
  - **Human Resource Shortage:** Limited trained epidemiologists and genomic specialists
  - **Data Fragmentation**: Over 400 health apps; minimal interoperability

Foundation – Pathogen Access & Benefit Sharing

Legal & Policy Landscape	Nagoya Protocol ratification (Law Number 11/2013) country's "sovereignty" over genetic resources Ministry of Health (MoH) Regulations on MTAs (e.g., MoH Regulation Number 85 / 2020)
Core Components (in principle):	**Access to Biological Resources**: Subject to licensing and ministry approvals **Benefit-Sharing Mechanisms**: Financial (royalties, licensing fees) + non-financial (tech transfer, co-authorship) **Fair & Equitable Sharing Criteria**: Emphasized but often underused in practice

Core Elements of MTAs in Indonesian Legislation

- **Parties**: MoH, local labs, foreign research or commercial entities
- **Requirement**: materials/data can only be transferred abroad if they cannot be processed domestically and if the receiving institution meets safety requirements
- **Ownership & Control**: The originating institution retains ownership; the receiving party is granted limited rights
- **IPR**: Ownership of resulting IP remains with the originating institution unless specifically negotiated otherwise
- **Confidentiality**: Protects trade secrets, know-how, proprietary data
- **Use of Materials**: Materials can be used only for agreed purposes; no unauthorized commercial exploitation
- **Return or Disposal of Materials**: Unused materials must be returned or disposed of under originating institution's direction

IPR and Pathogens in Indonesia

- **Patent “Thickets”**
  - Overlapping patents on pathogen sequences and related technologies (e.g., reverse genetics, cell culture)
  - Risk of hampering local vaccine or diagnostic development
- **Patent Law & Disclosure Requirements**
  - Indonesia’s Patent Law: Mandatory disclosure of genetic resource origin (aligned with Nagoya Protocol and the new GRATK Treaty)
  - Ensures local benefit-sharing, but enforcement challenges persist
- **Patentability**
  - Excludes “discoveries” of natural phenomena
  - Critique: Ambiguities around modified vs. naturally occurring sequences
- **Compulsory Licensing & Bolar Exception**
  - CL can bypass patent protection during national emergencies
  - BE allows manufacturers/researchers to begin development and testing of generic versions (or local vaccines) before the patent expires so they can launch immediately once it does.
  - Both rarely invoked due to trade and economic pressures from partner

GSD/DSI & Data Protection in Indonesia

- **Sensitive Data Uncer PDP Law**
  - Health and genetic data classified as “specific” □ extra safeguards (DPIAs, DPOs)
  - Explicit consent required: data subjects have right to access, delete, withdraw
- **Cross-Border Sharing**
  - Allowed only if the receiving country has “comparable” protections or explicit consent
  - Binding agreements or equivalency assessment to ensure compliance
- **Data Subject Rights & Enforcement**
  - Administrative, civil, criminal sanctions for violations
  - Individuals can claim damages, reflecting emphasis on accountability

Conclusions

Indonesia must strengthen domestic financing to reduce reliance on donor funding and invest in local labs and R&D.

- Reinstate mandatory spending in the Health Law
- Increase R&D budget

Indonesia needs to implement more IP flexibility to increase domestic capacity.

- Tighten patentability criteria
- Utilize Bolar exception and compulsory licensing as needed
- Enforce disclosure requirements

PDP Law provides a data protection framework, but real-time outbreak sharing still needs clearer protocols

Discussion

Discussion

Regional Perspectives

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Pathogen Access and Benefit Sharing: Global and Regional Legal Perspectives

Monday, 20 January 2025

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