

## **ECG Data Interchange Formats and Protocols – Status and Outlook**

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### **1. Introduction**

State-of-the-art medical technology requires communication among multiple medical devices and information systems. Existing communication architectures, interfaces, transmission protocols and codes, however, are still limited to specific components, applications, manufacturers or domains, resulting in unnecessary barriers, efforts and costs when exchanging information or even just replacing components. Motivated by this situation, groups from different clinical areas started work on standardisation of medical data exchange and communication primarily to improve the situation in their particular professional environments. Hence the resulting standards are generally based on incompatible concepts reflecting not only the requirements of typical domain-specific applications, but also their development history and conceptual paradigms. Examples are HL7 (for enterprise level / Hospital Information Systems – HIS) and DICOM (for Radiology Information and Picture Archiving and Communication Systems – RIS/PACS) which are all today well established in their specific area of application.

### **2. ECG Communication: Standards and Concepts**

For computerised electrocardiography, the ECG Standard Communications Protocol CEN ENV 1064 [1] specifies the exchange of data between ECG devices/carts and related computer systems. It provides a flexible data exchange format, a comprehensive coding scheme, and features like data compression etc. Due to the relevance of ECG data in numerous medical procedures and domains, however, diverse communication standards had to encompass ECG communication capabilities: Motivated by intensive care and operation theatre requirements, CEN standards ENV 13734/35 [1] – commonly known under the acronym “VITAL” – and related IEEE 1073 [2] documents have been aligned and extended to build the CEN ISO/IEEE 11073 family of standards [3]. It aims at real-time “plug-and-play” medical device interoperability for a wide range of medical devices, including real-time ECG data communication. It addresses transports (e.g. cable connected or wireless); general application services (e.g. polled vs. “event-driven” services); device data (specifying an object-oriented data model, terminology, nomenclature and coding scheme optimised for vital signs information); optional components for specific communication needs or device functionalities (“Application Profiles”/“Device Specialisations”) and internetworking and gateway standards (e.g. a gateway from 11073-based messaging and data representation to HL7 or DICOM). For off-line vital signs representation and exchange, particularly among sleep labs, CEN prENV 14271 “File Exchange Format” was inherited from VITAL. HL7 [4] has no practicable generic (ECG) waveform representation, but utilises external representation schemes to be “embedded” in (OBX) segments. The DICOM 3.0 Supplement 30 [5] provides “Waveform Object Definitions” for General ECG, Ambulatory ECG, 12-Lead ECG and Cardiac Electrophysiology. DICOM image(sequence-)related Waveform Objects enable combined processing of DICOM Images and related waveforms and are – in combination with coded diagnostic information – subject of DICOM “Structured Reporting”. Similar semantic concepts are also applied by joint IEEE/ISO/HL7 activities to meet recent FDA requirements for provision of original ECG data with clinical studies. The German IMEX project [6] defines a micro-system data format to extend the standard-based communication chain to the micro-system level.

### **3. Towards Interoperability and Integration**

Until today, departmental/clinical information systems are mostly historically grown “communication islands” with inconsistent patient-related/medical information representation. They are linked together using (proprietary) one-to-one data conversion. However, growing availability of interoperability standards is enabling and driving an ongoing process of transition: Health information integration (“eHealth”) aims at transparency not only among all information systems within one (hospital) enterprise, but between all healthcare-related processes and stakeholders (see figure 1). Future Electronic Health Records (conceptually) comprise data that are generated, stored and used by different systems at different places and at different points in time. Home care,

internet-based and mobile personal health scenarios require further extensions of traditional communication chains and medical workflow. Accordingly the system of communication standards has to be enhanced to provide inter-domain interoperability. Inter-domain interoperability includes the capability of systems or components to exchange information (“functional interoperability”, e.g. by shared architectures, protocols, frameworks) and to use the information that has been exchanged (“semantic interoperability”, e.g. by terminologies, coding schemes) [7] without further need for user interaction. While practicable solutions for bridging different transport media or communication systems are available, maintaining semantic interoperability among systems using coding schemes based on different terminologies is still a challenge to be met by various concepts and activities. Apart from international standardisation activities increasingly addressing cross-standard interoperability issues, the IHE (“Integrating the Healthcare Enterprise”) initiative [8] which was initiated in 1998 by HIMSS (Healthcare Information and Management Systems Society) and RSNA (Radiological Society of North America) embarks on a complementary strategy to “promote and support the integration of systems in a healthcare enterprise (hospital)“. Motivated by the obvious lack of interoperability among available HIS/RIS/PACS systems, clinical workflow optimisation (e.g. to provide continuity and integrity of patient information, to foster communication among information systems from different vendors, to avoid repeating tasks like typing patient names, to eliminate data redundancy etc.) is maintained by a set of “Integration Profiles” which specify the use of existing (DICOM/HL7) standards. Ongoing IHE work aims at integrating Laboratory/Point-of-Care Testing. All interoperability-related activities are expected to benefit from XML and related concepts and tools [9], which promise dramatic cuts of development time and effort for future interoperability component implementations.

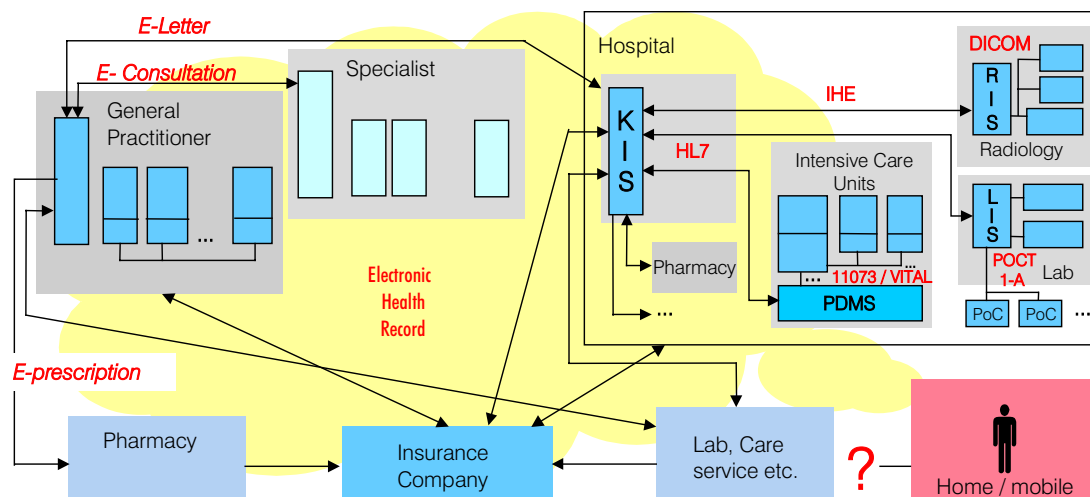


Figure 1. “eHealth” – Typical Stakeholders, Systems and Interactions

## References

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- [2] <http://www.ieee1073.org>
- [3] <http://www.iso.ch/tc215>
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- [8] <http://www.rsna.org/ihe>
- [9] <http://www.w3.org/>

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