Role of Ethics Committees in the European Health Data Space

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European Doctors ask for ethically sound governance on how to share health data

Medical research is essential for the development of new treatments and medicines. However, research opportunities using 'big data' should not result in the weakening of applicable ethical standards. Patient autonomy, dignity, privacy[1] and the right to self-determination must always be guaranteed.

- There should be the involvement of **research ethics committees or ethics review boards** when the legal base to share personal data is other than consent of the data subject.[2]
- Their composition should be diverse and tailored to the expertise required, while also involving laypersons, in particular patients or patients' organisations.
- Their role and governance scheme should not be inferior to those already in place under the Medical Devices Regulation or the Clinical Trials Regulation.
- They should be considered as a required institutional structure for accountability for databases concerning health.

Ethics Committees help to:

- Protect patients' rights and ensure "benefit sharing"[3] to the communities concerned;
- Verify whether specific measures have been taken to protect the persons the health data re-use may have an impact on;
- Guarantee that human rights are embedded in the research project from early planning stage;
- Define and ensure conformity with ethical standards;
- Qualify "genuine research for the common good"[4]
- Foster trust in health data sharing for secondary use.

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1. In this context privacy (the concept) is considered to be an ethical matter, contrary to data protection (the regulation) as a legal matter.
2. Paragraph 23 of the WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and as amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013.
3. Paragraph 17 of the WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks, adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016.
4. "Genuine research for the common good" is a term used by the European Data Protection Supervisor in its "Preliminary opinion on data protection and scientific research", 6 January 2020, <https://edps.europa.eu/sites/edp/files/publication/20-01-06_opinion_research_en.pdf> to distinguish from other research *"which serves primarily private or commercial ends"*.

Medicinal products, medical devices and databases concerning health should all abide to the same ethical rules

The rules should be in line with the most recent version of the World Medical Association Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks.

This Declaration achieves a balance between the rights of individuals giving their data for research and other purposes based on confidentiality and privacy rules while at the same time recognising that health data has become a very powerful tool for increasing knowledge.

The independent ethics committee or ethics review board must:

- Approve the establishment of a database concerning health used for research and policy-making;
- Have the right to monitor on-going activities, ensuring regular ethical oversight;
- Observe whether IT usage does not compromise the principles of medical ethics.

As physicians are the primary custodians of confidential health information, they feel an obligation towards their patients, who entrust them with their data.

EU legislation needs to safeguard the health, well-being and rights of data subjects that will feed, with their data (directly or indirectly), databases concerning health.

#CPDP2022 #ProtectHealthData

The European Doctors (CPME) represent national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.