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

Prof. Dr. habil. Bernd Blobel, FACMI, FACHI, FHL7, FEFMI, MIAHSI
Universität Regensburg, Medizinische Fakultät

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.

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.

proteomics, microbiomics, etc. ***Systems Medicine****, from art to multi-disciplinary science, from elementary particle to society*

- Cognitive care ⟹ informed decision

Analytics, NLP, Cloud Computing, Social Business (PB, YB)

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.

Interoperability Challenge

Provider Policy

Bridged Policy

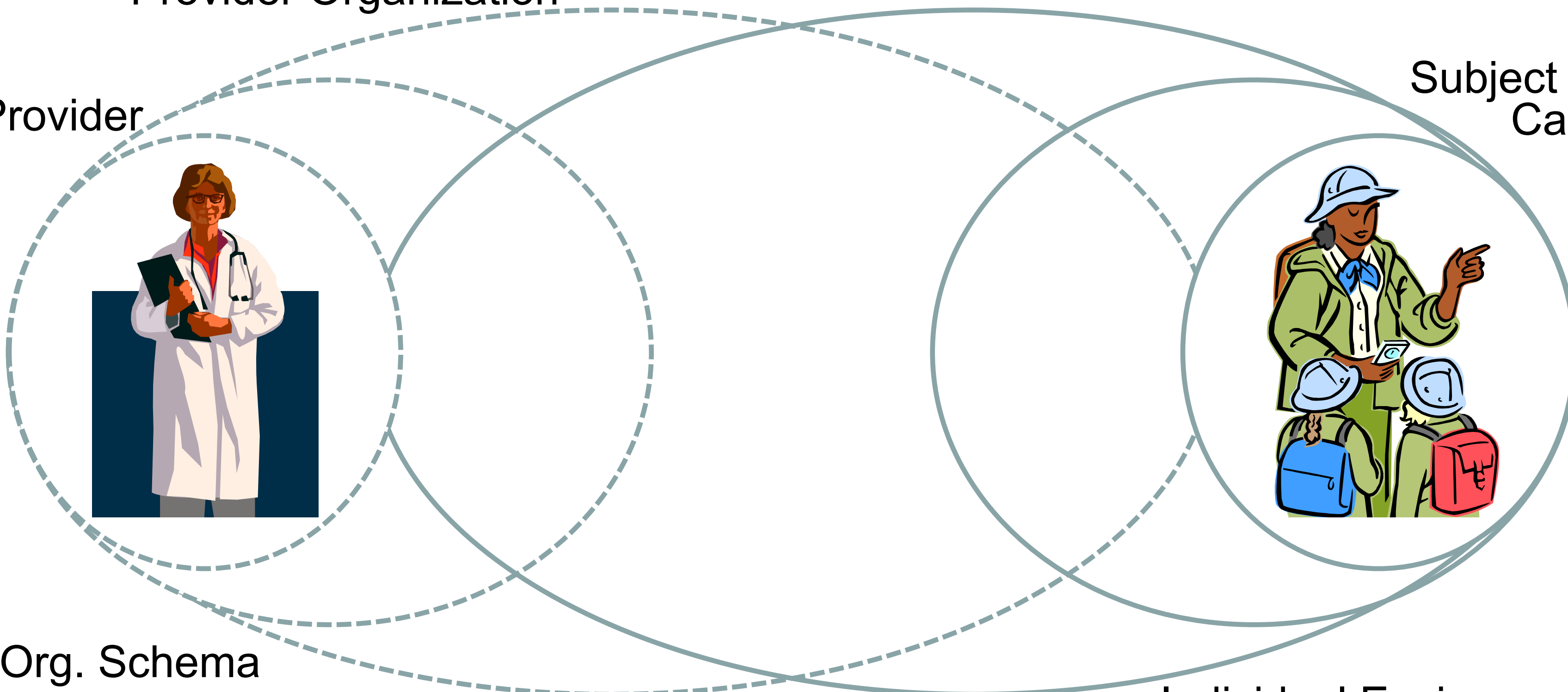
Subject of Care Policy

Care Process Environment,
Context and Conditions

Provider Organization

Provider

Subject of
Care



Org. Schema

Business Framework

Business Process Details

Individual Environment,
Context and Conditions

Social Environment,
Context and Conditions

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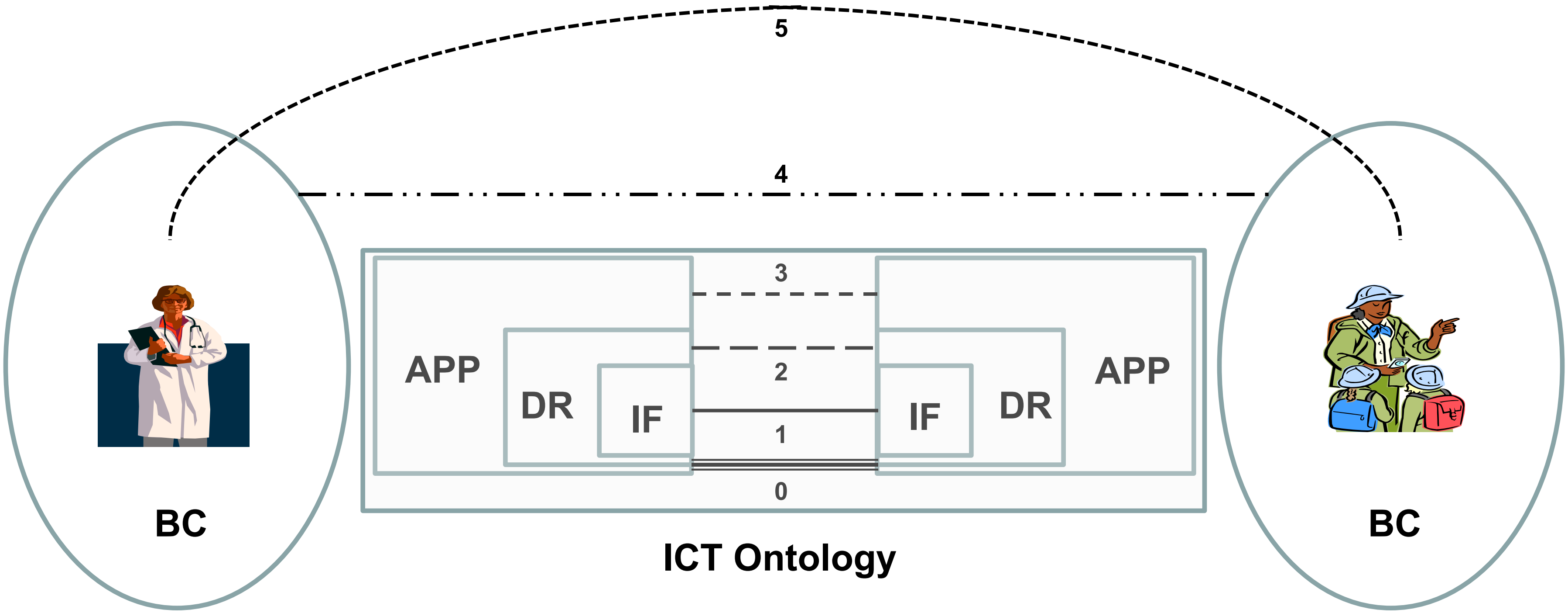
University of Regensburg
Medical Faculty

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.



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

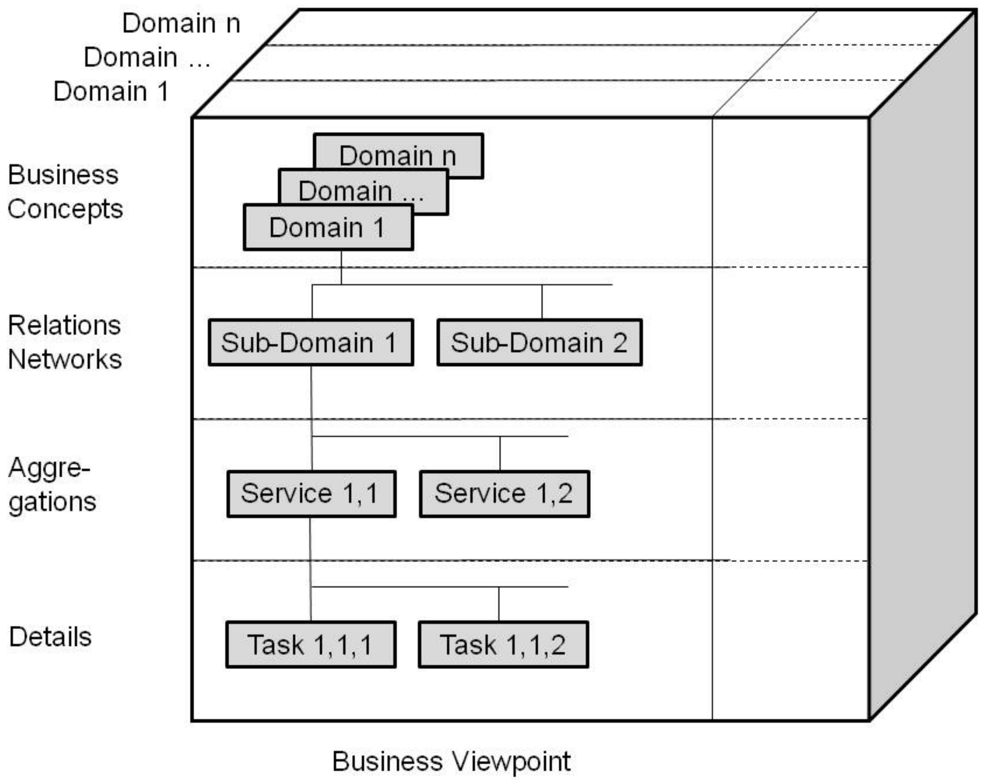
Interoperability Levels – Standards Classification and Orientation

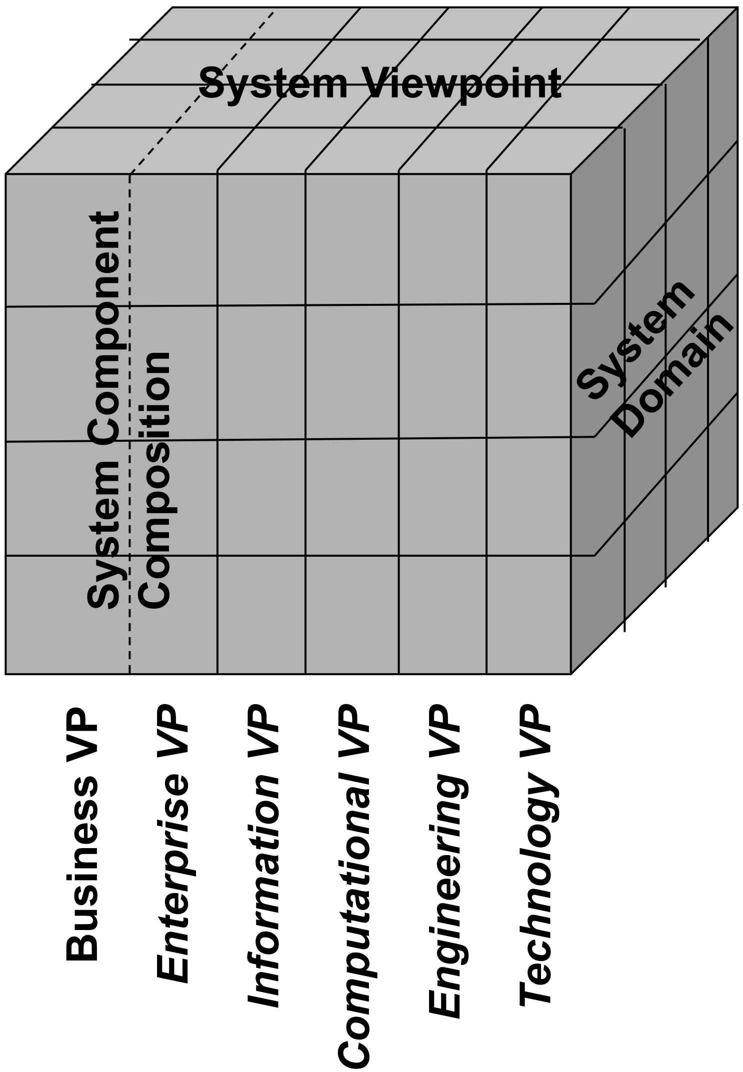
- Communication Standard – Connectivity Challenge → technical orientation
- Communication Standard – Data Interchange Challenge → communication protocol orientation
- Communication Standard – Information Exchange Challenge → semantic orientation
- Interoperability Standard – Service Functional Cooperation Challenge → operational orientation
- Interoperability Standard – Domain Knowledge Based Interoperability Challenge → intelligent systems orientation
- Interoperability Standard – Comprehensive Cooperation Challenge → 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 Barentregt 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.

Interoperability Reference Architecture Model





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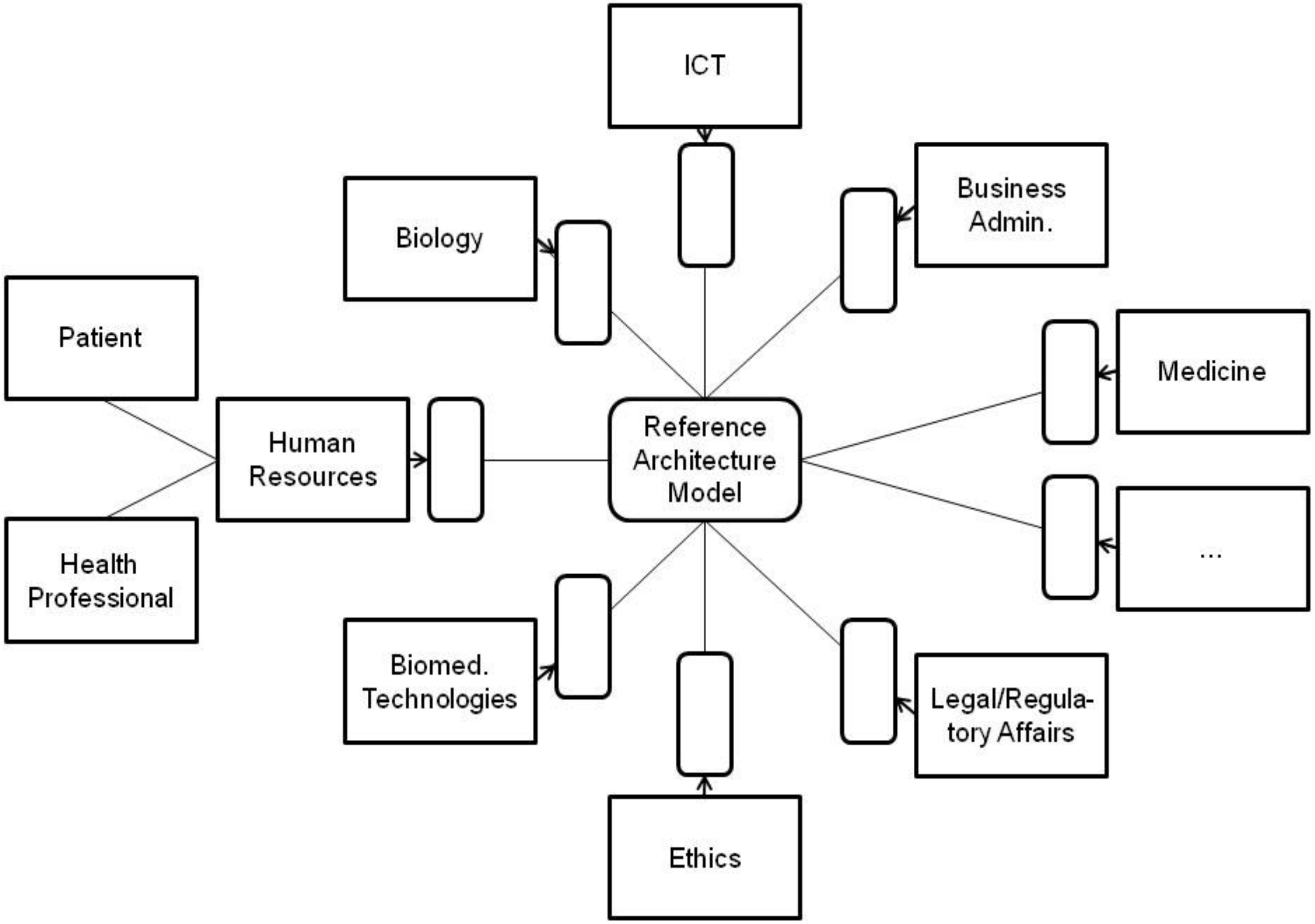
University of Regensburg
Medical Faculty

Interoperability Mediated by the Interoperability Reference Architecture Model



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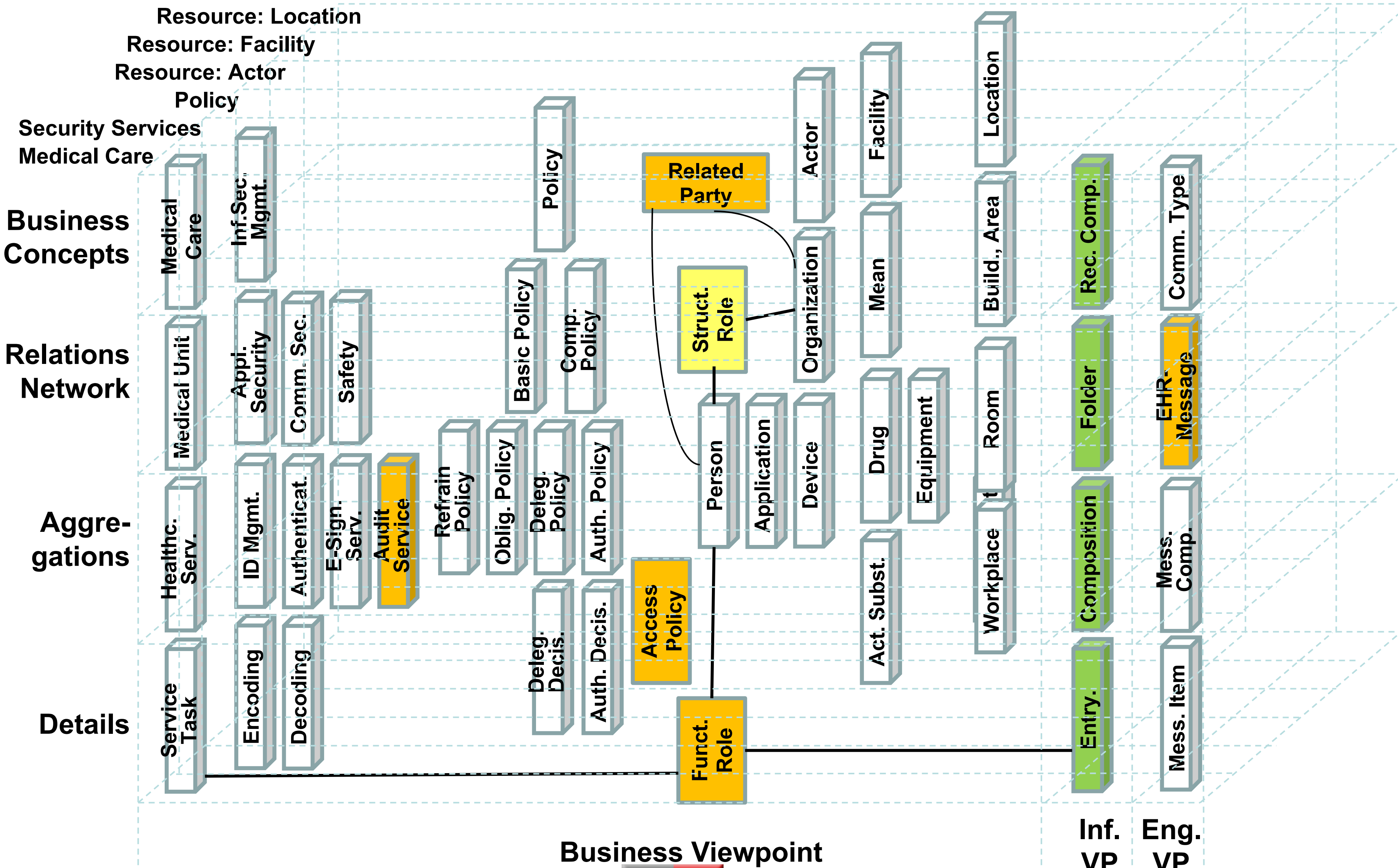
Re-engineering of the ISO 13606 Reference Model



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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
- CIMI 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

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

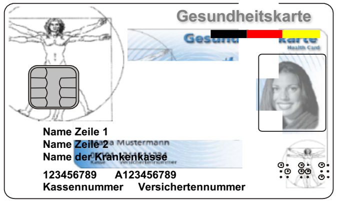
Dir./Reg. Services

Audit Services

Encoding Services

Privilege Management Infrastructure

Public Key Infrastructure



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.

Future EHR Components

Resources

- Knowledge Resources
- Terminology Services
- Health Systems Analytics
- Enterprise Data Warehouse
- BP Knowledge
- Domain Repositories
- Registries
- Common Repositories
- EHR Systems
- Health Data Warehouse
- Common Analytics
- Social Media Services
- Ontology Services
- Application Services

Infrastructure Services

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

Security Services

- Identification Services
- Logging, Monitoring, Alerting & Auditing Services
- Authentication Services
- Certification Services
- Network Intrusion & Prevention Services
- Single Sign On Services
- United Access Gateway
- Firewall Services
- Proxy Services
- Network Encryption Services
- Privilege Management Infrastructure Services
- Network & Transport Layer Security 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!

Corresponding Author:

Prof. Dr. habil. Bernd Blobel, FACMI, FACHI, FHL7, FEFMI, MIAHSI
University of Regensburg, Medical Faculty
Visiting Professor, Charles University, First Medical Faculty
c/o HL7 Germany
An der Schanz 1
50735 Köln
Germany
Email: bernd.blobel@klinik.uni-regensburg.de