MEDECINS EUROPEENS
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CPME position on European Health Data Space

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CPME MEDECINS EUROPEENS
EUROPEAN DOCTORS

We represent national medical associations across Europe, covering more than:

1.7 million European Doctors from 37 countries

We are committed to contributing the medical profession's point of view to EU institutions and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

We promote the highest level of medical training and practice but also the provision of evidence-based, ethical and equitable healthcare services.

POLICY - MARCH 2021

European Health Data Space

CPME starting point:

- Should have a clear legal framework, independent oversight, and transparent policies concerning the processing of patient data
- Medical confidentiality, privacy and personal data protection need to be respected, and secure infrastructures established
- Ethically sound governance for the secondary use of health data to prevent abuse

CPME COMITÉ PERMANENT DES MÉDECINS EUROPÉENS
STANDING COMMITTEE OF EUROPEAN DOCTORS

CPME/AG/Board/20032021/097_Final/EN

On 20 March 2021, the CPME Board adopted the 'CPME Policy on the European Health Data Space - Focus on Health Research and Policy Making' (CPME 2021/097 FINAL).

CPME Policy on the European Health Data Space
- Focus on Health Research and Policy Making -

The Standing Committee of European Doctors (CPME) represents 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.

Policy Summary

Sharing patient data needs to go along with strong legal safeguards and security. Governance structures and transparency are essential to supervise the use and re-use of data. To foster trust in the sharing, there should be the involvement of research ethics committees or ethics review boards when the legal base to share patient data is other than consent of the data subject. The default position for sharing patient data for other purposes than primary care should be irreversible anonymisation, which should be legally guaranteed. Encryption should be the pseudonymisation technique when anonymisation cannot be fulfilled. High encryption standards should be adopted. Clear legal definitions on new concepts should be included in the European health data space legal framework.

Introduction

The European Commission's communication on a 'European strategy for data'[1] aims at creating a single market for data, where data flows between Member States and sectors, where clear rules on data governance, data access and data use exist, and where data is available respecting European values and rules.[2] The communication foresees developing common European data spaces in strategic economic sectors and domains of public interest, such as the common European health data space (EHDS). The strategy is part of a wider package of strategic documents, including the European Commission's communication on Shaping Europe's digital future[3] and a White Paper on Artificial Intelligence – A European approach to excellence and trust.[4]

[1] COM(2020) 66 final, 1-35.
[2] European Commission, Inception Impact Assessment on a Legislative Framework for the governance of common European data spaces, 3 July 2020, <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12491-Legislative-framework-for-the-governance-of-common-European-data-spaces>, last accessed 3 August 2020.
[3] COM(2020)67 final, 1-16.
[4] COM(2020)65 final, 1-27.

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Events: for raising awareness

CNOM-CPME conference within context of French Presidency 6 April 2022

Current risks in healthcare:

- Identity theft of doctors and/or patients
- Legal validity and recognition of medical documents
- Connecting patients' records across borders
- Data controller responsibilities when using online platform to exchange health data

Outcomes:

- Safe and secure exchange of doctors' and patients' digital identity
- Ethical principles compliance to share health data
- Collect health data in an anonymous way

CPDP PANEL - 25 MAI 2022

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

CPME CPDP 2022

Role of Ethics Committees in the European Health Data Space

Wednesday 25 May, 14:15, La Cave

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.

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".

Events: for raising awareness

- When consent is not the legal basis, and data are identifiable, there should be greater involvement of ethics committees.
- Medicinal products, medical devices and databases concerning health should abide to the same ethical rules.

Independent ethics committees 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.

European Health Data Space – combining interests

1. Imply **a cultural shift** on health data sharing, **Efforts from all** involved parties will be needed:
   - **Governments** – financial (hardware, software, training), new public authorities with new competences and tasks (provide and manage access), new legal tools (data permits), new professions needed (e.g. certified IT in healthcare or digital health specialists abiding to codes of conduct and subject to disciplinary sanctions)
   - **Doctors** – obliged to provide data (medical confidentiality and privacy), adapt to digital infrastructures, responsible for semantic interoperability, improve digital health literacy and competences;
   - **Patients** – improve digital literacy, learn consent management practices
   - **Industry** – should avoid conflicting standards, work to achieve interoperable systems allowing portability and access (ex. different departments in the same hospital)

European Health Data Space – combining interests

3. **Telemedicine (Article 8) –** implies regulating on the organisation and delivery of health services. Already a game-changer in itself! Cross-border use of telemedicine is more challenging. Make reference to Art. 168 TFEU or provision needs to be deleted.

4. **CPME welcomes:**
   - Identification of priority categories of personal data to integrate in the EHR (step-based approach with transition period) – **patient summaries should be first!**
   - **Requirements for interoperable** (legal, technical and semantic) and **secure EHR systems** (Art. 14 & 17) - but unclear Art. 14(2)
   - **Registration of EHR systems** (Art. 32)
   - The rule to provide an answer to a data request only in an **anonymised statistical format** [Art. 47(1)]

European Health Data Space – combining interests

5. Recommendations:

- Address health data sharing in case of **minors and persons with disabilities** [(Art. 3(6)]
- Clear regime on the role and involvement of **ethics committees**
- **Patient's health data control paradox** [primary Art. 3(9)/4(4) vs secondary Art. 33(5)]:
  - ❑ Adopt a **differentiated approach for access to secondary use categories**: opt-out, opt-in, no consent with mandatory ethics committee involvement – DK example (Art. 33)
  - ❑ Clarify **consent in secondary use** (interplay GDPR and medical ethics) - cfr. EDPS/EDPB opinion on EHDS; **Art. 33(5)** compromises principles of medical ethics and breaches of confidentiality and professional secrecy.
- **Personal notes** by and to doctors and HCPs only – consider them outside the EHR – NL example.

European Health Data Space – combining interests

5. Recommendations (cont):

- Prohibition to re-identify and disclose personal data that has been de-identified (Art. 44(3) and 47(1)]– **becoming a criminal offence**
- Wellness applications (Art. 31) – **only certified apps** should be integrated into EHR systems; missing reference to ISO standards (e.g. ISO/TS 82304-2 on Health and wellness apps – Quality and reliability)
- Purposes for secondary use (Art. 34):
  - ❑ **Further delineate** 'scientific research', 'contributing to public health or social security' - **case-by-case assessment needed**
  - ❑ **Ensure benefit sharing** - publish results in a manner that can be useful for the public

European Health Data Space – combining interests

5. Recommendations (cont):

- Add an **explicit prohibition to profile individuals** under Art. 35
- Delete provision allowing **tacit data permit** as it concerns health data [Art. 46(3)]

Finally, and most important:

- ❑ Doctors' core activity is to provide care, not data for secondary use!
- ❑ Doctors – as data holders – should be excluded from the obligation to provide data for secondary use, incompatible with professional secrecy obligations [Art. 33(2)]
- ❑ Apply 'once only principle' (OOP) - provide data only once to public sector bodies under the primary use regime

European Health Data Space – combining interests

Challenges:

- Several delegated and implementing acts to follow;
- **Different speeds** in terms of digitisation and fragmented landscape (consent, DP in health, attitude towards sharing) – timeline not realistic in view of its complexity;
- **Implementation process** at national level: new public authorities, competences and tasks;
- Risks/consequences of access to health data by **big online platforms**;
- Mandatory **self-certification** of EHR systems (Art. 14) – is this sufficient to ensure compliance with essential requirements on interoperability and security?

European Health Data Space – combining interests

Specific challenges for Doctors:

- Investment in digital infrastructures (financial and resources) – **who bears the cost? Cannot be the doctor! MS should foresee specific budgets to support HCP willing to digitalise**
- HCP overwhelmed with **information in EHR** - what are HCP obliged to consult in 20-30m consultation?
- **Data quality in clinical file –** presence of registered doctor or HCP to validate clinical data
- Ensure that providing data to the EHR and EHDS **does not become a burden –** consider consultation duration and changing nature of interaction with patient.

European Health Data Space – combining interests

Conclusions

- The data economy must not lead to unequitable access to healthcare.
- No detrimental or discriminatory effects in receiving healthcare should fall upon those unwilling to share health data – no unequal treatment!
- Medical confidentiality, privacy and personal data protection and individuals' consent at the centre of secondary use of electronic health data.
- New tasks to be performed by doctors must not create administrative burdens or cost on professionals

Thank you for your attention

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