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

- Citizen and patient associations
- Clinical and biomedical research companies
- Health data aggregators and analytics companies
- ICT companies, standards developers
- Scientific centres, Reference Networks
- Health system funders, care commissioners
- Multi-national decision makers

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>
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#### 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
Big health data sharing initiatives

- 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

HEALTH
DATA
Primary Use
For health, care, wellness

Secondary Use
For research and strategy

Quality checked, Interoperable: EEHRxF

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Interoperable: EEHRxF

Consolidated, Free, Writable, Portable

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Secondary Use
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personally controlled access

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

Consolidated, Readable, Writable, Portable

Quality checked, Interoperable: EEHRxF

HEALTH
DATA

Quality labelled, FAIR metadata, Catalogued
Primary Use
For health, care, wellness

Secondary Use
For research and strategy

HEALTH DATA
- Quality labelled, FAIR metadata, Catalogued
- Purposes, Fees, Anonymised/pseudonymised

PERSONALLY CONTROLLED ACCESS
- Consolidated, Free, Writable, Portable
- National Contact Points, Certified EHR systems, Apps, MYHealth@EU

Quality checked, Interoperable: EEHRxF
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

- Medication Summary
- Allergies and Intolerances
- Problem List
- "Header"

- Immunizations
- History of Procedures
- Medical Devices
- Required

- Vital Signs
- Past History of Illness
- Pregnancy
- Recommended

- Functional Status
- Plan of Care
- Advance Directives
- Invalidity

- Social History
- Optional
The ten functional capabilities used as variables to generate the heat map and scorecard

- The presence of a vaccine register or equivalent
- Whether there is a cancer register
- Whether HPV vaccination was included in the register
- Whether vaccination related information was included in the cancer registry data set
- The level of interest in using ICT (EHR systems etc.) within healthcare provider organisations
- Whether there is an integrated national approach to managing vaccination information
- The level of interest in developing registers
- The extent to which best practices are being replicated
- Whether there is a cancer screening register
- The frequency with which reporting data is generated
Prioritised use cases

- Vaccination record access to individuals and families
- Continuity of care across borders
- Tracking complications and adverse events: individuals and populations
- Linking vaccination coverage to disease burden
- Linking outbreaks to vaccination coverage gaps
- Linking campaigns to vaccination uptake
- Academic and industry research
- Comparisons of vaccination programmes and delivery models
- vaccination administration record
- vaccination schedules & future appointments, as they would apply to an individual
- post-vaccination health issues
- personal disease screening results and disease occurrence
  - International Patient Summary (which includes vaccination information)

- customer relationship management (e.g., scheduling, reminding, informing, targeted education, personalised Q&A ...)
  - vaccination schedules, per vaccine and for different sub-populations
  - population level disease screening and disease incidence/prevalence information including geographic and demographic distribution

- vaccination supply chain
- structure and delivery of immunisation programmes
- health education campaigns targeting different groups
- location and tracking of outbreaks
- factors influencing vaccination hesitancy

Person specific

Population level

Programme specific