



1ª MESA: INFORME DE LA UNESCO SOBRE BIG DATA



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Big Data and Health

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Madrid 2017

Disclaimer

I am grateful for the conversations during the meetings of the IBC which have helped to shape my thoughts on big data, but:

The views expressed in this lecture are mine and do not necessarily reflect those of the members of the IBC, UNESCO, or of member states.



Big data and Precision medicine

Personalized prevention and treatment promises:

- targeted advice and
- the right intervention
- with the right dosage of drugs
- at the right time
- for a specific person
- regardless of the location on this world

The crucial ethical problem is neither the amount of data („It's good to know a lot.“) nor the linkage of different kinds of data („holistic approach of medicine“), but WHO uses data FOR WHAT PURPOSE?



Ethical Challenges related to big data

- Autonomy and Consent
 - Can we introduce the concept of broad consent?
 - Big data may also help to finally get rid of paternalism (E.Topol)
- Privacy and Confidentiality
 - Meaning of anonymity?
 - Treaty on data protection?
- Justice
 - Only for the happy few? Or for all, using telemedicine?
- Condition Humaine
 - Permanent observation/ control (cf Bentham's panopticum)



Ethical Challenges: this talk

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Some ways forward to meet ethical challenges

In the area of Autonomy and Consent:

- Broad consent
- Dynamic consent,
- Scientific citizenship
- Governance models using patient and public involvement



Broad informed consent, the concept

- Broad consent can be informed as well (!), but implies moving away from the paradigmatic specific informed consent
- Encompasses the range of future uses
- Broad informed consent is consent for governance
- Relevant for biobanks and databanks as specific use of material and data is unknown at time of collection
- Does not equal blanket consent, as limitations need to be described
- Increasing support in guidelines and regulations



Broad informed consent, the content

- the purpose of the databank or biobank;
- the conditions and duration of storage;
- the rules of access to the bank;
- the ways in which the donor can contact the biobank, remain informed of and may opt out of secondary studies (*dynamic consent*);
- the foreseeable uses of the data and materials;
- the intended goal of such use, whether only for basic or applied research , or also for commercial purposes;
- how unsolicited findings will be dealt with;
- to whom any benefits accrue;



Dynamic consent, the concept

- based on participation and transparency
- initial broad consent from the participant
- continuous update on the specific use of data
- individual can opt out from specific uses of data while allowing the use for other purposes
- requires education and information
- empowering individuals to shape the possibilities of research by 'voting' for those uses
- project becomes a shared or joint enterprise of the individual along with the researcher
- Conditions: some amount of health literacy, time, internet connectivity (scientific citizenship)



Scientific Citizenship

- biomedical research is a collaborative, social enterprise that does not occur in isolation (co-creation)
- research cannot progress without people being engaged
- refers to societal ideal of deliberate democracy where citizens are sufficiently well-informed and well-equipped to make decisions about participation
- participants consent to governance, meaning consent to a system that
 - regulates key measurements of protection
 - on the basis of accountability and fair stewardship
 - in addition to having direct influence if they want (eg through dynamic consent)



Governance

- Guiding principles: autonomy, transparency, lawfulness, privacy and the right to information
 - Multi-tiered governance structure as public structure or public-private-partnership
 - Should allow for public and patient involvement
 - Covering the entire process from collecting to using data
 - Comprehensive set of principles and rules as well as effective allocation of responsibilities and duties
 - Rules of ethical oversight and arrangements for data management
- Trust as prerequisite for progress in big data-driven health care and research
- But trust has to be (continuously) earned!



Governance: ethical oversight

- A clear statement of the purpose of the database.
- Procedures for consent, re-contact and re-consent.
- Procedures for dissent, as alternative to consent.
- Arrangements for ensuring the rights to access, to rectify, to cancel data.
- Arrangements for withdrawal, and a description of the extent to which withdrawal is technically possible.
- Arrangements for the protection of privacy, at least declaring the limits of privacy protection.
- Arrangements to provide special protection in case data of vulnerable persons or groups are used.
- Arrangements for the assessment of the legitimacy of requests for secondary use of data.



Governance: data management

- Data governance should guarantee that patient and public involvement, engagement, participation in the sharing of data does not become a form of exploitation, manipulation and control
- Quality control and safeguards to protect privacy and confidentiality.
- Arrangements for access to data.
- Arrangements for the duration of storage of data.
- Arrangements for decisions about data distribution and sharing and arrangements for traceability of data
- Transparency of the algorithms used for data selection, correlations, predictions



Conclusion

- Big data entails a huge promise, but can also degenerate into de facto control over individuals
- Goals of IBC is to find ways to use big data in ways that uphold human rights, and respect, protect, and are fair to individuals and communities
- At this moment: issues are getting clearer, but solutions are complex and involve many stakeholders and systems
- Still a lot of work to do!

