BIG DATA & ARTIFICIAL INTELLIGENCE – THE CHALLENGE OF INFORMED CONSENT

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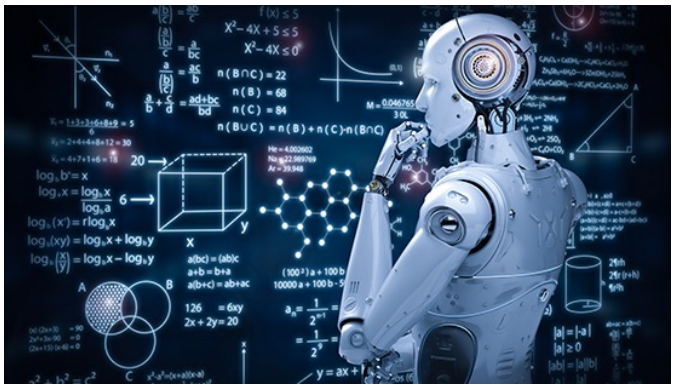

CLASSIC INFORMED CONSENT

- **Over the past 70 years, the development of several ethical principles and codes of ethics has resulted in a greater focus on informed consent in the biomedical context.**
- **Informed consent in clinical and research medicine is one of the most important achievements of modern bioethics.**

CLASSIC INFORMED CONSENT

- **The Nuremberg code—first created in 1947 - following the Nazi Doctors' Trial, stated that voluntary consent ought to be sought from patients before undertaking procedures.**
- **The Declaration of Helsinki—first adopted in 1964, and revised several times since, focused on informed consent, but provided explicit recognition to the vulnerability of certain individuals or groups, who may be incapable of giving consent.**
- **The creation of IRBs to supervise ethical conduct in human experimentations, with a great focus and emphasis on informed consent.**

CLASSIC INFORMED CONSENT – DECLARATION OF HELSINKI – 7TH AMENDMENT 2013

Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary … no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. … each potential subject must be adequately informed of the aims, methods, … the anticipated benefits and potential risks of the study and the discomfort it may entail, … The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal …

CLASSIC INFORMED CONSENT –
DECLARATION OF HELSINKI – 7TH AMENDMENT 2013

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative…

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

INFORMED CONSENT - DEVIATIONS

Invasive, physical-emotional harm vs violating human respect, autonomy and privacy

- Contrary to clinical trials that include direct interventions on human beings, data are detached from human subjects. One explanation for this asymmetry is that informed consent in the medical context can be associated with procedures that put a person at risk of death or serious injury, whereas allowing one's personal information to be used, or having one's privacy invaded in some way, might be seen as less of a significant risk inasmuch as it does not usually result in physical harm
- Lack of information of the nature and purpose of the use of big data, inability to explain correctly because of lack of knowledge, i.e., a machine learning algorithm may be so complex that not even the creators understand how it works, so there can't be a meaningful 'informed' consent

INFORMED CONSENT - DEVIATIONS

Currently, informed consent is waived – totally or partially – in various situations

- **In many experiments, especially at the early phases, there is lack of knowledge and hence the "informed" is lacking**
- **Informed consent by proxy - for a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorized representative**
- **For a long time, the use of data has been considered exempt from consent requirements under certain conditions. Hence, retrospective research projects use file data without consent**

BD & AI AND INFORMED CONSENT

- **BD & AI poses great challenges to the implementation of informed consent, and they seriously erode the role of informed consent as it pertains to the use of personal information.**
- **The era of BD & AI has exacerbated the ethical and legal debate about appropriate consent for data use, in the clinical and experimental medical arena and outside it.**
- **On the one hand, respect for autonomy requires the provision of maximum information and choice to those whose data are being used, and their protection against harm. On the other hand, there are interests that override the right to informed consent; for example, data may be accessed without consent to prevent epidemics or crimes.**
- **Furthermore, the complexities of big data make fully informed consent procedures impractical. A common example is the often uninformed "consent" given by users to the terms and conditions of apps and social media companies. Users rarely take the time to try to read and understand what they are "ticking themselves into" when they join Internet platforms or use services.**

BD / AI – ETHICAL ISSUES

PRO

- **There are clear, compelling and practical benefits from applying AI algorithms to large datasets – Big Data - containing our personal information.**
- **The use of medical data from entire patient populations is important to advance medical knowledge, and to detect adverse reactions to medications or other side effects of medical treatments.**
- **It has tremendous benefits in improving the quality of life, innovativeness, and problem-solutions.**
- **That justifies to override the classic informed consent notion, but not necessarily alternative and adjusted forms of consent.**

BD / AI – ETHICAL ISSUES

CON

BD & AI might violate many moral imperatives

- **Human dignity - treating individuals as a means to achieve certain ends, and as objects rather than free individual agents**
- **Autonomy, particularly as manifested in free informed consent**
- **Privacy, particularly by the ability to Re-Identification**
- **Transparency / Explanation, particularly due to lack of knowledge and expectation**
- **Abuse of AI & BD, i.e., moving large datasets to large private companies for business and profit purposes**
- **Significant biases, due to distorted mass data**
- **Discrimination, particularly of deprived and minority groups**
- **Uncontrolled / unexpected results**

AI / BD – POSSIBLE SOLUTIONS

- Strict legislations with greater penalties for those who fail to gain informed consent – problematic to implament
- Adopting a stringent moral rule-based approach to permissible and prohibited conducts – by adjusting the Declaration of Helsinki
- Looking into alternatives to express consent – not necessarily by the classic written detailed informed consent charts but perhaps by adjusted written consent, or by some electronic devices which may have control over the use of the data.

AI / BD – proposed solutions

The classic individual informed consent is impossible, but the idea of informed consent in protecting fundamental moral principles may be implemented in different ways

- Obtain a priori consent from every patient to use big data in the future. This can be achieved either by a classic but simplified, short and friendly written informed consent, or using a variety of technological methods, provided IRB will approve that research.
- Already currently such a written model is in practice regarding left-over unused human specimens where a person signs a permission to use such materials in the future for as yet unknown research, provided IRB will approve that research.
- There should be a clear and easy way to withdraw from the consent.
- Ensure and protect total anonymization and de-identification, although true anonymization is difficult.
- Complement this requirement with mechanisms that ensure protection from harm or guarantee appropriate compensation in the case of harm.
- Enact legislations and punishments against re-identification.
- IRBs should review the purpose of the use of BD & AI, and governments should require their approval. Since BD & AI are new and complex modalities, IRBs should be supplemented with experts in these fields.

THANK YOU