Health data drives innovation

European Health Data Space (EHDS): EU health data collection and data safety: impact on the estimation of burden of VPIs

Dipak Kalra
President
i-HD is a neutral not for profit body, bringing stakeholders together to co-create solutions for:

- the capture and sharing of better quality health data
- its trustworthy use for smarter health care and efficient research
### The spectrum of data use: from care to research

<table>
<thead>
<tr>
<th>Individual level health data</th>
<th>Population level health data</th>
<th>Big health data</th>
</tr>
</thead>
<tbody>
<tr>
<td>EHR systems, apps, sensors, genomics, Clinical Decision Support, AI</td>
<td>EHR systems, regional &amp; national eHealth infrastructures</td>
<td>national &amp; international research infrastructures, federated query platforms + cross-sectoral services</td>
</tr>
</tbody>
</table>

**Used for:**
- Health status monitoring
- Telehealth
- Continuity of care (including the patient and caregivers)
- Care pathway tracking, clinical workflow management
- Real-time feedback and guidance to patients and clinicians
- Personalised medicine
- Disease interception, prevention and wellness
- Healthcare provider reimbursement

**Reused for:**
- Healthcare provider performance and planning
- Quality and safety, care pathway optimisation
- Medical device and algorithm refinement
- Pharmacovigilance
- Public health surveillance
- Public health strategy
- Health services and resource planning

**Reused for:**
- Epidemiology
- Digital innovation: devices, sensors, apps
- AI development
- Personalised medicine and biomarker research
- Diagnostics development
- Drug development
- Disease understanding and stratification
Myriad of initiatives to share health data across jurisdictional, institutional and domain borders:
- Sharing data for cross-border care or for research

Emerging paradigm for analysing personally-identifiable health data:
- Federated infrastructure model: network of repositories with an overarching governance and interoperability layer
Proposal for a Regulation on the European Health Data Space

It sets out rules, common standards, infrastructures and a governance framework for the use of electronic health data for healthcare, research, innovation and policy making.

- Empower individuals to access and control their personal health data
- Unleash the data economy by fostering a genuine single market for digital health services and products (EHR systems)
- Ensure a consistent framework for the use of individuals’ health data for research, innovation, policy-making and regulatory activities
Primary Use
For health, care, wellness

Secondary Use
For research and strategy
Primary Use
For health, care, wellness

Secondary Use
For research and strategy

Quality checked,
Interoperable: EEHRxF

HEALTH DATA
Primary Use
For health, care, wellness

Secondary Use
For research and strategy
Primary Use
For health, care, wellness

Secondary Use
For research and strategy

- National Contact Points, Certified EHR systems, Apps, MyHealth@EU
- Consolidated, Free, Writable, Portable
- Quality checked, Interoperable: EEHRxF

HEALTH DATA
Primary Use
For health, care, wellness

Secondary Use
For research and strategy

HEALTH DATA
Quality labelled, FAIR metadata, Catalogued

HEALTH
Quality checked, Interoperable: EEHRxF

Consolidated, Readable, Writable, Portable

National Contact Points, Certified EHR systems, Apps, MyHealth@EU

Personally controlled access
Primary Use
For health, care, wellness

Personally controlled access

Consolidated, Free,Writable,Portable
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Secondary Use
For research and strategy
Primary Use
For health, care, wellness

Secondary Use
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HEALTH DATA
- Quality labelled,
- FAIR metadata,
- Catalogued

Digital Health Authority, Certified EHR systems, Apps, MYHealth@EU

Consolidated, Readable, Writable, Portable

Quality checked,
Interoperable: EEHRxF

Data Access Bodies, Audited safe havens, HealthData@EU

Data, Purposes, Fees, Anonymised/pseudonymised

Personal controlled access

Transparency to the public
The European EHR Exchange Format

• Patient summary - closely related to the International Patient Summary (IPS)
• Electronic prescriptions
• Electronic dispensations
• Medical images and image reports
• Laboratory results
• Discharge reports

Adopted in the EHDS Regulation
Implemented through MyHealth@EU
Main content of the International Patient Summary

IPS Composition

- Subject
- Author
- Attester
- Custodian

Required
- Medication Summary
- Allergies and Intolerances
- Problem List
- Medical Devices
- Diagnostic Results
- Social History

Recommended
- Immunizations
- History of Procedures
- Medical Devices
- Pregnancy status + history summary

Optional
- Vital Signs
- Past History of Illness
- Plan of Care
- Advance Directives
- Functional Status Autonomy/Invalidity

„Header“
List of abbreviations

- EHDS: European Health Data Space
- iHD: Institute for Innovation through Health Data
- ICT: Information and Communication Technologies
- EHR: Electronic Health Record
- IPS: International Patient Summary
- EEHRxF: European Electronic Health Record Exchange Format