Workshop on the GDPR and Secondary Use of Data for Medicines and Public Health Purposes

Feedback from academia

Consequences of local interpretations of GDPR

- “For some of the legal bases, GDPR determines that it should be based on Union or member state law (e.g. GDPR Article 9(2), (i) and (j)), which means that the **local legislator can still add stricter conditions if it deems it necessary** to protect the data subjects. **In some countries this has resulted in stricter conditions.**

- **Most projects I oversee finally were not stopped** by the GDPR regulation but processed with some extra effort by the PIs and the institutional boards in charge. However GDPR **interpretation of the same projects greatly differed between ethics boards, resulting in discrepant votes and change requests.**

- **New projects are not even undertaken because the stakeholders fear to be blocked by GDPR concerns**.

- E.g., we used to **screen our EHRs/lab system for patients who might meet clinical trials** in order for them to be contacted. Our **hospital IT does not allow this any more** since the procedure is felt potentially GDPR incompatible. Since there is no other way to identify patients who may be suitable for clinical trials, researchers must still screen the files, but **now have to look at patient by patient "manually"** ....

Consequences of local interpretations of GDPR

- '**Sensitive' data withheld** in some databases, e.g. miscarriage, elective termination of pregnancy, HIV, sexually transmitted diseases. How can we e.g. observe impact of OVID-19 on women or investigate thyroid disease if data on miscarriage are unavailable for analysis. **The legal basis of this discrimination is unclear.** We hope that the legal basis for data access will be more straightforward under GDPR.

- "Actual problem is not the GDPR but its **variable interpretation and application at the member state and even local IRB level…** can eventually only be dealt with by full centralization of the decision-making authority. As this is unrealistic, centralization should at least occur at the national level and national bodies **should be guided by precise guidance documents and a transnational consultation and mediation process**."

- Several EU projects the **planned data sharing has been delayed, due to legal uncertainties** (for instance uncertainties with regards to anonymization and broad consent) as well as due to **the lack of harmonisation** regarding the application of GDPR by Member States.

Use of definitions in EMA document

- "The discussion of specific consent (and seeing the definition of consent in the glossary at the end) very much **suggests that the EDPS had been misinterpreted** as EDPS was referring to informed consent under ethics regime. The statement in the report is therefore wrong, **unfortunately pushing towards the perception consent would / should be the prime legal basis for biomedical research, which it is not.**

- The **GDPR always uses the expression "further processing"** (and there is only one exception in the Recital that refers to the "further use" in this context). Therefore, speaking about the GDPR, **one should only use the correct expression "further processing",** not "further purpose", "secondary purpose", "secondary use" or "further use".

Definition of Secondary Use

Unclear definition of secondary use of data & variability in interpretation

- **Utilised interchangeably with the term of "purpose"** in GDPR (term used, but not defined by the regulation)… The term "purpose" is frequently used interchangeably with "processing activity", which is different again."
- "Same purpose may be achieved through multiple secondary uses and inversely one secondary use project can potentially pursue several purposes."
- "Processing these data **for the benefit of improving healthcare is surely a PRIMARY** use of the data?"

Informed consent

- "More **reflection is needed on how "broad consent" should be defined and implemented.** Patients may, for example, be happy to grant blanket permission for use of their data in specific types of research, or for a specific purpose, or by a specific type of organisation; or they may wish to opt out of specific types of research. The **parameters of broad consent should therefore be flexible to consider individual patients' preferences and values."**

- "If the individual has not given informed consent to secondary data use this is prohibited"

- "If the **individual does not know what the exact purpose** and procedure of the secondary data use will be **informed consent is not possible** - if generic enough to allow for future projects (not known in detail at the time of consent), this is not in line with the model of informed consent (which has to be highly specific) and thus a **generic consent for secondary data use is a contradiction in itself. "**

- Following this statements by the discussion of specific consent (and seeing the definition of consent in the glossary at the end) very much suggests that the **EDPS had been misinterpreted** as EDPS was referring to informed consent under ethics regime. The statement in the report is therefore wrong, **unfortunately pushing towards the perception consent would / should be the prime legal basis for biomedical research, which it is not.**

Anonymisation strategy

- There is not **enough practical guidance** in this field, in particular where clinical trial data together with data from medical records is being used for research purposes.
- The EU needs a **simple guideline for anonymization / de-identification** of health and health research data making it possible to share and reuse them for research purposes without losing the informative value of data, which is provided by the HIPAA rules in the US.
- **HIPAA approach** widely used in the US but may not be acceptable in a European context.
- Where secondary use are not ostensibly linked with the original ('primary') purposes : we **do not recommend the data to be anonymised as the data would lose its value for scientific research** (as clinical trial data represent relatively small data sets and would be **significantly altered by anonymization** techniques).

Questions, concerns

- “A **clarification on the acceptable granularity of the purpose** would be welcome. For example, can the purpose be formulated as following “using data for the purpose of cancer research and related diseases"?
- What would happen **if consent is withdrawn** while data processing activities / studies are ongoing
- How to handle the issue of the **practical impossibility of true anonymisation**
- Questions about **overwhelming patients with requests, and calls for guidelines** on how to explain the legal issues in lay language
- **What does ‘transfer’ mean under GDPR**? This is said to be not defined.
- Would the use of clouds and other **cloud-based IT solutions constitute a transfer?**
- More **clarification on how to treat data which was obtained earlier under different conditions,** e.g. where implicit consent was used, and where it is not practical or possible to revisit.

With thanks to

- Med. Univ. Heidelberg
- Univ. Luxembourg
- ECRIN ERIC
- Necker Children’s Hospital Paris
- All those providing feedback to the original consultation