MCBK: EUROPEAN PERSPECTIVES

Dipak Kalra
President of i~HD
The German Medical Informatics Initiative

Goals

Innovative IT solutions to improve research & patient care
- starting at university hospitals & extending to smaller sites

Intensify the exchange and sharing of data
- between research and the health care delivery system

Re-establish medical informatics as a progressive field
- in research, teaching and continuing education

Set up data integration centers (DIC)
- to pool local data resources and network with other sites
European Health Data & Evidence Network

Benefits of federated networks

- Data remains under the control of the data owner
- Locally required legal and ethical approvals apply
- No patient level data leaves the owner’s site, only aggregated counts, thereby ensuring patient privacy
- GDPR – ‘Privacy by Design’
- Analysis is “brought to the data” rather than creating central data repository
- Use of common data model allows for efficient search / analysis across multiple data sets
- Requires close collaboration with data owners which builds trust
EHR4CR and EHR2EDC
Reusing EHR data for clinical studies

Protocol testing with real world data

Speeding up recruitment

EHR data extraction (pre-filling of CRFs)

Now a commercial service, scaling up across Europe

Piloting about to start
Initial inventory of EHR2EDC data items & data item mappings generic approach

50 data items & > 60,000 concepts

- Available in EHRs
- Provenance & quality

- CDISC data elements in 4 libraries
- Most commonly used in CTs

- OMOP CDM attributes & domain vocabularies
- Most commonly used in epidemiology & pharmacovigilance
Clinical Information Modelling Tool

▪ Manage **projects, forms, terminologies and information structures** related with definition healthcare documentation.
▪ Define clinical documents easily from **existing library of examples** in collaboration with your clinical team.
▪ Functionalities for discussing the proposed medical form and **measuring level of agreement** between team members
▪ Promote **quality and best practice** in the definition of information structures and medical forms.
▪ Establishment of a **information governance process** within your organization.
▪ Applied for defining **more than 40 research registries**

**Export formats:**

alberto.moreno.sspa@juntadeandalucia.es
Standard data & FAIR is a challenge in Medicine

- **Increasing amount** of medical data
  - Clinical trials: approx. 180 pages / per patient, >300,000 studies
  - Routine care: > 25% working time

- Many sources and **proprietary** documentation systems

- **Complexity** of medical terminology
  (SNOMED > 800,000 terms)

- **Key problems**: Lack of transparency & similar, but incompatible data
Portal of Medical Data Models
https://medical-data-models.org

• Europe’s largest collection of Medical Data Models (est. 2011)

• **FAIR** principles, registered European information infrastructure

• 20,000+ data models / 500,000+ items (440,000+ annotated)

• 51 languages, 87% of items in English, 21% in German

Martin Dugas, Database 2016 [PMID 26868052]
The European Institute for Innovation through Health Data (i~HD) was created as an outcome of European R&D projects, to address needs confirmed by multiple healthcare and research stakeholders.

Developing solutions for improving health data and its trustworthy use, for enriching knowledge and enhancing care through health data.

i~HD is registered in Belgium as a not-for-profit organisation. It is financed by membership fees, by providing services e.g. data quality, certification and governance and through funded projects.
i~HD targets a convergence of opportunity from health data

Clinical Research
- Conduct faster, more efficient, clinical research
- Demonstrate the benefit from innovative products
- Create better Real World Evidence
- Generate new evidence for precision medicine and value based models

Healthcare
- Improve quality, safety and connectedness of care
- Empower patients in self-care and health maintenance
- Use outcomes to improve services
- Have better evidence for public health strategies

Need to collaborate to improve access to combined health data from multiple sources
i~HD is a neutral 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

Stakeholders include:
- 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
Some challenge with the existing standards development process - for clinical content

- Too technically driven
- Input limited to a few computer literate clinicians, mostly doctors
- Not engaging multiple professions, specialities, countries
- Not engaging enough other stakeholders, esp. patients
- Not allowing time for consensus building before developing technical specifications
- Limited capacity to support agility or a rapid pace of change (poor feedback loops)

Not invented here  Not trusted here
An iterative, interactive production and maintenance of interoperability assets is needed, involving all stakeholders.

- Clinicians and patients
- Research and public health
- Technical specifications
  - Modelling, terminology, ontology & workflow representations combined as harmonised semantic resources
- Clinical specifications
  - Rich visualisations

Validation within clinical workflows and through formalised testing.

Slide courtesy of Robert Vander Stichele
Clinical content modelling good practice

- Interoperability need (function, use cases supported)
- Scope, purpose and type of asset(s) needed
- Expertise inputs
- Evidence inputs
- Process methodology (human and organisational)
- Technical methodology (tools, prototype screens)
- Consultation, peer review
- Sign off
- Publication
- Asset bundles
- Generic conformance criteria
- Specific conformance testing

- Quality labelling, Asset register
- Evaluation

Align with standards e.g. ContSys ISO EN 13940

Specific conformance criteria
Textbooks, scientific studies, guidelines or care pathways, templates and forms in paper records, screens and data models from clinical applications and EHR systems, reporting and audit data sets, legal / billing requirements

Generic conformance criteria
Align with standards e.g. ContSys ISO EN 13940

Specific conformance testing
Evaluation

Quality labelling, Asset register

Generic conformance criteria
Textbooks, scientific studies, guidelines or care pathways, templates and forms in paper records, screens and data models from clinical applications and EHR systems, reporting and audit data sets, legal / billing requirements

Specific conformance testing
Evaluation
Interoperability Asset Register

A register and discovery service for interoperability assets

- **Legal:** frameworks, policies, agreement templates, ...
- **Organisational:** adoption guidelines, training resources ...
- **Technical:** information models, XML schema ...
- **Semantic:** clinical models, terminology subsets ..
Providing streamlined guidance to assist potential future adopters of an asset

All assets are described and quality labelled in a consistent way

- Purpose and usage
- Development process
- Maturity level
- Trustworthiness
- Technical support and skills needed
- Sustainability
- Semantic interoperability
- Cost and efforts
- Maintenance

Plus access information, and links to other related assets

Quality labelled through initial self assessment, editorial review and validation by an online community of asset users

Designed by:

Alberto Moreno Conde, Geert Thienpont, Inge Lamote, Dipak Kalra + Expand WP4

Acknowledged:

this service has been developed within the EU funded project EXPAND
Main quality metrics

1. DEVELOPMENT PROCESS
   • Evidence used
   • Consultation process
   • Conformance to standards
   • Quality processes used

2. MATURITY LEVEL
   • Technology Readiness Level
   • Domain completeness
   • Adoption scale
   • Market adoption

3. TRUSTWORTHINESS
   • Endorsements
   • Reliability of access
   • Communities of use

4. TECHNICAL SUPPORT AND SKILLS
   • Documentation and training
   • Available tools
   • Third party support
   • Skills required

5. SUSTAINABILITY
   • Viable business model
   • Extensibility

6. SEMANTIC INTEROPERABILITY
   • Clinical information model specifications
   • Clinical information model terminology binding
   • Value sets

7. COSTS AND EFFORTS
   • Validation costs
   • Asset use costs
   • Clinical information model implementation effort
   • Maintenance effort required

8. MAINTENANCE
   • Problem resolution by the asset custodian
   • Updating process
   • Response to incidents by the asset custodian
i~HD engagement with hospitals

- Many European hospitals have expressed to us a wish to be better Learning Health Systems
  - they want to measure and improve their outcomes
  - they want to collaborate with other hospitals working on similar outcome-related challenges
  - they want to scale up their participation in clinical research
  - they want to make better use of their EHR data to achieve these
- i~HD has formed a Network of Excellence of European hospitals to support these objectives
Incompleteness of EHR data for clinical research

Variables such as Weight are quite frequently not present.
i~HD Data Quality Taskforce

- Developing data quality assessment methods, tools and improvement strategies to maximise quality of health data
- Promoting the importance of data quality
- Guiding in assessing and improving data quality
- Scaling up a multi-stakeholder understanding and commitment to increase data quality

Focus on three areas:
- Healthcare
- Clinical trials
- Big data

Slide courtesy of Pascal Coorevits, Ghent University & EuroRec and Carlos Sáez, Universitat Politècnica de València
## Data quality dimensions

<table>
<thead>
<tr>
<th>Name</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completeness</td>
<td>Data values are present</td>
</tr>
<tr>
<td>Consistency</td>
<td>Data satisfy constraints (format, allowable ranges and values, domain rules, relations)</td>
</tr>
<tr>
<td>Correctness</td>
<td>Values are true and unbiased with respect to their real-world state</td>
</tr>
<tr>
<td>Uniqueness</td>
<td>Records representing a single patient are not replicated</td>
</tr>
</tbody>
</table>

- **Timeliness**: Data is up-to-date to their real world state for the task at hand
- **Stability**: Data inherent concepts and statistics are comparable among sources (hospitals, professionals, etc) and over time
- **Relevance**: Data are useful for their task
- **Contextualization**: Data are annotated with the acquisition context, their meaning and semantics
- **Trustworthiness**: Data can be trusted based on the reputation of the stakeholders involved in their acquisition

*Slide courtesy of Pascal Coorevits, Ghent University & EuroRec and Carlos Sáez, Universitat Politècnica de València*
Extracts from a sample i~HD DQ assessment: ICHOM heart failure outcomes data set
The Value of Health

Political and policy context

Economic context:
- Legacy of the crisis: high debts and deficits
- Continued increases in public health spending anticipated
- Concerns about how this will be paid for (sustainability of public finances)

Population health:
- Ageing and rising levels of chronic disease and comorbidity
- Public health problems and inequalities

Health systems:
- Challenge of responding to changing population needs
- Need for structural reforms – e.g. integrated care, eHealth
- Evidence of marked variation in clinical practices and significant levels of ‘waste’
Personalised Health and Learning Health Systems…

...need all stakeholders to collaborate, to maximise the insights we can gain from health data