Was müssen Elektronische Patientenakten für Personalisierte Medizin können und wie kommen wir dorthin?

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Definitions (according to ISO TR 20514 Health informatics - Electronic health record – Definition, scope and context)

EHR
A repository of information regarding the health status of a subject of care in computer processable form.
An EHR provides the ability to share patient health information between authorized users of the EHR and the primary role of the EHR in supporting continuing, efficient and quality integrated health care.

EHR system
The set of components that form the mechanism by which electronic health records are created, used, stored, and retrieved. It includes people, data, rules and procedures, processing and storage devices, and communication and support facilities.

EHR architecture
A model of the generic features necessary in any electronic healthcare record in order that the record may be communicable, complete, a useful and effective ethico-legal record of care, and may retain integrity across systems, countries, and time.
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EHR Types

- Centralized EHR
- Distributed EHR
- Organization centric EHR
- Personally moderated EHR
- Personal Health Record (PHR)
- Legal EHR
- Comprehensive Health Record
Co-existing Streams for Specifying and Implementing EHR Architectures

Currently, three streams for specifying and implementing advanced EHR architectures exist:

- **under a modeling focus:**
  - Data approach (data representation)
  - Concept approach (concept/knowledge representation)
  - Process/service approach (business process / service representation)

- **under implementation focus:**
  - Communication focus (message)
  - Document focus (clinical document)
  - Business process focus (application)

- **considering the time dimension:**
  - Episode focus (EHR extract)
  - Life-long record focus (EHR service)
Paradigm Changes in Health Systems

Organizational
- Organization-centric care

Methodological
- General care addressing health problems (one solution fits all)

Technological
- Mainframe (KB)
- Client/Server (MB)

Between electronic medical records, digitized diagnostics and wearable medical devices, the average person will leave a trail of more than 1 million gigabytes of health-related data in their lifetime, according to IBM estimates.
The Modeling Challenge of Transformative Healthcare Systems

• Data modeling is described as a series of processes to define data requirements for supporting business processes to meet the business objectives. Data modeling often focuses on conceptual, logical and physical data definition – each representing the informational components of the organization at differing levels of abstraction [R.S. Seiner, IDERA].

• The system represented by the subject of care and the processes analyzing and managing his/her health comprises all levels of granularity from atoms through molecules, cell components, cells, tissues, organs, bodies, communities, up to population.

• Regarding the functional, or in general inter-relational, aspects of that system, the relations, comprise, e.g., quantum-mechanical effects in the nano-world, biochemical processes, interrelations based on classical physics, and finally social interrelations in the macro-world.

• As we can consistently model and compute only systems of reasonable complexity, the system analysis or design has to address partial systems when considering higher granularity levels of the system in question.
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**Interoperability Challenge**

Provider Policy

Bridged Policy

Subject of Care Policy

Provider Organization

Care Process Environment, Context and Conditions

Provider

Subject of Care

Org. Schema

Business Process Details

Provider Policy

Care Process Environment, Context and Conditions

Social Environment, Context and Conditions

Business Framework

Social Environment, Context and Conditions

Bridged Policy

Individual Environment, Context and Conditions

Bridged Policy

Business Process Details
Interoperability Challenge

• Communication and cooperation in dynamic, highly distributed, heterogeneous systems sets special demands on interoperability between all actors (persons, organizations, devices, applications, components, objects) involved.

• Interoperability describes motivation, willingness, ability, and capability to cooperate for achieving common goals or business objectives.

• Interoperability requires knowledge, abilities and skills, shared and adapted a-priori or dynamically at runtime, for establishing adequately cooperating associated systems.

• In ubiquitous personalized health, business cases and related policies cannot be pre-defined, but are determined by the subject of care’s status, needs, wishes and expectations, frequently turning him to the health manager. Here, interoperability services at runtime are needed.

• Differences in meeting those interoperability requirements lead to different interoperability levels (structural, syntactical, semantic, service, domain, individual) for ensuring comprehensive cooperation.

• Interoperability in the context of ICT systems usually addresses the interoperability challenge with ICT facilities. It must be extended to the individual and its context.
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Information Perspective

<table>
<thead>
<tr>
<th>Interoperability Level</th>
<th>Instances</th>
<th>Organization Perspective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical I.</td>
<td>Technical Plug&amp;Play, signal &amp; protocol compatibility</td>
<td>Interoperability Level</td>
</tr>
<tr>
<td>Structural I.</td>
<td>Simple EDI, envelopes</td>
<td>Light-weight interactions</td>
</tr>
<tr>
<td>Syntactic I.</td>
<td>Messages and clinical documents with agreed vocabulary</td>
<td>Information sharing</td>
</tr>
<tr>
<td>Semantic I.</td>
<td>Advanced messaging with common information models and terminologies</td>
<td>Coordination</td>
</tr>
<tr>
<td>Organization/Service I.</td>
<td>Common business process</td>
<td>Agreed cooperation</td>
</tr>
<tr>
<td>Knowledge based I.</td>
<td>Multi-domain processes</td>
<td>Cross-domain cooperation</td>
</tr>
<tr>
<td>Skills based I.</td>
<td>Individual engagement in multiple domains</td>
<td>Moderated end-user collaboration</td>
</tr>
</tbody>
</table>

Organization/Service I.

Knowledge based I.

Skills based I.

[Diagram showing ICT Ontology and Domain Ontologies]
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Interoperability Levels – Standards Classification and Orientation

• Communication Standard – Connectivity Challenge \(\rightarrow\) technical orientation
• Communication Standard – Data Interchange Challenge \(\rightarrow\) communication protocol orientation
• Communication Standard – Information Exchange Challenge \(\rightarrow\) semantic orientation
• Interoperability Standard – Service Functional Cooperation Challenge \(\rightarrow\) operational orientation
• Interoperability Standard – Domain Knowledge Based Interoperability Challenge \(\rightarrow\) intelligent systems orientation
• Interoperability Standard – Comprehensive Cooperation Challenge \(\rightarrow\) personalized systems orientation
Interoperability Challenge and Solutions under the New Organizational, Methodological and Technological Paradigms

• It is impossible to represent the highly complex, highly dynamic, multidisciplinary/multidomain healthcare system by one domain’s terminology or even by using ICT ontologies (such as archetypes, HL7 RIM, Zackman Framework, etc.)

• There are approaches for representing multidomain concepts in an hierarchical set of ontologies.

• For representing advanced interoperability settings, different representations must be linked to the same real world component. For that reason, a abstract and generic reference architecture able to represent any viewpoint or domain of interest is needed.

• The mathematical language of Universal Type Theory further evolved by philosophers and its representation by a Parameterized Barendregt Cube provides a proper solution addressing those challenges, enabling to represent any system described by any formal or informal language.

• Current approaches claiming to solve that problem do this on the basis of implicit knowledge or by using representation tools the addressed domain experts, which should be in the lead, cannot understand. The abstract representation of the universe provide an alternative.
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Interoperability Reference Architecture Model

Domain n
Domain ...
Domain 1

Business Concepts

Relations Networks

Aggregations

Details

System Viewpoint

System Domain

System Component Composition

Business VP
Enterprise VP
Information VP
Computational VP
Engineering VP
Technology VP

Task 1,1,1
Task 1,1,2

Service 1,1
Service 1,2

Sub-Domain 1
Sub-Domain 2

Domain 1
Domain n
Domain ...

Domain n
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Interoperability Mediated by the Interoperability Reference Architecture Model
Was müssen Elektronische Patientenakten für Personalisierte Medizin können und wie kommen wir dorthin?

Re-engineering of the ISO 13606 Reference Model
The Implementation Challenge

• After developing an abstract system’s architecture, it must be instantiated for concrete business domains. The resulting real system components must be properly named and described, using pre-existent terminologies and ontologies where possible.

• To get closer to the vision of comprehensive interoperability, the ontological representations used by different domain experts for representing entities in reality must be harmonized. For that purpose, the ontological representation must be provided at a level of formalization and expressivity which guarantees common understanding, i.e. expresses meaning and rules as explicit as needed depending on education, skills, and experiences of the actors involved.
Relevant Concept Representation Standards

- Arden Syntax – Medical Logic Modules
- Archetype Models – ISO 13606, CIMI
- Clinical Document Architecture (CDA)
- Continuity of Care Record (CCR) → CCD
- CIIMI Core Reference Model
- EHR Infostructure (Canada Infoway)
- Logical Record Architecture (NHS)
- German EHR System Specification
- Future-Proof Approach
The German Approach

• There are two streams in the German EHR approach:
  – An architecture-centric, intelligent, adaptive solution specifications based on international standards and partially borrowed from the Canadian EHR-S Blueprint, launched by the Federal Ministry for Economy and realized by the eHCC (2007-2008)
  – An set of pilots more or less independent from international standards and international experiences, launched by the Federal Ministry for Health and realized by different hospital trusts, Fraunhofer Institutes and others
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German eHealth Basic Components (Logical View)

Knowledge Services  Application Services

Client Services  EHR Systems

Ontology Services  Terminology Services

Analytics Services  NoSQL Data Services

Harmonization Services

ACA Services  ID CA Services  Policy Services

Dir./Reg. Services  Audit Services  Encoding Services

Privilege Management Infrastructure

Public Key Infrastructure

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EHR Data Model Phases (after Brailer)

• **Definition of healthcare eras by the data sources someone relies on:**
  - Model 1: Health data model based on claims data.
  - Model 2: Health data model EHR based on enterprise result-oriented and test-oriented stuff.
  - Model 3: Health data based on one’s life and what’s going with someone, his inputs, his lifestyle, his culture of health.

• The predicted move relates somehow to the development of PHRs. The record will be centered on the patient and will include lifestyle data from wearables and apps, various -omics (genomics, proteomics, microbiomics), and even new data sources that haven’t yet been conceived. The difference is that success in person-centered records is going to require a stark departure from the enterprise world. However, PHR platforms failed because they were trying to graft an overlay, a solution on top of an enterprise system. Technical/legal/financial gravitational pull is away from the enterprises. The change could be led by tech companies like Apple, Amazon, Facebook, or Verily.

• EHR vendors such as Epic or Cerner will have a secure place in the ecosystem for time to come. Brailer can’t imagine a world without electronic architectures in the enterprise for a long time. We should not think about what to do with the current data models. Instead, we should think about the data we need to add value and how do we get that data. New products: HealtheIntent, Share Everywhere, etc.
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**Future EHR Components**

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<tr>
<th>Resources</th>
<th>Infrastructure Services</th>
<th>Security Services</th>
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</thead>
<tbody>
<tr>
<td>Knowledge Resources</td>
<td>Knowledge Services</td>
<td>Identification Services</td>
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<tr>
<td>Health Systems Analytics</td>
<td>Transformation, Enrichment &amp; Loading Services</td>
<td>Authentication Services</td>
</tr>
<tr>
<td>BP Knowledge</td>
<td>NLP Services</td>
<td>Certification Services</td>
</tr>
<tr>
<td>Registries</td>
<td>Resource Locator Services</td>
<td>Single Sign On Services</td>
</tr>
<tr>
<td>EHR Systems</td>
<td>Communication Bus</td>
<td>Firewall Services</td>
</tr>
<tr>
<td>Common Analytics</td>
<td>Replication Services</td>
<td>Network Encryption Services</td>
</tr>
<tr>
<td>Ontology Services</td>
<td>Translation Services</td>
<td>Network &amp; Transport Layer Security Services</td>
</tr>
<tr>
<td></td>
<td>Longitudinal Record Services</td>
<td>Privilege Management Infrastructure Services</td>
</tr>
</tbody>
</table>

**Security Services**

- Logging, Monitoring, Alerting & Auditing Services
- Network Intrusion & Prevention Services
- United Access Gateway
- Proxy Services
- Network & Transport Layer Security Services
- Security & Privacy Intelligence

**Future EHR Components**

- Infrastructure Services
  - Knowledge Services
  - NLP Services
  - Resource Locator Services
  - Communication Bus
  - Replication Services
  - Translation Services
  - Longitudinal Record Services
  - Transformation, Enrichment & Loading Services
  - Partitioning, Repartitioning & Pipelining Services
  - BP Harmonization & Optimization Services
  - BP Harmonization & Optimization Services
  - Termination Harmonization Services
  - Information Structuring & Normalization Services

**Security Services**

- Identification Services
- Authentication Services
- Certification Services
- Single Sign On Services
- Firewall Services
- Network Encryption Services
- Network & Transport Layer Security Services
- Privilege Management Infrastructure Services
- Security & Privacy Intelligence
Conclusions

Therefore, flexible, scalable, business-controlled, adaptive, knowledge-based, intelligent EHR systems must follow a systems-oriented, architecture-centric, ontology-based and policy-driven approach.
Thank you very much for your kind attention!

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