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The realisation that health systems should be of high quality and safe, as well as efficient and productive, is becoming more strongly focused on actual individual personal health. We can observe a transition from organisation-centred through process-controlled delivery chains to individualised health services. The latter is also called personalised care (personal care), or if including home care and social services it is called personal health, which transforms into e-health if it is provided independent of constraints in time, locality or resources and becomes ubiquitously available (ubiquitous care).

Ubiquitous care settings have to be supported by health information systems (HIS) adequately designed according to these paradigms. Highly distributed, specialised, integrated and individualised care requires all information to be shared, including actual contexts and underlying concepts.

System organisation and policy domain
System components can be grouped into domains according to common characteristics such as environment, technology and policy. Policy encompasses the legal, regulatory, social, organisational, functional or technical aspects of a system.

With this in mind, organisational boundaries can be overcome by bridging underlying policies to form a common policy domain. Policies can separate or connect systems, including organisations. This is true for departments within a hospital, GP office, social services or inter-organisational managed care settings, but also for regional or even global health networks. Therefore, system integration, networking and interoperability are a policy challenge.

Characteristics for information systems evaluation
In order to evaluate information systems, many parameters have to be considered. Not only functionality but user friendliness and trustworthiness are also of interest to the end-user. Both can be defined by exploited paradigms and architecture on the one hand, and via implementation details on the other. Because implementation has – unlike architecture – a shorter lifecycle and the same architecture can be implemented on different platforms, only implementation-independent aspects will be considered here.

Information cycle
Reality is typically described using simplified models that reflect the intentions and interests of the person creating and using the information. In the information cycle, observed data is interpreted according to objectives that aim to perform the right actions to achieve these objectives. Both steps require expert knowledge. The information cycle is represented in the different information definitions provided by CE Shannon, LM Brillouin and N Wiener.

Interoperability levels
Regarding the interoperability level, we must distinguish between technical, structural, syntactic, semantic and service-oriented interoperability. While technical interoperability establishes harmonisation at the plug and play, signal and protocol level, structural interoperability is based on the exchange of agreed data. Syntactic interoperability, on the other hand provides harmonised messaging and document exchange and semantic interoperability requires harmonised information models based on common references and agreed, ontology-based terminology. The
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higher level of semantic interoperability – service-oriented interoperability – is realised through invocation of services accessed via standardised interfaces. Here, common business models are needed. Interoperability levels reflect information cycle aspects. While communication focuses on the exchange of meaningful and correctly interpreted messages, co-operation depends on the applications’ behaviour and functionalities, defined by their structural components, functions and components’ interrelationships. Therefore, applications’ behaviour and functionality is defined by the application architecture. System interoperability assessment can be provided by analysing the architecture and the completeness of the information cycle.2

The terminology challenge

Personalised health does not only include many different and highly specialised units as specialised policy domains to be integrated by policy bridging. Personalised ubiquitous health services comprise a series of different disciplines such as, but not limited to, medicine, public health, natural sciences, informatics, telematics, biomedical engineering (including medical devices, sensors, actors, body area networks, etc), bioinformatics or genomics. Those disciplines that need to be interoperable follow different paradigms, deploy different knowledge and different knowledge representations using different terminologies.

It is impossible to endorse one harmonised terminology (which is sometimes even true within one discipline). Therefore, terminology services enabling terminology mapping and the integration of new concepts are needed. For this purpose, an ontology representing all domain concepts, their hierarchy, and their interrelationships has to be defined. This is not the end of the pathway, however. As domain experts established their own ontology, reference ontologies are required to communicate and collaborate between domains.

Characteristics of semantically interoperable HIS architectures

Architecture for sustainable health information systems have to be open, scalable, flexible, portable, distributed, standard-conforming, semantically interoperable, service-oriented, user-accepted, trustworthy and lawful to provide advanced and sustainable communication and cooperation. Therefore, the architectural paradigms presented in Table 1 have to be met.

Table 1
Architectural paradigms for realising the addressed system characteristics

<table>
<thead>
<tr>
<th>Architectural paradigm</th>
<th>Supported characteristics</th>
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<tbody>
<tr>
<td>Distribution</td>
<td>Interoperability</td>
</tr>
<tr>
<td>Component-orientation</td>
<td>Flexibility, scalability</td>
</tr>
<tr>
<td>Model-driven, service-oriented design, considering concepts, context and knowledge</td>
<td>User acceptance, lawfulness</td>
</tr>
<tr>
<td>Comprehensive business modelling</td>
<td>User acceptance, lawfulness</td>
</tr>
<tr>
<td>Separation of platform-independent and platform-specific modelling</td>
<td>Portability</td>
</tr>
<tr>
<td>Specification of reference and domain models at meta-level</td>
<td>Semantic interoperability</td>
</tr>
<tr>
<td>Agreed reference terminologies and ontologies</td>
<td>Semantic interoperability</td>
</tr>
<tr>
<td>Unified development process</td>
<td>Semantic interoperability</td>
</tr>
<tr>
<td>Performance, user friendliness</td>
<td>User acceptance</td>
</tr>
<tr>
<td>Embedding services in architecture</td>
<td>User acceptance, lawfulness</td>
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</tbody>
</table>

Practical interoperability architecture

Advanced HIS architecture should follow the principles of service oriented architecture (SOA) separating the services provided by different system components in tiers such as data access, service, business logic and presentation tiers. The services provide a transparent connection between client applications and business logic components or system functions. Services in SOA environments are published to be used by those applications using subscriber mechanisms. In that context, client applications use business function services instead of invoking single business object methods. Infrastructure interoperability profiles shaped as service component architecture patterns provide the needed flexibility and reusability of components. Here, enterprise service bus solutions for intelligent addressing and orchestrating services have to be mentioned as well.

The resulting interoperability architecture consists of three layers: local applications, interoperability services and infrastructure services. These services are designed and implemented as components which create flexibility and reusability.

At different interoperability levels, the presented architecture supports any interaction patterns for information system interoperability: point-to-point communication connected to the interface explosion problem, communication server (router) based on international communication standards, eg, HL7 and DICOM or mediator. To ensure semantic interoperability in a communication focus, information models, terminologies based on ontologies, concept representations, etc, have to be harmonised. This obstacle has been overcome with the mediator based approach by chaining the invocation of different services. The mediator based interaction advances the communication focus by an architecture focus, however, requiring the harmonisation of business models. Figure 1 presents the different interaction patterns presented.

Safety, security and privacy

Security and privacy aspects are bound to identity, policy and context. Specific requirements for qualifications, position within the enterprise, rights and duties in general as well as obligations or prohibition can be defined through policies. Thereby, policies and contexts specify constraints, described through formalised concepts. Those constraints are bound to communication and co-operation acts as well as to the principals involved in the acts. This extends the identification challenge to services and acts as well.

Successful management is highly complex and can define the relationship between entities and acts and related objects. By grouping entities, actions and objects, this complexity can be reduced. Constraint modelling of associations between entities (actors) and acts is provided by association roles – structural roles at the entity side and functional roles at the act side – as defined in ISO 21298 “Health informatics: structural and functional roles”. Privilege management and access control in semantically interoperable health information systems must be conform to ISO 22600 “Health informatics: privilege management and access control”.

Increasingly, the aspect of safety comes into consideration. Safety analysis, appropr-
Inteoperability

Interoperability is essential for designing, implementing, using and maintaining any health environment.

Discussion

Advanced HIS solutions can be applied beyond hospitals according to the definition of appropriate policy domains. Thereby the e-health paradigm covers hospital environments regarding both the architectural approach as well as the increasingly developing business model (shared care, managed care, integrated care, health networks) with dedicated hospital roles as a centre of excellence or specialised care setting, etc.

Health information integration has established a demand for interoperability between clinical and healthcare-related stakeholders, systems and processes or workflows. Domain-specific communication and interoperability standards are well established, but have to be supplemented for trans-domain use.

Interoperability concepts for medical devices and for personal or mobile systems need to involve all seven ISO/OSI reference model layers, more properly advanced to the generic component model, including terminology/coding aspects.

The advanced concept of personal health extends e-health by the inclusion of smart sensors, body-worn mobile systems and situation-specific activation of applications and human health professionals, thus providing personalised ubiquitous health services. Body area networks and micro-systems are building blocks of future personal health telematic infrastructures and extend existing interoperability concepts.

The transfer to advanced health information systems with process-controlled, service-oriented, context-sensitive, semantically-interoperable information and communication architectures requires open, highly flexible individually tailored application systems for the cared for and the caring.

Such applications cannot be prefabricated anymore, but must be dynamically created and adapted to the actual specific requirements. In that way, besides the well-established technology paradigms of mobile computing for realising accessibility (eg, teleconsultation) and pervasive computing for realising independency of location when providing services (eg, telemedicine), the paradigm of autonomous computing for realising self-organising systems can be introduced. The combination of the aforementioned technology paradigms leads to ubiquitous computing, which is bound to other paradigms and trends such as health grids. Security, safety and privacy concerns are crucial issues. Personal health also requires an adequate legal framework and the new orientation of traditional organisational patterns.

References