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Big Data and Artificial Intelligence for Achieving Universal Health Coverage:
An International Consultation on Ethics

Meeting report

12–13 October 2017, Miami, Florida, USA

World Health Organization

UNIVERSITY OF MIAMI
MILLER SCHOOL OF MEDICINE
INSTITUTE FOR BIOETHICS

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ORGANIZING PARTNERS

GLOBAL HEALTH ETHICS TEAM, WORLD HEALTH ORGANIZATION

WHO has had a longstanding interest in health data and information, notably through its department of Information, Evidence and Research. The aim of the department is to strengthen the availability, accessibility, quality, reliability and use of health information in WHO Member States and development partners. Within the department, the Global Ethics Team addresses ethical questions that arise in technical programmes, in support of Member States and in consultation with its collaborating centres and experts.

INSTITUTE FOR BIOETHICS AND HEALTH POLICY, MILLER SCHOOL OF MEDICINE, UNIVERSITY OF MIAMI

As the WHO Collaborating Centre in Ethics and Global Health Policy, the Miami centre has long been a partner with WHO in addressing challenges related to health information technology. A leader in the field of ethics and biomedical informatics, the Miami centre conducts research on ethical issues in research, public health and clinical practice and on issues of health information technology arising in international contexts.

Links to most of the presentations summarized below are available at https://bioethics.miami.edu/who-collaborating-centre/bigdata/index.html.

ACKNOWLEDGEMENTS

BACKGROUND TO AND PURPOSE OF THE CONSULTATION

WHO and the University of Miami Miller School of Medicine Institute for Bioethics and Health Policy have long collaborated in identifying and addressing ethical issues in global public health. Over the years, they have engaged stakeholders and encouraged debate, with the goal of providing guidance and standards in key topical areas. Topics of critical concern to WHO Member States in achieving universal health coverage are the acquisition, protection, governance and sharing of data and information on health. Countries, agencies and development partners face important challenges in this area, in part because of the rapid improvement in and availability of computing and information technologies, tools and methods as well as the size, scope and sources of data sets.

In health and medicine, expanding public and private sources of data (including non-traditional sources) and the ever-increasing capability to analyse, visualize and model data reveal patterns, problems and evidence for action for use by researchers and policy-makers. The tools, methods and technologies used in "Big Data" and artificial intelligence (AI) are already being used to improve health services and systems, and the policies, practices and capabilities to support them must keep pace. This is a major challenge, given that more human lives will be touched by health information technology than any other technology, ever.

Among the policy challenges are those of ethical collection, analysis and sharing of health data. Framed as ethical, legal and social issues, these include: the requirement for and scope of valid consent regarding data; protection of privacy, confidentiality and security; challenges of governance (ownership, use, publication, sharing); appropriate use of WHO-stewarded data and information; appropriate uses and users of public health and clinical decision support systems; and ethical difficulties in making decisions and policy recommendations on the basis of probabilistic, imperfect and even flawed data.

The purpose of the consultation was to identify the scope and range of ethical issues and questions related to Big Data and AI in health, in order to inform the work of WHO and to develop future principles and guidance for stakeholders. The participants included experts and representatives of international organizations, academia, industry and governments and from the Global Network of WHO Collaborating Centres for Bioethics (Annex 1).

EXECUTIVE SUMMARY

The World Health Organization has set three strategic targets – 1 billion more people benefitting from universal health coverage; 1 billion more people better protected from health emergencies, and 1 billion more people enjoying better health and well-being (see 13th Global Programme of Work[1]). Digital technologies and artificial intelligence will be vital tools in achieving all three of these targets. For example, electronic health records are essential for ensuring continuity of care, artificial intelligence is playing an increasing role in disease surveillance and our defenses against outbreaks; and digital technologies, which are already vital for diagnostics, are becoming more and more integrated into treatments as well. Expanding public and private sources of data and improving and expanding tools to analyse, visualize and model data increasingly allow researchers and policy-makers to identify patterns, problems and evidence for action.

Expanding use of "Big Data" and AI raises a number of salient, challenging ethical issues. In order to determine the scope and range of the ethical questions related to Big Data and AI in health, the WHO's Global Health Ethics Team and the Institute for Bioethics of the University of Miami Miller School of Medicine jointly organized an international consultation in Miami, Florida, USA, on 12–13 October 2017. The aim was to inform the future work of WHO in this area and to explore whether additional international guidance should be issued for stakeholders.

The meeting participants comprised some 30 experts and representatives from international organizations, academia, industry and governments and from the Global Network of WHO Collaborating Centres for Bioethics (Annex 1). Participants discussed the opportunities and ethical challenges of using information technology for improving health, the risks of and opportunities in linking various and varied data sets to create Big Data, the contribution of Big Data to AI and what AI could mean for public health and human health. The importance of restoring the balance of power in access to data and of building responsive, resilient health information technology systems was emphasized. All experts agreed that this did not and should not diminish the role of and the need for compassionate humans in patient care.

National e-health strategies based on national laws but taking into account internationally accepted norms, including ethical frameworks, could help countries manage data collection, acquisition and use. The health Internet represents a fundamental challenge for policy and governance, and the transfer and governance of information among patients, providers and devices and use of data by all stakeholders, including the sharing of health data among countries, is an area in which ethics guidance is of critical importance. The ability to track the movement of people, and to link it to other critically important data is very useful for advancing public health, but carries with it privacy and confidentiality risks; education about managing these risks ethically is required at all levels and sectors, including the telecommunications industry. The meeting elicited discussion on various consent models, especially those that provide more ownership and/or control to individuals. Similarly, the concept of ethics in or by design was advanced as a concept that supports trust and therefore ought to be explored

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[1] http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_4-en.pdf?ua=1

further. Case studies from around the globe were used to illustrate ethical challenges and contribute to workable solutions.

SUMMARY RECOMMENDATIONS AND NEXT STEPS

As the coordinating authority on public health within the United Nations system, WHO has a unique opportunity to provide guidance, build capacity, shape the research agenda and engage stakeholders in improving the ethical foundation for use of Big Data and AI in public health. This will require further expert consultation and reviews of evidence in a transparent process with stakeholder input. Developing global ethical guidance as well as guidance for Member States also requires an analysis of knowledge gaps and setting priorities for research to address those gaps. Reports and experiences of governments and other agencies should be taken into account for their potential relevance and to ensure that work is not duplicated. The consultation produced the suggestion that the WHO Global Health Ethics team undertake the following activities:

- **Identify case studies of the use of Big Data and AI** in health in order to map and describe salient ethical issues and values and the types of problems to be addressed and solved.

- **Elaborate on selected topics**, to include equitable access, privacy and governance, in consultation with expert groups and key stakeholders, according to the priorities of Member States. Background papers could inform and guide discussions.

- **Examine governance and the ethical duties of stakeholders in the context of Big Data and AI.** Relations among the private sector, the general public and Member States are evolving in the Big Data world. The private sector (e.g. Google, Facebook) is already working with governments to access and analyse both public and non-public data. Relations and data-sharing between and among governments and the international community are also evolving. This work would determine the role of governance in benefit-sharing and the ethical duties of stakeholders in these different contexts.

- **Prepare guidance for Member States** in a report on "Governing Big Data and AI in health: ethical considerations", describing the ethical issues and points to be considered by Member States in development of national policies on Big Data and AI. Though Member States will formulate ethical policies based on their own values and aims, WHO can ensure that they are well informed by current analysis and are compatible with global norms and standards.

- **Take into account the needs and challenges of lower-income countries** because adopting the tools of health information technology is complex and implementation needs to be context-specific. The proposed initiatives must be mindful of the risks of unintended consequences.

1. THE ROLE OF ETHICS IN PUBLIC POLICY

The keynote address by the President of the University of Miami, Dr Julio Frenk, emphasized the power of data to drive policy. He reflected on global work to collect evidence for policy and early deliberations on some of the ethical concerns, noting that technology has been fledged and accelerated in unforeseen areas.

Dr Frenk, former Mexican Minister of Health, gave as an example Mexican health reform in 2006, a textbook case of the use of both evidence and an ethical framework. The premise was that every health system is shaped by a set of values and assumptions and that national discussions should be held about the distribution of health and whether access to health care is a fundamental or human right or a product or service of the economy. Consensus and policy will both fail without such public debate and participation. At that time, discussions on the use of data and an ethical foundation together fostered political agreement in the Parliament. Now, 58 million Mexicans have health care coverage, demonstrating a fundamental association between ethics and real-world policy.

He said that Big Data have fueled broad advances in health and also raised questions of consent, privacy, intellectual property rights, appropriate use, responsibility and accountability. The reliability and fidelity of data sets are a concern, and the generation of meaningful, reproducible results continues to vex investigators.

Dr Vasee Moorthy, Coordinator, Research, Ethics, Knowledge Management at the Department of Information, Evidence and Research, WHO, thanked the collaborating centres and experts on behalf of WHO. He noted that WHO's new Director-General is focusing on outcomes and that the application of information and communication technologies to outcomes-based work will be critical. He said that the objectives of the meeting were to identify the ethical challenges for universal health coverage that arise from use of Big Data and AI and to develop principles for use by various stakeholders.

Dr Andreas Reis, Global Health Ethics Team, WHO, reviewed the declarations of interest of the meeting participants and presented the agenda (Annex 2). On the first day, the group would discuss technical issues and the state of the science and on the second day the ethical issues and the way forward.

In his overview of global health information technology, Dr Doug Fridsma, American Medical Informatics Association (AMIA), emphasized the importance of restoring the balance of power in access to data so as to build capacity in informatics and to focus on patients in building

> Already, Big Data and AI are having an enormous impact on the way we organize our health systems, and it is never too early to start discussing the ethical issues.
>
> **Dr Julio Frenk, University of Miami**

responsive, resilient health information technology systems. He discussed significant changes in health information technology in the United States, including a well-funded initiative to incentivize the transition to electronic health records. Within eight years, adoption of electronic health records in the USA increased from 17% to 74% of physicians and to 97% of hospitals. He said that one of the lessons of that finding is that "health information technology is an ultra-large-scale system. But it is not about technology ... rather it is about the strategic use of informatics." Creating a "top-down (system) means you will only accommodate what you thought about at the beginning." Moreover, complex systems are inherently prone to failure, and resilient systems should be anticipated, with continuous evolution and deployment: "Some hospitals have great systems, others are still trying to get a dial tone." He said that consideration of ethics had been delayed because of the speed of deployment of health information technology.

Dr Fridsma stressed the importance of thinking horizontally rather than vertically and said that serving patients should also serve the public interest. Patients are more than collections of discrete data: "We diagnose diseases, but patients experience illness. AI can't solve this." Moreover, most data for health originates outside medical systems; social media and other data sources must increasingly be included in comprehensive analyses.

Dr Paul Tang, IBM Watson Health, in a presentation titled "Evidence-based medicine meets the real world", said that the computer should be put in its place and thus be complementary to human action. The growth of Big Data has come to entail that it be used, and used appropriately. This, in turn, means that we must not lose sight of the role of patients and spend more time with them to add human insight to care: "In the AI world, we shouldn't have to put raw data together to give meaning. Machines can do this." With regard to evidence-based medicine, he said: "Is it really evidence-based medicine for the person in front of me? What we are trying to do with AI is to reduce all the variation... We usually consider demographics, diseases and medications. We need then to match (these factors to) social determinants (do you take your medications?). All these things add information to make recommendations to patients. AI can help in this."

2. CHALLENGES AND OPPORTUNITIES OF USING INFORMATION TECHNOLOGY FOR IMPROVING HEALTH

In this session, participants discussed international and global frameworks for addressing ethical issues arising in the use of health information technology.

Dr Joan Dzenowagis, in her presentation "The national context for eHealth and Big Data", said that a national eHealth strategy forms the foundation for using Big Data in the health sector, from clinical care to research, personal health, public health and global health. When data from health services and data produced by individuals using devices in the digital world are combined, new opportunities are opened in personal and public health.

A global survey by the WHO Global Observatory for eHealth in 2015 showed that countries entering the world of Big Data for health have a wide range of understanding, hold various expectations and require better capacity to use technology and develop policy. Slow adoption of legislation is a cause for concern, though countries are beginning to establish legal frameworks to take into account privacy, individual consent, transparency in data governance, liability for data and accountability for harm. The national context is critical, and international standards and principles will be required for cross-border sharing of data. Public trust in the reliability and transparency of data will be essential. Equally important in the evolving market are improving digital skills and knowledge and increasing the transparency of device, app and service developers.

Legal and policy support must also be developed. In particular, policy must evolve to address transfer and governance of information among patients, providers and devices, as well as use of data by all stakeholders. Sharing health data among countries and the health Internet represent a fundamental challenge for policy and governance. The political, economic and social dimensions must be better understood and the roles, interest and expectations of stakeholders better managed.

Ms Diana Zandi, WHO, speaking on "Mobile data in public and personal health", said producers and users of mobile data contribute to the growth of Big Data; in particular, smart phones are fledging a new generation of data. The survey by the WHO Global Observatory for eHealth showed that many countries are using mobile technology for health. There are more than 7.7 billion mobile telephone subscribers across the world, and the number of mobile broadband subscriptions was expected to reach 4.3 billion by the end of 2017. Over half the world's mobile connections are through smart phones in all regions except sub-Saharan Africa; in some developing countries, people share a mobile phone. More than 70% of Internet users are 15–24 years old.

The popularity of mHealth is growing because of its potential outreach and accessibility. The programmes are guided mainly by policies for eHealth and telehealth (60%). Yet policies are lacking on data ownership, device and mobile health app regulation and system evaluation. Analysis of mobile data use in emergencies, such as the cholera epidemics after the Haiti earthquake and the Ebola virus disease outbreak in West Africa, provides apt examples of opportunities created for predicting epidemics and outbreaks. Tracking individual use of mobile phones, tracing their movements and including other relevant data, such as on weather patterns and use of public transport, will allow more efficient preparation for and response to public health challenges.

Stakeholders include individuals using the services, the producers of data, the population when individuals' data are aggregated, service providers such as telecommunication companies; cloud services; medical, insurance or health care providers; data service providers; researchers; app, hardware, device and software developers; private marketing companies; governments and social service providers; and agencies that provide data-driven services. This wide variety adds to the complexity of ethical oversight.

Ms Zandi raised the following crucial questions: What laws and codes of conduct are in place? How can we address ownership and disclosure of personal data, given the diversity of the stakeholders and interests? How should telecom companies and app developers disclose the data they collect, how they collect it, how much is being shared and with whom? What about vulnerable populations such as migrants and refugees? Should different age groups be treated differently? Which ethical issues arise, and for which stakeholders? How should we communicate and otherwise address these ethical issues?

Dr Anthony Seddoh, World Bank Ghana, in his presentation "Making a difference in universal health coverage and the Sustainable Development Goals with Big Data", discussed the complexity of using Big Data to create real-world outcomes for health in Ghana and, indeed, in all sub-Saharan Africa. This raised a number of issues, some of which are fundamental and not necessarily about data or information technology. For example, although the goal of his organization is to find and reach the extreme poor, they first have to define "poor". Achieving the Sustainable Development Goals requires such definitions, followed by the provision of essential services for universal health coverage. Initial work is promising, perhaps especially in tracking progress in a complex environment.

Dr Christiane Woopen, UNESCO International Bioethics Committee and University of Cologne, made a presentation by videoconference on the Committee's report on ethics and Big Data,[1] to ensure that relevant documents by other organizations are taken into account in the WHO project. The report includes health aspects and raises some specific concerns:

- **Autonomy and consent:** includes the scope of consent, the question of broad versus dynamic consent (in some areas dynamic consent is more appropriate) and use of default settings (opting in or opting out).

- **Privacy and confidentiality:** in the absence of a guarantee of permanent anonymization,

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[1] http://unesdoc.unesco.org/images/0024/002487/248724E.pdf.

trust is important to ensure freedom from being profiled and from an environment shaped accordingly, i.e. the right not to be profiled by Big Data.

- **Ownership, custodianship and benefit-sharing:** the responsibility of all stakeholders and the common good (towards trust, benefit-sharing, trustees) to consider Big Data as a public good, but in which protection is required.

- **Justice:** the digital gap between and within countries in coverage, participation on the Internet and non-discrimination.

- **Sustainability:** energy, the environment.

Dr Woopen emphasized the ethical requirement of ensuring that the benefits of Big Data in health care and research go hand in hand with the protection of human rights, fostering the public good, keeping a balance between control and trust and ensuring an approach emphasizing cooperation and good governance. UNESCO's report calls on international agencies "to develop and support a global framework for the use of Big Data in health-related areas, especially in health care and research. For example … WHO is recommended to encourage the establishment of an agreement by app stores about presenting health-related apps in a way that autonomy, transparency and adequate information are guaranteed."

Dr Effy Vayena, Swiss Federal Institute of Technology, identified "Current trends in enhancing individual control of health data in the Big Data environment." She addressed the evolving global health data ecosystem and its expanding sources of data and capabilities, the evolving roles of stakeholders and the Internet. AI makes those sources especially relevant to health. She noted a trend towards greater innovation in consent models and information tools to ensure meaningful individual control, which will be crucial for data access and sharing.

She proposed that the term "control" be used instead of "ownership", as in the field of intellectual property, because many people appear to believe they have lost control of their information. While some information is not specific to health, it may in fact be relevant because of the inferences to be drawn from it. Although control is seen as being achieved through informed consent, this might have to be reframed in view of attempts to operationalize the consent process. Developments in enhancing individual control include:

- **Data governance,** in which data subjects become data distributers.

- **Data access and the right to data portability** (Article 20 of the European Union General Data Protection Regulation 2016/679). People have the right to receive the data that concern them in a way that they can use them. Data portability is different from the right to access data, as it allows people to put data somewhere else. The intent is to increase the power and control of individuals.

- **Data use and consent mechanisms,** which are being innovated in consent models and information tools.

The "participant centred consent toolkit",[1] for instance, is intended to include consent as an integral component. Governance and participatory schemes are also being studied, for example to ensure greater participation by those who provide data, such as data cooperatives, in which data sources collectively own and can vote for the direction of data reuse. If revenue is generated by use, it can be reinvested in the cooperative.

Dr Joana Namorado, European Commission, spoke about "Ethics review and data-sharing – bridging legal environments." She said that the mechanisms for ethics review in the European Commission include an essential tool for ensuring research quality and conduct. The role of the Commission in research is that of policy-maker for the European Union, a funding agency and a regulator. The challenges of designing European Union research policies are considerable, and a recent ethics review was intended to ensure all projects are uniformly excellent as regards ethics, on a par with scientific, technical and managerial quality. In the European Union, risk is seen as a legal hazard, and the approach is to anticipate and mitigate risk. There is support for initiatives that contribute to coordination of research with a responsible ethical approach. "Quality research demonstrates quality of ethics on an equal level with science and budget."

The new European Union data protection directive still requires clarification concerning data sharing. The particular case of health information and communication technology remains problematic: because data are collected, stored and processed electronically, their management should be re-conceptualized. The nature of data is itself an issue. Data are polymorphic, personal and contextual. Thus, the ethical aspects of all European Union projects are monitored from beginning to end.

Dr Jeroen van den Hoven, Delft University of Technology, made a presentation on "Responsible innovation with Big Data in health care", in which he underscored the importance of trust and an approach in which ethics is incorporated by design. The convergence of digital devices via the "Internet of Things" allows commercial companies to move into the domain of health care with a for-profit motive for obtaining data. Data protection by design is feasible, and the design should be value-based.

"We will not be able to make full use and realize the potential of digital technology if we do not solve the trust problem", he said. New information technology functionality could be a solution to some ethical problems. The European approach is conceptually helpful in that it starts by constraining access and interaction for moral reasons, with strong, clear, shared reasons for doing so. The reasons include prevention of harm and fairness in the market for personal data to prevent exploitation and manipulation. To make data protection effective, it should be converted into design requirements, so that values are built into systems. Value pluralism implies that design for values may encounter conflict. The moral axiom of responsible innovation is: "If you can change the world by innovation today so that you can satisfy more of your obligations tomorrow, you have a moral obligation to innovate today."

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[1] http://sagebase.org/governance/participant-centered-consent-toolkit/.

3. ETHICAL REFLECTIONS

Chair: Dr Michael Selgelid

Panel: Dr Amy Fairchild, Dr Keymanthri Moodley, Dr Johan Roduit, Dr Sergio Litewka, Dr Juan Pablo Beca.

Dr Fairchild, Columbia University and Texas Agricultural and Mechanical University addressed the promise and the limits of Big Data and technology. The WHO public health surveillance guidelines end with a section on advances in information and communication technology and what they can contribute. She said, however, that data in some jurisdictions are still "stored in a closet and not on the cloud", and it is therefore important not to forget the inequality shaped and represented by the digital divide.

Dr Moodley, University of Stellenbosch, cited the film "The Circle" as reflecting privacy as on a spectrum, from the ideal of complete privacy to privacy violations in the interest of the public good. In African settings, research may be conducted in the homes of participants, where there are families, friends and others, which may be acceptable to the participants. Thus, privacy and confidentiality are not necessarily considered critical in some settings. We should, moreover, be concerned about a world in which secrets are lies and personhood entails a perpetual presence on social networks.

Dr Roduit, University of Zurich, shared a thought experiment in which a startup firm sought to predict behaviour from Big Data generated by widespread monitoring. The company would like to deliver health care rapidly but could also discriminate against those who do not maintain healthy behaviour. Big Data therefore holds darker potential, in addition to improving health.

Dr Litewka, University of Miami, described the role of governance of data and AI applications, especially the rule of law and corruption. Moreover, in the case of large data sets, research ethics committees must evolve beyond their original remit, shaped by abuse and scandal, and anticipate and address ethical issues in which harm, wrongs and benefits are often difficult to distinguish.

Dr Beca, Universidad del Desarrollo, said that data should be managed in terms of values. That is a non-trivial challenge, given that people with a disease have their own narratives, and these, a form of data, must be respected.

4. EMERGING THEMES

Stimulated by the panelists' presentations, the discussion identified a number of issues.

- Principles and best practices for data-sharing should be elaborated.

- Privacy remains an ongoing concern, with stances ranging from "privacy is dead" and "privacy must die" to a traditional view that protecting privacy supports an important human right.

- It is essential to address trust and the interests and values of stakeholders.

- The role of governance is essential and should be elaborated, especially in international contexts.

- Empowering people through participation is a key value.

- The digital divide is an important ethical concern.

5. CASE STUDIES FROM AROUND THE GLOBE

Chair: Dr Ron Bayer

Dr Tony Solomonides, NorthShore University Health System, introduced a case of a large hospital organization which released over a million medical records to a technology company in a pilot project designed to improve clinical care. Algorithms were not shared, patients were not informed, and consent was not sought. Dr Solomonides explained that the "why" was not in question, but the "how" was the way in which both entities were at fault. It is reasonable to argue that consent would have been nearly impossible, but should breach disclosure have been mandated under the circumstances? He recommended the promotion of patient involvement in research. The case study illustrates the importance of addressing ethical concerns from the start.

Dr Sumin Kim, Seoul National University, spoke about the ethical challenges in health care represented by Big Data in the Republic of Korea. She noted that the development of precision medicine and AI policies pose difficult challenges, including:

- A perspective of universal health coverage and justice.

- The applicability of algorithm-applied services, such as whether new medical technologies or products involving AI and precision medicine should be included for payment and in compensation for mistakes.

- Issues related to privacy, including data and information re-identification, with inadequate social consensus on AI policy and the aggregation of data (e.g. medical data plus claims data).

- Little oversight of Big Data-producing companies, such as mobile carriers or phone companies.

- Issues related to democracy and the policy-making process.

Dr Nelson Arboleda, US Centers for Disease Control and Prevention, Dominican Republic, focused on "Medical tourism and international data sharing", with special regard for the difficult task of tracking travelers with infectious maladies. Easy access to international transportation has served as a lens through which authorities must attend to efforts to balance a suite of potentially competing rights: free movement, privacy, protection from stigma and so on. In the United States, for instance, there remains no nationwide surveillance program for a subset of travelers – those who cross international borders to receive medical procedures. Given that "a health threat anywhere is a health threat everywhere", governance and evaluation challenges remain difficult.

A presentation on "Challenges, ethical concerns and gaps in the context of Big Data In Argentina" by Drs Irene Melamed and Florencia Luna, Facultad Latinoamericana de Ciencias Sociales, described health information systems as a potential tool to improve equity, under the umbrella of open government. There is currently low capacity and high demand for Big Data, with gaps in knowledge, tools and methods. Public–private partnerships might provide capacity, but interests and potential conflicts of interest must be clarified. There should be a robust public debate on the use and sharing of information.

Dr Cathy Mwangi, mHealth Kenya, in "mHealth and the use of Big Data in Kenya", described her company's challenges in developing and delivering mHealth solutions. In particular, despite the collection of large amounts of data and information, the data are rarely used fully or analysed. Moreover, data systems are diverse, and data are often siloed or unconnected. Similar challenges are likely to be common in low- and middle-income countries.

Dr Calvin Ho, National University of Singapore, observed that many of the issues raised by Big Data and AI would be considered a luxury in a number of countries. In his presentation, "Singapore: health insurance companies and Big Data", he stressed the importance of data in fraud detection and insurance but also noted limited capacity and lack of reliable data. The problem of fragmentation will worsen if not resolved. For instance, Big Data are being used in insurance to personalize benefits packages and to run predictive and real-time analyses; however, retrofitting for interoperability has failed, and the economic incentives are not strong enough to drive change. In some regions, use of Big Data could accentuate inequity rather than foster equity. In Asia, empowerment and participation are not to be assumed or easy to achieve, as there are few expectations about these values, and equity remains elusive.

In "Digital technology and TB treatment adherence", Dr Harald Schmidt, University of Pennsylvania, described methods to document adherence to treatment of tuberculosis. Dr Andreas Reis and Dr Ernesto Jaramillo, WHO, noted in response that it has long been accepted that patients must make some sacrifices to protect others from transmission. Reaching the most marginalized people with digital technologies will help to advance universal health coverage, particularly as these populations often face co-morbidity with HIV infection. The situation poses several challenges for protecting confidentiality, including identifying who should have access to data. Moreover, when data on tuberculosis are in a national system, links could be established to migration data; this must be carefully managed.

Dr Jennifer Gibson, University of Toronto, spoke on "Governance issues – Who governs the use of data and Big Data?" and identified several emerging issues. Fundamentally, part of the work to be done entails deciding how to frame questions precisely. There are several definitions of governance, but in the world of Big Data and AI, governance establishes the locus of authority and the bases for action, puts limits on authority and supports accountability. AI can be seen as a disruptive innovation, as it can change what we can do and how we think about what we can do. The challenges already identified are horizontal, not vertical, and reveal asymmetrical power. Appropriate processes, research and guidance are essential.

6. SYNTHESIS

Dr Eric Meslin, Council of Canadian Academies, in "Big Data – a big role for ethics?" noted that many of the ethical, legal and social issues identified during the consultation are familiar and offer a platform for future work. On analogy with the Human Genome Project, a stepwise approach could be taken, involving mapping to find and name the ethical issues; sequencing, to unpack and describe their parts; function, to explain how they work; and proteomic, to recognize that they are non-linear. Some measure of innovation in ethics and policy is required, as ethics is not merely a taxonomic exercise. As ethics is the systematic study of morality, it must be included early on. While ethics has traditionally been seen as a brake on progress, it can also serve as an enabler and an accelerator or, at least, a lubricant. The skill of using guidelines for advancing knowledge is not yet fully realized. A well-crafted ethics process can determine how to better leverage the power of innovation. Policy-makers should use an approach of ethical "points to be considered" for designers of informatics systems. A robust, internationally defensible set of ethical strategies is needed to move ahead..

ANNEX 1
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ANNEX 2
AGENDA

Rapporteur: **Joan Dzenowagis**

DAY 1

Chair: **Roy Joseph**
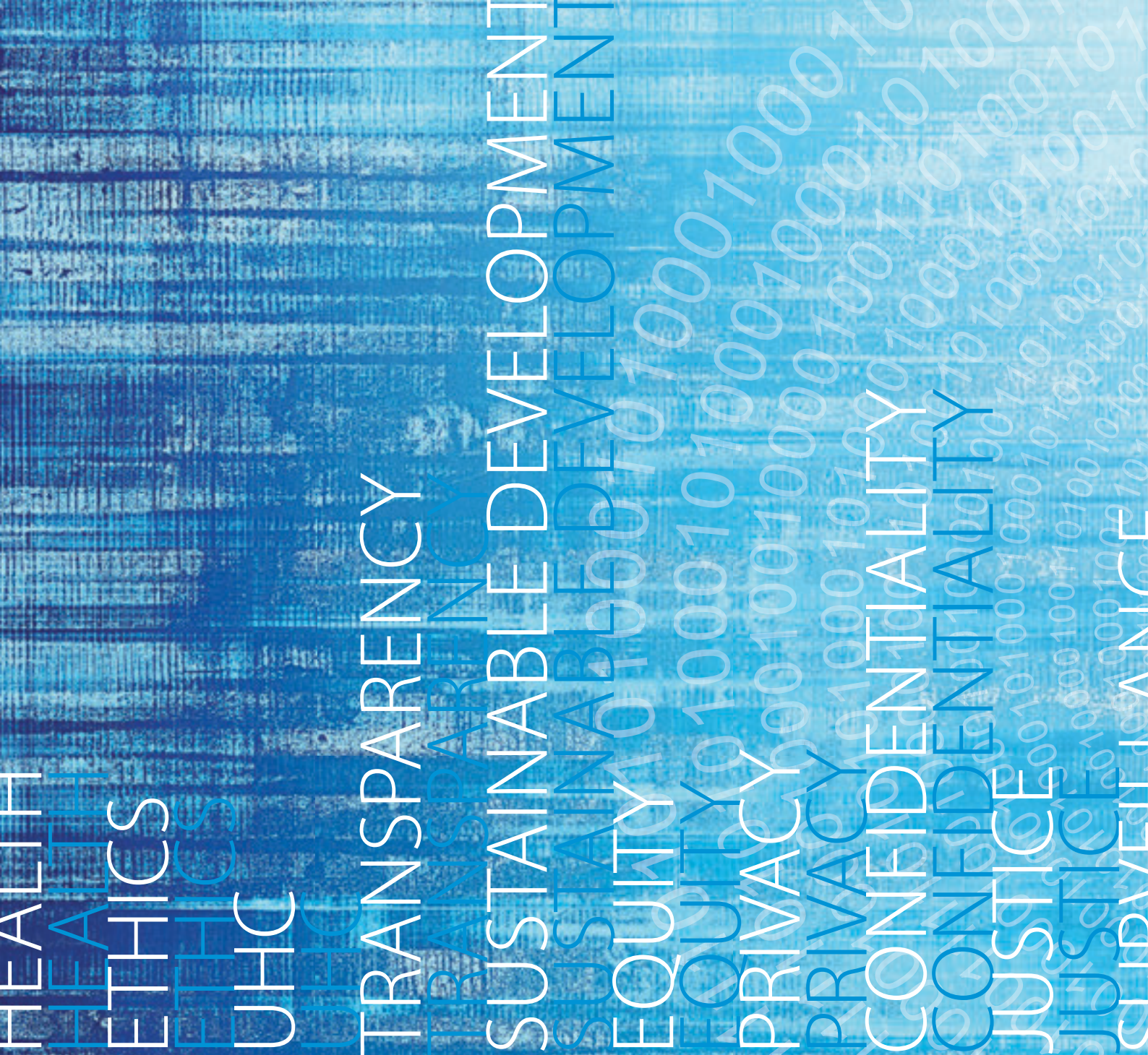
Time	Topic	Speaker(s)
08:30–08:45	Welcome	Ken Goodman Abha Saxena
08:45–9:00	Opening keynote	Julio Frenk
09:00–09:15	Objectives of the meeting	Vasee Moorthy
09:15–09:30	Introductions, DoIs, and agenda	Andreas Reis
09:30–10:00	Overview of global health information technology	Doug Fridsma
10:00–10:30	Big Data, AI and evidence-based practice in 2030	Paul Tang
10:30–11:00	Break	
11:00-12:30	Challenges and opportunities of using information technology for improving health	
11:00-11:30	Setting the scene	Joan Dzenowagis
11:30-12.00	Mobile data in public and personal health	Diana Zandi
12:00-12:30	Making a difference in universal health coverage and the Sustainable Development Goals with Big Data	Anthony Seddoh
12:30-13:30	Lunch	
13:30-14:00	Current trends in enhancing individual control of health data in the Big Data environment	Effy Vayena
14:00-14:30	Ethics review and data sharing – bridging legal environments	Joana Namorado
14:30-15:00	Emerging ethical challenges	Jeroen Van den Hoven
15:00–15:30	Break	
15:30-17:00	Ethical reflections	
15:30-16:30	Panel discussion Moderator: Michael Selgelid	Amy Fairchild Keymanthri Moodley Johan Roduit Sergio Litewka Juan Pablo Beca
16:30-17:00	General discussion	

DAY 2

Chair: **Ron Bayer**

Time	Topic	Speaker(s)
8:30–9:00	Recapitulation of Day 1	Rapporteur
9:00–12:30	Case studies from around the globe	Julio Frenk
9:00–9:15	Case study on Big Data and personalized medicine in the Republic of Korea	Hannah Kim
9:15–9:30	Haiti: International data-sharing during an outbreak	Nelson Arboleda
9:30–9:45	Challenges, ethical concerns and gaps in the context of Big data in Argentina	Irene Melamed and Florencia Luna
9:45–10:00	M-health and the use of Big Data in Kenya	Cathy Mwangi
10:00–10:30	Discussion	
10:30–11:00	Break	
11:00–11.20	Singapore: Health insurance companies and Big Data	Calvin Ho
11:20–11:40	Digital technology and adherence to treatment for tuberculosis	Harald Schmidt Comments by: Andreas Reis and Ernesto Jaramillo
11:40–12:00	Governance issues: Who governs the use of data and Big Data?	Jennifer Gibson
12:00–12:30	Discussion	
12:30–13:30	Lunch	
13:30–14:00	Big data: a big role for ethics?	Eric Meslin
14:00–15:00	Group work on selected issues	All Participants
15:00–15:30	Reporting back	
15:30–15:45	Structure and content of report	Rapporteur
15:45–16:00	Break	
16:00–16:30	Next steps and closing	Ken Goodman Abha Saxena

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