



HL7 Jahrestagung 2006
Entdecke die Möglichkeiten ...
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Die Kooperation zwischen den Standard-Entwicklungsorganisationen und Europäische Projekte

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Leiter der GMDS-AG "Standards für Kommunikation und Interoperabilität"

Chair EFMI WG "Electronic Health Records"

Chair EFMI WG "Security, Safety and Ethics"



Stakeholder-Meinung

- Es gibt zu viele SDOs und zu viele Spezifikationen, aber zu wenige brauchbare Standards und Normen. Viele der letzteren sind dann noch inkonsistent überlappend.



Standards-Klassifikation

- Architekturstandards
 - e.g. HL7 version 3, CORBA MDA, CEN EN 12967 Service Architecture (HISA), (openEHR), CEN EN 13606 EHR communication
- Modellierungsstandards
 - e.g. UML, ISO 10746 ODP, CEN TR 15300 Framework for formal modelling of healthcare security policies, OASIS WSDL
- Kommunikationsstandards
 - HL7 V2x, HL7 V3, DICOM, UN/CEFACT, ebXML, CEN EN 13608, CEN prENV 13609, prEN ISO 11073 Point of care medical device communications, CEN EN 14822 General purpose information components (GPICS), CEN EN 13606 EHR communication, W3C
- Infrastrukturstandards
 - ISO 17090 Public key infrastructure, ISO 21091 Directory services, ETSI TS 101733 Electronic Signature Formats, CEN ENV 13729 Secure user identification - Strong authentication using microprocessor cards, CORBA PIDS; HL7 SOA, ASTM PMI ↔ ISO 22600 Privilege Management and Access Control, ISO 27000 Information security management, W3C



Standards-Klassifikation

- **Datenschutzstandards**
 - e.g. ISO DTS 25237 Pseudonymisation ..., ASTM E1987-98 Standard guide for individual rights regarding health information, ISO 22600 Privilege Management and Access Control, ISO TC27, W3C, OASIS
- **Sicherheitsstandards**
 - e.g. CEN TR 13694 Safety and security related software quality standards for healthcare → CEN/ISO NWI, ISO TC27
- **Terminologie- und Ontologiestandards**
 - e.g. UMLS, SNOMED, LOINC, Identifier and identification schemes, LOINC, ASTM E1714-00 Standard guide for properties of a Universal Healthcare Identifier, CEN EN 13940 System of concepts to support continuity of care (CONTsys), ISO/CD 17115 Vocabulary on terminological systems



HL7-Kooperationen

- HL7 Inc. unterhält eine Reihe von offiziellen Kooperationsbeziehungen mit anderen SDOs und vergleichbaren Organisationen, die z.T. global und z.T. national agieren, z.B. ISO, CEN, DICOM, IHE, ASTM, NLM, SNOMED International, Liberty Alliance, ASC-X12 (Accredited Standards Committee X12), ADA (American Dental Association), NCPDP (National Council for Prescription Drug Program), etc.



- Basierend auf den gemeinsamen Prinzipien und rechtlichen Grundlagen sind Standards und Normen der europäischen SDOs CEN, ETSI (European Telecommunications Standards Institute) und CENELEC (European Committee for Electrotechnical Standardization) verbindlich, nicht aber die entsprechenden internationalen Spezifikationen.



HL7 und die Europäische Kommission

- European Commission: Draft eHealth Interoperability Staff Working Paper “Connected Health: Quality and Safety for European Citizens”:

“... European standards development organisations are strongly encouraged to collaborate with international standards development organisations such as Health Level 7 (HL7), SNOMED International and DICOM as well as international standards organisations and the International Telecommunication Union. ...”



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPAISCHES KOMITEE FÜR NORMUNG



CEN TC, ISO TC and HL7 Chairs Report Broad Agreement on Coordination and Collaboration

October 10, 2006
Geneva

The CEN TC251, ISO TC215 and HL7 Chairs met in Geneva to further advance shared plans to coordinate and collaborate in delivering global standards that enable interoperable capabilities in the healthcare domain. These plans will enhance the contributions of the three standards development organizations (SDOs), strengthen the delivery of standards-based solutions to all customers and support the goal of safe, accessible, quality and effective health service delivery.

The meeting in Geneva focused on key principles that will be applied in harmonizing the processes of standards development across the three SDOs. Building on existing collaborations and work already underway across the SDOs, the Chairs noted that their respective business plans all now include a focus on multilateral SDO collaboration, cooperation and coordination.

HL7 Chair, Chuck Meyer, stated that “we already have cooperative relationships with ISO and CEN and are undertaking a strategic initiative which will further develop our capacity and structure for coordinating our work program”. HL7 has clearly demonstrated great standards delivery capabilities and has a huge global volunteer contingent that participates in standards development.

Kees Molenaar, Chair of CEN TC251, provided an overview of the TC’s Business Plan, which includes an assessment of the current environment and the TC’s work program. “CEN is not in the business of competing in standards development and will be collaborating and cooperating with other SDOs, along with the vendor, government and provider communities as we fulfill our role in the EU.”

Dr Yun Sik Kwak, Chair of ISO TC215, agreed with the importance of engaging the three communities, particularly noting the recent Global Summit’s for National Health Information initiatives in 2005 and the just completed summit with health IT vendors here in Geneva. “ISO TC215 is undertaking a leadership role in the harmonization of globally based health informatics standards. This important effort is in response to a call for such action by government and industry leaders, and reflects the evolving business model of ISO TC215 which includes a greater global focus on orchestration of standards”.



The meeting identified a number of principles that will be incorporated into a draft terms of reference for SDO collaboration, coordination and cooperation. Building on the shared goodwill of the organizations, the principles included agreement to:

- Continue to accommodate member bodies needs and processes, individual SDO mandates and external influences,
- Be business requirements driven,
- Be customer focused through strengthened connection with governments, vendors and providers,
- Undertake joint strategic and operational planning,
- Coordinate standards starting at the beginning of the standards development processes,
- Jointly determine which standards to harmonize and include in respective work programs,
- Be topic and project-focused in undertaking collaboration, coordination and cooperation,
- Support, facilitate and effectively use collective resource capacity and expertise in the development of health information standards, and
- Provide common communications to our various external stakeholders and communities of interest.


These principles will be applied to the processes for choosing, launching, communicating, resourcing, marketing and supporting standards that need to be developed or are being developed.

Recognizing the commitment of ISO/TC 215 to serve as a coordinating mechanism and focal point for the collective work of the SDOs, the three SDOs clearly acknowledged that they will be inclusive and open to other international SDOs joining in this growing and evolving harmonization effort.

A small work team has been assigned the task of detailing and continuing the planning process in time to table a full plan for the next ISO/TC 215 meeting in Montreal, in March 2007. At that meeting, further specific plans will also be tabled for collective harmonization work targeted for delivery in 2008.

HL7 Jahrestagun
Kees Molenaar
Chair, CEN TC251


Dr. Yun/Sik Kwak
Chair, ISO TC215


Charles C. Meyer
Chair, HL7



- ISO TC 215 is undertaking a leadership role in the harmonization of globally based health informatics standards. This important effort is in response to a call for such action by government and industry leaders, and reflects the evolving business model of ISO TC 215 which includes a greater global focus on orchestration of standards.



Agreement Principles

- Continue to accommodate member bodies needs and processes individual SDO mandates and external influences,
- Be business requirements driven,
- Be customer focused through strengthened connection with governments, vendors and providers,
- Undertake joint strategic and operational planning,
- Coordinate standards at the beginning of standards development processes,
- Jointly determine which standards to harmonize and include in respective work programs,
- Be topic and project focused in undertaking collaboration, coordination and cooperation,
- Support, facilitate and effectively use collective resource capacity and expertise in the development of health information standards, and
- Provide common communications to our various external stakeholders and communities of interest.



- These principles will be applied to the processes of choosing, launching, communicating, resourcing, marketing and supporting standards that need to be developed or are being developed.
- They recognize the commitment of ISO/TC to serve as a coordinating mechanism and focal point for the collective work of the SDOs.



HL7-Anpassungsprozess

- Transformation - Transparency - Teamwork, Team Report of Strategic Initiative
- HL7 Strategic Initiatives and Implementation Plans



Strategische Initiativen (Strategic Initiatives)

- HL7 will implement a new business model and organizational structure.
- HL7 will formally approve a product and services strategy that is reviewed annually by the Board of Directors.
- HL7 will optimize the effectiveness of its volunteers and other resources.
- HL7 will develop a brand hierarchy that helps the marketplace understand the relationship of its products to each other and to the overall organization.
- HL7 will develop consistent organizational messages and a communications strategy to disseminate those messages.
- HL7 will implement a product-oriented project management approach to ensure development of high-quality standards and associated products in a committed timeframe.
- HL7 will ensure that all standards undergo quality testing at key stages of the development process.



Veränderungen in Struktur, Organisation und Kontrolle in HL7

- Organizational Issues
 - Recognition of HL7 as “international” SDO
 - Formation of HL7 US Affiliate
 - Concept of “joint” membership
- Governance
 - Streamline the Board of Directors
 - Broaden Affiliate representation
 - Continued reliance on Affiliate Council and Advisory Council for national, international, and industry trends
 - Transition operational control to “the Chiefs”
 - Revise Bylaws/Policy & Procedure to support new organizational structure and efficient development and implementation process



- Drei Arbeitsgruppen:
 - Foundation & Technologies
 - Structure & Semantic Design
 - Domain Experts



Kontext der europäischen Entwicklungen

Die eHealth Working Group wurde im Februar 2005 als eine Untergruppe der eEurope Advisory Group etabliert

Die Stakeholders Group wurde im Dezember 2005 geschaffen, um zu:

- Patient Summary
- Patient/Heilberufler Identifikatoren
- Notfalldatensatz

einschließlich der Datenschutz- und Datensicherheitsaspekte sowie Demonstrationsaktivitäten und Kontakten zu Implementierungsinstitutionen zu beraten und zu untersuchen.



Kontext der europäischen Entwicklungen

- Erarbeitung eines eHealth Interoperability Staff Working Paper auf dem Wege zu einer EC Recommendation on eHealth Interoperability (2007)
- Lancierung von 5 Studien im Rahmen des eHealth Action Plan:
 - Productivity and economic Impact of eHealth (2005)
 - Good practice exchange in eHealth
 - Study on Identity of Patient and Practitioner in eHealth
 - Study on Legal and regulatory aspects of eHealth
 - Study on use of ICT in Patient Safety
- Lancierung von 5 EU-geförderten Projekten auf dem Gebiet der Interoperabilität und Unterstützung des eHealth Action Plan (eHealth ERA, I2Health, RIDE, Semantic Health, Q-REC)



Vorschlag für die *ad hoc* Group

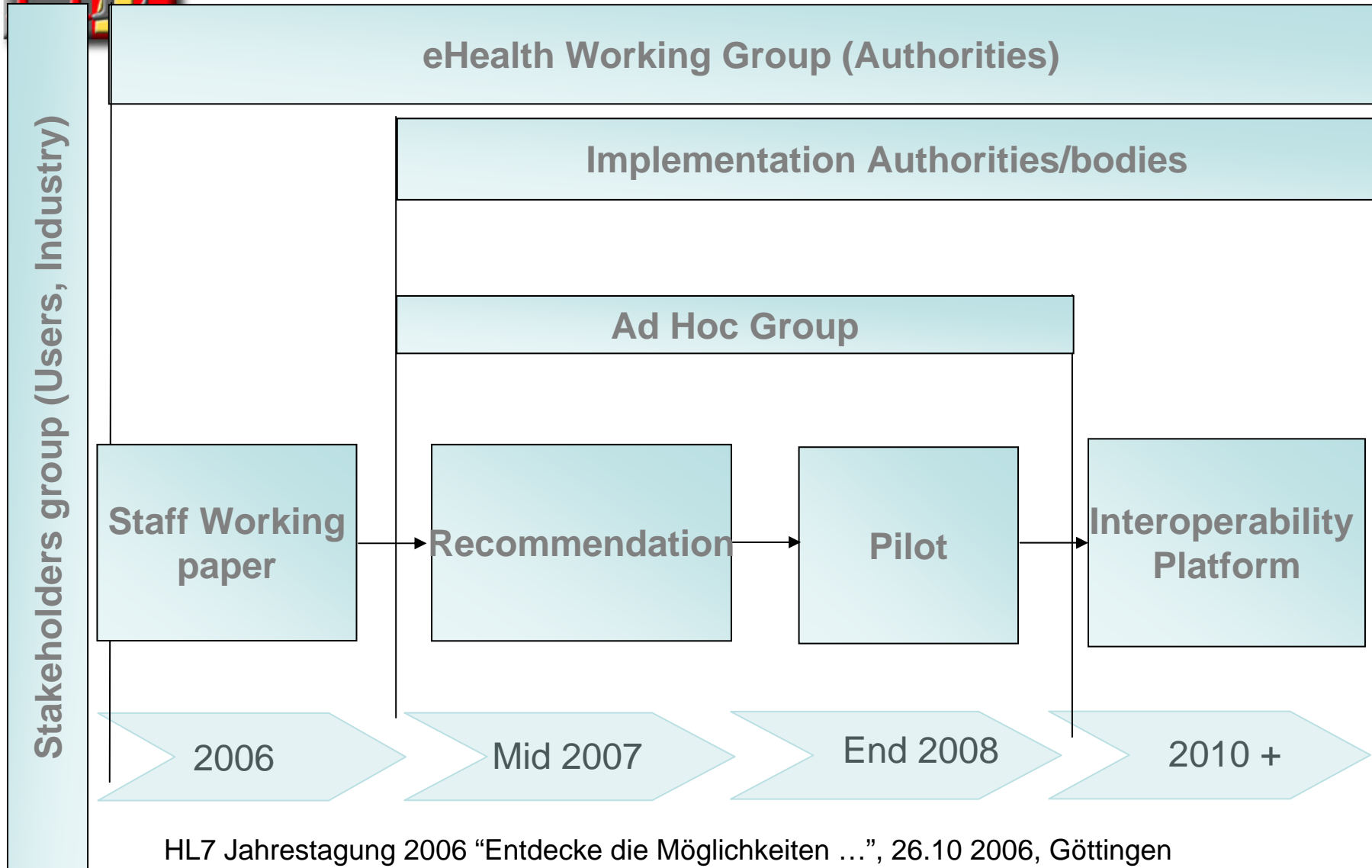
- Es wird eine *ad hoc* Group für die Definition von Patient Summary, Patienten- und Heilberufler-Identifikatoren sowie den Emergency Data Set vorgeschlagen.
- Diese *ad hoc* Group könnte auch ePrescribing adressieren.
- Die Gruppe wird im Rahmen der durch das eTEN-Programm geförderten Common Interest Preparatory Activities etabliert.



Mitgliedschaft

- Die Mitglieder der *ad hoc* Group werden von der eHealth Working Group vorgeschlagen.
- Sie werden als designierte Repräsentanten der Implementierungsinstitutionen der verschiedenen Mitgliedsländer betrachtet.
- Externe unabhängige Experten können erforderlich sein, um zusätzliche Beratungen zu geben.

Roadmap



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Aktivitäten

- (1) Beratungen zu notwendigen Anforderungen zur Erreichung der Interoperabilität im mittleren Zeithorizont (3 Jahre) auf dem Gebiet des Patient Summary und langfristig (6-7 Jahre) für den EHR. Innerhalb von 12 Monaten soll eine EC Recommendation für eHealth Interoperabilität formuliert werden.
- (2) Konzeption von ausgedehnten Piloten auf dem Gebiet der Interoperabilität von Patient Summaries und ePrescriptions (2006-2008).
- (3) Beitrag zur Impementierung von interoperablen eHealth Lösungen entsprechend den Prioritäten, die durch die Mitgliedsländer definiert wurden und der Recommendation on eHealth Interoperability folgen (2007-2010+).



Ausgedehnte Piloten (2007)

- Austausch von Patient Summaries in reifen Gebieten oder Regionen für eine gemeinsame Näherung an Interoperabilität auf der Grundlage gemeinsamer Spezifikationen.
- Die Förderung kann bis zu 15 Mio € betragen und 7-8 Mitgliedsstaaten einbeziehen.
- Testimplementierungen von technischen und organisatorischen Lösungen für Patient Summaries, Patienten-Identifikatoren und Heilberuflerakkreditierungen sowie einen Notfalldatensatz auf EU-Ebene.



Ausgedehnte Piloten (2008)

- ePrescription Pilot
- Erfahrungsaustausch auf diesem Gebiet auf EU-Ebene
- Die rechtlichen, semantischen und Industrie-Barrieren werden beschrieben und mögliche Lösungen werden getestet.
- Testung der Interoperabilität zwischen Regionen zur Untersuchung der Bereitschaft zu grenzüberschreitender Interoperabilität.
- Bis zu 15 Mio € Förderung unter Einbeziehung von 6-8 Mitgliedsstaaten.



New Services Deployment Pilots (NSDP)

- Proof of Concept – Zertifizierung der Patient Summary Platform, der eMessages und der semantischen Interoperabilität. Diese Projekte werden zu akzeptierten Leitlinien für die Zertifizierungen Patient Summary, Blue Prints und Spezifikationen für die umfassende Anwendung.
- Kleine Piloten für die Verwendung von eMessages mit semantischer Interoperabilität auf EU-Ebene.
- Bis zu 5 Mio € Förderung.



Zusammenfassung

- Die Standardisierung gewinnt zunehmend an Bedeutung für die Realisierung einer offenen, verteilten und semantisch-interoperablen eHealth-Umgebung. Die SDOs und die Europäische Kommission haben ihre Aufgabe erkannt. HL7 spielt in diesem Konzert eine besondere Rolle. ISO TC 215 kommt dabei die Funktion des Konzertmeisters zu. Dann wird das Resultat harmonisch und überzeugend klingen.



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