

Big Data and Health

Report of the IBC

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REPORT OF THE IBC ON BIG DATA AND HEALTH

Within the framework of its work programme for 2016-2017, the International Bioethics Committee of UNESCO (IBC) decided to address the topic of Big Data and health, including but not limited to the issues of autonomy, consent, data protection, governance, etc.

At the 22nd (Ordinary) Session of the IBC in September 2015, the Committee established a Working Group to develop an initial reflection on this topic. The IBC Working Group, using email exchanges, started preparing a text on this reflection between October 2015 and May 2016. It also met in Cologne in May 2016 to refine the structure and content of its text. Based on this work, the IBC Working Group prepared a preliminary draft report which was discussed during its 23rd (Ordinary) Session in September 2016. As a follow-up to this discussion, the IBC Working Group started to revise the preliminary draft report between September and December 2016. The IBC Working Group met in Spain in March 2017 to further refine the text. A revised text in the form of a draft report was submitted to the IGBC, the IBC, and COMEST between May and June 2017 for comments. The draft report was then revised based on the comments received. The final draft of the report was further discussed and revised during the 24th (Ordinary) Session of the IBC, and was adopted by the Committee on 15 September 2017.

This document does not pretend to be exhaustive and does not necessarily represent the views of the Member States of UNESCO.

“IBC uses the term Big Data in the area of health as referring to large collections of complex health-related data sets from multiple sources. Typically such data sets cover very large numbers of individuals, but analysis of all available data from one single patient under certain conditions can also be considered Big Data analysis.”

Big Data: The 5 Vs

Volume

- The size of data

Velocity

- The speed at which the data is collected, processed and applied

Variety

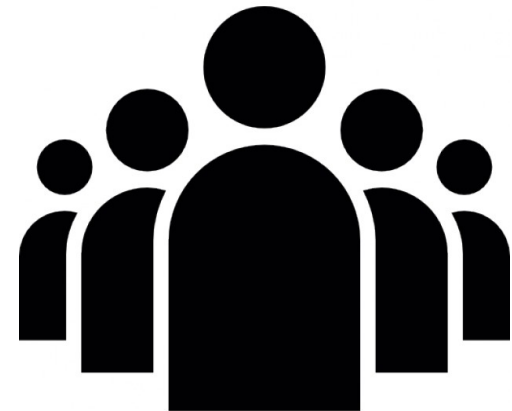
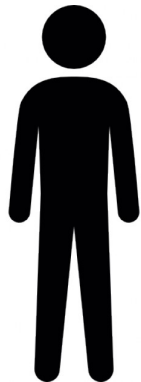
- The different types of data from different sources and in different forms

Validity

- The meaning and impact of data

Value

- The quality of data



Constitution of the World Health Organization

THE STATES Parties to this Constitution declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples:

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States.

adopted 22 July 1946, New York



Berlin 2016
16 – 18 March

11th Global Summit of National Ethics / Bioethics Committees

Converging Technologies and Cybernetic Loops

*Rules for the digital human park
Two paradigmatic cases of breeding and
taming human beings: Human germline
editing and persuasive technology*

Rinie van Est, Jelte Timmer, Linda Kool, Niesl
Nijsingh, Virgil Rerimassie, Dirk Stermerding



*„So while individuals are becoming
increasingly transparent,
our technological environment is
becoming ever more opaque.“*

Ethical Aspects

1. Autonomy and Consent

- Scope of consent: broad and / or dynamic consent
- Default settings

2. Privacy and confidentiality

- Lacking guarantee of permanent anonymization
- Freedom from being profiled and from an accordingly shaped environment

3. Ownership → Custodianship → Benefit Sharing

- Responsibility of all stakeholders and the common good

4. Justice

- Digital gap between and within countries
- Non-discrimination

5. Sustainability

- Energy
- Environment

Recommendations

➤ Aims

- Harvest the benefits of Big Data in healthcare and health research
- Protect fundamental human rights
- Foster public good
- Keep the balance between control and trust

➤ Approach

- Cooperation
- Governance
- Participation

Four crucial areas of recommended measures

1. Governance
2. Education
3. Capacity Building
4. Benefit Sharing

A multi-tiered governance framework should address and include e.g.:

- i. Purpose of the database
- ii. Procedures for (broad) consent, re-contact and re-consent
- iii. Arrangements for ensuring the rights to access, to rectify, and to cancel data
- iv. Arrangements for withdrawal
- v. Arrangements for the protection of privacy
- vi. Policies after the death of a participant
- vii. Arrangements on ownership of the data and products derived from them
- viii. Transparency of the algorithms used for pattern recognition; arrangements to check profiling of individuals or groups according to ethical considerations
- ix. Arrangements for benefit sharing

- Codes of conducts
- Self-binding instruments
- Ethical policies
- Ombudsmen
- Checklists

International Agencies

- UN: International Legal Instrument on Data Protection in Health Care and Health Research
- UNESCO: Convention on the Protection of Privacy
- WHO: Agreement by App-Stores
- OECD: Framework for Sharing of Benefits from Big Data Applications
- Public data infrastructure
- Global Vigilance System
- Definition of technical standards according to the ethical principles (e.g. IEEE, regional and national institutions)
- IEA: pooling and coordination of efforts for a sustainable and responsible use of energy in Big Data management
- Environmental Protection Agencies (e.g. UN Environment together with WHO: Action Plan for saving rare resources; program to avoid e-waste)

National Governments

- Implementation of globally accepted data protection principles
- Establishment of effective Data Controlling Agencies, working together with the Global Vigilance System → International Legal Instrument on Data Protection
- Capacity-Building including an efficient data infrastructure
- Promotion of learning healthcare systems
- Enabling effective cross-border cooperation
- Education with regard to Big Data-related skills, competences, and awareness about ethically relevant implications
- Introduction of diverse models of consent
- Protection of privacy by default as well as by design
- Implementation of a Research Ethics Committee or a similar institution overseeing commercial Big Data research
- Instruments for public and patient involvement
- Coordinated programs for communication protocols that enable energy savings