Importance of Data Standards in the European Health Data Space

DG SANTE, European Commission
Digital Health and European Reference Networks (B3)

18/05/2021
Digital transformation of health and care

We need to make the most of the potential of e-health to provide **high-quality healthcare and reduce inequalities**.

I want you to work on the creation of a **European Health Data Space** to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes.

As part of this, you should ensure **citizens have control** over their own **personal data**.

Mission letter of Stella Kyriakides
Commissioner for Health

- **Health challenges**
  - Accessibility, affordability and availability of care
  - Health threats (COVID-19)
  - Ageing population
  - Chronic diseases
  - Cancer (Europe’s Cancer Beating Plan)
  - Mental health
  - *And so many other…*
EHDS: Data ecosystem principles

- Embrace diversity (of data types and sources)
- Cross-health domain
A common European Health Data Space (EHDS)

**Data Governance Act**

LEVERAGING THE POTENTIAL OF DATA FOR THE ECONOMY AND SOCIETY

**Pillar 1:** Re-use of sensitive data held by public sector bodies

**Pillar 2:** Framework for new data intermediaries in the Single Market: Data brokers

**Pillar 3:** Framework for data altruism

**Pillar 4:** Co-ordination and interoperability: European Data Innovation Board (expert group)
EHDS: Data ecosystem principles

• Embrace diversity (of data types and sources)
• Cross-health domain
• Cross-sector
## EHDS: Challenges

<table>
<thead>
<tr>
<th>Access to health data for healthcare in cross-border context</th>
<th>Access to health data for secondary purposes (research, policy making, regulatory activities)</th>
<th>Limited free movement of digital health services (e.g. tele-health, m-health)</th>
<th>Development and deployment of AI in health</th>
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<td>• Insufficient <strong>health data exchange</strong> negatively impacts on the provision of healthcare services (primary use of health data)</td>
<td>• <strong>Low re-use of health data for research and policy making</strong></td>
<td>• <strong>Low uptake of digital health services and products</strong></td>
<td>• <strong>Difficult access</strong> to health data for AI development</td>
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<td>• Exercising access and <strong>control over their own health data</strong> is often difficult for citizens</td>
<td>• <strong>Cross-border access rules to health data</strong> for secondary purposes are unclear and cumbersome</td>
<td>• There is <strong>fragmentation of digital standards and limited digital interoperability</strong> between healthcare systems</td>
<td>• <strong>Complexity of AI</strong> hampering deployment in health</td>
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<td>• <strong>Fragmented infrastructures</strong> for data use in research and policy making</td>
<td>• Challenges related to <strong>assessing of digital health products/services</strong></td>
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EHDS: Data ecosystem principles

- Embrace diversity (of data types and sources)
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- Privacy-preserving
- Extensibility
Doctor access to foreign citizen Patient Summary

Patient Summary

Used while traveling abroad and being in necessity of consulting a doctor in that country.

Provides information on important health related aspects such as your allergies, current medication, previous illness, surgeries.

Helps doctors to formulate an adequate treatment, avoid some possible risk (for instance in case of allergy) and overcome linguistic barriers.

eHealth Network Patient Summary guidelines, including minimum dataset
MyHealth@EU: Cross-border infrastructure for healthcare provision

Patients access to ePrescriptions abroad

Electronic prescription in Europe – a Finnish patient purchasing medication in a pharmacy abroad

- Remember to visit My Kanta pages and give consent
- Give consent via My Kanta pages and take a journey
- Show your passport or ID card
- Dispensation details
- Purchase medication in a pharmacy abroad

ePrescription allows citizens in Europe to retrieve their medication in a pharmacy located in another European country without having to bring the printed prescription and without being concerned about the language barrier.

eHealth Network ePrescriptions and eDispensation guidelines
EHDS: Data ecosystem principles

• Embrace diversity (of data types and sources)
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• Cross-sector
• Privacy-preserving
• Extensibility

- Structured and unstructured data (diverse data models and formats)
- Multiple controlled vocabularies
EHDS: FAIR

Findable
Data has rich meta-data and unique identifier

Accessible
Data is available through standard protocols

Interoperable
Meta-data use a standard language

Reusable
Data is well described and provides clear re-use conditions
EHDS: Data ecosystem principles

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- FAIR
EHDS initiative framework

- **Legal/Governance**
  - Legal proposal on a EHDS covering e.g. citizens’ rights, cross-border interoperability, governance, digital health.

- **Quality of Data**
  - E.g. FAIRification projects

- **Infrastructure**
  - Cross-border infrastructure for health data exchange (MyHealth@EU)
  - EU-wide infrastructure for secondary uses
  - EU4Health
  - EHDS2 Pilot

- **Capacity building**
  - E.g. Trainings, cross-border cooperation, best practices, etc.

- **Use of health data (primary)**
  - Better healthcare
  - Better policy making, regulatory activities
  - Better Research and Innovation

- **Re-use of health data (secondary)**

- **EU4Health**

- **eHealth Stakeholder Group**
  - TEHDaS Joint Action

- **eHealth Network**

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What the (short-term) future holds

- **Legislative proposal** on the European Health Data Space
  - Proposal on Data Governance Act already published
  - Inception impact assessment feedback (closed in Feb. 2021)
  - Open public consultation open for input! ([Have your say](#) until 26 July 2021)

- Cooperation with Member States and stakeholders in the **Towards a European Health Data Space (TEHDaS) Joint Action**

- Preparations for the **EHDS2 infrastructure pilot (architecture of standards)**
Questions?

Challenges?

Suggestions?

Further information

eHealth Network

All events
https://ec.europa.eu/health/ehealth/events_en#anchor0
Thank you