EXPAND: Sustainable Cross Border eHealth Services

Parachutist (person) – or: SNOMED activities
Legal Notice

Ownership and content
HL7 International Foundation
(European Office of HL7)
Square de Meeûs 38/40
1000 Brussels
Belgium
E-mail: euoffice@hl7.org
Website: www.hl7.eu  Wiki: wiki.hl7.eu

Concept, design and realisation
Heitmann Consulting and Services | Max-Ernst-Str. 11 |
50354 Hürth, Germany
E-Mail: info@heitmann-cs.com

Photography
Fotolia.com © Bashkatov, Ray, GiZGRAPHICS, beerkoff, Sergii Figurnyi; © Geert Thienpont; © HL7 Italy

Copyright
Copyright © 2016 Health Level Seven International
3300 Washtenaw Avenue, Suite 227
Ann Arbor, MI 48104
USA
E-mail: HQ@hl7.org
Website: www.hl7.org
All rights reserved!
| Contents |
|------------------|--------|
| First eStandards Conference | 4 |
| Developing Evidence supporting Terminology Decisions for Europe | 12 |
| The Real Costs and Benefits of SNOMED-CT | 14 |
| Switzerland new Member of IHTSDO | 15 |
| Adoption of Patient Summary Guidelines across the European Union | 16 |
| EXPAND: Final Event and Outcomes | 19 |
| How ART-DECOR supports the Handover of the Patient Summary Specifications to the Connecting Europe Facility | 21 |
| Insights from Concurrent Use of Standards | 26 |
| The Case for Formal Standardization in Large-scale eHealth Deployment | 29 |
| eStandards: Extension of the Antilope Use cases Repository | 30 |
| Frank Ploeg appointed as HL7 "Lead Expert" in European mHealth Project | 31 |
| A Case Study for Hemodialysis Patient Referral based on HL7 CDA R2 using ART-DECOR | 32 |
| Mapping and Harmonization of i-Standards (Care) and HL7 Standards (Cure) in the Netherlands | 35 |
| openMedicine – One big Step towards Safe Medication | 37 |
| Fifteen Years on the Board of HL7 Netherlands | 40 |
| eHealthWeek 2016: In Search of a Digital Health Compass: My Data, My Decision, Our ePower | 42 |
| IHIC 2016: 16th International HL7 Interoperability Conference | 43 |
The first eStandards Conference took place in Berlin on the 21 of April 2016, collocated with conhIT, Connecting Healthcare IT, a large Healthcare IT Industry trade show with accompanying congress, networking and educational events. The purpose of the meeting was twofold. Firstly, to present key results of the eStandards project in 2015-2016, the draft eStandards roadmap on “essential standards development: strategic options and policy instruments.” Secondly, to listen to the perspectives of the health system and the industry, and reflect on the collaboration among Standard Development Organizations and competence centers to make interoperability affordable and sustainable for Europe and beyond. The final program of the event and presentations are available online from www.estandards-project.eu.

The conference opened with the vision of the global eHealth ecosystem where eStandards nurture large-scale eHealth deployments with co-creation in interoperability, trusted dialogs on costs, plans, and expectations and strengthen Europe’s voice and impact with digital assets that fuel creativity, entrepreneurship, and innovation so that people (digital natives and immigrants) enjoy timely safe and informed health no matter where they are.

Robert Stegwee, chair CEN/TC251 (Health Informatics) presented the case for formal standardization with the four perspectives of the health system seeking to balance costs and responsibilities, the workforce struggling to cope with the digital, the eHealth market seeking new opportunities in a data-driven world, and the consumers having difficulty navigating the health system. These perspectives realign interests of stakeholders looking at the value, cost, and direction of standardization in new light. They highlighting the value of supporting the full cycle of standards with standard sets and tools that allow to connect standards development with testing, deployment, use, and maintenance, making them ‘live’.

eStandards Draft Roadmap for Essential Standards Development

Marco Eichelberg (OFFIS) presented the draft eStandards roadmap that includes eleven recommendations and alternative options for proceeding with collaborative standards development. The audience was asked to comment and vote on the draft recommendations, with a rating from 1 (strong disagreement) to 5 (strong agreement). The emerging recommended areas of work are as follows:

1) Localisation of standards sets should be supported by knowledge exchange and strengthened by conformance testing to prevent unintended adaptation of the underlying standards that “break” cross-border or cross-realm interoperability (average rating 4.44)

2) Develop open-access tools to computable standards specifications for implementation and deployment, to increase the accessibility and usability of standards (average rating 4.37)

3) Make it simple to refer to eHealth standards and specifications in (public) procurement by
making available a state-of-the-art overview of standards sets tracking their maturity (average rating 4.26)

- 4) Detail a clear governance and maintenance process for each standards set in line with the standards development life cycle and the evolving processes among participating SDO's (average rating 4.22)

- 5) Support the flow and mixed use of health data across record systems and (mobile) devices (break down the silos) (average rating 4.22)

- 6) Provide guidance on the interpretation of the medical device directive in case information from personal Health and Wellness or Active Assisted Living services is shared with (a team of) healthcare professionals (average rating 4.12)

- 7) Increase the visibility of clinical best practices in terms of professional guidelines linked to generic workflows and information sets (4.11)

- 8) Encourage the incorporation of mature and shared clinical models in digital health applications, irrespective of the particular use case and formalism (4.07)

- 9) Ensure that shared European Health Terminology Service initiatives have a scope broad enough to cover also patient generated sensor and medical device data. (4.0)

These draft recommendations will be further refined and updated with the detailed input provided by the engaged workshop participants and the eStandards community. Furthermore, recommendations towards a establishing an eStandards repository and addressing issues related to cloud services need to be further explored.

Marco also outlined the strategic options in addressing the co-existence of competing or overlapping standards or specifications, namely: (a) allow full blown competition between Standard Developing Organizations (SDOs), leaving it to the eHealth Market and individual decision makers to choose the realization scenario that fits best for them; (b) Employ the envisioned European SDO Platform to achieve coopetition among SDOs in creating fit-for-purpose realization scenarios for Europe; (c) Delegate to a European eHealth Competence Centre to achieve harmonization of standards across Europe.

Marco highlighted that SDOs are rooted in, depend upon, and service a broad community of stakeholders that develop and deploy eHealth solutions and services. In the deployment phase, a realization scenario will be selected or developed that specifies the set of standards to be implemented. To be effective, realization scenarios need to have a conformance testing and attestation process connected to it, so that: (a) Implementers are brought together and learn from each other; (b) Standards developers are confronted with standards use in practice; (c) Attestations can be easily referenced in procurement documents; (c) The standards development life cycle actually comes alive across SDOs. Through active engagement and collaboration SDOs can together assume the responsibility to monitor the development and maturing of realisation scenarios in real life projects.

In support of the standards development life-cycle, Marco stressed that tools and data need to be shared across SDOs. Moreover, when standards sets and tooling provide software components for interoperability, an open source licensing model is recommended. What gets increasingly important, however, is monitoring of and feedback from the user community on the usage of standards sets in terms of implementation and adoption and that is a functionality that can be incorporated in the tooling.

In the end monitoring of standards sets is part of the lifecycle and is needed to ensure quality and maturity of the standards.

Marco moved on to stress the “global vision/local insight” continuum with the ultimate focus being on local deployment where maturing of realization happens by engaging the community. A European SDO Platform can coordinate such activity through national mirror organization that localize the realization scenarios making local deployment easy and cost-effective, but stakeholders need to invest in global participation in SDO activities, furthering European interests at a global level.
Case studies on the coexistence of standards

After the coffee break, Marco presented the lessons learned from 19 case studies on the coexistence of standards. He shared that in “real-world” eHealth deployment projects, there was little concurrent use of competing/overlapping standards other than terminology mapping such as International Classification for Primary Care (ICPC) and ICD-10 (DK), ICD-10 and SNOMED-CT (NL), National and regional EHR terminology (IT), ICD-10 Procedure Coding System (PCS) and SNOMED-CT procedures (ES). Marco concluded that there is “no magic bullet” to address coexistence of overlapping/competing standards: there are three fundamental approaches: gateways, model driven and semantic mediation, but terminology mapping (and security) remain “hard” problems. The good news is that there is lots of experience and tools available to learn from!

Use case repository

Karima Bourquard (IHE Europe) presented the use case repository developed by IHE-Europe as part of the effort to elaborate the refined European eHealth Interoperability Framework and define new use cases and realization scenarios. The use case registry is available at https://usecase-repository.ihe-europe.net. The voluntary eHealth Network of government officials in Member States established under article 14 of the European Directive on patients’ right to cross-border care, in its November meeting adopted the ReEIF, which forms the backbone of the eStandards Roadmap.

Healthcare Executive Panel

Catherine Chronaki and Morten Bruun-Rasmussen chaired the healthcare executive panel, comprising three hospital CIOs, a clinician and the representative of the Croatian health insurance fund. The panelists introduced themselves and answered two questions:

- What are the priority areas for information sharing within and between organizations that you are now striving to achieve?
- What are the difficulties you encounter in meeting these needs, in terms of products, standards, data, human or organizational factors?

Lively discussion followed.

Prof. Björn Bergh, CIO/CTO, University Hospital Heidelberg, User Chair of IHE Germany indicated that he would like to see “accelerated adoption of IHE profiles in the products of the vendors in Germany. Currently, implementation of IHE profiles takes one year on the average”. He also expressed the impression that we focus too much on semantics where for him as an MD a free text letter is sufficient. Asked whether a different “language” is needed for (standards) development that is understood both to clinicians and engineering Prof Bergh notes: “Rolling out a shared care record does not mean that clinicians have to understand standards like XDS. We only talk to clinicians about what kind of documents they need in the shared care record; the answer is usually: “we want everything in there, every single report”. My impression is that clinicians really want a shared record, they are not against it, the problem is rather that you need to change processes in the hospital, which is always hard”.

As for immediate priorities, Prof Bergh, observes that “in the Shared Care Record (IHE XDS) interoperability is mostly on a syntactical level. Interoperability on a semantic level such as value sets were not a priority for a long time in Germany, but getting more important now. The priorities are to address Semantic issues (terminology) within one affinity domain, while focusing on deployment and evaluation of cross-community profiles for cross-regional communication”.

Prof. Dipak Kalra, President EuroRec Institute, Belgium, recalled his 12 year experience as a general practitioner in London. He noted that “Clinicians want connectivity. They need this to support shared care (especially to deal with rising co-morbidity), for patient safety (e.g. needing a complete view of medications, allergies). Sharing information must include the patient and their family. Clinicians want “smart” solutions, giving them overviews and trends, risk stratification, decision support for prescribing and referral, care pathway and workflow support (and not form filling)”. Prof. Kalra went on to recognize significant gaps in (a) semantic standards (clinical models and term lists); (b) guidelines and decision support rules that can be executed on different systems; (c) quality metrics that truly reflect outcomes oriented care; (d) access policies that scale across care settings and borders; and (e) connectivity with Personal health records.

On the topic of communication with physicians, Prof. Kalra said: “Our concern is that once we voice a new idea, you technicians disappear in a “technical ether” and never come back. You need to actually keep communicating with clinicians: have you gotten the
needs right; does the implementation fulfil the users’ needs. We need both a bottom-up approach based on successfully implemented interoperable use cases, and a top-down approach starting on the political level. Procurers need to understand the value of standards; otherwise this is a missed opportunity”.  

Domíngos Silva Pereira, CIO, Centro Hospitalar Vila Nova de Gaia/Espinho, Portugal, presented the needs of his hospital, highlighting the struggle with multiple HL7 engines supported for different products. He notes: “…many problems in our hospitals that we need to solve locally. The move to the use of IHE profiles has been understood as a necessity for 10 years, but still has not happened... So things will have to happen on local/national level first to close the gap to international standardization”.  

Vanja Pajić, Project Manager at the Croatian Health Insurance Fund, presented the situation in Croatia noting that it has a very flexible healthcare system that can implement new standards relatively quickly. In offering pan-European services key obstacles are lack of standardized national clinical terminologies, pathways and procedures (work on implementing EU recognized standards); rising cost of healthcare provision (thus priority on eHealth). On the topic of a different language to communicate with clinicians, Vanja Pajić agrees that the technical perspective dominates the discussion: “Once you get systems to interoperate, you get to the next challenge: how to make the systems interact with non-technical people. One thing we noticed in JASEHN is that systems get technically more interoperable, but then there are other layers of interoperability that are lacking: organizational (health IT policy) and legal/regulatory. This also needs to be addressed”.  

Bernd Behrend, Vice-Chair KH-IT, German hospital CIO association raised the issue that in Germany as in many places around the world the outpatient sector uses different standards than the hospital sector for the same use cases. According to Bernd Behrend, the priority areas for information sharing within a single hospital are patient admission, ordering, results, patient identification, and universal viewer. Between hospitals the top use cases are patient identification and reporting. He identified the high cost of interfaces, the inability to transmit information between systems, difficulties in scaling (many devices to connect), gaps between catalogues, scheduling of appointments, as well as problems with identity management and access rights. Bernd Behrend stressed the importance of use cases: “I am happy that you are thinking about common use cases, and not just technical issues. This is a good starting point for a good IT architecture. Also, learning from other projects is important”.  

Pia Jespersen, Senior Advisor at the Danish eHealth Board (DeHB) indicated that the DeHB is the authority for issuing eHealth standards for the Danish health system. Pia observed that “standards development is too slow and SDOs need to speed up their processes, and become more agile”. Pia also noted the need for ‘controlled’ localization: “We are actually going for international standards; we just need the minimal national localization/adaption that clarifies how an international standard can be used in our national healthcare system”. Pia added that “Member states should share localization work, because today we replicate much work in each country. Also use cases (and sharing thereof) are important.” In Denmark we are reluctant to identify mandatory standards, unless we sure sure that the relevant standards are mature and usable with some market uptake”.  

**Tools for the formal Standards lifecycle**  
Giorgio Cangioli (HL7 Foundation) presented on Tools for the formal Standards lifecycle. Giorgio pointed out that deployment of services compliant to standards requires an architectural approach based on a portfolio of standards artefacts. The use of tools that enable consistent adoption and cooperative use of the selected standards has strong impact on the effectiveness and efficiency of the resulting services in cycle that interlaces the formal standards lifecycle (see figure below), supporting the parties involved.  

With the digital evolution, Giorgio argued, “standards are changing from text-based (paper, excel, pdf) to computable artefacts exemplified by HL7 FHIR®.” Information on standards needs to be adapted to the recipient: “Each type of human or non-human user needs different types of information and artefacts in a format that is understandable and fit for the purpose of use. Tools are essential to assure the consistency between the reference standards’ and/or profiles’ specifications and the published human readable (html, pdf, etc.) and computable artefacts” shared Giorgio. He stressed that “SDOs should promote tools that are designed to facilitate the adoption of portfolios of standards by users (not only for standards developers!), work seamlessly within and across the different phases of the standards’ lifecycle and rely
Finally, Giorgio announced that – convinced that use of tools should be monitored – HL7 Europe is working on a registry for tools and a first version is available for comments at: http://wiki.hl7.eu/index.php?title=Tools.

Then, Kai Heitmann presented ART-DECOR as an example tool that offers computable specifications, its validation capabilities has been integrated with IHE Gazelle ObjectsChecker and has been already used to support connect-a-thons. Kai indicated that ART-DECOR is an open source tool and a methodology to facilitate health care information exchange among multiple stakeholders by supporting comprehensive collaboration of team members within and between governance groups. The tool allows separation of concerns and different views on one single formalized documentation for different domain experts. It supports creation and maintenance of HL7 templates (STU), value sets, data sets and scenarios and a formalized documentation of the artefacts as HTML, PDF etc. ART-DECOR repositories with collection of templates (building blocks for clinical document definitions) and Value Sets (code lists) have been established in several countries i.e. Germany, Austria, Netherlands, Poland, and Switzerland, and sharing of templates and value sets is now common practice.

**Bridging ICT standardization with Procurement**

Marcelo Melgara (Region of Lombardy) presented the European public procurement directive 2014/24 and advocated educating procurers, noting that still the language of standardization and procurement are very far and apart. Marcello started with an overview of the legal and regulatory requirements in Europe, the EU ICT standardization policy, the Data Protection Regulation, and Medical Device Directive and their national interpretation. Marcello presented the terms mentioned in the directive: (1) National standards transposing European standards, (2) European Technical Assessments, (3) Common technical specifications, (4) International standards, (5) other technical reference systems established by the European standardization bodies, Then, he called upon the SDOs to work together, establish a common language with procurers, and help them reduce the cost and increase the effectiveness of the procurement processes. On conformance testing, Marcello referred to article 44 of the public procurement directive, noting that procurers should learn to request evidence in the form of Test Reports and Conformance Reports on compliance to IHE profiles as demonstrated in Connect-a-thons since the 27 IHE profiles identified by the MSP to be eligible for reference in public procurement (Decision 2015/1302, 28/7/2015).

**Industry Panel**

Next, Robert Stegwee moderated the industry panel comprising Horst Merkle, Director of Diabetes Management at Roche Diagnostics, Chair of Personal Connected Health Alliance, Nicole Denjoy, Secretary General of COCIR, Jaime Gamboa, Philips Health Informatics Solutions, and Alexander Ihlis Telecom Healthcare Solutions. The questions addressed to the panel were as follows:

- Do you feel that the lack of, or uncertainty about, standards has held back the market uptake of your eHealth solutions? If so, could you please expand on this?
- Has the lack of, or uncertainty about, standards influenced your strategic choices in product or service development? Or the other way round: have you developed products or services specifically to meet certain standards?
- Where do you feel are standards most needed to contribute to more favorable market conditions for your (current/future) eHealth products or services?

On the role of standards on the diabetes care market, Horst Merkle noted that the market is consumerized and rapidly commoditizing. Without good standardization the market will spiral down very fast. Thus, it is a matter of survival to establish good communication with the customers (patients) and ‘rich’ standard datasets are needed. Consumer electronics is a fast moving market, and time is the main opponent. So, the answer is: yes. We have spent too much time putting data into silos. For example it would be good to complement our bonus calculator with data from a step tracker, but the data is not available. The typical deviation of trackers is up to 48%, making them next to useless for clinical use. On the question of where standards should contribute, Horst highlights education: "We already have a good set of standards for personal health and healthcare IT. Deployment and adoption is a problem, and guidance for users on which stan-
dards are there or needed is a challenge. We have an education task at hands”. Horst adds: “Test tools are important for implementers and for users”. We need to re-think our wording Horst urges: Don’t talk about “implementing an interoperability framework”. We need to say that “we want to help you to make your data flow freely from here to there. Interoperability is infrastructure for innovation and standards give consumers freedom of choice” Horst Merkle, inspired us.

Nicole Denjoy underlined that with respect to standards Industry is always very pragmatic. For us it is important to have standards with market relevance. "Large-scale deployment is happening albeit slowly. Despite standards and activity at the national level, the eHealth market is still very fragmented...we need to raise awareness for the importance of standards. We have many standards and just need to use them smartly. As technology moves forward, we need to expand standards, but not continuously invent new ones. And we don’t need to standardize everything. We all would be happy if interoperability in the healthcare sector would be as good as in banking”. Nicole adds: “However, the situation in healthcare is more complex, with many stakeholders such as patient, doctors, social care, insurance, policymakers, etc. Also the question who owns the data: there are very different positions in the different EU countries”. Nicole also highlights the need to invest in infrastructure. The ministries of health would have to discuss with their neighbors (ministry of industry, ministry of communication) because the money for infrastructure should not come from the healthcare budget.

Jaime Gamboa highlighted two trends of interest to Philips: (a) personalization of care that produces more data, big data, too much data, perhaps and (b) industrialization of care and optimization of care processes. Standards are key in identifying what is relevant data. Jaime shared the views that education on standards is important. Otherwise users will drown in data sooner or later. Jaime also notes that data is becoming a value, an asset to be shared and that raises questions on the potential business model. Healthy living and prevention are areas where governments need to invest according to Jamie, if they want to limit healthcare costs. Policymakers need to create incentives and provide guidance for vendors to provide interoperability. It is important that SDOs understand the market needs, identify gaps, and coordinate to avoid unnecessary overlaps. Young people are empowered, but there is still education to be done on the benefits of standards and interoperability even for the healthy, i.e. to make sure data is available at the point of care as needed. Jamie stressed that once EU member states and healthcare providers should look into their roadmaps and determine where they want to go, the industry would be happy to support them.

Alexander Ihlis, Vendor co-chair of IHE Germany, observes that today it is difficult to combine data from a fitness tracker with data from medical devices. There is due to lack of standards and inadequate precision of the fitness trackers. However, activity trackers have a life cycle of less than 12 months. Customers that change their tracker wish to compare data from different trackers and that is not possible when data is stored on a proprietary vendor portal. Alexander shares their commitment to standards: “At Telekom, we have intensive discussions with vendors and try to convince them to implement standards into their products so as to add value to our customers though these devices.” Alexander firmly supports that infrastructure should be financed by the government “Everyone agrees that regional or national patient records are a good thing. However: who pays for that? I personally believe that infrastructure must be financed, not by the insurance companies, but by the nation, by taxes. Medical IT infrastructure should be provided such as streets and water pipes. On top of that, there can be reimbursement models for healthcare service provision.” On gov-
ernment-mandated standards, Alexander pointed to examples from EU countries that are publishing regulatory guidelines on standards required or strongly recommended such as the IHE XDS based ELGA in Austria and vital parameter devices supporting Continua in Denmark. Alexander concluded: “I agree that some business models are not based on standards, but the world is changing”.

**International Patient Summary standards**

Stephen Kay, Vice Chair of CEN/ TC 251, presented current initiatives related to the International Patient Summary Standards.

Stephen started with the notion of a patient summary considered as part of the healthcare fabric, commonplace, and even mundane with so many different variants (e.g. discharge summaries, handovers), and numerous regional or national implementations. Although, Stephen argues, one might assume that with many implementations standardization would be easy, this clearly is not the case. Making the Patient Summary Structure & Content available for global use, independent of whether the demand is for cross-border or within a national state, or locally across organizations is tricky and Stephen cited several reasons for that:

(a) “The value of data lies in their use.”
(b) “Data have no value or meaning in isolation”
(c) “Data can be assets or liabilities or both.”
(d) “The information necessary to interpret data is specific to the problem”.

Stephen moved on to report on several initiatives related to patient summaries including the EU patient summary guidelines, specific EU projects like Trillium Bridge dealing with patient summaries, the HL7 InterPAS project on clinical summaries, ISO TC 215 Reference Standards Portfolios (Bundles) on Clinical Imaging, and the JIC Standards Sets addressing Patient Summaries for unplanned/emergency Care.

**Panel discussion on the European eHealth SDO Platform**

Michiel Sprenger, Strategy adviser at Nictiz, the National Competence Center of the Netherlands (NCC-NL), moderated the panel of the European eHealth SDO platform, Michiel Sprenger recognized three geographic layers: Global, Europe as the main focus of the discussion, and national. He recognized the partners to the discussion as SDOs and Profiling Organisations that develop base standards on international scale and assisting localisation on national level, National Competence Centres (NCCs) that localize and combine standards to new national specifications and/or standards, and policy makers, namely Ministries of Health in the Member states, the eHealth Network, and JAseHN the joint action to support it. He then introduced the panelists: Christof Gessner (German NCC, HL7 Germany, European HL7 Strategic Advisory Board), Pim Volkert (Dutch NCC, SNOMED terminology release center), Manne Andersson (Swedish NCC and JAseHN), Karima Bourquard (IHE-Europe), Catherine Chronaki, (European HL7 Foundation), and Robert Stegwee, (Chair CEN-TC251).

The main questions addressed to the panelists were:

- What is, or are, your main collaboration issues? How should we pick them up? What should be the result?
- Do we really need European standards? How to liaise with industry? How to liaise with stakeholders like citizens and professionals?

Christof Gessner, reflected on collaboration between SDOs in Europe and felt it is already pretty good. In Germany, he notes, there is a good collaboration between IHE, HL7 and DIN, bvīg, and the German NCC (Gematik). One challenge that all SDOs are facing is that clinical experts are not involved in standardization. The engagement of Gematik might offer the chance of mediating between standardization efforts and stakeholders in the health area. In Germany, an “interoperability forum” is a two-day open SDO meeting organized four times a year, where all the experts meet, discuss their standardization projects and their problems. Agenda and minutes are posted in the HL7.de wiki. The results are taken back at the Technical Committees in the various SDOs. Christof felt that this is a very constructive way of bringing people together, motivating them, and involving clinical experts and could be one of the models that could work for Europe as well.
Pim Volkert works on terminology on national level, at the Dutch SNOMED-CT release center. He sees Europe as a geographical area where people can exchange experiences between SDOs. In the end, however, Pim felt standards need to be implemented on national level in the healthcare system. Sharing experience of how standards are implemented and localized in the different products on the market, will no doubt help users, and also vendors.

Manne Anderssen from the Swedish eHealth Agency, active in JAseHN, the joint action supporting the eHealth network, notes that it is hard for a hospital or small care provider to take into consideration the European policies when they define requirements for procurement. Manne feels that projects usually have tight deadlines and detailed requirements analysis is typically overlooked. Someone needs to analyze policies and break these down into requirements -including interoperability and standards related requirements- that hospitals can use in procurement. Who is that to be?

Karima Bourquard notes that IHE as a profiling organization needs to work with users (such as NCCs) on one hand, and SDOs on the other hand. Karima feels that this collaboration is happen already now on national, European and global level. However, according to Karima, there is indeed need for procurement guidelines. In France, where Karima serves as User co-chair of IHE-France, such a guideline exists, it is very useful and is used by hospitals, but on a European level, this is more difficult of course. Karima agreed that developing and implementing standards is not so easy and needs expertise. Training is part of change management and should be further developed in order to increase the consistent adoption of standards and profiles in eHealth projects.

Robert Stegwee said that “CEN TC/251 has done a lot of ‘soul searching’ in the last years and has changed their focus from being a ‘standards development organization’ to a ‘standards delivery organization’ that also thinks about educating people how to use our standards”. He thought that the challenge of all SDOs is to focus on their clients, the value they bring to the standard users, and not on the rules of how standardization works. We need to work based on use-cases, but also coordinate across use-cases. In the question of Catherine Chronaki, what do the different SDOs bring to the table, Robert responded that CEN can offer its recognized processes, and invites SDOs to get together in CEN workshop agreement and collaborate to deliver specifications that procurement people can reference in their RFPs and concluded that “SDOs need to solve the real problems of the users, and for that we need to understand each other”.

The discussion picked up and several people commented. Morten Bruun-Rasmussen felt that learning from others is always beneficial and his experience suggests that standards are usually more complex than the implementer expects. “We have a problem with the way standards are written. Too few practical examples, too many pages, very hard to read”, Morten concludes.

Stephen Kay responded that “technical writing can be difficult”. SDOs can improve the way they write standards, but there are other issues why clinicians are not involved. We need more ways of interacting with a specification. However, I am worry that the pressure put on the SDOs to “dumb down” specifications may be inappropriate. Not each specification can be understandable to the layman. Especially when it comes to safety critical aspect, you need to be very formal to the degree of using mathematical concepts.
Giorgio Cangioli joined the debate underlining that "specifications should formal, precise and technical when developing standards". Relaxed specification are error prone "but suitable solutions should be adopted (e.g. tools) and supporting material should be provided to make their usage easier". A good example of that is DICOM: the availability of open source tools and libraries like CTN or DCMTK has been a strong enabling factor for the adoption of this standard. Such implementations tools do not necessarily have to be provided by the SDOs.

Marco Eichelberg felt that we need tools (testing, reference implementation etc.) for the implementers, but also guidance for end users on the benefit of a standard, and the way it can be requested in procurement. Standards need marketing!

Michiel Sprenger in closing the debate felt that the discussion was a lot about Education and Knowledge and the question "...how can we educate users about using and deploying standards". However, anyone who wants to use standards actually needs more than one standard to solve his specific problem, which again would be a topic for SDOs. Michiel concluded that "SDOs and NCCs need more communication, with users and with policy people". In the fields of knowledge and communication the SDOs should work together to improve awareness and diffusion of standards.

Conclusions and next steps

Robert Stegwee in his summary reported that eStandards will consolidate the feedback received and the first draft version of the Roadmap will be published in May. He welcomed submissions to the questionnaire and any further input, since eStandards has another year to finalize its roadmap for collaborative standards development.

In his talk Steve Kay, presented a picture of the day break, hoping that indeed this work is the sunrise for high standards.

Further information

www.estandards-project.eu

The presentations from the First eStandards conference are available at: http://tinyurl.com/j88ghqv

Catherine Chronaki
Secretary General, HL7 Foundation
Brussels (BE)

Developing Evidence supporting Terminology Decisions for Europe

ASSESS CT (Assessing SNOMED CT), an EU coordination & support action, is currently assessing the fitness of SNOMED CT for Large Scale eHealth Deployments in the EU. ACCESS CT includes a number of investigations, some of which aim to build new evidence about standardized terminologies and their use. Three studies are applying different empirical methods:

- the use of terminologies for manual semantic annotation of clinical narratives,
- for terminology binding,
- for machine annotation.

The studies had a special focus on issues relating to cross-border use of terminologies.

All studies have focused on comparing terminology scenarios. To this end, a SNOMED CT-only terminology setting with SNOMED CT terms in four languages was compared to a setting with multiple non-SNOMED CT terminologies, named the alternative setting. In both manual studies grouping of codes, a simplified form of post-coordination, was allowed.
In the manual annotation study, nine medically trained annotators from four European countries assigned codes from the two terminology settings to a corpus of 60 highly diverse text snippets from clinical documents in different languages. This corpus was translated in all native languages of the annotators. The alternative terminology setting consisted of language-specific subsets of the UMLS metathesaurus (extended by existing localised versions not included in the UMLS metathesaurus) for the languages of the annotators. Concept coverage, term coverage, and inter-annotator agreement were measured.

The coverage results for the manual free-text annotation study showed no significant superiority of the extended UMLS terminologies compared with SNOMED CT for languages in which a full translation of SNOMED CT is available (English and Swedish). The coverage of translations of SNOMED CT subsets (in French and Dutch), however, was not surprisingly, lower than available alternatives. The benefit of the availability of synonyms could also be clearly shown. Apart from the English alternative scenario, analogously built alternative terminologies in Dutch, French, and Swedish showed much lower concept and term coverage compared with what could be shown in the English SNOMED CT scenario.

In the manual terminology binding study, six annotators from six different countries assigned codes to twelve information model extracts, from both national and international sources, containing a total of 101 elements for each of the two terminology settings. For each element and terminology settings the annotators could assess the coverage of the code in relation to the element and also provide comments. The alternative terminology settings consisted of the four terminologies/classifications ICD-10, ATC, LOINC, and MeSH. Concept coverage, inter-annotator agreement was measured. Additionally, the comments provided by annotators are being analysed qualitatively.

The terminology binding study showed better performance for the SNOMED CT setting both regarding concept coverage and agreement compared with the alternative terminology setting. In the use of the terminologies for binding, annotators deviated from guidelines and made errors, especially when grouping codes. However, when even simple guidelines were enforced, agreement improved.

Both the annotations made in the manual free-text annotation and in the terminology binding study were studied qualitatively to identify categories of terminology use and specifically types of disagreement. Similar types of disagreement occurred in both free-text and binding experiments, most likely due to features of the terminologies used.

The machine annotation study is currently being performed. Here, Natural Language Processing (NLP) techniques were applied for automatic annotation of clinical free-text documents. For this study, the terminology settings were the same as those in the manual annotation study.
Considerable efforts have been invested into the development of standards for health information representation and communication, with an increasing focus on semantic interoperability. SNOMED CT (Systematized Nomenclature of Medicine-Clinical Terms) is increasingly seen as a unifying ontological standard, with the potential to solve many semantic interoperability issues. However, the evidence on the benefits of SNOMED CT for semantic interoperability of eHealth services and for the challenges associated with the adoption of a comprehensive clinical terminology is limited. The EU-funded ASSESS CT project investigates the fitness of SNOMED CT as a potential standard for EU-wide eHealth deployments. To cover core implementation aspects, a dedicated work package of the project analyzed SNOMED CT’s impact from technical, business, organizational, governance and socio-economic viewpoints. The main contribution of our developments is the development of a socio-economic assessment framework that can be used to assess SNOMED CT and other terminologies’ systematically. Such economic assessments are valuable for public authorities when deciding on future investment in clinical terminologies, because they allow customization to different contexts, and help to forecast the likelihood of a reasonable return on investment. The figure below broadly summarises the working tasks.

Through the interdisciplinary nature of both the project and the actual task of economically assessing semantic interoperability, a diverse array of methods was used in the framework development process:

- Systematic literature review of existing SNOMED CT implementations and documented costs and benefits
- Health economic cost-benefit analysis and social scientific indicator development operationalisation
- Documenting, analyzing, interpreting existing implementation and adoption experiences across – through semi-structured interviews, focus groups, and case study design and analysis
- Consultation and knowledge extraction of extensive expertise assembled in consortium
- Exploratory interviews and expert panels validated through workshops with European domain experts.

For a comprehensive socio-economic analysis, data to measure the benefits and costs for each specific stakeholder are needed. The economic performance can be evaluated by assigning monetary values. This enables, in the aggregate, potential common patterns, trends, and relationships to be identified. The method that supports the linking of these data is cost-benefit analysis (CBA). CBA allows different outcomes to be evaluated through common measures, and it can reflect a different allocation of resources before and after an investment. A key merit of CBA is that it allows for comparative, as well as single-option evaluation over time. Within the Assess CT working group 3, costs and benefits are captured in indicators, which are central to the assessment. The cost and benefit indicators in Assess CT are measurable outputs comprised of variables incorporated into formulae. Combined, these indicators provide the socio-economic data that allow assessing interventions, such as the adoption of SNOMED CT for regional or national implementation projects.

A key step towards assessing SNOMED CT is to fill the indicators with real data, i.e. figures and monetary values. In most cases actual evidence is
not available and assumptions need to be made. For the cost indicator example, skills development and training, for example, we developed assumptions about average numbers of trainers needed, whereby possible sources of information are reports on experience of countries having implemented SNOMED CT or alternatives. This is highly dependable on the scope of training as well as the number of trained staff, their level of understanding, etc. Semi-structured interviews with professionals and statistics on salaries are among the best suited methods here.

Finally, the indicators are integrated into a Microsoft Excel-based CBA tool to allow for interested parties to perform their own analyses. Comprehensive information based on the indicator descriptions, available figures and assumptions are incorporated to guide the stakeholders through the assessment process for their specific case.

The ASSESS CT project attempts to develop the first economic assessment model to base any impact assessment on scientific methodologies, real observations, and actual data. Next step is to a) finalise the CBA method and b) produce a toolkit for general use by practitioners, scientists, and policy-maker alike.

For more information: Please consult D3.1 in the ASSESS CT website: http://assess-ct.eu

Dr. Rainer Thiel  
empirica Communication and Technology Research, Bonn (DE)

---

**Switzerland new Member of IHTSDO**

Switzerland has worked intensely over the last three years to learn how SNOMED CT can have strong, positive effects on its healthcare environment and on patient care throughout the country. We have developed a forward-thinking SNOMED CT implementation strategy and are now ready to take the next steps towards IHTSDO membership and national SNOMED CT adoption. "eHealth Suisse" has been designated by the Swiss government as the SNOMED CT National Release Center, meaning it will coordinate SNOMED CT adoption for Switzerland and serve as the first point of contact within the country. “eHealth Suisse” is a Coordinating Office in charge of ensuring that the various eHealth projects in Switzerland are goal-oriented and strategy-compliant and that synergies between the projects can be harnessed.

SNOMED CT will play an important part in the future national electronic health record in terms of semantic interoperability. Additionally, "eHealth Suisse" manages a semantics expert group to help define and implement a national strategy for handling semantic standards. This expert group agrees that it is necessary to connect the different terminologies by a reference terminology, such as SNOMED CT. With this reference terminology, experts can exchange clinical information across specific domains as it is planned for the electronic health record.

Therefore, SNOMED CT is already used in three of the exchange formats suggested for the national electronic health record, namely:

- Electronic Vaccination Record
- Reportable Findings in Lab
- Lab for the transplantation process.

In addition, some Value Sets for the IHE XDS.b Document Metadata defined for the electronic health record includes SNOMED CT Codes. To adopt SNOMED CT in Switzerland, a key factor for success is to increase the awareness for semantic interoperability among users and industry,
namely vendors of information systems. It is important to stress, that SNOMED CT is not just a code system, but a bridge to connect existing code systems used for billing, statistics, quality assurance, registries etc. and that it is not necessary for end user to understand SNOMED CT technically. Today, the same information is entered multiple times for different usage. On the one hand, the end user have to understand that SNOMED CT could solve this problem by connecting code systems from multiple sources, so that they ask for such a reference terminology from their vendors. On the other hand, vendors have to weaken their reservation against complex terminologies such as SNOMED CT. With the IHTSDO eLearning courses and specific workshops, they should acquire necessary knowledge to adopt SNOMED CT in their systems.

Besides building up the necessary awareness and knowledge, Switzerland plans to translate the concepts ‘use case driven’ with the previous mentioned exchange formats in a first step. The concepts will be translated in the three languages German, French and Italian. Switzerland also has been participating with the Canton of Geneva in the epSOS/EXPAND – Project. The “Patient Summary” used in this cross-border Project uses SNOMED CT Codes to encode parts of clinical data and allows, with a standardized translation, the transcoding from French into another target language, such as Portuguese. Knowing this and given the multilingualism in Switzerland, this could be an important use case within Switzerland across the different language regions. In a second step, we want to release these translations, along with a national extension by the end of this year.

Johannes Gnägi
“eHealth Suisse”, Swiss coordination Office for eHealth, Bern (CH)

Adoption of Patient Summary Guidelines across the European Union

Patient Summary Guidelines history and initialization
The Patient Summary (PS) specification defined a minimal dataset of essential information for unplanned or emergency care initially defined in the epSOS project with aim to improve patient safety. The European Union (EU) adopted Patient Summary guidelines in November 2013 meeting of the eHealth Network established under Article 14 of the EU directive 2011/24 on patients’ rights in cross-border healthcare.

Assessment of the Patient Summary guidelines implementation
On 11 March 2014, the European Parliament and the Council adopted a Regulation establishing the third program for the Union’s action in the field of health (2014-2020). This program entered into force retroactively from the 1 January 2014 onwards. The European Commission wanted to assess the implementation status of the Patient Summary guidelines in all member states through the Joint Action to support eHealth Network (JAseHN) project.

Work package 6 of JAseHN assumed the responsibility to analyse the implementation status of the Patient Summary guidelines in EU Member States (MS). Implementation of the Patient Summary guidelines was assessed with regard to the four interoperability levels¹ of the European Interoperability Framework (EIF): legal, 

Action to support eHealth Network (JAseHN) project.

¹ The European Interoperability Framework uses the term ‘Interoperability layer’ when discussing the different aspects of interoperability; see more here: http://ec.europa.eu/isa/documents/isa_annex_ii_eif_en.pdf
organisational, semantic and technical. The result is a report on the adoption status of the Patient Summary guidelines.

A questionnaire that was distributed to the relevant MS representatives (on national or regional level, in accordance to the healthcare system approach) with the assumption that each country representative is able to answer the questions.

The questionnaire findings are as follows:

- In most MS the Patient Summary implementation is at an early stage.
- Some MS already have many of the components in place to support the Patient Summary guidelines implementation, but in most Member States the implementation of recommended interoperable public services has not finished yet.
- Most MS actively participate in cross-border interoperability projects such as epSOS, PARENT, EXPAND, eSENS and others, testing the national infrastructure and preparing the interoperability framework for cross-border data exchange. However, full deployment of all services needed to rollout the implementation of the Patient Summary guideline remains.
- Feedback from MS suggests that prioritization of other national projects in healthcare is one of the main obstacles for full deployment of eHealth services recommended by the Patient Summary Guidelines.

Although MS expressed broadly interest in implementing the eHealth guidelines that would lead to the creation of the Cross-border eHealth Information Services (CBeHIS), there are some additional steps to be taken before starting cross-border data exchange in terms of semantic standards, technical solutions, and supporting infrastructure for the eHealth guidelines to become operational.

**What is the Patient Summary?**

The European guideline on minimum non-exhaustive patient summary data set for electronic exchange in accordance with the cross-border directive 2011/24/EU or EU patient summary guideline (Nov 2013).

The patient summary focuses on emergency or unplanned care in a cross-border context, i.e. the range of healthcare services available to people who need medical advice, diagnosis and/or treatment quickly and unexpectedly. The guideline is also meant for reference use at national level.

MS showed a high degree of awareness regarding the benefits from enabling cross-border data exchange, and expressed their strong motivation to provide public information via the National Contact Point for eHealth (NCPeH) websites.

The next-critical step in the implementation of eHealth guidelines is to find the best way to involve a wider community of experts and official authorities that would provide information for validating and amending the guidelines. Updated guidelines could then include recommendations for other groups of stakeholders that are interested in cross-border healthcare.

The following advanced step is building a more robust environment providing cross-border healthcare data would be the adoption of the more complete eHealth guidelines that would advance from the technical and semantic aspects of interoperability towards legal and organizational ones. What is also needed is the strengthening of eHealth NCP role in Member States that should provide the continuity and sustainability to all future eHealth implementations.
The future of the Patient Summary Guidelines

At the same time, there are very concrete activities on the MS level that will help to establish legal framework for cross-border data exchange that will be obligatory for all MS.

Figure 3: Q16. Does your country make use of the coding schemes (e.g. Emergency Dataset (EDS), ISO 215493, Patient Health Card Data – Limited Clinical Data, Hospital Data Project dataset, HL7 Terminology, IHE Recommendations) described in the Patient Summary guidelines? (5.3. LEVEL 3: Assessing semantic preparedness and interoperability).

In the meantime, the Connecting Europe Facility (CEF) as a key funding instrument opened the call for projects that would improve cross border exchange of patient data using ICT tools.

The call aims to support the deployment of generic services by MS, namely in the areas of Patient Summary and ePrescription/ eDispensation, as defined in the relevant guidelines and documents adopted by the eHealth Network and in coherence with the core services in order to allow EU-wide interoperability”.

This call will allow EU MS to improve their technical readiness by upgrading necessary infrastructure for cross-border data exchange, developing generic services as a common mechanism for cross-border exchange of data, including Patient Summaries for emergency and unplanned care.

Vanja Pajić, MBA, MPH, MAA, PHM, PHEM
Croatian Health Insurance Fund (HR)

Ana Vrančić-Mikić, Bsc Math
Croatian Health Insurance Fund (HR)

Vesna Kronstein Kufrin, Bsc Math
Croatian Health Insurance Fund (HR)
Final Event and Outcomes

The EXPAND project

The EXPAND project (www.expandproject.eu) is a two year thematic network project which ended on December 2015 having as its goal to “progress towards an environment of sustainable cross border eHealth services, established at EU level by the Connecting Europe Facility (CEF) and at national level, through the deployment of suitable national infrastructures and services.” The project has been coordinated by SPMS – Serviços Partilhados do Ministério da Saúde, Portugal involving 17 Participating Nations (Austria; Belgium; Bulgaria; Croatia; Finland; France; Germany; Greece; Italy; Luxembourg; Netherlands; Portugal; Slovenia; Spain; Sweden; Switzerland; United Kingdom).

For achieving its goal EXPAND set up two main workstreams:

- The maintenance and preparation of assets for CEF (Connecting Europe Facility, https://ec.europa.eu/digital-single-market/en/connecting-europe-facility) supported by the “maintenance shops”;
- The exploration of potential implications of future expansion to other priorities of the eHealth Network and Directive 2011/24/EU.

The involvement of a wide range of relevant stakeholders such as representatives from the European Reference Networks and the Rare Disease community, projects, initiatives, health professionals, patients and Member States has always been a key factor for the success of the project to ensure that inputs and proposals from stakeholders are captured and further actions identified.

The EXPAND second Multi-stakeholder engagement workshop (EXPAND Final Event), organized in Lisbon from 9th to 11th December 2015 to share the results obtained by the project and prepare for the next activities for CEF, realized this strategy.

The EXPAND final event

The EXPAND 2nd Multi-stakeholder engagement workshop (EXPAND Final Event) held in Lisbon on December 2015 was attended by a broad representation from Member States, Competence Centres, EU Projects, European Commission (DG SANTÉ and DG CONNECT), Patients/Citizens, Health Professionals and the ICT Industry: 18 stakeholder groups represented and 157 individuals from 25 countries. Figure 1 shows the distribution of attendees.

Figure 1: Attendee distribution
This event aimed to convey the results of EXPAND and to assist the preparation for the deployment of cross-border eHealth services, giving Member States also the opportunity to assess their own readiness and encourage their cooperation and coordination. This has been done through dissemination activities (including testimonials) and engagement of a wide group of stakeholders contributing to critical mass among the different Stakeholders and their readiness.

Parallel sessions were scheduled for the conference giving the opportunity also to other projects and initiatives to present and discuss EXPAND-related topics: eStandards organized a workshop about the handover of the Patient summary specifications to CEF using ART-DECOR (see next article) and a session on Rare diseases and European Reference Networks also took place. In addition to that, a testing session focused on the CEF use cases was organized (EXPANDathon) involving nine countries (Cyprus, Portugal, Luxembourg, Italy, Switzerland, Greece, Croatia, Malta), the European Commission (DG SANTE) and seven country observers.

The first day of the main conference track was aimed at engagement of high-level stakeholders and policy makers, presenting the EXPAND results and highlighting its contributions to the maintenance and handover of assets to CEF. Henrique Martins (SPMS) introduced the EXPAND vision and CEF use cases; Michèle Thonnet (MoH France), stressed the need to involve people and recalled the ultimate goal of the project; Dipak Kalra (EuroRec) introduced and demonstrated the Interoperability Asset Register; Zoi Kolitsi (AUTH), described the EXPAND work looking at new services for rare diseases, patient registries and European Reference Networks; Jeremy Thorp (UK HSCIS) introduced the eHealth Network Guidelines for successful deployment of cross-border eHealth services; Karima Bourquard (IHE-Europe), introduced the EXPANDathon; and finally Marcello Melgara (LISPA), moderated a panel on Multi projects, with mini presentations and discussion.

The day closed with a testimonials session about the value-added of EXPAND.

The focus of the second day was to provide practical support to Member States to best exploit EXPAND assets and guidelines towards their own preparation of the current and future CEF calls, with presentations from Henrique Martins, Tapani Piha (DG Santé); Ana Rath (INSERM US14) and Isabella Weber (Austria MoH) giving context updates on epSOS via EXPAND to CEF implementations and introductions to the CEF call, JAseHN (the Joint Action to support the eHealth Network) and the Rare Diseases action. In the afternoon the CEF call was discussed in more detail with several presentations and panel session with the direct involvement of Member States and Competence Center representatives.

The third day was dedicated to discussing how EXPAND results may impact cross-border eHealth services for the benefit of patients and health professionals: patients: pharmacists and clinicians representatives were involved in the discussion.

The project coordinator (Henrique Martins) underlined – in his closing remarks - how the success of EXPAND would be measured by its capability to create the determination, the capacity and the will to launch eHealth services that could be meaningful for patients and professionals, and therefore by the amount, the capacity and the readiness of Member States bidding for CEF.

Links to the presentations may be found at http://www.expandproject.eu/follow-up-of-the-lisbon-ehealth-week.

Conference Outcomes

Relevant outcomes have been achieved by the EXPAND final event, among them:

- the high level of stakeholders/policy makers engaged: the most relevant experts and people responsible for eHealth were in fact present at the conference providing positive contributions;
- the awareness that EXPAND has helped Ministries of Health;
- the significantly large and enthusiastic group of Member States (MS) willing, able and interested in applying for CEF support for deployment of services;
- the intention of the Rare Disease community to pursue activities that will hopefully lead to a future CEF call;
- the consciousness that EXPAND follow-on work will continue in the eHealth Network and individual Member States;
- the expressed support for the work of deploying cross-border solutions by patients and health professional representatives;

EXPAND Outcomes

The initial goals of the EXPAND project have been successfully achieved evidenced by the following outcomes:
The publication of the Vision: it consolidates concepts of expandability and activities of the EXPAND Network, in line with the cross-border Directive and the decisions made by the eHealth Network.

The documentation of re-usable Assets: an online Interoperability Asset Register accompanied by a practical and affordable governance model has been developed in order to adopt a framework for the re-use of such assets. Other important achievements include securing sustainability and establishing future user communities including ERNs.

The expansion to new use cases: EXPAND, in close cooperation with the ERNs and the Registries’ Joint Actions, has explored requirements for the eHealth Digital Service Infrastructure (DSI) beyond the Patient Summary and ePrescription services and has issued an extensive exploratory paper.

The Handing over to CEF: a major task of EXPAND has been the handover of the assets to CEF. Several Maintenance Shops have been set up that assured the maintenance of the specifications, semantic resources and software components (OpenNCP) to be used in CEF.

Giorgio Cangioli
HL7 Foundation, Brussels (BE)
Jeremy Thorp
Health and Social Care Information Centre, UK
Henrique Martins, Lilia Marques, SPMS Portugal

Acknowledgments

This article is based on the EXPAND Deliverable 1.8 and Final Report, authored by Lilia Marques (SPMS Portugal), Jeremy Thorp (HSCIC UK) and Henrique Martins (SPMS Portugal).

How ART-DECOR® supports the Handover of the Patient Summary Specifications to the Connecting Europe Facility

Foreword

The eStandards project during the EXPAND final event in Lisbon (9th December 2015) has organized a workshop discussing how standards and tools could support the eHealth deployment. The concrete case of the epSOS CDA specifications and their future usage in the eHealth Digital Services Infrastructure (DSI) deployment has been considered.

Lessons learned during the long journey from epSOS to the Connecting Europe Facility (CEF), via EXPAND, were presented justifying why the adoption of formal languages for expressing the CDA templates and tools for handling them is a critical factor for the CEF. A large part of the workshop has been therefore dedicated to the ART-DECOR® tool and to its integration with IHE Gazelle environment.
providing also live demonstrations of those tools. Hereafter the agenda of the workshop:

- **Session 1 – How ART-DECOR® supports the handover of the Patient Summary specifications to CEF:**
  - Giorgio Cangioli: “The epSOS CDA specifications: from epSOS to CEF”
  - Kai Heitmann: “An introduction to ART-DECOR”
  - Abderrazek Boufahja: “The ART-DECOR IHE Gazelle integration”

- **Session 2 – ART-DECOR and IHE Gazelle Demo**

The most significant elements of each presentation are therefore described in the following sections.

**The epSOS CDA specifications: from epSOS to CEF**


This experience enforced the awareness about the critical role of having computable specifications formalized using standard formats, as the HL7 STU Template exchange format (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=377), and supporting tools as ART-DECOR for the future success of the CEF.

**In the beginning was epSOS...**

The large scale pilot project epSOS (2008-2014) aimed to design, build and evaluate a service infrastructure to demonstrate cross-border interoperability between electronic health record systems in Europe (with focus on the exchange of Patient Summaries and ePrescription/ eDispensation documents). For supporting this goal a team of European experts, including clinicians and pharmacists, engaged in defining the documents’ data set, that was thereafter used as reference for the “Guidelines on Minimum/Nonexhaustive Patient Summary Dataset for electronic exchange in accordance with the Cross-Border Directive 2011/24/EU”, adopted by the eHealth Network in November 2013. The HL7 CDA R2 standard was selected for the implementation of those documents and text-based CDA R2 Implementation Guides developed. Those specifications have been implemented by the epSOS Participating Nations, tested and revised based on the feedback collected during the pre-pilot and pilot phases. Amazing results have been achieved by the epSOS project and extended by the follow-up projects as EXPAND or Trillium Bridge, and offering suggestions for improvement such as increasing clarity and formalizing specifications:

- It was in fact not always easy to navigate through the document: information were described in different pieces of the document (or in different deliverables)
- Some formal inconsistencies were discovered in different parts of the text
- Functional and implementation rules were sometimes mixed-up, at the conceptual, logical and implementation levels.

For that reason, just before the end of the project, a task was planned to move the epSOS CDA specifications in ART-DECOR. The first porting was completed on the Nictiz ART-DECOR server (decor.nictiz.nl), but unfortunately it was not possible to complete the full QA process cycle (country implementation, testing, feedbacks processing, revision and validation). As a result formal adoption of the ART-DECOR based specification was deferred.

Figure 1 describes the status of the epSOS CDA Implementation guides at the end of the epSOS project.
...then EXPAND came…

After epSOS all the semantic assets (the epSOS CDA Implementation Guides, the Master Value Catalogue,…) were then taken in charge by the Semantic Maintenance Shop under the EXPAND project (http://www.expandproject.eu).

Known issues were further analyzed, prioritized and handled by means of a formalized change proposal process. Due to lack of time and resource an incremental approach was chosen for the formalization of the epSOS CDA guides focusing first on the consolidation of the existing text-based specifications, with the purpose to continue the work on the HL7 STU template version in a second step.

The authors of the updated version of the epSOS CDA specifications were however aware about the need to improve the quality of the text-based specifications in order to:

- reduce the ambiguities
- increase the consistency
- improve the overall comprehensibility, allowing – for example – different classes of users (decision makers, clinicians, modellers, interoperability architects, implementers) to access the information of their interest in a form suitable for their purposes
- facilitate the use and the re-use of the specified templates
- advance in the control on the template lifecycle, providing also support for templates registries/repositories.

… CEF the future

The quality goals mentioned in the previous section are very relevant for CEF, where cross-border services (Patient Summaries and ePrescription) have to be move from the pilot phase to operation. It becomes therefore essential to support the epSOS template specification (figure 2):

- formal languages and standard formats, including template metadata, that documents the context in which the template has been created/updated;
- computable specifications;
- availability of supporting tools.

In our case this means the adoption of the HL7 STU template exchange format and of the ART-DECOR tool suite.

The choice of the HL7 STU Template Exchange Format (open standard based on XML) assures in fact:

- the computer-to-computer exchange of templates’ specifications and their processing
- the automatic generation of human readable formats (html, pdf, …)
- the consistency of the information used by all the actors
- the re-use of specifications among different tools within and across the different phases of the template usage cycle (development, publication, test, implementation and deployment, maintenance, …).

A concrete example of the added value of this choice is evident in the new validation capability of the IHE Gazelle tool that allows to automatically generate input for the Gazelle ObjectsChecker, used in the CDAs scrutiny tests, directly from the HL7 STU template exchange format. Thus inconsistencies due to the human interpretation of the published specifications are avoided.

The value-added of this integration was demonstrated during the eStandards workshop at the EXPAND final event.

The ART-DECOR tool suite offers support for the different phases of the template life-cycle by a web-based users interface and REST services, and provides developers with a single point of access for all the needed information about the CDA template specifications (rules, terminologies and examples). This tool uses an open format (DECOR) that is a superset of the HL7 STU template exchange format.

In order to assure the continuity of the “technical” maintenance of the epSOS CDA template specifications after the end of the EXPAND project,
to support CEF in the eHealth Digital Services Infrastructure (DSI) deployment, HL7 Europe started a dedicated project, with the involvement of the HL7 European Affiliate organizations, to complete the formalization of the epSOS specifications according to the HL7 Templates exchange format and validate them, as a result of a collaborative and alignment activity facilitated by the adoption of ART-DECOR.¹

The Patient Summary and the ePrescription/eDispensation specifications are available in: https://art-decor.org/art-decor/ep-sos.

ART-DECOR®

In the second presentation Kai Heitmann provided a detailed description of the ART-DECOR tool suite, supporting that presentation with a live demonstration of the main ART-DECOR features.

Information about this tool suite can be found on www.art-decor.org (see also HL7 EU Newsletter #4 (download at hl7.eu) and HL7 International Newsletter September 2014).

In synthesis, the Tool Suite ART-DECOR is an open-source tool and a methodology for various stakeholders of healthcare information exchange that supports comprehensive collaboration of team members within and between governance groups. It allows separation of concerns and different views on one single formalized documentation for different domain experts and it supports creation and maintenance of HL7 templates (STU), value sets, data sets, and more.

The usage of this tool – together with the HL7 template interchange format – enables in fact the expression of semantically clear re-usable blocks (templates) that can be used in many contexts (scenarios) with link to concepts and terminologies. The focus of templates is made more clear and their specification and implementation “much easier”.

This suite provides in fact – among the other features – a template viewer that allows to navigate the Templates STU R1 exchange format specifications, to browse contextually template and terminologies; and edit – if needed – also the value sets. It allows also to publish the templates as HTML or PDF or wiki-format.

ART-DECOR provides built-in support to CDA instances validation and enable the integration with external testing tools and environment as the IHE Gazelle (figure 3).

Finally, ART-DECOR can support Building Block Repositories (BBRs), that is shared repositories of reusable artifacts, including:
- Prototypes for Templates
- Data sets
- Ready-to-use Templates to refer to, to specialize or to adapt
- Needed Value Sets

The IHE ObjectsChecker

The last presentation – made by Abderrazek Boufahja from IHE Europe – showed with a concrete example (the integration between the gazelle ObjectsChecker and ART-DECOR) how the availability of standard and computable specifications can sensibly improve the effectiveness and the efficacy of the validation phase.

The Gazelle ObjectsChecker is a methodology to describe informal (text-based) requirements and conformance criteria applied to CDA based specifications into a formal description (UML Model and OCL constrains) that can be used to generate validation objects that allows to:
- validate the conformance of any kind of XML
- provide metrics and documentary features
- improve the coupling between rules and requirements
- support the validation of inheritance between healthcare standards.

¹ The HL7 Europe project is not meant to overlap with the content (e.g. PS, eP,..) maintenance activities that will be driven by the groups identified by the EC/eHN for CEF. It can however provide them support, mainly for the maintenance of the specifications in the HL7 Template Exchange Format and their publication in the Building Block (templates) Repository [ART DECOR].
This validation method is currently widely used in several national and international projects around the world and during the European and North American Connectathon by IHE.

The Gazelle ObjectsChecker provides a good requirement coverage capability, allowing to support complex requirements; data types checking and conditional/iterative validation. It allows moreover to validate the coded elements against the defined value set accessing runtime to terminology services.

The ObjectsChecker approach offers improved maintenance capability respect to hand written schematrons.

All those aspects become even more relevant when the formal rules can be automatically derived from computable CDA specifications, as in the case of the integration between IHE Gazelle and ART-DECOR (figure 4).

In fact, on one hand, ART DECOR provides support for a rigorous specification and publication process for the CDA templates, that allows to improve the specifications quality and to save them in a format compliant with the HL7 DSTU exchange format. On the other hand, the ObjectChecker can automatically import those formal specifications, reducing therefore gaps and avoid human misinterpretations and improving the consistency of the validation performed.

The workshop showed how this has been addressed for the epSOS CDA specifications using the HL7 STU Template Exchange Format and the ART-DECOR tool suite. A process has started at the end of the epSOS process and continued during the EXPAND project.

However, in order to assure the continuity of the of the “technical” maintenance of the epSOS CDA template specifications after the end of the EXPAND project, and support CEF in the eHealth Digital Services Infrastructure (DSI) deployment, HL7 Europe started a dedicated project, with the involvement of the HL7 European Affiliate organizations to complete the formalization of the epSOS specifications according to the HL7 Templates exchange format and validate them. This includes:

- fixing of the formal inconsistencies discovered,
- issuing of change proposals for the revision of the used templates and Value Sets,
- refinement and specification of the way negations, unknown or not present information are conveyed,
- enhancement of the specifications with a library of examples,
- promotion of a continuous improvement process of specifications through also the integration with terminology servers and testing tools.

This is the first HL7 project realized under the European REALM.

Conclusions
The workshop organized by the eStandards project in Lisbon during the EXPAND final event, taking in account the lessons learned from epSOS and EXPAND, demonstrated how the “quality” of the CDA specifications plays a critical role for the future of the Connecting Europe Facility in term of specifications maintenance, usage and testing.

The essential objectives of reducing ambiguities, increasing consistency of assertions, and improving the overall comprehensibility and control on the CDA template life-cycle can be achieved easily and effectively with the combination of:

- formal languages and standard formats
- computable specifications
- supporting tools.
Benefits derived from the rigorous approach required by ART DECOR on a better identification and specification of templates have been already experienced with changes. Changes that will facilitate the future maintenance of the epSOS templates.

This project will also contribute to the development of the European Building Block Repository, facilitating the reuse of artifacts within and across countries. The sharing of artifacts between countries has already started by Germany, Austria, Netherlands, Poland, Switzerland and now can be enhanced with European (and hopefully international) templates.

To conclude, big improvements have been and will be obtained on the quality of the epSOS CDA templates specifications. SDOs, and in particular HL7, are working for providing CEF with enhanced solutions and integrated tools, however, appropriate functional and technical competences have to be involved and formally organized at the European level in order to guarantee that specifications and related assets day-by-day management activities are realized.

Giorgio Cangioli  
HL7 Foundation, Brussels (BE)

Acknowledgements

This article is based on the material prepared for the eStandards project workshop during the EXPAND finale event in Lisbon. I'd like to thank Kai Heitmann (HL7 International Foundation) and Abderrazek Boufahja (IHE Europe) for their contributions on ART DECOR and IHE Gazelle tools suites.

Large scale eHealth deployment in Europe

Insights from Concurrent Use of Standards

The convergence towards a fully harmonized set of eHealth interoperability standards at international or European level is a long-term vision, but far from the reality today. Different approaches in terms of technical solutions, standards and profiles used, terminologies adopted, etc., are the natural consequence of the many factors influencing architectural decisions in eHealth deployment, including culture, domain, country, implementation timeline and the interoperability layers addressed. It seems unlikely that international consensus on a common reference information model for eHealth deployment can be reached in a reasonable timeframe and budget and we need eHealth interoperability now! To support large-scale eHealth deployment, we need to tackle the important question how coexistence between competing or overlapping standards and standard options can be achieved to ensure practical and sustainable interoperability.

The eStandards project [1], funded by the European Commission, has carried out a study to provide evidence on concepts for managing the coexistence of competing or overlapping standards in large-scale eHealth deployment nationally and cross-border [2]. The evidence has been organized as a collection of case studies about technical approaches and real-world eHealth deployment projects offering solutions for the concurrent use of overlapping or competing standards. The case studies also describe the successes, failures, and lessons learned from the individual projects. The insights gained from this analysis aim to serve both as a source from which recommendations for future large-scale eHealth implementation projects will be derived, and as part of the “baseline” (i.e., documentation of the state of the art) for the draft “eStandards Roadmap for Essential Standards Development Strategic Options and Policy Instruments” that will be defined by the project in 2016 to inform collaboration among standards developing organization and SDOs.

A case study template guided the contributors in describing the case studies comprising project overview, technical approach to the concurrent use
of standards, governance and lessons learned. For each case study, available project information was mapped to the interoperability layers of the refined eHealth Interoperability Framework [3]. Tools and technical approaches to coexistence, as well as lessons learned were collected.

Ten of the studies were national, bringing insights from Greece, Portugal, Spain, the UK, and the Netherlands. There was remarkably little evidence on the use of competing and overlapping standards in the real-world eHealth deployment projects other than a mapping between different controlled terminologies. Terminology mapping is a critical issue, because a direct mapping is usually possible only for a subset of the terms. In Denmark, International Classification for Primary Care (ICPC) codes are mapped to ICD-10 diagnoses when a GP sends a referral to a hospital, or a hospital sends a discharge letter to a GP. In the Netherlands, a mapping between ICD-10 and SNOMED-CT has been defined. In Italy, work is ongoing to map terminologies defined by, and used in regional implementations to a nation-wide terminology used for the longitudinal electronic health record. In Greece, local terminologies used for patient summary content are mapped to the epSOS Master Value Catalogue. In Spain, mapping of SNOMED-CT procedures and ICD-10 PCS (procedure coding system) classification is planned.

The epSOS project (www.epsos.eu) developed the concept of the pivot document as an intermediate format for the document conversion, for which a mapping from and to each national format was defined. The pivot document was used to convert the patient summary, ePrescription, eDispensation, or patient consent document in the sending country’s format and language to the same document in the receiving country’s format and language. Pivot documents are exchanged between epSOS actors and it is the responsibility of national contact points to “hide” the conversion process to/from national formats. The Master Value Set and Master Transcoding Catalogue support national contact points in terminology mapping necessary in converting between a national document format and the epSOS pivot document. As a safety measure, the original document is always delivered along with the translated document in PDF format, offering a human-readable representation of the document prior to conversion.

Figure 1 provides an overview of which of the layers of interoperability of the refined eHealth Interoperability Framework are discussed in which case study. The mark “X” refers to a layer of interoperability discussed in depth in the case study, whereas “(x)” refers to a layer only discussed briefly. The collection of case studies focuses on the four lower layers. The limited attention to policy and strategy in many of the case studies can explain the difficulties encountered in long term sustainability of these efforts.

**Practical Recommendations**

Several of the case studies have expressed pragmatic, practical recommendations for future eHealth deployment projects that are briefly summarized in this section:

1. **Do not “reinvent the wheel”**. There are many eHealth standards, architectures and tools available. Try to understand the existing standards and tools before re-inventing your own.

2. **Think big, start small**. It is better to start with a small system and grow over time, than to aim for the perfect solution immediately. Look for the "low-hanging fruit", such as a quick integration of edge systems using HL7 FHIR, which worked very well in the Greek Patient
Summary project and in the Portuguese National Broker, which reports use of the HL7 FHIR standard to be a huge success.

3. Make sure that more than one end user application can be built as edge system for the eHealth network (e.g. for accessing and visualizing information from the eHealth network), catering for different user needs and user preferences.

4. Take the European requirements under the cross border healthcare directive into account when designing your system – to the degree possible today.

5. There are useful components developed outside the eHealth community. Topics such as electronic identification, end point detection, non-repudiation, the use of electronic signatures and trust establishment are in no way eHealth specific topics. Mature solutions have been developed outside the field of eHealth, and these are readily available for use in eHealth projects. One example for this is the STORK project (https://www.eid-stork2.eu/), which focused on innovative electronic identification and authentication mechanisms and provided solutions that were successfully integrated into the epSOS eHealth toolchain in the context of the e-SENS project (www.esens.eu).

6. Be pragmatic with regard to content formats. While a complete semantic encoding of information is certainly desirable, it may not be possible with today’s technology, and even with the most powerful terminologies there may still be a reason to use free text. If a health professional is “only” able to provide a PDF document, then this is not “semantically enabled”, but still very useful information for the recipient – a good first step that should not be neglected just because the solution is not perfect.

7. Develop your architecture layer by layer. The Dutch case study reports that they found it both necessary and useful to separate between the layers of interoperability: create the architecture within each layer; clearly define the relationship between the layers and the way lower layers are derived from the layer above.

8. Decouple components by defining clear interfaces (such as gateway protocols). This makes it easier to separate responsibilities and security requirements for parts of the overall system and can help to “hide” parts of the overall system complexity. Furthermore, it simplifies the development of compliant system components.

9. Ensure developer training and experience. The Spanish case study reports that the worst “enemy” the project has found is poor implementation of standards, guidelines and specifications in products, caused by insufficient training and knowledge of the software developers.

It can be concluded that there is no “magic bullet”, no simple solution for solving the challenge of interoperability in large-scale eHealth projects – but nobody involved in the field would have expected this. The combined experience of the case studies collected in this document, both positive and negative, is a valuable source of information for future eHealth projects.

In the eStandards project, the next step will be to condense the information from this collection of case studies into a document entitled “Interoperability guideline for eHealth deployment projects”, which will be published in late 2016.

References


Internet: www.estandards-project.eu

Marco Eichelberg
OFFIS-Institute for Information Technology, Oldenburg (DE)

Catherine Chronaki
HL7 Foundation, Brussels (BE)
The Case for Formal Standardization in Large-scale eHealth Deployment

Standards development organizations often assume the reasons for adoption of standards are well understood. However, the fragmented adoption of incompatible standards is also quoted as a key obstacle to large-scale eHealth deployment. Within the eStandards project we have developed the case for formal standardization to support large-scale deployment of eHealth from four distinct perspectives that entail a balance of roles with different interests, costs, and benefits. Each perspective reveals a compelling case for formal standardization that can be empowered by collaboration and coordination among standards development and profiling organizations and their constituencies at all levels. It is the resulting trusted dialogs that will lead to co-creation in interoperability and nurture large-scale eHealth deployment. The four perspectives are: (a) Citizens as consumers of health services, (b) the workforce in the delivery and administration of health services, (c) the eHealth Market, where eHealth solutions and services are traded and (d) the health system where care is delivered and cost, quality, and access decisions are made.

Citizens navigate the health system (or systems) looking for prevention, care, and wellness. They wish to be actively involved and engaged in health maintenance and decisions on their care and for that they need standards that make sense and they can trust. The health workforce needs to communicate and coordinate care by sharing relevant and trusted information within and across health systems making the most of new technologies. Sharing relevant and trusted information can create knowledge that is the key for better decisions at the point of care. In an increasingly data driven market, standards create opportunities for new health and IT services, while expanding the choices for providers and consumers. Well established standards make procurement easier and predictable. Finally with standards, health systems can rely on evidence-based rules and guidance for sustainability and innovation. Standards can facilitate public health reporting, surveillance, and analysis as well as communication and coordination across health systems.

However, to reap these benefits, actions need to be taken to promote cooperation and coordination across standards developing organizations, while promoting the development of standards sets and tools that work together throughout the life cycle for development, deployment, testing, certification, monitoring adoption, and eventual revision.

The eStandards Project (www.estandards-project.eu) aims to create a roadmap for the cooperative creation of essential standards and standards sets for the delivery of use cases in the context of the revised European eHealth Interoperability framework, exploring strategic options and policy implications. In this work, it will take into account the work of the Joint Initiative Council on standards sets, and evidence collected for 17 case studies throughout Europe. The first debate of the roadmap has been scheduled for April 21, 2016 in Berlin, in the frame of the conhiT conference and trade show. Progress with the roadmap will be presented in Amsterdam in June 8-10, 2016 as part of the premier eHealth event of the Dutch presidency of the European Union.

Further information:
- Case for standardization full report: http://tinyurl.com/estandards
- First eStandards Conference: Next steps for standardization in health information sharing http://www.estandards-project.eu/index.cfm/first-conference/

Robert Stegwee
Chair CEN/TC251, Brussels (BE)
Past Chair HL7 Netherlands

Catherine Chronaki
Secretary General, HL7 Foundation
Brussels (BE)
The eStandards (www.estandards-project.eu) project funded by the European Commission is focused on a consensus building on eHealth standards and their adoption and will provide among other deliverables a contribution on the Antilope eHealth European Interoperability Framework (ReEIF, www.antilope-project.eu) use cases focusing on clinical content.

The Antilope ReEIF provides eight main domains where use cases are distributed among four levels of scale: Cross-border, National/regional; Intra-organizational and citizens at home. For each use case, one or more accompanying realizations describe how to implement the use case, and provide a selection of profiles and standards, transactions and actors. All the use cases and realization scenarios are formalized following the dedicated template for facilitating their readiness.

Based on the results of previous and current projects – Antilope, Trillium Bridge (www.trilliumbridge.eu), PHC34 projects, JASeHN (www.jasehnproject.eu),… – eStandards has developed a consistent Use Case Repository that will support healthcare providers or implementers of solutions to design and deploy their own clinical use cases and projects by facilitating the selection of the interoperability profiles and standards.

Potential use cases were first collected from different sources such as PHC 34 European projects, eHealth stakeholder group (eHSG, http://ec.europa.eu/information_society/newsroom/cf/dae/document.cfm?doc_id=5168), Hope (European hospital Healthcare Federation, www.hope.be) and other EU projects. The additional use cases proposed by eStandards have been selected based on the availability and readiness of standards and/or profiles that are already been used in operation. Other important criteria that have been selected in VALUeHEALTH (www.valuehealth.eu), a PHC 34 project, were also considered for supporting our analysis such as the level of interest from stakeholders and the impact on the quality of patient life.

Finally all the selected use cases are documented by using the ReEIF methodology, the use case and realization scenario templates defined by the Antilope project in the ReEIF, reviewed by the JASeHN project and endorsed by the 8th eHealth Network meeting in November 2015. The adopted ReEIF framework describes the interoperability world based on a six level model, proposes templates for a uniform description of the use cases and their accompanying realization scenarios.

After reviewing and updating the templates, the additional Use Cases and realization scenarios are described in order to facilitate their integration in the Antilope Refined eEIF. Domains are extended with two new domains:

- Public Health, research and epidemiology
- Antenatal care

These two domains were pointed out by more than one organization for the two new use cases. Additionally eStandards extends the scalability types with the international level by adding a realization scenario to the Cross border Patient Summary use case (Exchange of Patient Summaries across Atlantic).

Finally the list of use cases and accompanying realization scenarios are the following:

**Use cases:**
- Integrated antenatal care
- Immunization use case

**Realization scenarios:**
- Neonatal care plan management at the local or regional scale
Mobile services to empower patient with heart failure
- Exchange of Patient Summaries across Atlantic
- Structured Report in radiology
- Monitoring the radiation exposure
- Immunization use case at the local or regional scale with a national immunization register
- Healthcare Provider Registry
- Workflow care plan management

A selection of standards and profiles are also provided in order to be consistent with other real-

The expected benefits for healthcare stakeholders are an easy access of existing and deployed use cases that can serve as a support for the description of the needs. Accompanying realization scenarios by providing a set of standards and profiles facilitate the development of consistent and harmonized specifications of future projects in order to increase interoperability and development of the digital single market in Europe.

Karima Bourquard
IHE-Europe

Frank Ploeg appointed as HL7 “Lead expert” in European mHealth Initiative

Frank Ploeg is appointed – on behalf of the HL7 International Foundation – as “lead expert” in the workgroup mobile Health Assessment Guidelines of the European Committee. Congratulations!

The HL7 International Foundation (or sometimes referred to as HL7 Europe) acts on behalf of HL7 International as a central contactpoint for European projects. By way of the HL7 Foundation HL7 is promoted to get and play a prominent role where standardisation is at stake.

Recently the European Commission announced its intent to establish of a working group to create mHealth Assessment Guidelines.
This working group will develop reference frameworks, guidelines and assessment rules for mobile applications in Healthcare, to achieve maximum standardisation, interoperability and reliability in the exchange and use of data produced by mobile platforms, devices or apps.

The HL7 International Foundation has been selected him as one of the 20 members of this workgroup, for which 70 applicants signed up. He will act in this working group on behalf of HL7 Europe as “lead expert”. The working group was formally installed in February and met for the first time face to face on the 8th of March in Brussels.

Prior to the first meeting there was consultation with both the Mobile Health Workgroup from HL7 International as well as the members of the European HL7 Affiliates in order for Frank to fulfill his role as good as possible in alliance with HL7 developments. Relevant activities will engage also the European Strategic Advisory Board that was established end of 2015 to strengthen the collaboration between European HL7 affiliates. In 2016 we will see its first concrete actions and results.

We are proud that one of our (Dutch) HL7 experts will represent HL7 in Europe in a EU initiative on mHealth. In contrast to the skepticism that is expressed about “Europe” we are expecting this project will lead to practical and concrete simplification and acceleration of crossborder exchange of Health Care information.

HL7 The Netherlands

A Case Study for Hemodialysis Patient Referral based on HL7 CDA R2 using ART-DECOR®

Semantic Interoperability for specialized medical documents using HL7 CDA remains until today a very difficult task, especially when you must ensure that requirements are captured in a correct way, mapped to CDA document, appropriate terminologies are chosen and tested so as to produce a complete specification. Different people roles must collaborate in a most efficient and fast way to produce quality results.

Hemodialysis referral case study is an implementation of a “Hemodialysis Report” (Patient Referral for Hemodialysis Procedure) electronic report, based on HL7 CDA R2 document standard. The implementation was held on behalf of a major IT Company (INTRASOFT International), supporting integration of third party systems and transforming the existing manual procedure (web based application) to an electronic interchange procedure. Development process – under the supervision of HL7 Hellas – focused on the design and development procedure of an HL7 CDA R2 document along with the implementation of exchange rules using appropriate software interfaces. One of the key factors for successfully implementation was the decision about the development methodology and the appropriate tools that will support the actual process. Chosen methodology was based in DECOR, an international methodology, by using the ART-DECOR tool, mainly focused on collaboration between clinicians and health IT.

What are Hemodialysis and Hemodialysis Referral and the case study use case?

Hemodialysis is a process of purifying the blood of a person whose kidneys are not working normally. Hemodialysis can be an outpatient or inpatient therapy.

Hemodialysis referral is the process when a nephrologist refers a dialysis patient for the first-time to a dialysis center and includes clinical, hematological and biochemical parameters in patients presenting for the first-time to dialysis

by Nikos Kyriakoulakos and Aram Balian
Hemodialysis referral also includes administrative data elements such as demographics information for patient and identification numbers useful for insurance providers and payers.

The use case that has been actually implemented includes a patient visit to nephrologist and the process where the doctor creates the referral report including administrative data and medical data (vital signs, clinical, hematological, biochemical parameters and diagnosis coding) produced during the patient examination. Finally a description of the desired and appropriate type of hemodialysis procedure is coded. A third party Electronic Medical System (EMR) is responsible to transmit a message, using HL7 CDA format, to the Insurance provider System that includes all the information regarding referral.

What is behind DECOR Methodology and Tool?
DECOR (stand for Data Elements, Codes, OIDs and Rules) is an innovating methodology that helps to capture the data needs of clinicians in terms of data sets and scenarios and use it to generate various artifacts like documentation of specifications, value sets, XML validation, generation and processing support and testing. DECOR improves data and link together input from different experts like clinicians, terminologists, modelers, architects and software interface specialists. DECOR mainly registers datasets, data types, allowable value ranges, identifications, codes, business rules with an underlying version management. The underlying data format is XML, and transformations with style sheets can be used for HTML and PDF-based documentation.

Why we choose ART-DECOR as a Template Manager?
HL7 Hellas members already have sufficient experience in designing and developing similar cases and in particular CDA document types. We chose to focus on a development methodology with the support of an appropriate tool. The main choice was template manager/editor with two candidates: MDHT (mainly used in the US) and ART-DECOR (mainly used in European countries). Both of these template managers allow defining templates using their own domain specific language (DSL). For the hemodialysis referral project the choice of tooling was based on the fact that ART-DECOR is a European Project and contains a library of the templates. The most important factor was that behind the actual tool exists a very powerful methodology (DECOR) that drives the whole process and advance capabilities for collaboration between clinicians and IT.

What about the Core Design and Development Process?
We follow precise the DECOR methodology starting from “medical domain” and detailed description of the use cases. Then we proceed with the “terminology domain”, and at this stage we decide medical terminologies that must be used. For this project we choose to use LOINC (Logical
Observation Identifiers Names and Codes) and ICD-10 coding for diagnosis as this is the only diagnosis related terminology translated in Greek Language. Next was the "ICT Domain" where we select HL7 CDA which is the HL7 v3 RIM as a backbone of the electronic description and notation of data.

Participants involved, according to development cycle, were Clinicians, Terminologists, HL7 v3 Modelers, Testing and of course IT developers.

During first stage we described all the data requirements in the form of data sets elements such as administrative and medical data and grouped them accordingly and then we defined use cases, actors and transactions. A critical stage of the development process was the OIDs definitions. OIDs are preferred form of identifier in all HL7 standards. During this definition the ART tool help us to automate the process generating OIDs based on a project base OID.

Major step was the design and development of the HL7 templates. Templates are predefined structures describing structure and semantics of mostly clinical content and specify what the associated XML instance looks like. During this step each of the data set elements were linked with the relevant template attributes and added the Schematron rules that were necessary in order to properly validate the CDA document.

A critical outcome of the process was the proper representation of additional identifiers. HL7 CDA cannot support all the required identifiers so we use HL7 templates (ART-DECOR: Template type not specified) to define them. For example Medical Order Institution Type (Hospital/ Clinic/Doctor etc.).

Conclusion

HL7 Hellas hosts a local installation of ART-DECOR, mainly for training and evaluation proposes, while we encourage similar cases to be hosted at the ART-DECOR main site. Using ART-DECOR we succeeded to design, develop and test a complete HL7 CDA R2 electronic document of specifications that meet in the best way the desired requirements. Implementation time was longer than a usual similar implementation needs due to first time learning curve, but the actual results
showed a complete implementation which gives us the option to re-use components and decrease implementation time in next cases. The result was a consistent and comprehensive documentation as an aid for specification, implementation and testing of the “Hemodialysis Report” electronic report. Despite the increased initial work, re-using of produced components and easier testing is an efficient way to produce cost effective interoperability solutions based on well-defined document requirements and rules.

Nikos Kyriakoulakos  
HL7 Hellas Director of Standards and

Aram Balian  
HL7 Hellas Board Member - Technical Steering Committee Chair

References
HL7 Standards Product Brief - CDA® Release 2  
DECOR (Data Elements, Codes, OIDs and Rules)  
http://art-decor.org
Ringholm, CDA Implementation Guides, 2013  
Principles of Health Interoperability HL7 and SNOMED Book by Tim Benson, December 2009
Kai U. Heitmann, ART-DECOR: a tool bridging the chasm between clinicians and health IT, in HL7 EUROPE NEWS, May 2014

Improving Information Exchange between Care and Cure Organizations

Mapping and Harmonization of i-Standards (Care) and HL7 Standards (Cure) in the Netherlands

Background
One of the leading national Healthcare IT priorities in The Netherlands is to significantly improve the electronic information exchange between institutions and organizations in the care sector and in the cure sector. The main problem to achieve this goal however is, that the care sector (nursing homes, rehab institutes, elderly homes, home care organizations) is using the so called “i-Standards” as their national standard, whereas the cure sector (academic and general hospitals) is using HL7 standards – mainly HL7 Version 2.4/2.5, CDA and V3) – as their national standard. The “i-Standards” and HL7 v.2.4/2.5 are different in terms of reference information model, format, coding systems as well as semantic definitions.

Objectives
The objective was to initiate and execute a project to (a) investigate the possibilities to bridge the gap between the two standards via mapping and harmonization, (b) develop syntax as well as semantic consistent translation algorithms vice versa and (c) publish an implementation guide which describes the mapping on the functional level as well as the technical format level. The explicit preset condition for the project was that the mapping and harmonization solutions should not require or cause any change in the fundamentals of either of the two standards.

Methods
The project was executed in 3 consecutive phases. Phase 1 was the investigation phase, in which phase the feasibility of the mapping and harmonization was analyzed. Based on the positive out-
come of this investigation, Phase 2 was started. In this phase, all data elements from the “i-Standards (care) were evaluated, from which evaluation those data elements were selected which were considered to be highly relevant to exchange between the care and the cure sector. For these selected data elements, the corresponding (or alternative, or candidate) data elements in the HL7 V2.4 NL standard were searched and defined. In Phase 3 the mapping and harmonization solutions for the selected data elements were developed and described in terms of algorithms, coding translations, table mappings, format translations, and so on.

These mapping specifications were developed vice versa.

**Results**

The project was successfully executed from February through November 2015. In January 2016 the final results have been published in an implementation guide, which – after some intermediate revisions by the mirror group – was balloted in February 2016 and is now an official DSTU HL7-NL Standard.

**Conclusions**

A total of 55 data elements from the i-Standards were defined as highly relevant for the exchange of information between care and cure organizations. Almost all of these 55 data elements did have corresponding data elements in HL7 Version 2.4. In some cases several candidate data elements in HL7 Version 2.4 were found, some of which choices are still under discussion (open issues) and will be resolved during the DSTU phase (until December 2016). The main conclusions from the project are that

- (a) consistent vice versa translations via mapping are possible and have been defined,
- (b) without affecting the fundamentals of both standards, but also that
- (c) especially tables need to be further harmonized and
- (d) the wording of several semantic definitions and descriptions needs to be aligned.

The open issues as mentioned under (c) and (d) are considered as not fundamental and therefore no barrier to start practical pilot implementations based on the DSTU implementation guide.

**Discussion**

The specific results of the project are considered as not (too) relevant for international re-use, since the i-Standards are typically Dutch standards. The mapping and harmonization solutions itself from this project will therefore not be transferable to other countries. On the other hand, it would be very valuable to learn whether in other EU countries the same situation exists (two different information exchange standards in the care and the cure sectors), how these countries are (or have been) approaching the mapping and harmonization issue, as well as to learn what the visions and priorities are with regard to the information exchange between the care and the cure sector, both on the practical level as well a the national policy level.

---

**Figure 1. Care / Cure Mapping Options**

---
Presentation

Based on the above, a presentation on this project will be presented at the IHIC 2016 conference in Genova (June 13-15, 2016), consisting of the following parts:

- A brief focus on the mapping and harmonization problems found for the basic selection of data elements, as well as the developed mapping and translation solutions
- A preview on the next step: medical/nursing/treatment information exchange and the selection of the appropriate standard: HL7 CDA or HL7 FHIR?
- An open discussion with the audience on topics such as: which countries are also confronted

Ing. Bert L. Kabbes, RI CMC
Chair, HL7 The Netherlands

Peter Snaterse, Gert Florijn, Wouter Franke
Dutch National Healthcare Institute, project managers

Adri Burggraaff, Alexander Henket, Helen Drijfhout-Wisse
Review team HL7 The Netherlands

openMedicine – One big Step towards Safe Medication

The ongoing openMedicine project, funded by the European Commission, has the goal to provide guidance concerning the identification of medicinal products across Europe throughout their lifecycle, in a scalable and sustainable way to bridge local, European, Transatlantic, and global perspectives for large scale eHealth deployment.

Identifying medicinal products across borders is essential for continuity of care and pharmacovigilance. This identification must seamlessly cover the complete medicinal product lifecycle, including regulatory and patient care activities. However, such identification poses many challenges: How to identify a substance, or a formulation, or a branded name, while there are no common identifiers for all of these? What to do when brand names are different? Or when a brand name is used in different products in different countries? How to handle clusters, substitution, and prescribing and dispensing rules?

The correct, unambiguous identification of medicinal products is thus a complicated matter.

During 2015, the openMedicine project has provided insight into the subject of medicinal products identification, by providing clarity on the context and goals, by documenting and analysing the issues, and by selecting a candidate standards-enabled data set to support cross-border identification of medicinal products.

The timing is decisive: The ISO IDMP set of standards is finalized, and the European Medicines Agency (EMA) works on a database of all medicinal products including their different attributes and metadata. The ISO IDMP standards are expected to be adopted by EMA and the industry in the next few years. The ISO 19256 standard, for Medicinal Product Dictionaries, has been finalised, and other standards are expected to play a role and openMedicine has worked closely with several

by José Costa Teixeira and Isabel Lazaro
organisations to ensure a good alignment.

The openMedicine communication and dissemination highlights engagement with Standard Development Organizations (SDOs). Involvement of SDOs is vital, as openMedicine needs to build upon existing standards, and the problem of identification of products requires proper use of standard like HL7 SPL for product information, HL7 CDA, V2, V3 messaging and perhaps HL7 FHIR for the clinical content.

This is how openMedicine addresses these issues:

openMedicine analysed the outcome and challenges in establishing and operating the European Digital Health Infrastructure initiated in the Connecting Europe Facility in the context of the selected use cases and other possible ones. The use cases for ePrescription and patient summaries were the starting point to understand the constraints and problem of cross-border identification. However, the identification solution was designed to seamlessly cover all steps in the regulatory and clinical activities including monitoring the effectiveness of drugs and adverse event reporting, etc.

This analysis was exposed in openMedicine D2.2 with cross-border prescription and dispensation as the reference case to understand the different variables at play. The results of this analysis can also be used in resolving other cases where implementation of cross-border medicinal product identification would likely have more immediate adoption and benefit, namely the secondary use of clinical data (for pharmacovigilance, data governance etc.).
This case reveals that in the lifecycle of medicinal products, it is clear that two different cycles co-exist:

1. The regulatory cycle, where products are registered, described and authorised, and where several entities contribute to register a product and make it available.

2. The clinical cycle, where the intended product is specified and eventually described through attributes by one party and this description is used by the other party.

It is obvious that the identification of the products must be unambiguous across these cycles. In other words, the clinical cycle must identify the products as they are defined in the regulatory cycle data must be available for this.

This is depicted in the figure on the bottom of the previous page, which shows a prescription being issued in one country and sent to another country, where the prescription information is used for dispensation. The picture also shows the different drug databases that provide and enrich product information, and are expected to be synchronised with the central EMA database in the next 3 to 5 years.

In summary, here are some key elements noted in openMedicine:

- One key obstacle is the diversity and ambiguity in identification like brand names, generic names, active substances, etc. ISO IDMP provides a foundation to resolve that, by establishing a key set of concepts that serve as an anchor or pivot for other levels of identification.

- The PhPID - Pharmaceutical Product Identifier - is the only identifier that could be globally unambiguous, and can therefore serve as the pivot for the identification of products when needed.

- Product attributes like brand names, package sizes, substances etc. are important at identifying a product, provided these concepts are commonly understood, and shared vocabularies exist for their values.

- In addition to product characteristics, the clinical data also plays a role to enable the dispenser to identify the corresponding product: total quantity to dispense (to determine package sizes), indication (if therapeutic substitution is needed), etc.

openMedicine has outlined how this information can be used, and identified the need to establish the roadmap to broad implementation and adoption.

Although, for pre-packaged products, the data needed is expected to be available, there are concrete challenges related to substitution, clusters, and other products. This is being analysed now in openMedicine WP3 and WP4, and WP5.

Finally, ensuring that the right information is available to all parties requires a vision, awareness, and engagement with the refined roadmap design and execution in each of the Member States. EMA has been providing outstanding support for these matters and other entities are expected (and required) to jump in. openMedicine will undertake workshops in several Member States to bridge regulatory authorities and eHealth stakeholders.

These are the big challenges for openMedicine for this second year.

Stay tuned.

For further information, please check www.open-medicine.eu

José Costa Teixeira  
HL7 Foundation, Brussels (BE)

Isabel Lazaro  
Spanish Agency of Medicines and Medical Devices (AEMPS) (ES)

Catherine Chronaki  
HL7 Foundation, Brussels (BE)
Fifteen Years on the Board of HL7 Netherlands

HL7 Netherlands will celebrate 25 years of healthcare interoperability in 2017. In areas such as lab, clinical imaging and patient administration, HL7 has become a household name within hospitals. Starting from that strength, I have been privileged to serve on the Board of HL7 Netherlands for 15 years of evolution toward much broader support for patient care across sectors and institutions. At the turn of the millennium, in 1999, I chaired a committee that advised the national initiative for the integration of medical data on the use of international standards in healthcare. Our recommendations centred on HL7. The fact is that HL7 is one of the few international standards that has seen broad adoption across the world. This contribution to the debate on standards in healthcare prompted a study, commissioned by the Dutch Ministry of Health, into the landscape of standards development organizations (SDOs). Bert Kabbes was appointed to carry out this study, which prompted him to (temporarily) hand over his position as chair of HL7 Netherlands to me. That way he could rise above the parties and provide an impartial overview of the standardization landscape. The temporary hand-over lasted almost 13 years, until October 2015, when Bert was re-elected as chair of HL7 Netherlands. I would like to take this opportunity to look back and thank everyone for their support on our journey.

The rise of HL7 version 3

Around the same time that Bert started his work, we also initiated a close and eventful collaboration with Nictiz, our national Health ICT institute, on the topic of HL7 version 3. This relatively new standard was chosen as the basis for the national infrastructure for health information exchange that was being developed at that time. We had a lot to learn and a lot to develop. Tom de Jong and Irma Jongeneel from HL7 Netherlands worked closely with Jos Baptist (honorary member of HL7 Netherlands) and Michael Tan from Nictiz to make this happen. To manage all this HL7 v3 work from a business point of view, we needed to start the HL7 Project Office, which Tom, Irma and Bert have run for a number of years. In addition to Nictiz, the Project Office also carried out work for the restructuring of health care finance project DBC and DBC-GGZ. This also provided us with the knowledge to translate the financial reporting requirements to HL7 v2 financial management for the hospitals. Today the financial Grouper is champion in handling HL7 v3 messages with more than a million a month. HL7 v3 has also found its way to the national rectal cancer screening program and to the national youth healthcare program. In all, national projects have found their way to HL7 v3 specifications, both messages and documents.

SDO-NL Council

Notwithstanding the success of HL7 NL, matching user requirements with available standards and specifications remains a complex issue. Just the fact that the specifications adhere to the HL7 v3 modelling and representation guidelines, does not mean that the specifications constitute a well standardised HL7 v3 interface. Even HL7 v2 specifications suffer from different perspectives, such as the HL7 NL v2.4 implementation guides and the international IHE profiles that sometimes refer to v2.5 or v2.6 (or even v2.2!). It is not always clear how to resolve these issues. However, a clear prerequisite is for the SDOs involved to coordinate their work and their communication messages to the users of standards. This is why HL7 Netherlands and IHE Netherlands decided in 2011 to collaborate more closely, prompted also by the wishes of the Dutch Health IT Vendor Association. At the same time we issued a position paper on the structure of...
Health IT standardization. This has led to the creation of an “open SDO agreement” for all SDOs in healthcare in the Netherlands to coordinate their activities. This agreement was signed in 2013 by HL7 Netherlands, IHE Netherlands, Dutch National Standards body NEN, the Dutch IHTSDO Release Centre (run by Nictiz) and Nictiz itself. Since then GS1 Netherlands and the Dutch Public Health Agency RIVM, the steward for the ICD and ICF classifications of the World Health Organization, has joined the SDO-NL Council. Together, the Council engages in joint marketing and education and coordinates the delivery of standards to national initiatives.

Information Council
The agenda on the requirements side of health information standards has been organized by the Ministry of Health through an Information Council, in which the most relevant associations of healthcare institutions and healthcare professionals are represented, as well as the different directorates within the Ministry. The mandate of the Information Council is to set the agenda for the joint development and improvement of information services in healthcare, focusing on the “managerial” or “system-wide” responsibility, rather than on the individual patient-professional relationship. All stakeholders not directly represented in the Information Council are invited to participate in two ways: through membership of one of a number of expert teams advising the Council and through their presence on public gallery during the meetings of the Information Council. The SDO-NL Council members are all member of the Expert Team on standardization, which advises on the use of standards in the initiatives that constitute the agenda of the Information Council. HL7 Netherlands is also getting more structurally involved with the work of the National Health Care Institute, harmonizing the specialized (administrative) standards for long term care with the HL7 v2 standards in acute care. This will enable a smoother transition from acute to long term care. The National Health Care Institute and Nictiz have agreed to have an information standard as a mandatory component of every quality standard in specialized medical care. HL7 Netherlands is studying the use of the HL7 eMeasures standard for the specification and use of quality indicators in these information standards.

International perspective
Both in the work on quality information and the information council we have run into a familiar face: our honorary member Kees Molenaar who, together with Bert Kabbes, was among the founding members of HL7 Netherlands. His efforts to establish a productive and respectful collaboration in health information standards has led me personally to develop a strong international involvement. In 2006 Kees was appointed chair of European Standards Committee CEN/TC 251 Health Informatics. Together with Ed Hammond on behalf of HL7 International and Yun Sik Kwak as chair of ISO/TC 215, Kees was instrumental in the formation of the Joint Initiative Council. The JIC was formed with the intention to collaborate, coordinate and cooperate in order to provide the set of standards necessary to resolve health care problems and fulfill health care requirements. Over the years IHTSDO, CDISC, GS1, IHE International, and DICOM have joined the JIC. Personally I joined the JIC representing the HL7 Affiliates in my role as co-chair of the HL7 International Council. Later, Kees approached me to take over his role as chair of CEN/TC 251 and thus continue my JIC membership in a different capacity. In 2011, I have taken on the chairmanship of CEN/TC 251 in the same spirit of productive and respectful collaboration, which has now led to the European initiative to form an SDO Platform for all participating eHealth SDOs. Through the collaboration with Catherine Chronaki, who is leading the European office of HL7 International and who now represents the HL7 Affiliates in the JIC, we have been able to bring all relevant SDOs together in different European projects, including Antilope, Trillium Bridge, eStandards and OpenMedicine. My being part of the leadership of both HL7 Netherlands and CEN/TC 251 has helped create the synergies and momentum to advance collaboration among standards developing organizations in Europe.

Finally
One of the first European meetings I attended as a board member of HL7 Netherlands was in April 2000 at Schiphol Airport. Present (if I remember correctly) were Bernd Blobel on behalf of HL7 Germany, Niilo Saranummi for HL7 Finland, Leo Fogarty representing HL7 UK (just formed in 2000), Bert Kabbes and myself for HL7 Netherlands. The main message that I remember from that meeting is that we did not feel the need to have a European HL7 organization, because “European HL7 Affiliates have as much in common with each other as with other HL7 Affiliates, or with the US”. Even today the focus remains on global standards and the way we use them in each of our respective domains. However, the European projects and the policy agenda of the European eHealth Network has triggered the beginnings of a common European eHealth agenda. Therefore I am
happy that the HL7 European Strategic Advisory Board has been formed, in which the chairs of the European Affiliates coordinate and collaborate. The European Office has paved the way and the European Realm is just around the corner! Our European venue for the HL7 International in 2015 (Paris) and 2017 (Madrid) will undoubtedly advance our European collaboration. I have thoroughly enjoyed all the team work in the past 15 years on the Board of HL7 Netherlands and I fully intend to be part of the team that will shape the future of health information standards in the Netherlands, in Europe and across the globe.

Robert Stegwee
Past Chair HL7 Netherlands

Knowledge is power. Despite extensive investments in digital health technology, navigating the health system online is hard. The low adoption of eHealth services, the persistent disparities in health, and the huge opportunity that big health data provide, trigger a call for multidisciplinary action. Unfortunately, the “Inverse Care Law” proposed by Hart in 1971, seems to apply on digital health services. The availability of good medical or social care services and tools online, varies inversely with the need of the population they serve.

Barriers and challenges are not to be underestimated. Culture, education, skills, costs, perceptions of power and role, are essential when considering digital health literacy as an integral part of the health system. Citizens and patients living with chronic disease, caring for an elderly relative, neighbor, or sick child need a digital health compass.

The panel will engage the audience to elaborate on how health systems can unlock the power of health data by targeted digital health literacy interventions that leverage opportunities for open, massive, and individualized delivery. This way, engaged and confident eHealth consumers join health professionals and researchers to work with precision medicine, age-related health and wellness changes as well as chronic disease.

Co-chairs
Catherine Chronaki, Secretary General, HL7 Foundation: will speak on initiatives like myHealthData and quantified self, able to deliver tailored, adaptive and actionable health experience for individuals, families and communities.

Prof. Anne Moen, President European Federation for Medical Informatics will argue on the pressing need for health professionals, patients and health informatics to jointly develop the research and policy roadmap for digital health literacy

Panelists
Prof. Christian Lovis
Petra Wilson
Prof. Panos Vardas
Ed Hammond

Moderator
John Rayner, Regional Director - Europe & Latin America; Healthcare Advisory Services Group, HIMSS Analytics, will moderate the session facilitating interaction with audience.

For more information: http://www.ehealthweek.org/ehome/128630/hi7-efmi-sessions/?
The 16th International HL7 Interoperability Conference (IHIC 2016) will be held from 13 to 15 June 2016 in Genoa, Italy. The meeting will be hosted by HL7 Italy, with support from HL7 Germany as permanent IHIC supporter - other HL7 Affiliates are invited to join the supporters’ team. The motto of the 2016 conference is: Interoperability is more than just technology.

**Agenda**

**13 June 2016: Tutorial Day – Morning session**
- Kai Heitmann: “General introduction to CDA”
- Ewout Kramer: “FHIR Introduction”
- Bernd Blobel: “Security and privacy challenges of interoperability”
- Libor Seidl: “Use of the HL7 InfoButton standard”

**Tutorial Day – Afternoon session**
- Kai Heitmann: “ART-DECOR”
- Ewout Kramer: “FHIR for Developers”
- Stefano Lotti: “Service Orientated Architecture”

All registered attendees will receive one complimentary tutorial with the opportunity to book further tutorials. Special Session or Workshops of HL7 Committees may be accommodated here, offering sharing of information and experiences between committee members and participants from all around the world.

**14 –15 June 2016: Main Conference**

**Audience**

The intended audience encompasses all who have developed, implemented, investigated, or otherwise used any of HL7 standards.

**Conference Topics...**

...are the following topic (and more)
- The advancement of interoperability
- Harmonization of interoperability standards and specifications among different SDOs
- Terminology and ontology challenge of interoperability
- Concepts and frameworks for Smart Interoperability Infrastructure Services
- Local, regional or national Electronic Health Records solutions
- Business Intelligence and Clinical Decision Support
- Specification and implementation tools
- FHIR and CDA – controversy, coexistence, or synergy?
- “Show me your CDA” – CDA implementations at all levels

**IHIC 2016 Program Committee**

Mauro Giacomini, (IT, Chair), Giorgio Cangioli (IT), Silvana Quaglini (IT), Bernd Blobel (DE), Sylvia Thun (DE), Kai Heitmann (DE), Libor Seidl (CZ)
HL7 Affiliates in Europe

see also http://www.hl7.org/Special/committees/international/leadership.cfm

<table>
<thead>
<tr>
<th>HL7 Austria</th>
<th>HL7 Germany</th>
<th>HL7 Serbia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair: Stefan Sabutsch</td>
<td>Chair: Sylvia Thun</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HL7 Bosnia and Herzegovina</th>
<th>HL7 Greece</th>
<th>HL7 Slovenia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair: Samir Dedovic</td>
<td>Chair: Alexander Berler</td>
<td>Chair: Brane Leskosek EE, PhD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HL7 Croatia</th>
<th>HL7 Italy</th>
<th>HL7 Spain</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.hl7.hr">http://www.hl7.hr</a></td>
<td><a href="http://www.hl7.it">http://www.hl7.it</a></td>
<td>Chair: Giorgio Cangioli</td>
</tr>
<tr>
<td>Chair: Miroslav Končar</td>
<td></td>
<td><a href="http://www.hl7spain.org">http://www.hl7spain.org</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HL7 Czech Republic</th>
<th>HL7 The Netherlands</th>
<th>HL7 Sweden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair: Libor Seidl</td>
<td>Chair: Line Saele</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HL7 Denmark</th>
<th>HL7 Norway</th>
<th>HL7 Switzerland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair: Lene Nielsen</td>
<td><a href="http://www.hl7.no">http://www.hl7.no</a></td>
<td>Chair: Marco A. Demarmels MD, MBA</td>
</tr>
<tr>
<td></td>
<td>Chair: Line Saele</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HL7 Finland</th>
<th>HL7 Romania</th>
<th>HL7 UK</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://www.hl7.fi">http://www.hl7.fi</a></td>
<td><a href="http://www.hl7romania.ro">http://www.hl7romania.ro</a></td>
<td>Chair: Philip Scott PhD</td>
</tr>
<tr>
<td>Chair: Juha Mykkanen PhD</td>
<td>Chair: Florica Moldoveanu</td>
<td></td>
</tr>
</tbody>
</table>

| HL7 France | HL7 Russia | |
|------------|------------| |
| Chair: Francois Macary | Chair: Sergey Shvyrev MD, PhD | |

About HL7 International

Founded in 1987, Health Level Seven International (www.HL7.org) is the global authority for healthcare Information interoperability and standards with affiliates established in more than 30 countries. HL7 is a non-profit, ANSI accredited standards development organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7’s more than 2,300 members represent approximately 500 corporate members, which include more than 90 percent of the information systems vendors serving healthcare. HL7 collaborates with other standards developers and provider, payer, philanthropic and government agencies at the highest levels to ensure the development of comprehensive and reliable standards and successful interoperability efforts.

E-mail: HQ@hl7.org • Website: www.hl7.org

HL7 Europe Listserver

If you want to be up to date regarding HL7 Europe, please subscribe to europe@lists.hl7.org at hl7.org.