HL7 EUROPE
07

Seven years European Office

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HL7 Foundation in Europe

Seven years of growth for the European Office

by Catherine Chronaki

The whole idea of regional offices for HL7 goes back to Ed Hammond's third HL7 chairmanship in 2008-2009, aspired by the vision to turn HL7 into truly international organization starting with a name change. It was not the first time that HL7 Europe came up in discussions. In the 1990's, some 10 years before, the European HL7 Affiliates abandoned the idea thinking there wasn't enough common ground: HL7 was the place for global standards development and localization was national business: France, Italy, and Germany had as much in common as with Australia, Canada, and Japan.

But that changed with epSOS. Under the leadership of a dynamic Swede, Fredrik Linden, the 36.5 M Euro epSOS large scale pilot project (2008-2013) co-funded by the European Union (EU) and Members States, was a game changer. epSOS pushed cross border ePrescription and patient summaries at the front of national and European eHealth policy agendas.

HL7 CDA was chosen by the epSOS industry forum as the exchange format of patient summaries. The eHealth Network of 28 health ministry representatives, formed under Article 14 of the EU cross-border directive (2011/24) catalyzed the process of advancing EU-wide eHealth services by adopting the epSOS specifications as the basis for European guidelines. Jeremy Thorp, member of the HL7 Board of Directors, has been instrumental in the development and currently the revision of the guidelines.

At that pivotal time, the HL7 Foundation was established to serve as the European office of HL7 with the mission to promote HL7 standards in Europe, to convey the European requirements to HL7 WGs, to form relations with European umbrella organizations, and to participate in EU funded projects and initiatives.

Today after seven years of growth, the HL7 Foundation expands its efforts with the active engagement of the European Strategic Advisory Board, chaired by Christof Gessner. The HL7 EU realm is getting traction and tooling support with the work of Giorgio Cangioli, Kai Heitmann, and the ART-DECOR team, while work advances in Detailed Clinical Models and profiles of the EHR-S Functional Model. FHIR is attracting a lot of interest among implementers, and HL7 CDA adoption is spreading.

In parallel, membership in the mHealth assessment guidelines WG (Frank Ploeg, Netherlands), the European Network and Information Security Agency (ENISA) eHealth expert group (Alex Mense, Austria), the Alliance for the Internet of Things Innovation, and the eHealth Stakeholders Group offer input, advice, and insights into the EU policy agenda.

Participation in EU funded projects ANTILOPE (eHealth testing), Semantic Healthnet (Charlie McCay), EXPAND (Giorgio Cangioli), eHGI, and Trillium Bridge helped increase the visibility and impact of HL7 in Europe. Trillium Bridge "Bridging Patient Summaries across the Atlantic" was the first project led by the European office of HL7. Funded by the European Commission, Trillium Bridge served as the operational arm of the EU/US memorandum of understanding on eHealth. Its key recommendation advanced the concept of a globally consistent patient summary standard serving as the springboard for accessing core patient information when and where is needed. The HL7 International Patient Summary Project furthers this vision in cooperation with CEN TC251.

Looking forward, a common eHealth services infrastructure is emerging in Europe. It heralds even bigger challenges and opportunities for the European office of HL7 and its community. Check out four related strategic questions in part II.

Four strategic questions for the HL7 Foundation

What is the role of HL7 Standards in the eHealth Digital Services Infrastructure (eHDSI)?

eHDSI calls for EU-wide specifications and national extensions or localizations. Interoperability assets and shared terminology resources supporting HL7 standards adoption are needed to streamline large scale eHealth deployment at a reasonable time and cost.

The eStandards project, led by the HL7 Foundation, aims to create a roadmap for collaborative eStandards development fit for the purpose of large scale eHealth deployment. CEN/TC251 and IHE Europe participate in the eStandards project along with key eHealth stakeholders in Europe.

In view of these developments, it is worth reflection on:

- How should HL7 standards be promoted at the national and European level? What kind of tools and resources can HL7 offer to support its European members? What synergies does HL7 need to engage in Europe?

Does Europe need a common shared HL7 template repository?

Thanks to the efforts of Giorgio Gangioli, Kai Heitmann, Stefan Sabutsch, and Christof Gessner, Art-Decor now hosts the templates associated with the epSOS specifications as updated by the EXPAND project and is now under the maintenance of eHDSI. Moreover, the team identified specific improvements that would improve the specifications.

For the next steps we need to reflect:

- Should HL7 formally offer a common European template repository to accelerate adoption of HL7 standards and streamline localizations across Europe?
- Can HL7 through its European Office, with Affiliates support, sustain this effort?
- Should relevant efforts be expanded to FHIR profiles and extensions for Europe?

Does the HL7 EU realm fit with a common terminology strategy for Europe?

A European terminology center offering a European extension for SNOMED-CT as one of the core reference terminologies has been proposed in the ASSESS CT EU-funded project. The HL7 Health Terminology Authority addresses issues relevant to the use of external terminologies and value sets in HL7 standards.

The European Medicines Agency will be offering a Medicinal product database based on the IDMP standard from 2019 and the specifics are explored in the recommendations of the openMedicine project. HL7 Project Scope Statements are developed by HL7 WGs to address relevant standardization issues.

Reflecting on the implications for Europe it is worth reflecting on

- What is the role of HL7 in supporting localization or translation at a regional or national level? Can HL7 facilitate localization work and national roll out of IDMP? Are there best practices to be shared?
- ...and overall: What synergies should HL7 pursue in Europe?

Is it time for closer cooperation of HL7 with CEN/TC251?

Recently CEN/CT251 led by long term HL7 NL chair, Robert Stegwee, was awarded a contract by the European Commission to develop IPS, a European standard for patient summaries, aligned with global standards developments. Giorgio Cangioli (HL7 Foundation), Karima Bouquard (IHE Europe), Vincent van Pelt (NICTIZ), participate in the project team led by Stephen Kay. I was invited along with Charles Parisot (IHE Europe) to serve on the IPS Steering Committee chaired by Robert Stegwee.

Meanwhile, the HL7 IPS project offers fertile ground and a unique opportunity for collaboration and alignment of efforts at the Universal and EU Realm. In retrospect,

- ...can this collaboration built a closer relationship between CEN/TC251 and HL7 in Europe?

As HL7 International celebrates its 30th birthday, HL7 shines brightly in Europe. With the support of HL7 International, the European Office of HL7 will continue its growth, investing on synergies, innovation and long term partnerships.

HL7 will continue to create the best and most widely used standards in Healthcare, standards that empower global health data interoperability so that everyone can securely access and use the right health data when and where they need it!

Catherine Chronaki
Secretary General, HL7 Foundation

Reinforcing the Bridges and Scaling up EU/US Cooperation on Patient Summary

Trillium Bridge II

by Catherine Chronaki

The Trillium-II project supporting the EU-US Memorandum of Understanding on cooperation in eHealth interoperability had its kick off meeting on February 6-7, in Brussels.

In this second phase of the Trillium Bridge project, the HL7 Foundation joins forces with MedCom, the Danish eHealth Competence center to scale-up standards cooperation and implementation to the global scale.

The first day of the meeting, hosted by the European Office of the Region of Southern Denmark, at Ave Palmerston 3, welcomed 22 participants from Europe and the United States. Building on the EU-US MoU roadmap and the success of Trillium Bridge (www.trilliumbridge.eu), Trillium-II aims to create a global community for the practice of innovation in digital health, scaling up adoption of patient summaries worldwide for the benefit of individuals and communities.

The Trillium team celebrated the end of the first day with ribs and gambas at the famous Brussels.

On the second day, there were two work streams. The first one, WP2 (Assembling Interoperability Assets for Patient Summary Components) and WP3 (Extending the Scope beyond Emergency and Unplanned Care) met at the premises of CEN, the European Standards Institute to evaluate the status of on-going standardization efforts related to the Patient summaries. Trillium-II aims to complement standardization efforts by offering information on tools and resources, by facilitating knowledge sharing, and by catalyzing synergies that will lower the cost of implementing standards and advance the practice of interoperability.

Starting from the broadly endorsed recommendation of Trillium Bridge to...

> "*...advance an International Patient Summary (IPS) standard to enable people to **access and share their health information** for emergency or unplanned care anywhere and as needed. At minimum, the IPS should include **immunizations, allergies, medications, clinical problems, past operations and implants**,*" *Trillium-II aims to open up a window to our health data and to allow safe and secure use of health data, where and when needed to support individuals and communities in situations ranging from unplanned care to emergencies or disasters.*".

The second work stream was hosted by European Heart Agency of the European Society of Cardiology. WP1 (Stakeholder Engagement), WP5 (Context, role and adoption of the International Patient Summary in the global ecosystem), WP6 (Making it Real: Engaging with the practice of Digital Health Innovation), and WP7 (Dissemination, Market Outreach and Sustainability), analyzed the key stakeholders for patient summaries and articulated key messages that should appeal to their needs and interests. The two work streams met for lunch and shared their findings in the afternoon, preparing for the International Patient Summary Workshop hosted by the European Commission on the next day.

With a consortium that brings together 25 organizations from Europe and United States, Trillium-II aims to reinforce bridges and help realize the benefits of eHealth investments with standards and supporting tools. In this way, it will contribute to lowering cost of interoperability offering patient summaries as a route to productively engaging health & care standardization and support innovative solutions leading to much-improved patient outcomes.

■ NEN the Danish standardization institute represents CEN TC251, leads Work Package WP5 and

along with HL7, IHE Europe, and CDISC Europe are the participating standards organizations.

- ■ The European Institute for Innovation through health data leads WP4 focusing on the context, role and adoption of the International Patient Summary in the global ecosystem.

- ■ Empirica (Germany) leads development of an assessment framework to measure adoption (WP4/WP6).

- ■ Gnomon Informatics SA (Greece) leads WP2 and the Assembly of interoperability assets for Patient Summary components.

- ■ SRDC (Turkey) leads development of a cookbook for security and privacy tools.

- ■ PHAST ASSOCIATION (France) will help collect resources for medication and lab results.

- ■ OFFIS (Germany) and team address imaging tools and resources for the patient summary.

- ■ Lombardia Informatica (Italy) leads WP6 – Making it real by engaging broad stakeholders with the practice of Digital Health Innovation through patient summaries.

- ■ THL (Finland), the national eHealth competence center of Finland, spearheads efforts to collect tools and resources for the vaccination component of the patient summary.

- ■ ADI and DHACA (UK) lead WP7, the dissemination, market outreach, and sustainability efforts

engaging partner networks such as the Connected Health Alliance (UK) and its ecosystems.

- ■ SPMS (Portugal), the national eHealth competence center of Portugal will lead the work on allergies.

- ■ TICSALUT (Spain), the competence center of Catalunia will lead the work on problems and procedures.

- ■ AHIMA (US), Reliant (US), Lantana (US), Prosocial (US), Kaiser Permanente (US), along with eSante (Lux), SPMS, and TicSalut will be among the organization that will participate in the demonstration of project results.

For more information check: http://cordis.europa.eu/project/rcn/206099_en.html and soon the updated www.trilliumbridge.eu website.

Catherine Chronaki
Secretary General, HL7 Foundation

Polish National Implementation Guide for HL7 CDA

by Sebastian
Bojanowski

Introduction

The main trigger for the development of Polish implementation guide for HL7 CDA was the nation-wide e-health project, called P1 platform. It has been started by Centre for Healthcare Information Systems (CSIOZ) for the purpose of providing a centralized repository for e-prescription and e-referral documents and a centralized registry for other kind of clinical documents exchanged at national cross-enterprise level. Despite the fact that the whole platform is still in analysis and development process, the HL7 CDA implementation guide specification seems to be the most valuable artifact of the project so far. It is consumed by a growing number of new electronic documentation implementations on regional or organizational level, as the specification covers all Polish realm related requirements derived from legal regulations and good practice.

The first phase of the development process of the Polish national implementation guide for HL7 CDA was the creation of templates and value sets for document types to be processed and hosted in a centralized repository: e-prescription (drug prescription, prescription for medical equipment) and e-referral. The development process consisted of clinical modelling, terminology analysis, OID tree design and preparation of real-life examples of document instances. Then, during the second iteration, other important templates, from the clinical document exchange perspective, were introduced: consultation note, diagnostic study note, lab report and discharge summary note. In the following releases, the specification was further extended by adding document-level templates for: surgical operation note, refusal note, immunization card item, as well as nursery document types for history note, patient status assessment note, report item and discharge prescriptions note.

At the very beginning the specification was created in a form of text document, with common use of H7 Version 3 Hierarchical Description format for the purpose of template structure definition. In 2014, the whole specification was translated to the HL7 Templates standard (formerly DECOR) using ART-DECOR tooling environment. Since then, the template and terminology development, publication process and validation artifacts generation are based on ART-DECOR functionality.

Polish Building Block Repository

The specialization hierarchy and granularity of templates of the Polish implementation guide for HL7 CDA has been designed in a way to ensure maintaining the function of a building block repository. The latest version of the specification was published in the global ART-DECOR repository to be a source of templates and value sets for other implementations.

The center pillar of the implementation guide is the base template (see Figure 1), which covers all the common requirements related to the Polish realm. There is also influence of the P1 platform on the specification in a form of specialized base template which introduces new layer of requirements for clinical documents to be processed in central repository.

On the top of the base rules we have designed templates for specific document types driven by the need for cross enterprise document exchange (i.e. lab report, discharge summary note, consultation note). In case of e-prescription and e-referral there was a need for further specialization. Because of the fact, that requirements for specific types of drug prescription and referral documents in Poland are precisely specified in legal regulations, we were obliged to create more detailed templates (i.e. reimbursement conformant drug prescription, referral to psychiatric hospital) beside the common drug prescription and referral templates.

The Polish implementation guide is not only about document-level templates. One of the recent versions of the specification has introduced several templates for clinical statements regarding nursing assessment scales with extensive use of ICNP coding. Probably the most valuable way of extending the specification in the future will be the development of the new templates on the
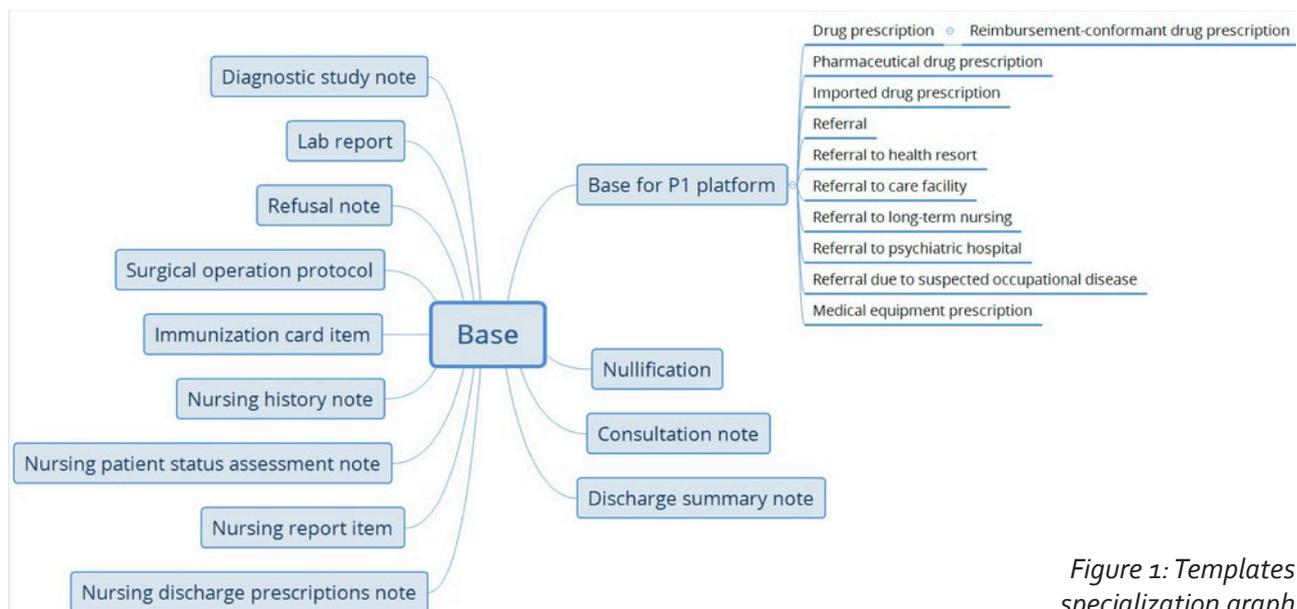
Figure 1: Templates specialization graph

HL7 CDA entry level to provide guidance, how to represent the atoms of common clinical data using CDA R-MIM, also by deriving the templates from other implementations.

As far as terminology is concerned, we have defined several value sets on the top of LOINC and SNOMED CT coding systems. Polish translation of ICD-10 is required for diagnoses, and Polish realm specific flavor of ICD-9 is used as a coding system for medical service events. We had to define specification-specific dictionaries mainly for qualifiers (i.e. precise document types, coverage payment levels, etc.)

At this point of time Polish National Implementation Guide for HL7 CDA covers 221 templates (including 24 on document level), 99 value sets and 14 embedded local coding systems.

Polish HL7 CDA extensions

As is it seen in case of HL7 CDA implementation guides around the globe, we have also met the problem of extending CDA R-MIM model, because of the local requirements. In process of defining extensions we have kept the line with "proper methodology" by clinical modeling supported with HL7 Version 3 RIM conformant approach and utilization of existing domain models. All extensions have been presented during 14th International HL7 Interoperability Conference (IHIC) in Sydney and we have resolved minor issues basing on the valuable feedback. We have designed extensions mainly for header part of the document, but some of them have been defined on the CDA entry level (all defined in extPL namespace):

■ patient multiple birth indicator and order number,

■ physician specialty,

■ entitlement documents (non-clinical document allowing patient's entitlement to the particular medical service coverage plan),

■ special entitlement (e.g. drug refund coverage plans) that should be indicated in the prescription document,

■ coverage eligibility confirmation (identifier of the online transaction of ensuring patient coverage eligibility),

■ close person (not a guardian, reserved for specific kind of documents in Poland where parent's given names are additional identifying information),

■ drug payment level,

■ drug substitution (for realization of "no substitution" remark on drug prescription),

■ reimbursement related contract.

Unfortunately, the introduction of extensions to HL7 CDA standard has impact on implementers. The additional effort must be done to use popular tooling like MARC-HI Everest or Open Health Tools MDHT for document instance generation or IHE Gazelle ObjectsChecker for validation purposes. These tools must be therefore supplied with object model representation of Polish extensions to build solutions upon them.

Specification publication

The publication process of the specification is entirely based on the ART-DECOR environment functionality and services. The generation mechanism has been changed to reflect specific needs related to the Polish implementation.

The major difference is that we create intermediate DECOR files before the main generation process of the HTML documentation and Schematron validation artifacts. First flavor of main DECOR file generated is so called "fixed" file, which contains additional Schematron rules added for proper support of closed templates (because of the fact that ART-DECOR does not support mixed environments with open and closed templates in one specification). On the other hand, regarding the fact, that we have all versions of all templates and value sets in the one, main DECOR file, we also generate so called "cleaned" DECOR file containing only the latest versions of templates and value sets. "Fixed" DECOR file is used for generation of Schematron files, and "cleaned" one is used for generation of HTML documentation – to make the HTML publication output much cleaner and easier to read.

We have added additional features to publication process which affect HTML output:

- document templates tab as a list of templates on document-level with references to DECOR specification, Schematron files set and browse-able fist of real-life document XML instances examples for particular templates,

- list of dictionaries defined in the specification,

- extPL XML Schema Definition (XSD),

- OID tree structure,

- visualization tab for displaying example documents content using dedicated XSLT stylesheet.

Support for implementers

During the process of development of Polish implementation guide, the Centre for Healthcare Information Systems (CSIOZ) has delivered the supportive document in a form of a guide for implementers. This document aims at being the entry point for those of vendors, who are not already familiar with HL7 Version 3 ecosystem of standards. It covers basic requirements for electronic documentation implementation in Poland, introduction to HL7 CDA standard, detailed description of document-level templates and other technical aspects concerning implementation.

Another supporting CSIOZ activity was the development of nation-wise global, universal, centrally maintained XSLT stylesheet for displaying clinical documents conformant with the Polish implementation guide. It is versioned in the same manner as the main specification and became a common part of the release publication package.

The important benefit of using ART-DECOR environment is the ability to generate validation artifacts in a form of Schematron specification. Every Polish implementation guide release contains full set of validation files per document-level template to be evaluated by implementers.

The further step in improving the quality and effectiveness of validation tools has been taken during the development process of the latest release (version 1.2) of the Polish specification.
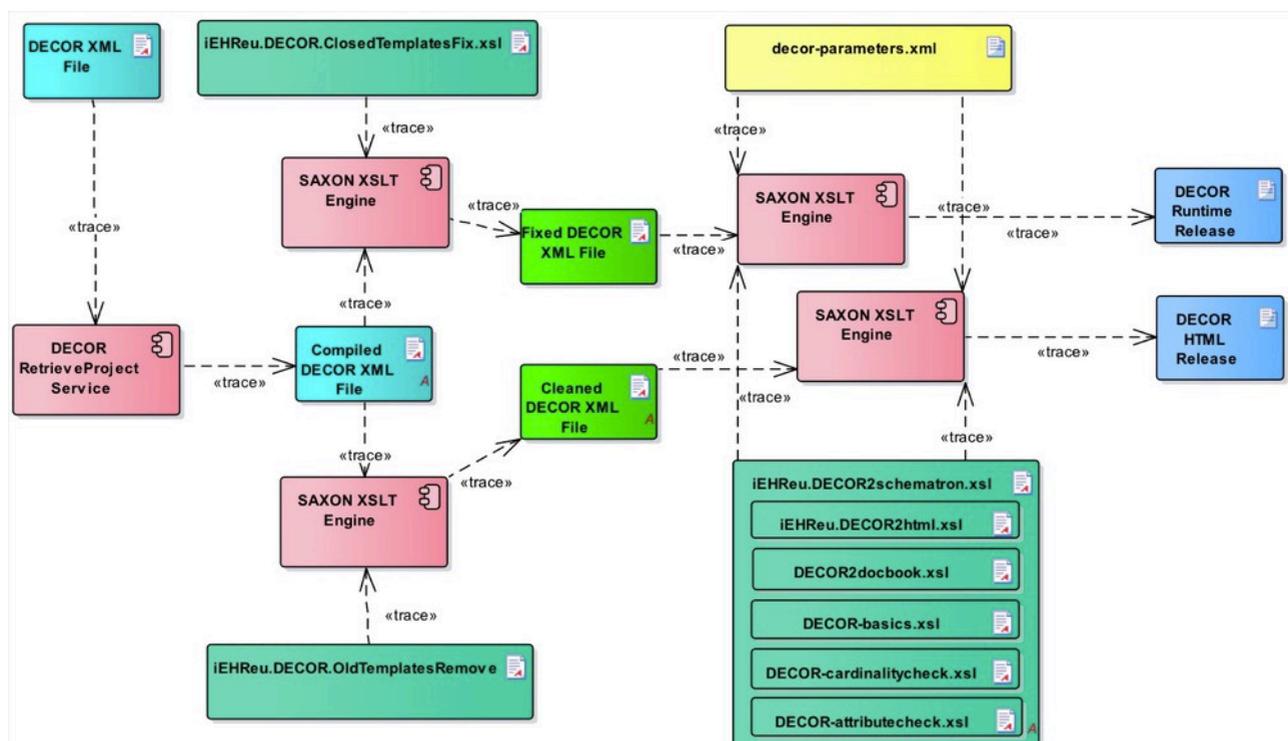

Figure 2: Polish National Implementation Guide for HL7 CDA DECOR publication process.

In collaboration with IHE Europe we made some initial step in importing one selected document-level template rules to IHE Gazelle ObjectsChecker. The goal is to develop production-ready, Gazelle-based, fully featured validation suite in near future.

Current status

With the beginning of 2017, the new version 1.2 has been released. New section and entry level templates has been introduced, mainly to provide ability for embedding binary content as clinical document body. Templates for document types, that were not intended to be fully processed in a central repository (all templates excluding

e-prescription and e-referral) – have an "active" status now. Regarding the fact, that the e-prescription project is reactivated by CSIOZ and it is on full throttle now, we can predict that the next versions of the Polish implementation guide will be released this year.

Sebastian Bojanowski
Consultant in Healthcare IT at iEHR.eu

HL7 International Working Group Meetings May 2017 and May 2018

Madrid (Spain) 6–12 May 2017
Madrid Marriott Auditorium Hotel and Conference Center

Cologne (Germany) 12–18 May 2018
Maritim Hotel

Poland has joined the HL7 Global Community

by Roman Radomski

Polish HL7 Association (HL7 Poland)

In January 2017 the Polish HL7 Association came into being. The founding members of HL7 Poland have successfully completed the application and registration process and the affiliate agreement with HL7 International has been signed. Behind that initiative are several individuals from Polish software vendors, medical providers and independent health IT consultants, who have been already involved in implementation of HL7 standards. We also succeeded to involve three major organizations: the National Centre for Healthcare Information Systems (CSIOZ), which is an official eHealth government agency, the Polish Chamber of Healthcare IT (PIIM), associating healthcare software vendors and their clients - medical providers in the form of professional self-government body, and the Association of Healthcare Software Providers (STORM), which is the organization of leading software vendors interested in healthcare market.

Beside the Board and the Technical Committee, there are a few other statutory bodies of HL7 Poland, including Program Board, that gathers together representatives of all organizational members and all members of the Technical Committee. It seems, that this would be the main platform for merit and policy discussions across the organization.

HL7 standards in Poland

Many years ago there was a short episode of HL7 affiliate organization in Poland, but since then, for more than 10 years, our country was one of the latest large or medium size European countries, where was no official presence of HL7 organization. It does not mean that HL7 standards where not used here. Some companies decided to become organizational members of HL7 International and some individuals where members of other European affiliates of HL7. For years the only HL7 standard commonly used in Poland was HL7 V2 messaging, which is still the most popular way of electronic exchange of laboratory orders and results. The first large scale implementation of HL7 CDA standard took place in 2010. LUX MED Group, the biggest private medical provider in Poland, introduced electronic clinical documentation in more than 100 medical facilities across the country. The project led to tens of millions of CDA-conformant document instances being issued every year. Since then, several other local implementations of CDA took place. In 2012 the official eHealth government agency (CSIOZ) for the first time recommended HL7 CDA as a standard for clinical documents. The first draft of the National Implementation Guide for HL7 CDA was published in 2013, covering just 3 types of clinical documents - only those, that were planned to be exchanged by central exchange platform (P1). Despite a few of failures of the central eHealth projects, the national IG for HL7 CDA kept to be developed by CSIOZ and is well received by our healthcare IT community. At the beginning of 2017 version 1.2, consisting of more than 200 CDA templates, including 24 on document level, all in DECOR format, has been published. Version 1.3 is planned to be released later this year.

The national IG for CDA is currently available also at the main ART DECOR server. HL7 Poland will soon publish there another building block repository for non-normative CDA templates developed by various teams across Poland. Now,

Key founding members of HL7 Poland (left to right): Tomasz Judycki, President of the Polish Chamber of Healthcare IT, Marcin Pusz, Board Member of HL7 Poland, Roman Radomski, Chair of HL7 Poland and Vice President of the Polish Chamber of Healthcare IT, Andrzej Strug, President of the Association of Healthcare Software Providers, Paweł Masiarz, Deputy Director of the National Centre for Healthcare Information Systems and Board Member of HL7 Poland

the Polish National IG for HL7 CDA need to be adopted formally by HL7 Poland as a national localization of CDA standard. The balloting process is probably required, but first we need to make necessary agreements with CSIOZ and other parties to clarify the status of the specification and to agree common strategy for its further development and maintenance.

First things first

Our organization started just couple of months ago, but we are rather active from the very beginning. We have initiated pretty ambitious education program, including two HL7 CDA courses: one for beginners and one for those individuals, who are planning to take CDA certification exam. Our program includes also a workshop on CDA conformance validation and introductory training in HL7 FHIR. All courses are free for members of HL7 Poland. Our organization was also a merit partner of the "IT in Healthcare" conference, organized by GigaCon, that took place in Wroclaw in March, where I had a pleasure to deliver key note speech on HL7 CDA standard. Now we are co-organizing, together with CSIOZ, another conference on healthcare interoperability. HL7 Poland will host the second day of the conference and the core session will consist of case studies of successful implementation of interoperable

solutions, delivered by representatives of selected organizational members of HL7 Poland. The official representation of HL7 Poland will participate in May HL7 WGM in Madrid and at least couple of Polish papers should be submitted for IHIC 2017 in Athens. As an incentive to submit more articles, the HL7 Poland is going to cover the conference fee for all presenting authors from our organization.

HL7 Poland is also one of the founding organizations of Interoperability Council, lately established structure responsible for coordination of strategic eHealth activities in Poland. Polish eHealth agenda is at the critical point now. 2018 is still a target year for implementation of EHR systems by Polish medical providers and go-live for central ePrescription system. Both timelines are not very realistic and most of the stakeholders expect that they will be postponed. At the same time, there is a visible quality change in the approach and methods used by the stakeholders in their attempts to build interoperability in Polish healthcare. HL7 Poland is trying hard to keep the balance between proactive participation in the central projects led by government bodies and delivering support for interoperable solutions implementation in bottom up model.

Roman Radomski, Chair HL7 Poland

A short introduction to the eStandards Roadmap

Standards for European Reference Networks for Rare Diseases – a case study for a new approach to eStandards Development and Adoption

by Petra Wilson

The European Reference Networks for Rare Diseases (ERNs) are networks of healthcare specialists who work together in virtual groups to support the diagnosis and care of patients with rare diseases. The legal basis for ERNs was created by Directive 2011/24/EU of the European Union on Cross Border Care, in recognition of the fact that the low density of rare diseases means that the necessary expertise for a particular condition might not be available in each Member State. In order to address the commitment of the European Union to promote access to healthcare for all European citizens, whilst respecting the right of Member States to organise their own healthcare systems, the objective of ERNs is to allow knowledge and expertise on rare diseases to 'travel' to support a patient, without either the healthcare professional or the patient having to travel. As such, ERNs are entirely dependent on trusted systems of data exchange, and on a standards based eHealth infrastructure. To function well an ERN, which may include a large number of healthcare provider institutions across several Member States, requires **trusted flow of data, information and knowledge** so that patients may benefit from the pooled expertise of an ERN.

Trusted Flow of Data

Patient registries and databases constitute key instruments to advance clinical research in the field of rare diseases, to improve patient care and healthcare planning. They are the only way to pool data in order to achieve a sufficient sample size for epidemiological and/or clinical research.

They are vital to assess the feasibility of clinical trials and facilitate the planning of appropriate clinical studies. They are also critical to support the enrolment of patients in trials and the post-marketing surveillance of orphan medicinal products. Registries depend on the capture, storage and transmission of data in a standardised, semantically interoperable format that can be accessed and trusted by any authorised partner in an ERN. At present, no uniform, accepted standards govern the collection, organization, or availability of these data, and often more than one registry exists for the same rare disease. The need for engagement of Standards Development Organisations (SDOs) on the refinement and promotion of standards for European level registries for rare diseases is therefore paramount.

Trusted Flow of Information

Alongside the data points of a registry, healthcare information in the forms of laboratory results, images, text based records, sound recording and other information artefacts need to be exchanged. Here again, a harmonised uptake of the existing standards for image and record acquisition and sharing is of key importance to the good functioning of ERNs.

Trusted Flow of Knowledge

Bringing together the shared data and information, clinicians need to be able to work together to create new knowledge. It is only in the trusted flow of data and information that knowledge is created, to support the diagnosis and treatment of patient.

The eStandards support action "Standards and Profiles in Action for Europe and beyond" works towards the vision of a global eHealth ecosystem where people receive safe and informed health care using interoperability assets to drive creativity, entrepreneurship, and innovation. The aim is to nurture digital health innovation and enable co-creation of trusted provider-user relationships.

In the eStandards project (www.estandards-project.eu), standards developing organizations join up with eHealth stakeholders to build consensus on eHealth standards

- to create and adopt a Roadmap for alignment, iterative consolidation, and broad adoption of eStandards,
- to contribute to the eHealth European Interoperability Framework by resolving ambiguities embedding quality management, and
- to explore the socio-economic aspects of interoperability standards.

On April 5, 2017, the eStandards project, along with the CEN IPS project, organized a one-day workshop in Venice as part of the IHE Connectathon to explore the proposed model for the eStandards roadmap, in particular the concepts of co-creation, governance and alignment as core components of a roadmap for better standards development and adoption. These are outline below.

The eStandards Project roadmap builds on two core concepts:

- a compass of perspectives, to help SDOs embrace the viewpoints and interest of all eHealth stakeholders,
- a model of collaboration, based on principles of active co-creation, adaptive regulation and stant alignment at all levels of eHealth sharing: data, information and knowledge.

These two components are explored below within the framework of responding to the needs of ERNs

A Compass of Perspectives

It is clear that concerted action is needed from within the SDOs in order to support development and adoption while responding to the needs of ERNs as seen from the perspectives of the patients and informal carers they serve, the clinicians
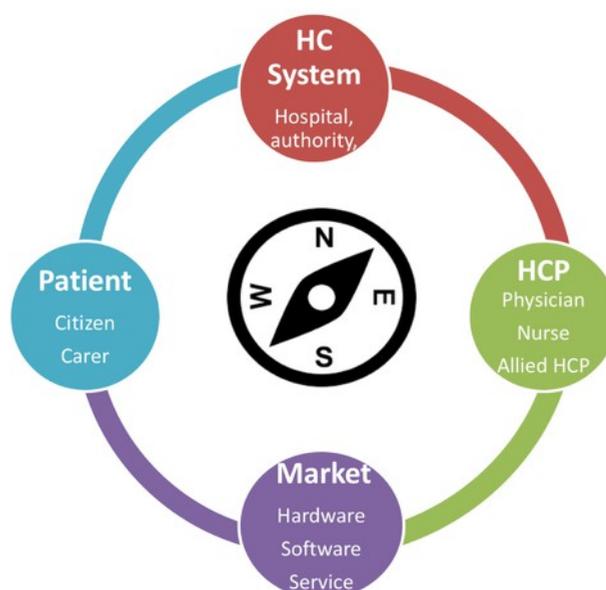
Figure 1: Compass of perspectives

who use them, the healthcare systems who administrate them, and the vendors who sell the products on which they run.

The four groups named in figure 1 represent four perspectives, which together form the healthcare eco-system. All four perspectives must be taken into account as SDOs embark on initiatives to promote the adoption of standards for ERNs. SDOs must therefore have a way of working together with these groups in order to be able to adjust their 'design compass' in such a way that allows them to integrate the perspective of each group, relate those perspectives to one another and develop standards which address the needs of all.

A Model for Development

However, it is not enough simply to see their perspective, new models of collaboration between SDOs and between SDOs and stakeholders must be developed in order to ensure that standards are developed according to the needs of the stakeholders, and that they are able to bring their perspectives directly to bear on their development.

Co-creation is needed at each level to ensure that the solutions developed (whether that is a standard for a data point, or a data exchange interface, or a patient consent capture tool) responds to real needs. Governance is needed to establish the rules that reinforce the trust in the system and ensure that no unnecessary duplication of effort occurs. A facility for constant adjustment and alignment is required so that any item needed in an ERN can be adjusted to meet the changing needs to various stakeholders, can accommodate new discoveries and can adapt to new operational

To design, develop and deploy standards based solution which are properly adapted to a responsive healthcare system, we need a constant flow of interaction between three types of activities:

➢ **Co-creation** between all relevant stakeholders
  ➢ to make it *real* using standards

➢ A supportive and appropriate **governance** system
  ➢ to make it *scale* toward large-scale deployment

➢ The flexibility to **adapt and align** as needs and requirements change
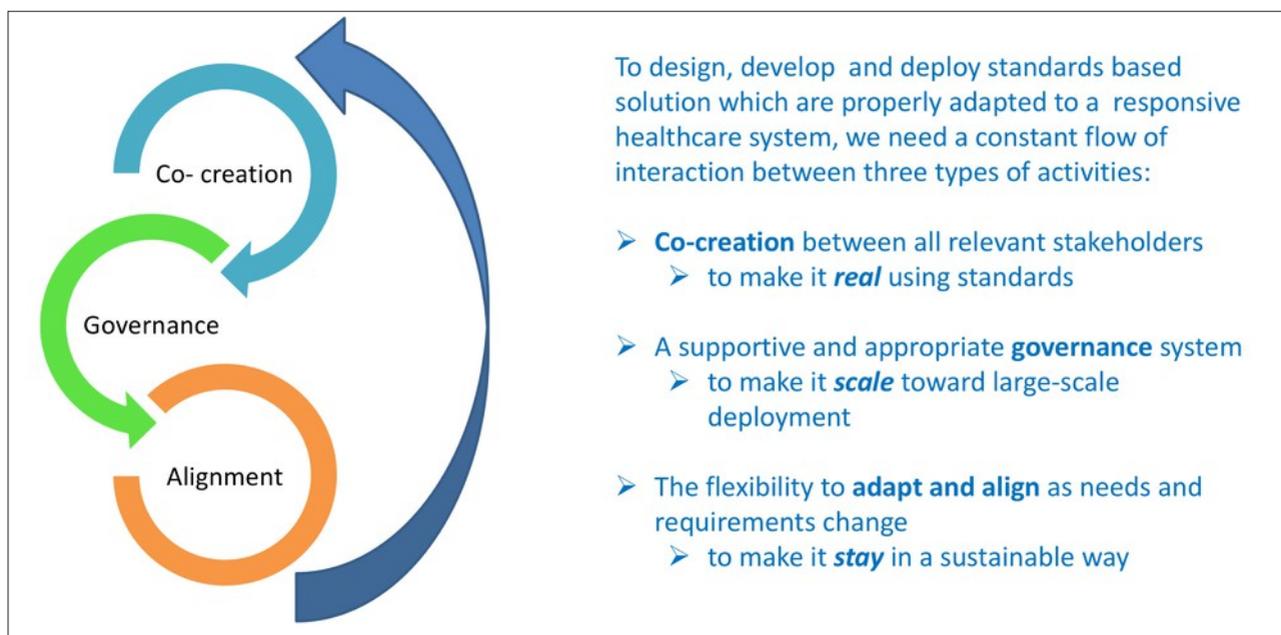 ➢ to make it *stay* in a sustainable way

Figure 2: The secret in the recipe is its constant flow

demands. The secret in the recipe is its constant flow, active co-creation, adaptive regulation and constant alignment never stop, but continue in virtuous cycle which meets the needs of all stakeholders.

The eStandards project has brought together actors representing the perspectives of the four stakeholder groups and has worked with them to look at a range of issues spanning the six layers of interoperability as set out in the Refined eHealth European Interoperability Framework (ReEIF).

This work constituted the first part of building the eStandards Roadmap, and will be available in the annexes to be published with the final Roadmap. Building on the needs identified by the stakeholders the project team are now engaged in developing aRoadmap to help allow SDOs to work together productively, both with each other and with the stakeholders, to apply a model for co-creative standards development and deployment which encompasses the need for governance and constant adaptation as real world needs and opportunities change. The concepts of an Iterative Co-Creation Process, as well as the use of a Perspectives Compass are now being tested on a number of case studies, of which the ERN example outline above is one.

The eStandards project will be debating its roadmap for collaborative standards development in a two-day conference hosted by CEN/TC 251 in Brussels on June 26-27, 2017. Email us if you wish to receive an invitation to participate at euoffice@HL7.org."

Dr. Petra Wilson
Task 3.5 eStandards Roadmap Leader for CEN TC251
Director Health Connect Partners

For more information: www.estandards-project.eu

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HL7 v2+: The Future of HL7 Version 2?

by Frank Oemig

Introduction

HL7 version 2.x is in use since its inception at the end of the 1980s. It has been adopted by global interoperability initiatives like IHE [1] and is therefore part of several Technical Frameworks. The most prominent versions used by IHE are v2.3.1 and v2.5. Obama's Meaningful Use initiative executed by ONC is based on v2.5.1 with enhancements (pre-adoption) stemming from v2.8.1 and v2.8.2. Other countries, e.g., UK, are facilitating v2.4. Worldwide, each vendor is implementing its own mixture of versions.

The community is currently balloting HL7 v2.9 combined with a discussion about what will come after v2.9. A lot of efforts have been placed on the maintenance and further development of the different versions for HL7 v2.x during the past two decades leaving a large burden on the individual editors who tried to keep the different MS Word documents in sync. As we know today, we have not been successful in that regard all the time, an improvement appears to be necessary.

Observing the way other standards (e.g. HL7 V3® and FHIR® [2]) are written, the time has come to take the opportunity for a major step forward and getting rid of old-fashioned conformance constructs. The first step will be done with HL7 v2.9 where chapter 2C (Vocabulary) will not be maintained by hand any more, but generated from a database (Figure 1). A recently completed HL7 project [3] has examined all tables across all v2.x versions and provided detailed feedback about the consistency, asked for clarification and suggested

necessary technical corrections. The ultimate target of this project was (and still is) a common vocabulary model and future maintenance across all HL7 product lines in the same way. The result of this project is worth another article and would lead to far here.
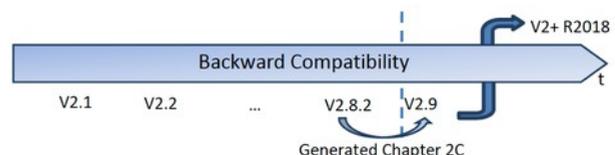
Figure 1: Transition to HL7 v2+

As first step, for v2.9 the tables and their values are consolidated into a solid vocabulary model consisting of vocabulary domains, value sets and code systems. The next step would be the complete generation of the standard from a database. The best input is the HL7 Comprehensive Database that contains the whole documentation already [4]. However, changing the maintenance process should also result in a fresh look of v2.x combined with an upgrade of the conformance constructs to the state of the art: HL7 v2+.

Preparing the Change

A thorough analysis [5] of the conformance constructs used by HL7 v2.x supports the conclusion that a migration to a better and common representation is possible. A first step is to isolate implementation aspects from runtime information. As such, the "R" (required) and "RE" (required but

Value	Description	V2.x compliance	Specialization in profiles
Y	Must support this element, i.e. a development must handle this element	"R", "RE"	Y
N	Element is forbidden	"W", "B", "X"	N
(empty)	Optional	"O"	O, Y, N

Table 1: Value Set for "Must Support"

Value	Description	V2.x compliance	Rep./#
0..0	Forbidden	"W", "B"	
0..1	Optional	"RE", "O"	
0..n	Optional, repeating n-times	"RE", "O"	"Y"/n
0..*	Optional, repeating	"O"	"Y"
1..1	Required	"R"	
1..n	Required, repeating n-times	"R"	"Y"/n
1..*	Required, repeating	"R"	"Y"
n..m	Required, repeating between n to m-times (does not occur yet)		

Table 2: Value Set for "Cardinality"

may be empty) indicators as the cause for long-lasting discussions are to be replaced by "Must Support". Table 1 demonstrates how this conversion is done. The second conversion concerns the transition of "repetitions" into cardinality, table 2 demonstrates how.

Using this machinery, a transition can be done automatically. Another algorithm can be used to convert the Abstract Message Syntax into a hierarchical folder structure (Figure 3).

A New Fresh Look for v2

Following, the current status is demonstrated. More details can be found at [6]. The most prominent visualization of the current enhancements may be seen by the HTML rendering using the newest style that is borrowed from FHIR® (Figure 2).

The topmost navigation bar allows for accessing the different areas of the specification. Each starting page is new and allows an easy entry

Figure 2: Modern Representation of HL7 v2+ (current home page)

Figure 3: Message Structure Representation

into the requested topic. These pages must be created manually because a semantically correct association to the new structure cannot be computed.

New Abstract Message Syntax

Another improvement is the overall representation form that does not use the Abstract Message Syntax (AMS) any more. As can be seen by Figure 3, instead of different kind of parentheses a hierarchy is introduced that can directly be generated from the "old" specification (AMS) using a 4 phase algorithm. In addition, use of "Must Support" and "Cardinality" flags unifies the appearance.

The segments are directly hyperlinked to a complete segment documentation which will be provided on a separate page. The segment groups are indicated with a folder icon and an associated segment group name so that all related segments will become a sub-element thereof.

The "Cardinality" and "Must Support" column only indicate a value, if a constraint is placed onto this segment or group. The default cardinality is 0..* and there is no basic statement about a request to support an element. Therefore, the amount of provided details is reduced without a loss of information.

Segment Representation

The segments are provided in an enhanced way as well. Again, the usage/optionality information in

combination with the repetition indication is replaced by "Must Support" and "Cardinality" and therefore unifies with other standards.

Vocabulary Model

As mentioned in the introduction, a major step forward that is partially provided with v2.9 already is the migration to a common vocabulary model. This is accompanied by an enhanced set of meta data including a movement away from a simple numbering of tables. The common four digit notation will go away in subsequent steps.

This step is visualized by a vocabulary domain name (short name) used in the vocabulary column of the data types and segment definitions (Figure 5). Figure 4 demonstrates the current meta data for vocabulary that is still open for improvements.

Release Cycle

Changing the publication format also allows for a more suitable release cycle. Requests for vocabulary updates enforce an annual release already. Hence, it appears reasonable to release the official standard every year as well.

Next Steps

The whole transition process requires a lot of effort until its establishment and acceptance. This article presents the current status in this long-lasting process realizing that some more steps are necessary:

■ Completing the rearrangement into different domains (ADT, billing, orders&observations, pharmacy, etc.),

Figure 4: Meta data for Vocabulary

Value	Display Name	Interpretation	Comment	Usage Note	Modification Date	Active
F	Female	weiblich			Jul 13 2015	X
M	Male	männlich			Jul 13 2015	X
O	Other	andere			Jul 13 2015	X
U	Unknown	unbekannt			Jul 13 2015	X
A	Ambiguous	mehrdeutig			Jul 13 2015	X
N	Not applicable	nicht zutreffend			Jul 13 2015	X

Seq#	Data Element	Description	Must Support	Cardinality	Length	C.LEN	Vocabulary	Data Type
1	00104	Set ID - PID		0..1	1..4			SI
2	00105	Patient ID	No (withdrawn)					
3	00106	Patient Identifier List	Yes	1..1				CX
4	00107	Alternate Patient ID - PID	No (withdrawn)					
5	00108	Patient Name	Yes	1..1			nameType2	XPN
6	00109	Mother's Maiden Name		0..1				XPN
7	00110	Date/Time of Birth		0..1				DTM
8	00111	Administrative Sex		0..1			administrativeSex	CWE
9	00112	Patient Alias	No (withdrawn)					
10	00113	Race		0..1			PH_RaceAndEthnicity_CDC	CWE
11	00114	Patient Address		0..1				XAD
12	00115	County Code	No (withdrawn)					
13	00116	Phone Number - Home	No (backward)					XTN
14	00117	Phone Number - Business	No (backward)					XTN
15	00118	Primary Language		0..1				CWE
16	00119	Marital Status		0..1			maritalStatus	CWE
17	00120	Religion		0..1			religion2	CWE
18	00121	Patient Account Number		0..1				CX
19	00122	SSN Number - Patient	No (withdrawn)					
20	00123	Driver's License Number - Patient	No (withdrawn)					
21	00124	Mother's Identifier		0..1				CX
22	00125	Ethnic Group		0..1			ethnicGroup	CWE
23	00126	Birth Place		0..1		250#		ST
24	00127	Multiple Birth Indicator		0..1	1..1		expandedYes-NoIndicator	ID
25	00128	Birth Order		0..1		2=		NM

Figure 5: PID segment with new Representation

■ Integrating the two current ITSs (ER7, v2.xml),

■ Harmonizing the data types for vocabulary,

■ Separating data types, vocabulary and segments into different pages,

■ Removing duplicate message definitions by introducing interaction diagrams,

■ Including other artifacts like XML schemas for conformance profiles, and

■ Perhaps allowing for a dynamic behavior, e.g., when working with message structures.

Closing Remarks

Although this change in representing and providing the standard does not impact any running interface, some kind of retention and therefore rejection is anticipated, e.g. because there are no chapter assignments or table numbers any more. Of course, a change in writing the standard is always accompanied with further education requiring time but the benefit in harmonizing the different product lines will pay off in the near future leading to better implementations and more interoperability.

Frank Oemig
Deutsche Telekom Healthcare and Security Solutions GmbH, Mülheim, Germany
HL7 Germany, Cologne, Germany

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Recently published by the Professional Record Standards Body (PRSB)

New Standards to Improve Patient Care Records

by Lorraine Foley et. al.

Patients and service users want joined up health and social care so they can get the right services when and where they need them, without having to repeat their history and needs each and every time. Integrated care needs a coherent care record system – something the NHS and social care currently lacks.

Working with the NHS and social care, the Professional Record Standards Body (PRSB) is developing a series of standards for information in care records, that will allow them to be shared digitally so comprehensive records are available immediately to health and care professionals.

Designed to improve the quality, safety and efficiency of patient care, the PRSB's goal is to share this vision and support clinicians, professionals and patients to make these changes, so that information flows across health and care systems.

In the past year, the PRSB has established itself as the 'go-to' organisation for digital health records, growing its membership with clinical, professional and patient-led groups, represented by an advisory board. Last December the PRSB's progress was formally recognised by NHS Digital and NHS England, culminating in an agreement to fund infrastructure for further work on standards and their implementation. The contract also recognised the organisation's strategic role as an authority on the development and adoption of standards.

To date, the PRSB has published a series of five standards for use in health and social care. These include standards for the clinical structure and content of patient care records, professional guidance on the structure and content of ambulance records, the e-discharge summary standard, the crisis care standard and the mental health summary discharge standard.

The standards are developed through a series of workshops and surveys, to ensure they closely reflect what professionals and patients need. Approximately one million people are seen every 36 hours in the NHS, and their care records are fundamental to good care. Research shows that both patients and professionals want their records to be available at the time the patient is receiving care, and these new standards are a step forward in providing better care through digital technology.

In 2017-2018, the PRSB will be supporting the work of NHS England and NHS Digital, developing standards for child health and outpatient letter standards, amongst others. The organisation is also committed to offering support for standards development and adoption in Scotland, Wales, Northern Ireland and local communities in England.

Current priorities are focused around standards for transfers of care, but the PRSB has also been working on standards which will help to coordinate care planning for patients with complex needs, such as people with long-term conditions or those receiving end of life care. Standards for recording child health events including results of immunisation and screening tests are being developed, and an innovative information hub is being created to store the information. In addition, the PRSB has expanded its work with social care, as well as the NHS.

PRSB Standards

The PRSB develops and helps to implement standards for the structure and content of care records. These cover, for example, hospital referral letters, handover communications, discharge summaries, and inpatient and outpatient letters.

The standards are developed using published evidence and consultation with doctors, patients, the social care system and allied healthcare professionals. The standards are regularly reviewed and updated. As agreed with the Academy of Medical Royal Colleges, the latest published and approved set of standards are Standards for the clinical structure and content of patient records.

The PRSB's strength in developing, maintaining and implementing standards reflects our broad network of experts and membership, including organisations representing patients, service users and carers; doctors and nurses; other health professionals; social care professionals; and developers and suppliers of software used in health and social care. Members are drawn from across the UK - England, Northern Ireland, Scotland, and Wales.

This strength in expertise ensures that new standards are practical and realistic, and ensure that a comprehensive picture of care information can be accessed easily by anyone, when and where they need it.

PRSB's networks provide additional support for the PRSB to help to implement the standards that they have developed.

Moving forward, the PRSB recognises the need for a patient-centric approach, with emerging areas of work including the facilitation of self-care through patient-held records and patient-facing apps and devices. Other priorities include ensuring that information can be used for research and audit purposes and considering how to resolve complex issues, such as diagnostics reporting, recording consent, allergies and medicine dosage.

The PRSB is currently working with HL7, exploring a new collaborative approach to developing Fast Healthcare Interoperability Resources (FHIR) profiles to support its standards. While existing record standards have been based on transfers of

records between professionals and patients/carers. They're also designed to support health apps and opportunities for self-management of care, particularly for people with long-term conditions.

The PRSB is now working with professionals to ensure the health and social care sector is actively adopting standards as an essential foundation of integrated care, rather than imposing them. Over time, the organisation is hoping to establish these standards as 'the norm', rather than the exception, with clinicians, professionals and patients at the heart of these changes. Without their active involvement, the potential benefits of shared records and the investment in IT will not be successful.

Reducing the burden of implementing change is essential for the success of standards, and the PRSB will be working with partners including the CCIO network, vendors, member organisations and local health and care teams to address this. The organisation is providing definitive implementation guidance for standards and will be exploring how to embed these standards into education and training programmes for health and social care professionals, as well as inspiring groups, such as nurses, junior doctors and social workers to lead the change.

Lorraine Foley
Chief Executive Officer of the PRSB

Lizzie Cernik
Communications officer

care and structured documents, such as discharge or admission summaries, FHIR supports the transfer of data at a more granular level, and is suited to supporting new models of care and interoperability.

The future FHIR-based standards will facilitate vital information sharing such as real-time shared

Meeting Highlights

Phast hosts HL7 International Patient Summary Meeting

by François Macary

Initiated in the context of the ongoing cooperation between the EU and US, and extended to other continents such as Oceania, the HL7 International Patient Summary (IPS) project aims at the definition of a standard patient summary exchangeable across borders to support the delivery of emergency and unplanned care to persons out of their residence country. This HL7 project is sponsored by the Structured Documents Work Group and co-sponsored by the Patient Care, Templates, Emergency Care, Electronic Health Records, Healthcare Standards Integration and Vocabulary Work Groups as well as by the HL7 International Council and HL7 International Foundation. The expected initial deliverable of the project is an Implementation Guide (IG) with a set of CDA R2 templates and the associated value sets to enable the cross-border exchange of patient summaries as standardized electronic documents. It is anticipated that an equivalent FHIR IG and set of FHIR profiles and value sets will be produced soon afterward.

The HL7 IPS project is tightly coordinated with the IPS project mandated to CEN TC 251 by the European Commission. Illustrating this coordination, CEN TC 251 actively participated on the first day of the 3-day IPS intensive working session held in Paris and hosted by the French organization Phast on March 21-23, 2017. The HL7 project is producing the implementable patient summary specification, based on CDA R2 and a set of reference terminologies, and the CEN prEN work item references the HL7 specification and focuses on its implementation in the European context.

The objectives pursued and fulfilled by this Paris working session were to confirm some key orientations and to close a number of open issues that had been identified and documented during the weekly calls over the preceding months. This article highlights four of those objectives and outcomes:

1) International reference terminologies for all the value sets. The "I" of IPS logically led to this structuring choice, which was confirmed in Paris. To be universally exchangeable, a patient summary must rely on multilingual reference terminologies. This is for two reasons: a) Reference terminologies are international. b) Reference terminologies represent the state of the art of coded vocabularies within their semantic scope. The IPS project will strive to the extent possible for the availability

and use of globally accessible standards with licensing at no cost, according to one of the agreed CEN and HL7 IPS principles. Thus, the number of countries that will be able to use such a patient summary will be maximized, irrespective of their local adoption of these terminologies. When a particular reference terminology is not used (yet) in a country, the local or national interface terminologies that are used by the country will be mapped to it. In an instance of the patient summary, the primary code of any coded element, if known, will be obtained from the reference terminology. Alternate codings that rely on an interface terminology may be provided as translations included in the coded element.

2) The value sets of the IPS specification are built upon a set of reference terminologies, with in particular these standards: LOINC for the type of sections of the patient summary and for the coding of its observations, UCUM for all units of measure, terminologies selected by the IDMP standard, where applicable, and SNOMED CT for most of the remainder.

3) Furthermore, the representation of "condition or activity unknown" and of "condition or activity known absent" has been normalized for the IPS by leveraging the expressiveness of SNOMED CT, as opposed to relying on specific mechanisms of the underlying syntactical standard (such as nullFlavor and negationInd for CDA). The main rationale for this choice is to provide one single method to express either the presence or absence of a particular condition (e.g., an allergy) or activity (e.g., an immunization), or the lack of knowledge regarding this kind of condition or activity, resulting in a more robust and easily implementable specification. The other rationale is to have a representation of the clinical content of the patient summary which is less dependent on a particular format or syntax, enabling a more practical path to transforming and exchanging data from one standard format (e.g., CDA R2) to another (e.g., FHIR).

4) The IPS specification (CDA templates and value sets) is built in ART-DECOR in combination with MediaWiki. The formal and processable specification from ART-DECOR will be published on the IPS project MediaWiki site, and enriched there with the additional textual explanations as needed. Then, an XSL style sheet will be used to produce the PDF format of the specification, which will be submitted for the HL7 ballot. All three forms of the specification (ART-DECOR, MediaWiki and PDF) will be accessible online.

After these three days of fruitful production, the team expects to keep to the project schedule with the intent to publish the IPS CDA Implementation Guide (UV realm) in the upcoming September 2017 HL7 ballot. The equivalent publication of the standard as a FHIR IG is hoped to be able to follow soon in a future ballot cycle.

François MACARY
Phast – Large scale semantic
interoperability manager
IHE International – Technical co-chair
of PaLM committee
Interop'Santé – Chair HL7 France

Terminology Mapping Tool minimizes interpretation failures in exchanging diagnosis and treatment information

by Bert Kabbes

The Dutch National Care Institute, in cooperation with HL7 The Netherlands, several national care institutes and software developer Tagologic, recently developed a "real world working prototype" of a mapping tool, which translates the terms and codes of any given terminology standard into any other terminology standard. This mapping tool helps to improve the quality of the information exchange of medical diagnoses and treatment information related to the transfers of patients between care givers in various settings. The tool helps to minimize misunderstandings and wrong interpretations of the specific terminology terms used by different care givers and care organizations in healthcare chains. It also helps to decrease the administrative burden of (manual) translating terms and codes from one terminology standard to other terminilogy standards. It is an example of the innovative use of a combination of existing, general smart-IT solutions for healthcare specific domains. HL7 The Netherlands has been involved because of it's knowledge and experience with terminology standards as well as practical advises how to best implement medical information in HL7 standards.

Improvement of information exchange between cure and care

The improvement of the quality of diagnostic and treatment information between the cure sector (hospitals) and care sector (social care, nursing homes, eldery care, etc.) is one of the top priorities of the Dutch Ministry of Health, the national Healthcare Inspection Authority as well as healthcare organizations in general. In 2016, a first project was completed, by which the national "i-Standards" for healthcare information specifically in the care sector were mapped to HL7 V2, the national standard in the cure sector. This mapping project enables for an automatic and consistent translation of all general and administrative patient data from i-Standards formats into HL7 V2 formats and backwards.

By the end of 2016 a second project has been initiated, aiming specifically to bridge the gaps between the various different terminology standards used in the cure and in the care sectors. Virtually all medical and treatment disciplines are using their own specific terminology languages and standards, as well as their specific coding. However, in many cases, care givers are using free format text, using terms and abbreviations invented by themselves. Research and literature show that at about 20–25% of the transfers between cure and care, the terms used for medical diagnosis information as well as the related treatment information in patient summaries, discharge and transfer documents, are (partly or fully) misunderstood, wrongly interpreted or even unknown by the receiving care giver.

Next to misunderstood or misinterpreted diagnosis and treatment information, resulting in risks for the patient's treatment, there are also negative effects regarding administrative, statistic and billing data. In many cases, medical transfer information is translated, re-entered and stored manually every time a patient is tranfered or treated by different care givers, diagnostic and treatment codes cannot be aggregated on a national level to serve for statistical information and billing information due to different terms and codes used, resulring in a situation where data cannot be compared consistently to budget information by insurance companies. These effects are costly, increase the administrative burden and consume valuable time of care professionals.

Bridging the terminology gap

As a result of many changes in the Dutch healthcare system structure as well as the use

of IT technology, care givers in all disciplines are exchanging an increasing amount of medical and treatment information at an increasing frequency. Every care discipline is using its own specific terminology standard. Some of these terminology standards have been formally mapped such as ICD-10 and Snomed-CT, but the majority of terminology standards are not (yet) mapped. The formal mapping of terminology standards is a cumbersome, time consuming and costly exercise which in general will take several years of hard work by volunteers of the many disciplines involved. The resources required to perform these immense jobs are very scarce, resulting in a situation where it will take at least some 10-15 years time from now to formally map all existing terminology standards in The Netherlands into each other. To be followed by several years of acceptance and implementation. Meanwhile, the failures and risks of misunderstanding as well as misinterpretations will continue, which has been considered as not acceptable.

It was therefore concluded that a creative approach to bridge this terminology mapping gap would be very useful, which was the start of a project that aimed for the search of ways to help to bridge this gap and thus to minimize the current negative effects and risks of terminology differences between disciplines by using modern, advanced software tools.

Basic functionalities of the terminology mapping tool

The developed terminology mapping tool is based on a client-server architecture. Initially the tool pre-indexes the terms and codes of any relevant terminology standards and stores these indexes on the server. Terms and codes of those standards which already have been formally mapped and have been accepted by professional disciplines are specifically marked by the tool, which markers will be shown in the user interface. Currently the pre-indexed terminology standards in the tool comprise: ICD-10, Snomed CT, ICPC, Radlex, Omaha, ATC, ICF and LOINC. Other terminology standards can easily be added.

The basic user functionality of the mapping tool is briefly described in three steps, as follows. The first step is the selection and import of any digital (or scanned) source document which contains terms that the user wants to map to the user's own standard or any other preferred standard(s). The source document may be in any format, such as Word, .pdf, HL7 V2 format, OCR or else. The imported document is shown in the tool screen,

after which the user has a number of options as to how the tool should map the content of the document. First, the user selects one or more terms in the document by just clicking the terms that should be mapped, or the user can select the full document to be mapped. Secondly, the user selects one or more terminology standards which the tool should use to interpret and map the selected terms in the source document. Finally, the user selects whether the mapping should be on exact term(s), part of the terms or beginning or end of term(s). This completes step 1.

In the second step, the tool searches for the selected terms and user preferences in (all of) the selected terminology standard(s). The results are presented in a screen, displaying the comparable terms in the selected standards. Depending on the number of selected terms and terminology standards, the amount of results found will vary. The user then selects the most appropriate term(s) in the preferred standard.

In the third step, the tool will insert the selected term in the original source document just after the original term in the format [standard / term / code]. The document will then be exported in any preferred format, equal or different from the source document. The user can store this document and/or use the exported document for further distribution. This way the original terms will always remain unchanged (which is a legal requirement): the mapped i.c. translated term in the selected standard will appear as an addendum.

In addition to the basic functionality as described above, the tool offers several extra options, such as: escape to the original standard source by just clicking on any displayed term, add synonyms for terms, show formally mapped terminologies, etc.

Key issues for using the mapping tool

Some key issues of the use of the mapping tool are:

- The user is fully responsable for selecting the appropriate term: the tool only presents which terms in which standards equal the selected terms in the source document. The tool itself will never "decide" nor "select" a mapping.

- Users should be classified as "key users" or "users", where only key users have the rights to select and define and select terms. The tool provides for various authority levels of users.

Prime users and use cases

The prime users are:

- Care givers, triage of intake personnel, transfer departments: received transfer documents can

be checked and translated to the preferred own terminology standard

- ■ Medical administration departments: translate terms in any standard, free text and personal text into the terms and codes of the terminology standard which is required for internal and external data collection and statistics

It should be clear that users of the mapping tool should have a good knowledge of at least the terminology standard of their own discipline, sector or organization.

Actual status and follow-up

As of April 1, 2017 the mapping tool has been released for Beta-testing by a selective group of key users from the prime user categories is indicated above as well as terminology specialists.

The results of the Beta-testing period will be evaluated and will obviously lead to changes

and additions to respond to the functional requirements of the users.

The final version of the mapping tool will be presented at a national conference in June 2017. Meanwhile the tool will be presented at a number of conferences, congresses and healthcare IT symposia and fairs.

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

References and contact

Further information about the mapping tool can be obtained through Bert L. Kabbes, Chair of HL7 The Netherlands and member of the Project Team via kabbes@wxs.nl.

OPENMEDICINE

ePrescribing Across Borders: Improving Patient Safety, Solving the Delivery Problem

The problem

by Karl A. Stroetmann

The epSOS pilot services to exchange ePatient Summaries and ePrescriptions between member states of the EU basically solved the message transfer problem. However, they en-countered a serious 'delivery' problem: the univocal identification of a medicinal product that was noted in a prescription from a given country by a pharmacist dispensing it in another country. For safe dispensation to the patient, s/he must be able to select from the medicinal products available in that country the one that matches the prescribed product.

The fragmentation of national markets for medicinal products lies at the root of this identification problem. About 600,000 different medicinal products are marketed across the Union, but even in a large country like Germany only ca. 50,000 are readily available. However, the same trade name may be used in different countries for different sets of ingredients adding safety concerns to naming issues. Shortages in national markets are addressed through imports and add to these concerns.

Options to identify medicinal products in a prescription

The identification/delivery problem is also impacted by how a country regulates the way in which medicinal products can be specified in a

prescription. Most member states provide three basic options for identification:

- a) the name of an innovator ("given") brand name

- b) a generic brand name ("common name plus company name")

- c) prescribing by active ingredient only making use of the "international non-proprietary name" (INN) or the "anatomical-therapeutic-chemical (ATC) classification"/code

Using the name or code of a nationally predefined subset of medicinal products (also called cluster prescription) is presently available in only four countries.

Such prescriptions may require the specification of additional attributes like quantity/package size, pharmaceutical form, strength, route of administration etc.

A prescribed medicinal product and all its attributes may also be univocally identified just by its package identifier, like usage of the GS1 GTIN (Global trade item number) in Poland.

The solution

As a first, key step towards solving the identification challenge, the ISO standards family on "Health informatics – Identification of medicinal products (IDMP)" was created with the active engagement of regulatory agencies like EMA and FDA as well as of competent national authorities. These ISO IDMP standards establish definitions and concepts, and describe data elements and their structural relationships that are required for the unique identification of:

- Medicinal products (MPID/PCID) – ISO 11615

- Pharmaceutical products (PhPID) – ISO 11616

- Substances (Substance ID) – ISO 11238

- Pharmaceutical dose forms, units of presentation, routes of administration and packaging – ISO 11239

- Units of measurement (UCUM) – ISO 11240

As a further step towards concrete implementation, EMA and FDA together work on European and trans-Atlantic semantic assets (codes) relating to four domains of master data in pharmaceutical regulatory processes: the so-called SPOR data on

- Substance data (describing the ingredients of a medicine)

- Product data (describing the marketing and medicinal information relating to a product)

- Organization data (providing the contact details of organizations and individuals responsible for various aspects of a medicine over its life cycle)

- Referential data (providing controlled vocabularies, e.g. dosage, pharmaceutical forms, country codes, package codes, weight codes)

The logical model of how such information on packages, medicinal products, pharmaceutical products and substances may be synchronized and exchanged across member states of the EU, their medicine agencies, and providers of data bases.

Here it is important to note that the Commission Implementing Regulation (EU) No 520/2012 on "the performance of pharmaco-vigilance activities" already obliges various players to apply ISO IDMP standards and other terminologies for certain application fields as of July 2016.

As illustrated in Figure 1, if the local medicinal products data base used by a physician's prescribing system is synchronized with the core identifying and fully coded attributes available from the EMA data base (or if it can access these data as needed), then any prescription or other clinical document can be filled automatically with all the IDMP identifiers without any additional effort. Whether the prescription specifies a GTIN, or a brand name, quantity and other identifying attributes, or an INN/ATC code, it will be possible to univocally identify the active substance, the PhPID, and – if prescribed and available in the foreign country – also the medicinal product ID (MPID) and package ID (PCID).

Roadmap towards ISDO IDMP implementation across the Union

At the MS level, it is first of all a political decision when and how to implement IDMP in the context of both national and cross-border healthcare services. EMA (and FDA) are moving for-ward in line with agreed roadmaps and availability of resources, but they have no power to "force" this change onto national competent authorities.

Nevertheless, it will be prudent to not engage in short-term solutions but rather to aim for a future-proof and stable cross-border healthcare services delivery system, in sync with European law and the international regulatory environment. At the same time, such an approach would be aligned to the ethical imperative of optimizing patient safety.

The following three-step generic approach will be helpful in sketching such a pathway:

1. Exchange of IDMP compatible, core identifying and coded attributes

As a first step, as long as the various IDMP IDs are not yet available, an exchange of IDMP compatible, core identifying and coded attributes
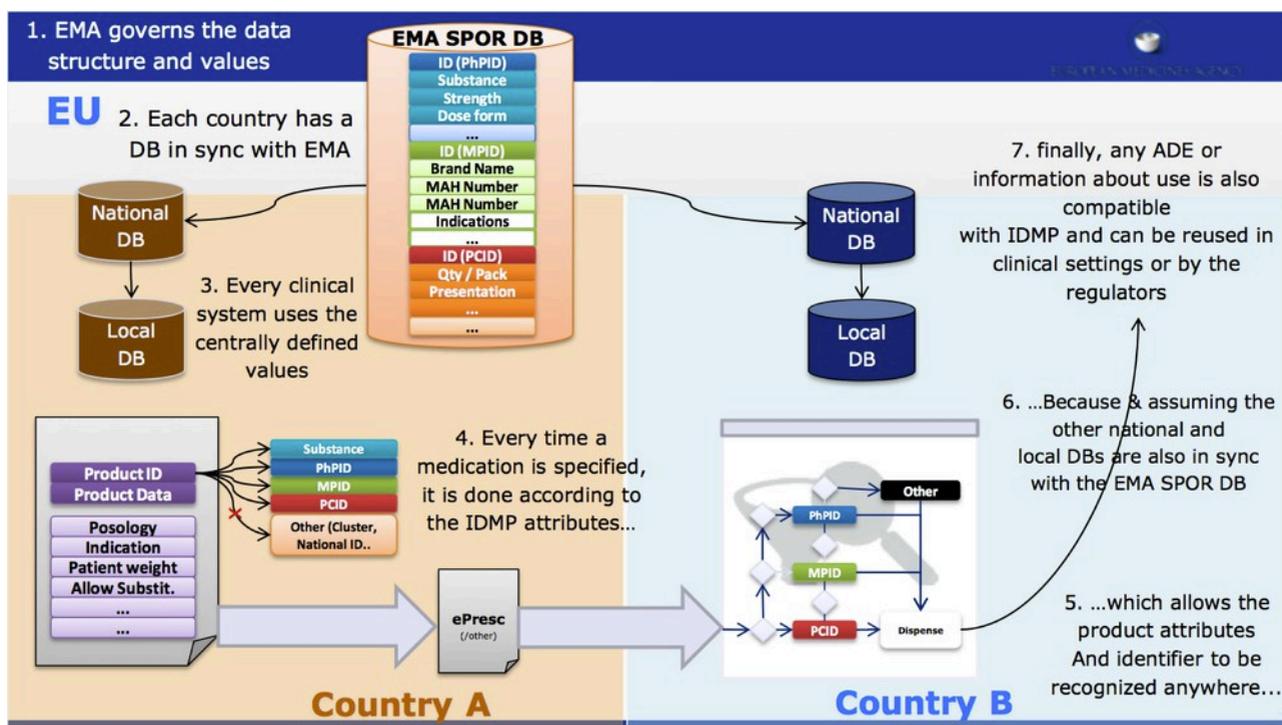
Figure 1: Synchronizing data on medicines across the European Union, Source: © EMA 2016

will suffice to solve the delivery problem of the starting CEF (Connecting Europe Facility) ePresription service. In cross-border ePrescriptions medicinal products (and/or pharmaceutical products) can be specified by using their respective attributes, provided that

- a common minimal set of identifying, IDMP compatible attributes has been agreed among the initially participating countries and players

- (only) these attributes are fully coded by the same value sets, i.e. they have the same meaning in the participating countries (which may require mapping in some instances, e.g. by making use of the EMA/FDA SPOR data bases)

- preferably, they should also have been quality assured/validated by the responsible national competent authority.

Mapping national attributes and identifiers into IDMP

A second step would involve implementing a conversation service towards IDMP compatibility in participating member states. This will require deploying a mapping service which, matches the set of national attributes and identifiers into the IDMP set of attributes and identifiers.

As an alternative, a single European conversion service would have to contain the attributes and logic for all member states involved.

This approach is appealing for a phased implementation by member states, not requiring all to move at the same time.

Full implementation of IDMP

As a longer term endpoint, it is envisaged that all member states adopt and implement the full IDMP terminologies, data elements and sets, formats, and standards/encoding systems and value sets. This would render a mapping service dispensable. National IDs may still exist for other purposes like reimbursement, etc.

Depending on the national situation and the propensity to fully adopt (or not) the data base provided by EMA, national medicinal product databases, ePrescribing software and ePrescription infrastructures would need to be updated, which may require quite some effort.

As already mentioned earlier, all of this will not require basic changes in the prescribing behavior of healthcare professionals. The correct coding and synchronization of data bases and messages sent across borders will be facilitated and assured by the electronic services under development or already proven, e.g. in the context of epSOS.

Karl A. Stroetmann and the openMedicine team

Final recommendations of the project ASSESS CT give answers on future-oriented developments

SNOMED CT within a strategy towards eHealth Interoperability in the EU

by Heike Dewenter et. al.

The goal of ASSESS CT is to make a significant contribution to the debate on semantic interoperability of eHealth services in Europe. It focuses on SNOMED CT and studies its potential as a core reference terminology for EU-wide deployment.

Methodologically, the adoption of SNOMED CT as a core reference terminology has been scrutinised against two alternative scenarios:

- To abstain from actions at the EU level

- To devise an EU-wide semantic interoperability framework alternative without SNOMED CT

The main outcomes of the 1.5 year-long project in 2015/2016, with 14 European partners, have been summarized and published in five final recommendations:

Recommendation 1

Any decision about the adoption and role of terminological resources, including SNOMED CT, must be part of a wider, coherent and priority-driven strategy for optimizing the benefits of semantic interoperability in health data, and of the overarching eHealth Strategy of the European Union and its Member States.

A European terminology strategy should be part of an overarching European eHealth strategy. The strategy should support the principles of collecting clinical data once and using them multiple times, where allowed and required. Thus, administrative, public health and research information should almost always be derived from routinely collected clinical information.

This strategy should have Member State commitment and should consider human and financial resource implications, incentives, as well as technical and semantic requirements.

Recommendation 2

SNOMED CT is the best available core reference terminology for cross-border, national and regional eHealth deployments in Europe.

A main advantage is its content coverage, which is superior to any other single terminology, making it the most complete point of reference for health related concepts. Another advantage of SNOMED CT over a set of other clinical terminologies is its principled ontology-based architecture with a logic-based coordination syntax.

Recommendation 3

SNOMED CT should be part of an ecosystem of terminologies, including international aggregation terminologies (e.g., the WHO Family of Classifications), and including local/national user interface terminologies, which address multilingualism in Europe and clinical communication with multidisciplinary professional language and lay language.

No country sees SNOMED CT as a standalone solution, but rather as an important part of the national terminology infrastructure.

Recommendation 4

The adoption of SNOMED CT should be realized incrementally rather than all at once, by developing

terminology subsets that address the interoperability requirements for prioritized use cases, and expanding this set over a number of years.

Such incremental use, but across all Member States, might be subject to specially negotiated licences on behalf of the whole of European Union.

Solutions must be in place for legacy conversion, guaranteeing the continued exploitation of historical data, for user interface terminologies, and for assuring the continuation of global mortality and morbidity statistics.

Recommendation 5

Mechanisms should be established to facilitate and co-ordinate European Member State co-operation on terminology and semantic interoperability, including common areas of governance across national terminology centres, eHealth competence centres (or equivalent national bodies).

This should maximise the value of Member State and SDO alignment on the approach to advancing semantic interoperability, including the implementation and deployment of SNOMED CT.

Based on these insights, ASSESS CT formulates recommendations for Standards Development Organizations (SDOs), like:

- ◼ SDOs and other relevant specification developers should each prepare clear and stakeholder-friendly guidance on how their various standards, specifications and profiles that represent or communicate clinical information fit together and can be used concurrently as part of a coherent semantic interoperability strategy, from the perspective of different stakeholder viewpoints and needs.

- ◼ SDOs should collaborate with clinical professional organizations, the health systems of European Member States and with the European Commission in supporting the development and maintenance of end user interface terminologies in the native languages of health and care actors and patients, across Europe.

- ◼ All SDOs contributing to the development and maintenance of semantic interoperability assets should be prepared to contribute to strategic and governance structures that become established to support Member State co-operation in the adoption of a single core reference terminology for Europe.

- ◼ SNOMED International (the new trade name of IHTSDO) should negotiate, with the eHealth network and the European Commission, flexible licence arrangements to support Member States, individual ICT vendors and non-vendor

bodies with adopting SNOMED CT as a reference terminology, at varying scales of piloting and actual use.

- ◼ SNOMED International, European Member States and the European Commission must support and fund the development of training resources and adoption support tools (such as mapping tools) to facilitate the wider high-quality adoption of SNOMED CT as a reference terminology; these should be targeted at enabling stakeholders to contribute in each of their roles to better data quality and semantic interoperability, rather than only how to use the specific terminology.

The prioritization of the key-drivers behind semantic interoperability, at European and Member State levels, is important in directing the downstream priorities of an implementation strategy.

An elaborate communication strategy with the scientific associations of health care providers (medical sub-disciplines, primary care physicians, allied health personnel) is needed to inform, educate and convince with regard to the necessity of semantic interoperability, well-structured electronic health records, performant end user terminologies, suitable international reference and aggregation terminologies, and clinical documentation skills.

Further project information on www.assess-ct.eu as well as the project brochure http://assess-ct.eu/final-brochure.html

Heike Dewenter, Sylvia Thun
Niederrhein University of Applied Sciences, Krefeld, Germany

Veli Stroetmann, Empirica GmbH, Bonn, Germany

Robert Vander Stichele, Dipak Kalra
EuroRec Institute, Gent, Belgium

Annual Conference of HL7 Austria

The annual conference around HL7 Austria's annual assembly has become an insider's tip in the eHealth community. The small but mighty event, which is always held at a "Heuriger" (a local wine maker's tavern), offers a day full of presentations balanced between information, education and networking and has attracted more and more people over the last years. The 8th edition was characterized by the celebration of the 10th anniversary of HL7 Austria and more than 100 participants represented a new record attendance.

More than 20 speakers from four countries presented highly interesting topics around the importance of standardization and HL7 in the eHealth area. The presentations covered a wide range and showed what goals have been reached so far and what needs to be done to support interoperable electronic health data exchange in the future.

Besides international and EU projects (presented by Catherine Chronaki and Philip Scott) and Austrian projects like the ELGA, the e-Immunization Record, the Survivorship-Passport for oncology patients or the Austrian eHealth-Telemonitoring Platform, standardization and the role of HL7 naturally was an essential focus of the event. Based on general requirements for interoperability and a comparison of HL7 standards presented by Bernd Blobel all major HL7 versions were put on stage - from new aspects on HL7 V2 over V3 CDA R2 tools and implementation guides to first projects using FHIR. "Alternative" topics like a general view on integrated care or the role of eHealth for the

ICT landscape in Austria and Europe made up for a very interesting mix of information for the participants.

"We are working hard to offer a dense program with highly interesting up-to-date topics", Dr. Sabutsch – chair of HL7 Austria an organizer – says, "... therefore, this year we also tried a new kind of presentation format– the flashlights, which are short five minute presentations about key facts of a subject and - I think - were very appreciated by our participants". In addition, the two workshops on HL7 V2 and HL7 FHIR offered the day before and after the conference reached high attendance.

A fixed highlight for five years now is the "Student Award" ceremony. HL7 Austria awards the prize to students for their bachelor, master and PhD degree theses on HL7 standards. The winners receive a money award and have the opportunity to present their work to the public.

In their traditional double act at the end of the conference, Stefan Sabutsch (chair HL7 Austria) and Alexander Mense (TC chair) recalled the last 10 years of HL7 Austria. Their talk ranged from the initial spark by Frank Oemig (HL7 Germany) in 2006 over all the several balloting activities, activities offered like the eLearning courses, up to the current event. At the end their acknowledgement
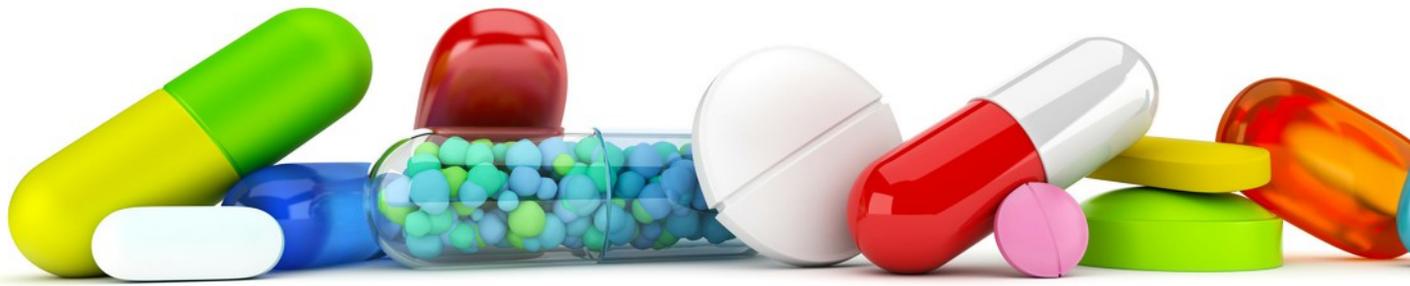
> "HL7 Austria – it's not us alone and it's not the board – HL7 is you and all the people and organizations having supported us over the last 10 years with their work and engagement! Thank you very much!"

Further look?

The twitter time line is available under #HL7JT2017

The photo gallery is accessible here:
 http://www.hl7.at/das-war-die-jahrestagung-2017/#tab-id-2

The Impact of openMedicine Findings in the European and in the International Patient Summary

by Giorgio Cangioli

This article provides an overview of the impact of the openMedicine findings in the standardization, as discussed during the OpenMedicine workshop in Stockholm on 20th December, 2016. This article focuses in particular to the impact of IDMP in the Patient Summary, with a special view to the European Patient Summary (Digital Service Infrastructure for eHealth project eHDSI [1]) and to the International Patient Summary specifications.

Introduction

The OpenMedicine project

The openMedicine project ([2]) is a two years European H2020 project, ended at the begin of 2017, aiming to "better enable cross-border healthcare delivery, particularly the exchange of ePrescriptions and safe dispensation of prescribed medicinal products, the openMedicine global initiative advances the unique identification of medicinal products (MPs) and thereby patient safety in cross-border settings."

The Stockholm workshop

On 20th December, 2016, the Swedish eHealth Agency hosted the "OpenMedicine Workshop Implementing ISO standards for the univocal identification of medicinal products (IDMP) in Europe - The impact on Sweden and Scandinavia". This workshop was part of the events organized by

OpenMedicine to reach out to EU member states, their national agencies and stakeholders to increase awareness of the globally ongoing activities in the domain of medical product identification and discuss further steps needed. Particular focus was put on whether the implementation of openMedicine results would be feasible, realistic and useful at the national level, identifying potential challenges and costs. In particular this workshop aimed to :

- provide a concise overview of ongoing developments in medicinal product identification

- raise awareness on the impact of the pending IDMP roll-out in EU member states

- explore the implications and potential impacts of implementing global standards for the univocal identification of medicinal products (IDMP) at the national level

- explore the expected added value for medicinal care, public health, clinical decision support, pharmaco-economics, and pharmaco-vigilance
- explore further steps and activities necessary to fully exploit the benefits foreseen.

The workshop involved about 25 experts coming from northern European countries (Norway, Finland, Estonia, and Sweden).

IDMP and Patient Summary

As described in previous articles [3] , the IDMP standards were identified by the openMedicine project as the reference standards to overcome the issues of identification of medicinal products experienced for the Patient Summary and ePrescription European services. The implications of using IDMP attributes and identifiers for other purposes [4] were investigated, as well as the existing gaps in the available standards in the regulatory-clinical information loop [5]. The results of this high level analysis was reported in the openMedicine deliverable D3.2 [6] and presented in the Stockholm workshop during the "The impact of openMedicine findings for standardization" session (figure 1).

The main question addressed during this session was however what can be done meanwhile, considering that years will be needed before most of the IDMP identifiers and attributes will be available for actual use. In this discussion about

the migration path towards the full adoption of ISO IDMP, the European services for the patient summary within the Digital Service Infrastructure for eHealth (eHDSI [7]) and the International Patient Summary (IPS) standardization project(s) [8] were taken as study cases.

For the scope of the International Patient Summary, the Allergies and Intolerances and the Medication Summary sections seems to be the most affected by the absence of common identifiers and vocabularies about products, substances and other attributes. The migration path for those concepts was therefore discussed starting from attributes as the (administrable) dose form, the Route of Administration and so on (see figure 2).

For these attributes there was a common agreement about the possibility of using the EDQM Standard Terms [9]; even if, it was highlighted the need of a better understanding about the implications of extending the scope of EDQM standards beyond the regulatory purposes (above all in term of governance of this code system).

For what concern the substances all agreed that long term solution will be the adoption of Global Ingredients Archiving System (GInAS) identifiers [10]. Different approaches for the short and medium term solutions were however discussed: the usage of substance names (as suggested by OpenMedicine); the adoption at the European Level of the EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) [11] as interim solution; the potential usage of SNOMED CT for substances in the IPS (figure 3).

Figure 1: openMedicine and related projects
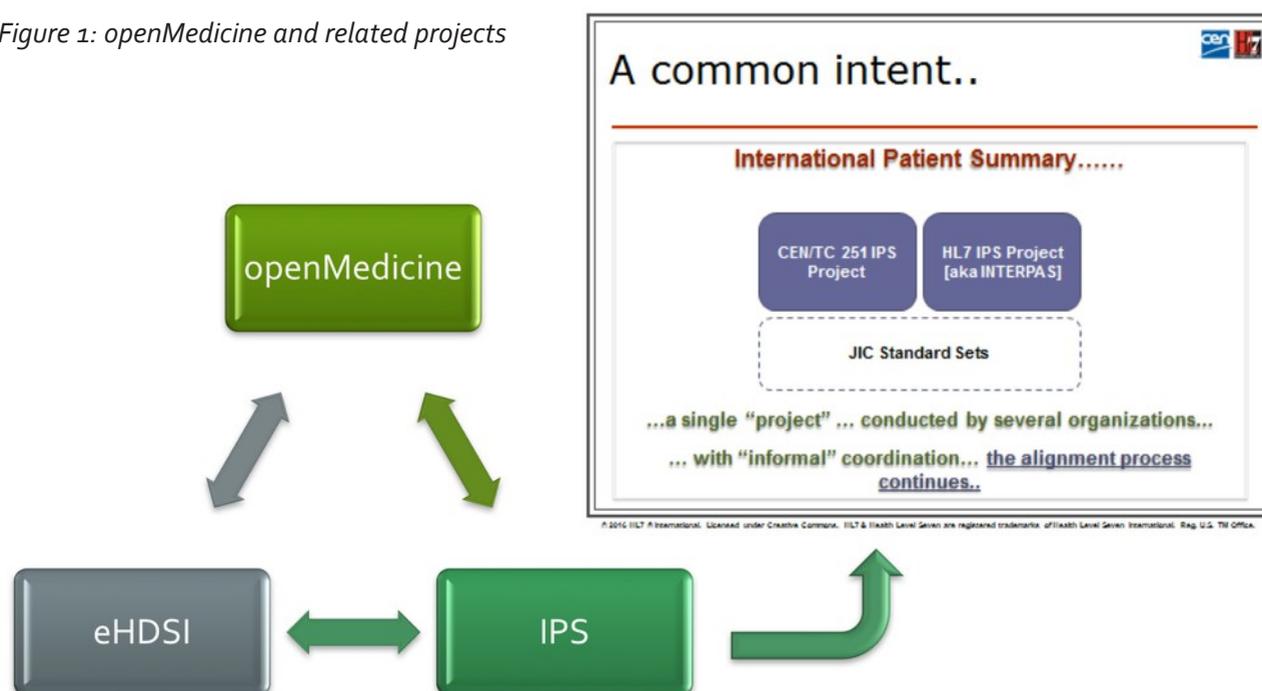
Figure 2: IDMP and Patient Summary

Figure 3: Substances identification

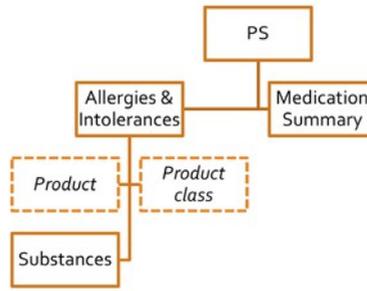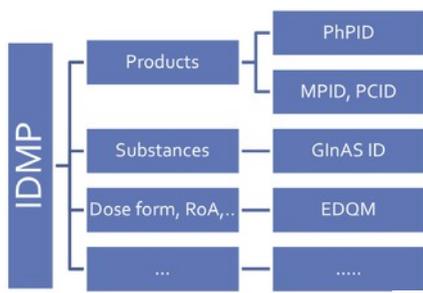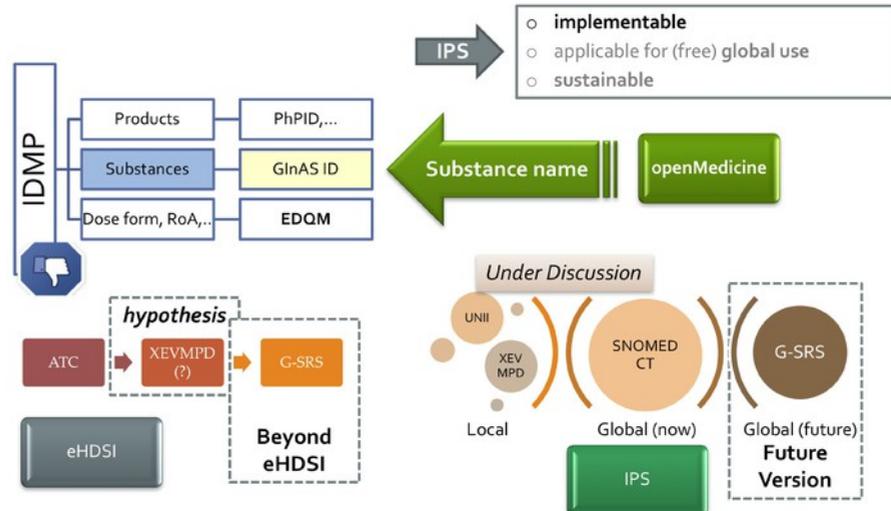Some concerns were raised by participants about the usage of the XEVMPD code system, supposed to be mainly used for pharmaco-vigilance purposes. Drug agency experts present in the workshop suggested to keep on using as interim solution the WHO ATC [12] waiting for a more stable and accurate solution [13]. As possible alternative it was also considered the adoption of the UNII code [14] system being this likely the basis of the future Global Ingredients Archiving System [15]. Balancing however costs for adoption and next future availability of GInAS, it was suggested at the end not to proceed in that direction. For the IPS standards the choice of a suitable value set for the substances is still under discussion (figure 4).

Similar considerations done for the substances were also repeated for product identification. The hypothesis of relying on the European Medicines Agency (EMA) Art. 57 Database [16] for the European cross-borders services, taking advantage of the availability of „scientific product identifiers" [17], was investigated in OpenMedicine and discussed in this session. As for the XEVMPD substance identifiers, experts suggested not to consider at this stage this solution waiting for the PhPIDs and the other IDMP identifiers. The current thinking for the IPS project is instead that of not suggesting any specific product identifier, designing however the solution in order to be ready for supporting the future IDMP identifiers. The adoption of IDMP, as defined now, does not solve however the problem of identification of medicinal products independently by their marketing authorization [18], this topic should be further analyzed.

Figure 4: Product identification
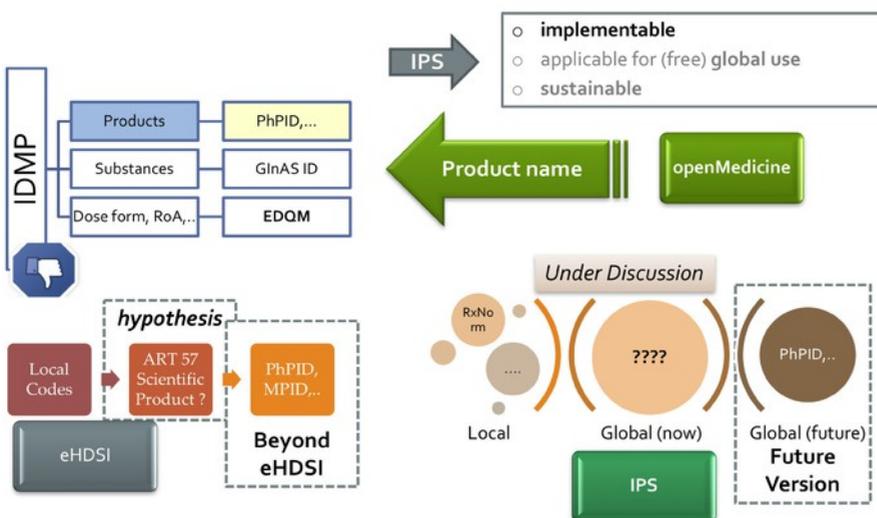
Finally, it was discussed the need of a future harmonization of the CDA extensions used for supporting identifiers and attributes that are not part of the HL7 CDA R2 model, with the hope of having a common way to handle them in SPL and CDA documents. A final choice on this purpose has not been yet done in the HL7 IPS project, waiting for a better evaluation of the possible extensions that will be included as part of the HL7 CDA R2.1.

Conclusions

The implications of the adoption of IDMP for identification of medicinal products in the European cross-borders services and for the International Patient Summary were discussed with experts from European northern countries during the 20th December, 2016, the Swedish eHealth Agency hosted the "OpenMedicine Workshop Implementing ISO standards for the univocal identification of medicinal products (IDMP) in Europe - The impact on Sweden and Scandinavia".

A general agreement on the openMedicine project approach (IDMP adoption) was expressed. Different options were discussed on the way to handle the transition to the full availability and adoption of the IDMP identifiers and attributes. As a general conclusion experts involved suggested – for the European cross-borders services – not to invest on possible transient solutions (e.g. XEVMPD for substances) that will not completely solve the identified issues; but rather to promote an incremental inclusion of those resources (vocabularies, identifiers...) as soon they will be progressively made available for use.

Giorgio Cangioli
Chair HL7 Italy
HL7 International Foundation

References

[1] https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/eHealth

[2] http://www.open-medicine.eu

[3] e.g. "openMedicine – One big step towards safe medication" J Teixeira; I. Lazaro. http://www.hl7.eu/download/eun-06-2016.pdf

[4] The IDMP standards were originally designed for regulatory purposes.

[5] That is, the IDMP identifiers and attributes are made timely available to the "end users" systems (e.g. prescribing systems) to be used in their business processes; and eventually reused for the communication from the clinical domain to the regulatory agencies (e.g. pharmacovigilance).

[6] http://www.open-medicine.eu/fileadmin/openmed/deliverables/634796_d3.2_identification_and_description_of_special_products.pdf

[7] The Digital Service Infrastructure for eHealth under CEF is an EU funded initiative planned to support several services using information and communication technologies (ICTs) that can improve prevention, diagnosis, treatment, monitoring and management, including the Cross-border patient summary service. This service will allow authorized health professionals to have access to the person's Patient Summary (EU guidelines) when a citizen makes an unplanned cross-border healthcare visit to a health provider in the EU.

[8] The IPS project is a "virtual" SDOs-driven project involving CEN, HL7 and other SDOs aiming to develop coherent artifacts for supporting International Patient Summary services. This is realized through SDOs specific projects (the CEN IPS and the HL7 IPS, also known as INTERPAS) informally cooperating. These projects agreed about a common scope, derived from the European Patient Summary Guidelines ("Minimal and non-exhaustive Patient Summary, specialty-agnostic, condition-independent, but readily usable by all clinicians for the unscheduled (cross-border) care of a patient."); and principles: the IPS shall be implementable; applicable for (free) global use and sustainable.

[9] https://standardterms.edqm.eu/

[10] https://tripod.nih.gov/ginas

[11] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000336.jsp

[12] Experts were aware about the well-known shortages of this choice being the WHO ATC not an identification system for substances.

[13] The decisions made so far by the eHDSI semantic Task Force have confirmed the indications raised during the Workshop: ATC for identifying substances for European cross border services waiting for more stable solutions.

[14] https://fdasis.nlm.nih.gov/srs/

[15] Some countries already started the mapping their local substance identifiers to UNII.

[16] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000594.jsp

[17] The concept of the ART 57 scientific product is comparable with that of the IDMP Pharmaceutical Product.

[18] IDMP links the identification of a Medicinal Product to a specific Marketing Authorization (two "similar" products with two different authorizations have two different identifiers), in the clinical context it might be useful to identify such a kind of products independently by the authorization process.

Connected health data meet the people: diversity, standards, and trust.

EFMI-HL7 Partner Event at the eHealthWeek 2017

Thursday May 11, 2017, 11:45-13:00, Room Jupiter, Hotel Intercontinental, Valletta, Malta

Using health data in a connected world requires new competencies, a personal digital health compass calibrated to individual personalities and needs. Patients and clinicians able to collect and manage data, data-operational informatics professionals able to analyze data, and cutting-edge researchers, innovators, and educators able to apply knowledge, will take learning health systems to the next level. In this EFMI-HL7 event using innovative technology and surprises to engage the audience, we will discuss strategies for empowering and activating people to engage, share and use their health data. We will point to diversity, trust and open standards like HL7 FHIR to open access coupled with capacities to manage data safely for patients, care-givers, and the health system.

Program

Welcome: *Catherine Chronaki, HL7 Foundation, Anne Moen, EFMI*

The Maturing Telemedicine Infrastructure in Denmark: Building the Human Capital, *Morten Bruun-Rasmussen, CEO MediQ*

The Maturing a Telemedicine Infrastructure (MaTIS) project prepares the ground for roll-out of telemedicine services as part of an agreement between the Danish Government, regions, and municipalities. Morten shares activities leading to development of the Human Capital necessary when scaling up such integrated home monitoring services for COPD patients in five Danish regions. The infrastructure builds on sharing of clinical documents in HL7 CDA between hospitals, municipalities, and general practitioners using an IHE XDS infrastructure. These also include complexity management, education by code camps, performance testing using large scale synthetic data sets, quality management and interoperability testing.

Health Professional Education in Biomedical & Health Informatics: the EFMI AC2 approach, *Professor John Mantas, University of Athens, Greece, EFMI Past President*

Health care systems need continuously updated professional knowledge and technical skills. Accreditation of programs in Biomedical and Health Informatics that are Bologna compliant to update and endorse quality of contents, and ascertain a certain level of knowledge and skills of graduates. John will introduce EFMI AC2, the Accreditation and Certification initiative for health informatics programs in Europe, and discuss opportunities for comparable international, professional standards that increase workforce mobility and capacity to balance health informatics with health professional development across Europe.

Digital health literacy: a necessity for Activating Citizens, *Professor Anne Moen, University of Oslo, Norway, VP for IMIA, European Federation for Medical Informatics*

Citizen employs personal, robust strategies for self management, maintenance, prevention, or early intervention to ensure health and wellness. Citizens seeking care for oneself or a family member can take an active role in their healthcare provision, stay informed and make decisions to ensure quality and efficiency of the health delivery processes. To take full benefit of these opportunities they need to develop digital health literacy competence. Personalized and universally designed tools allow citizens to co-create services that help them access, generate or share relevant data or information about related health issues respecting diversity and cultivating trust.

"Internet of People": the element trust, *Stephen McAdam and Eva Turk, Global Healthcare Director, DNVGL.*

Stephen discuss how the "Internet of People" builds demand for data literacy, governance and

custodianship, as well as standards. Using lessons learned in other industries on how to create and maintain trust, the concept "Internet of People" comes with potentials to deliver benefits to citizens and other stakeholders, if the myriad of barriers and risks are recognized and addressed. Trust between partners, stakeholders and citizens can be built through open transparent processes, education, and dialogue enabled by robust standards, systems and governance models.

Workforce meets volumes of electronic information: Why and how HL7 FHIR creates value for stakeholders in learning health systems, *Doug Fridsma, President and CEO, American Medical Informatics Association, US*

Drawing experiences from the recent HL7-AMIA datathon, Doug will reflect on the potential and practical experiences from using HL7 FHIR to tap the potential of health data for research and decision-making. In this way, operational and research standards can be bridged, making learning health systems a reality. Doug will also share insights from preliminary results of market analysis conducted by AMIA on current and future professional recognition pathways. Health care delivery in the 21st century requires patients and clinicians that know how to manage data, informatics professionals that are data operational in the focus, and cutting-edge researchers, innovators, and educators that will take learning health systems to the next level.

Key Points and Discussion, *Catherine Chronaki, Secretary General, HL7 Foundation, Institutional Officer, European Federation of Medical Informatics*

Participants

Morten Bruun-Rasmussen, BEng, MS is CEO in MEDIQ. He has been working with medical informatics and quality development for more than 25 years within it-strategies, procurement, regional and national health care networks, standards quality management and interoperability testing.

John Mantas, PhD in Computer Science began his academic career firstly at the University of Manchester and then at the National and Kapodistrian University of Athens. Professor Mantas is Director of the Laboratory of Health Informatics and Director of Postgraduate Studies. He was Vice President of the Cyprus University of Technology and Dean of the School of Health Sciences; during his deanship, he established in Cyprus the international Department of Public Health with the close collaboration of Harvard University. He has been President of EFMI for the period 2010-2012, and Vice President IMIA for the

European Region from 2012 to 2014. As Working Group chair on Education, he led the initiative in revising the Educational Recommendations in Biomedical and Health Informatics. In 2016 he became Honorary Fellow of the European Federation for Medical Informatics.

Anne Moen, RN, PhD, FACMI is professor at the Institute for health and society, Department of Nursing Science, and the director of UiO:eColab. She is adjunct professor at University of Wisconsin-Madison, WI and the University College of South east Norway. Her research activities combine in-depth insights in healthcare with design and deployment of accessible, user-empowering ICT-solutions. She served as President of the European Federation for Medical Informatics (EFMI) 2014 - 2016, and is the current regional EFMI – IMIA Vice President (2016 – 2018). She is member of EU eHealth Stakeholder Group (2016 – 2019), and task leader of subarea "Citizen - Health Data".

Eva Turk, MBA, PhD is a senior researcher in DNV GL - Strategic Research and Innovation, Healthcare program. Her current research is focused on Person centred care and digitalization of healthcare- Internet of People. Eva has a PhD in Health Sciences from University of Oulu in Finland and an MBA in Healthcare management from Vienna University of Economics and Business Administration.

Stephen McAdam is currently Global Technical Director at DNV GL Healthcare. An immunologist by training, Stephen spent much of his early career in laboratories working with pathogens such as HIV and HCV in hospitals in the United States, Africa, and Europe. In 2001 Stephen moved to DNV GL's Research department to head up the Healthcare and Biorisk program where he was responsible for exploring how systems-based approaches to management and risk assessment can be adapted and applied to areas related to patient safety and to biorisk. Stephen has collaborated many of the world's leading organizations in the area of biorisk management, including the WHO, European Centre for Disease Prevention and Control, the Canadian Science Centre, the UK health Protection Agency, and GSK.

Doug Fridsma, MD, PhD, FACP, FACMI, is the President and Chief Executive Officer of AMIA, representing 5000 professional and student informaticians members and their interests and activities in academe, industry, government and nonprofit organizations. Dr. Fridsma was the Chief Science Officer for the Office of the National Coordinator for Health Information Technology, responsible for the portfolio of technical resources

needed to support the meaningful use program and health information technology interoperability. While at ONC, he developed the standards and interoperability framework. In collaboration with the NIH and other federal agencies, he was instrumental in establishing the key priorities in the PCOR Trust fund. He has served as a board member of HL7 and the Clinical Data Interchange Standards Consortium (CDISC) where he was instrumental in developing standards that bridge clinical care and clinical research.

Catherine Chronaki, BEng, MS is the General Secretary for the HL7 Foundation. She is active in eHealth Policy and Standardization projects.

Following the success of Trillium Bridge project on the transatlantic exchange of patient summaries, Catherine now leads the Trillium II to scale up adoption of patient summaries in an innovative global community. She is also coordinator of the eStandards project, set up to develop a roadmap for collaborative standards development in large scale eHealth deployment. Catherine serves on the eHealth Stakeholders group of the European Commission and the board of the European Federation of Medical Informatics and she is member of the eHealth Unit of the European Society of Cardiology, and founding member of the HIMSS community of women in Healthcare Information Technology.

HL7 FHIR® Resource Profiles and Implementation Guides for France

by François Macary

FHIR-based projects have been experimented in various places and organizations in France for the past two years. This first spontaneous sprouting on the breeding ground of DSTU2 has happened on a rather anarchic and confidential mode, each project working in silo and ignoring the others. Save one or two exceptions, most project teams selected and extended/constrained freely their set of FHIR resources, applying their own recipes without bothering so much to share their experience and knowledge with the outer World. This period fitted the level of maturity of the standard itself, a Draft Standard for Trial Use calling for as many experimentations as possible on its way to normative standard. Not much to worry about albeit the limited feedback provided to the FHIR standard by French projects.

However, the publication of STU3 in March 2017 puts an end to this Eden-like period of free uncontrolled growth. Giving up the "D" of "Draft", the FHIR specification has passed a significant milestone on its journey to HL7 normative standards, incrementing the maturity level of many of its resource types, a handful thereof (Patient, CodeSystem, ValueSet, Bundle …) having reached

level 5, last level before "normative".

In France, the non-profit association Interop'Santé (www.interopsante.org), which hosts both HL7 France and IHE France, considers that with STU3 publication, comes the time to better organize the growth of FHIR projects, and to build assets at the national level for these projects. On March 7, our kickoff meeting for national profiling of FHIR resources, gathered twenty attendees representing a number of FHIR-based local ongoing projects. The necessity to define FHIR resource profiles at the national level was consensually established and the decision was made to set up the first work groups for the creation of national profiles. The first priorities identified are:

- Administration Module (Patient, Practitioner, Organization, Encounter …)
- Financial Module (Claim, ClaimResponse, Coverage, ExplanationOfBenefit, …)

Interop'Santé will start to build a library of national profiles of FHIR resources, with the goal to make these profiles visible at the international level, hence to publish them onto an international

registry so as to broaden the potential feedback on these profiles. The method of elaboration of the profiles of a set of resources has been agreed upon:

- 1 .Inventory of existing projects, generalization of use cases at country level
- 2. Inventory of regulatory and organizational constraints applicable in the country
- 3. Inventory of standard profiles and extensions of potential interest to fulfill these constraints
- 4. Profile build and documentation, using Forge tool
- 5. Implementation, tests and feedback
- 6. Approval, publication and dissemination.

At a later stage, these profiles will be assembled into FHIR implementation guides by the projects, with again the intent to register these IGs onto an international registry, for a maximized visibility and potential feedback.

This work involves the resources of both HL7 France and IHE France, which have always worked hand in hand in France. Thus, the first FHIR-based IHE integration profiles published by IHE International for the scope of mobile applications, will also be part of the input material to our activity.

François Macary
Phast – Large scale semantic
interoperability manager
IHE International – Technical co-chair
of PaLM committee
Interop'Santé – Chair HL7 France

Validation, management, maintenance and publication

HL7 FHIR® Profiles in the Netherlands

Introduction

by Bert Kabbes

The open source character of the HL7 FHIR® standard implies that any organization or individual(s) can create FHIR profiles, derived from the core FHIR profiles as published on Simplifier.net. This situation can (obviously will) lead to many different, overlapping or duplicate profiles for the same purpose, published via numerous sources, without any objective validation or qualification: e.g. whether profiles meet the specific requirements, laws and regulations in a certain realm, whether extensions and/or constraints are defined consistently or if profiles meet the specific functional requirements of a certain domain.

For any realm, this situation will indefinitely lead to "chaos" instead of local standardization. Users will be confronted with many sites where HL7 FHIR profiles are published, never knowing for sure if profiles meet the requirements of a certain domain or whether profiles are consistent with local laws and regulations.

What is needed in each realm is a validating organization, a validation certificate (stamp) as well as one single publication source where all validated national HL7 FHIR profiles can be found. These validated profiles should be clearly defined as the "national standard HL7 FHIR profiles". These profiles will serve as the national generic profiles, which everyone should use preferably, either "as is" or as the basic profiles for possible specific extensions. A central local managing organization should control the validation process and procedures, publication and maintenance.

Leading role of HL7 Affiliates in FHIR validation

In general, the HL7 Affiliates are in a unique position to respond to the need for standardization of local HL7 FHIR profiles in their realm (country, continent), by taking the lead in creating an organization as described above. Moreover, only HL7 Affiliates are best positioned to validate, stamp and publish standard FHIR profiles with an official "HL7 FHIR approved" certificate.

Recently HL7 The Netherlands (in collaboration with the National Healthcare IT Institute Nictiz)

has taken the initiative to set up a specific organizational group within the HL7 Netherlands Affiliate, which will respond to take the lead in the certification of national HL7 FHIR profiles. This organizational group will validate HL7-FHIR profiles against several sets of national requirements, judge profiles on technical and functional consistency and quality as well as provide central publication, maintenance and updates.

Overlapping and duplicating profiles as well as incorrect profiles will be filtered out and will be discussed with the creator(s) for improvement. Successfully validated profiles will receive the qualification stamp "Validated HL7-FHIR-NL standard profile" and will be published through a by HL7 The Netherlands via a specific project within the central international HL7 FHIR website Simplifier.net. This project on Simplifier.net is the single source for all validated national standard HL7-FHIR-NL profiles.

By creating a specific HL7 FHIR-NL entity within the HL7 The Netherlands Affiliate which will take up the role and actions as mentioned above, users will be provided with a single national publication source for generic, validated HL7-FHIR profiles, easy access and certain guarantees that these validated profiles do meet the requirements of specific domains and national laws, regulations and standards.

Organizational set-up

The organizational set-up is effective as of January 1, 2017. Within the organization of HL7 the Netherlands a specific HL7-FHIR-NL entity has been created, operating on 2 levels:

- A **FHIR-NL Management Board**: each organization who wishes to have their profiles validated and published as a "national HL7-FHIR-NL profile" should (must) send a representative to this board.
- A **FHIR-NL Validation & Publication Team**: each organization who wishes to have their profiles validated and published should (must) send a functional/technical representative to this team.

Any organization who develops HL7 FHIR profiles will be actively invited to have their profiles validated and published centrally. Organizations who (will) have their FHIR profiles validated will automatically become a member of the two entities as mentioned above. This will lead to user driven groups who cooperate and share their views. In the spirit of HL7, this set-up will create cooperation by and in favour of HL7 NL members.

HL7 The Netherlands will widely advertise to the Dutch market to only use FHIR profiles which have been validated. The risks of implementing non-validated FHIR profiles will be explained.

The main tasks of the FHIR-NL Management Board are:

- define general and specific validation criteria and requirements
- judge on validation readiness of validation requests
- initiate validation process by the validation team
- provide resources for validation process
- formal approval of the validation results
- manage the validation team

The main tasks of the FHIR Validation & Publication Team are:

- define detailed validation criteria, validation sets and requirements,
- conduct and execute the validation procedure,
- report the validation results including advice regarding failures and improvements,
- maintenance of validated profiles,
- publication,
- maintenance of the publication environment in Simplifier.net,
- act as central contact point / help desk, publish FAQ's.

The background for the organizational set-up as outlined above is that this way automatically a growing group of HL7 FHIR members i.e. profiles developing organizations will perform the validation work. As will be the situation in many HL7 Affiliates, we as HL7 The Netherlands are unable to take up and execute all the work, next to our prime Affiliate responsibilities and tasks. The chosen set-up therefore is in line with the fundamental character of HL7: a user community.

Added value of the HL7 FHIR-NL initiative

The added value of the initiative and organizational set-up as described, are the following:

For parties who develop HL7 FHIR profiles:

- receive an official certificate as "national HL7-FHIR-NL standard profile",
- explicit recognition and publication as being the developing organization,
- marketing opportunities,

- business opportunities to sell paid support, education and implementation support to parties who wish to use validated profiles,

- contribution to national standardization of open source software,

- active participation in the HL7 FHIR-NL management board and validation team.

For parties searching for HL7 FHIR profiles:

- certainty that profiles are formally validated and do meet local realm specific laws and requirements,

- check available profiles via 1 national publication source,

- save costs by using validated profiles and avoid risks,

- availability of a central contact point and help desk,

- availability of experienced support by the developing parties,

- availability of specs and requirements for RFP's.

For HL7 Affiliates:

- contribute to national standardization

- strive to avoid chaos as a result of random development and publication of profiles by numerous parties

- provide a member driven organizational entity within the Affiliate

- add value for HL7 Affiliate members and membership

- create continuity for the Affiliate by fulfilling an important role in the open source world of HL7 FHIR

Conclusion

This initiative seeks to avoid the risks often connected with using open source software. Without measures aiming for local validation like this initiative, HL7 FHIR as being "open source" might eventually become a "danger" to national standardization in healthcare.

The initiative and organizational set-up as described does not interfere with nor violate the open source character of HL7 FHIR. This aspect has been thoroughly checked with the HL7 FHIR management as well as with several key persons within HL7 International.

The set-up does not in any way create a barrier in the free use or development of any HL7 FHIR profile. On the contrary: it just adds value to local FHIR profiles by formal validation, central publication and providing support. It will remain any organization's free choice and decision to request validation and to take part in the national standardization of FHIR profiles. As a general advice, HL7 The Netherlands will clearly communicate to the market to only use validated HL7 FHIR-NL profiles.

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

Swedish Drugs on FHIR

by Fredrik Ström

The working group *Drugs on FHIR* was founded in late 2016 as a working group affiliated with HL7 Sweden. The goal of this group is to support organizations to understand the Medications module in FHIR, coordinate localization of medication resources in Sweden and to support the international work on standardization of the Medication module.

The group consists of members from 14 authorities, organizations and companies, and we meet roughly every 4 to 5 weeks. The initial function of the group is to facilitate an understanding of the different resources in the

Medication module and how they can be used in Sweden. Our goal is to spread knowledge about how to user FHIR when working with medication information. One task we are planning is to support pilot projects that implement relevant resources, and to investigate how resources should be profiled in Sweden.

Our plan is to attend Working Group Meetings regularly and we will hopefully meet in Madrid.

For more information contact Fredrik Ström, chair Drugs on FHIR (fredrik.strom@cag.se).

Fredrik Ström
Chair Drugs on FHIR
Former Chair of HL7 Sweden
C.A.G Mawell

Getting closer to 2.0: ART-DECOR® 1.8+ published

by Kai U. Heitmann

Another intermediate ART-DECOR® release – 1.8.36 – has been published mid of January 2017. Since the last update to 1.8.29 in September, a lot of new features and improvements have been implemented so the ART-DECOR Expert Group felt, that an intermediate release – before ART-DECOR® 2.0 gets published later this year – would be of great support for the community.

ART-DECOR® is an open-source tool suite that supports the creation and maintenance of HL7 templates, value sets, scenarios and data sets. The tool features cloud-based federated Building Block Repositories (BBR) for Templates and Value Sets. It supports comprehensive collaboration of team members within and between governance groups. ART-DECOR® allows separation of concerns and different views on a single common documentation for different domain experts and multidisciplinary stakeholders of healthcare information exchange.

BTW: 1.8 is the stable release series of versions, 1.9 is handled internally by us as the development edition. That's why we're close to 2.0 :-). This is a summary of the recently added features and enhancements, sorted by areas.

Templates

- Add support for multi lingual editing instead of one language at a time
- Introducing artefact history: history list for templates, triggered upon save-template
- Setting status now allows for recursion: you may recursively apply status and expiration on all templates hanging of the focal template. Because this is a very powerful feature you may first inspect the list of templates that would be affected by the update
- Added setting all statuses with respect for the template lifecycle

Template editor (base)

- Fixed disappearing gear icons when the contents of the table exceed the max table width

- Improvements in retrieval of info under new attributes and elements

Development, Validation and Testing

- Script changes, additions and adaptations in order to serve properly for Live Runtime Compile LRC and Instance Fragment Validation IFV
- Live Runtime Compile LRC now is fully functional
- Synchronized validation output layout with IHE Gazelle layout

Publishing

- Publishing now supports a dialog for setting the most important parameters that were defaulted before
- Added support for partial publications through filters for ADRAM: now you may publish just a particular set of transactions (with all associated data sets, templates and value sets for example).
  This feature has been pushed forward by a project in British Columbia (Canada).

Terminology

- Added a self-link like on all other forms
- Updates for LOINC 2.58

Value Sets

- Replaced the XForms based rendering engine with the publishing rendering engine. ART and publications thus now support a unified view.

- Great performance improvements in loading the tree of value sets.
- Add read/write support for concept and exception designations. This allows for multiple displayNames on codes based on language and/or type: preferred, synonym, abbreviation. By default, but user can disable this, copies all known descriptions from SNOMED CT and LOINC into value set.

Projects

- New: upon creation of a new project version or release you now get a summary of all changed issues since the previous version|release as part of your release info. You may review/edit that summary before saving.
- Added support for new property "type" on copyright holders. Default is 'author'
- Added runtime compilation fixes so validation of examples is active.
- Improved rendering of project compilation and validation results
- Visual tweaks to BBR rendering

Data sets/Scenarios/Transactions

- Add shortcut to RetrieveTransaction service to allow view/download in table mode
- Fall back to first element with a value when it is not available for requested language on concept/ name / desc and conceptList / concept / name
- When the transaction editor deletes a group it now marks underlying concepts too so after saving, the transaction viewer does not list group contents until you reload it.

Issue Management

- Authors can now edit the status/labels/description of tracking/assignments they authored (action is logged)
- Decor-admin can now edit the description of tracking/assignments of anyone (action is logged)

Visual improvements and menu changes

- Layout tweak: visual update in the titles of most DECOR pages
- Improved rendering of references to repository artefacts (value sets and templates)

Miscellaneous

- Functionality improvement in project-ids editing. Now supports editing all languages at once and includes setting the type

- Redesign of the decor-explore page
- Retrieve Concept Diagram now supports filtering based on concept status. Data sets form new sends this info
- Implemented support for new format type of a building block repository (default: decor, added fhir)

ADRAM

The external service ADRAM (ART-DECOR Release and Archiving Manager) is now released as version 2.24 and got an option to allow partial publications and handle governance group publications appropriately.

ADRAM is used since a couple of years for publication management in the Netherlands (Nictiz) and Germany. Recently it has successfully installed and tested on the official ART-DECOR sever hosted by IHE Europe and parametrized for the National Infrastructure Projects in Switzerland (eHealth Suisse) and Austria (ELGA).

ADAWIB

ADAWIB (ART-DECOR Automatic Wiki Interface Bot) is now released as version 6.1. HL7 Germany uses ADAWIB since years to extract the project artefacts to a Wiki Environment. Production use of wiki exports features by ADAWIB is now also set up and used for eHealth Suisse (Switzerland) and for ELGA (Austria) the publication facilities through wiki enhanced by ADAWIB was started.

What to expect for ART-DECOR® 2.0

A row of new features are in preparation by the ART-DECOR Expert Group, here are a few:

- A Diff Engine allows to compare templates, value sets and transactions/data sets. First this will be introduced in conjunction with the new History Feature where one can easily compare an older version of a template to the actual version.
- FHIR profile viewing and data set integration (logical models), base terminology services
- Instance Fragment Validation (IVF) allow to validate example instances against the template design
- Template Design Base Standards Validation for CDA (TDV) as collaboration with IHE Gazelle ObjectsChecker.
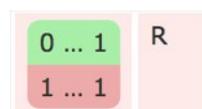
Dr. Kai U. Heitmann
ART-DECOR Expert Group, ART-DECOR Open Tools

Re-shaping healthcare systems

International HL7 Interoperability Conference 2017 in Athens

The International HL7 Interoperability Conference 2017 (IHIC 2017) will be held from 22-24 October 2017 in Athens, Greece. It is the 17th in a series of international conferences, originated in 2001 by HL7 Germany. This year's event is embedded into the Greek National eHealth Forum 2017. The venue selected for IHIC 2017 is the "Purifier", located in the Technopolis City of Athens.

Athens is a vibrant city, uniquely combining ancient heritages and innovations, spectacular Mediterranean landscape, traditional hospitality and culture. So both, the event at its environment are truly worth to be visited. The meeting will be hosted by HL7 Hellas, with support from HL7 Germany as permanent IHIC supporter. On that basis, the IHIC 2017 Program Committee is co-chaired by Alexander Berler (Greece) and Bernd Blobel (Germany).

After having dedicated the successful IHIC 2016 in Genoa to "Interoperability is more than just technology", IHIC 2017 is organized under the motto "Re-shaping healthcare systems". That way it addresses current challenges Greece and other European countries are facing on the way of health systems transformation. This move is justified by one IHIC 2017 session, dealing with Greek national initiatives such as the ePrescription System and

the Primary Care Reform, enriched by related experiences from other countries. Another session will address EU projects European HL7 Affiliates are involved in.

Also IHIC 2017 aims at playing the role of an interface between science, research and practice with regards to interoperability in the health and social care domain to share experiences and best practices. Therefore, it addresses both implementers and scientists to present and discuss concepts, models and implementations for innovative interoperable e-Health solutions. IHIC 2017 envisions being the meeting place that will connect academic community and industry, enabling digital transformation of Healthcare in very near future.

As the interoperability challenge is year by year getting more complex, covering more stakeholder groups from a growing number of domains

and disciplines, the topic list of IHICs is growing as well. Scientific papers on the one hand and demonstrations, practice reports, success and failure stories on the other hand will cover, but not be limited to, topics such as

- ■ 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
- ■ Security, safety and privacy
- ■ Specification, testing and implementation tools
- ■ Creating new clinical and integrated care pathways through effective information exchange
- ■ Enabling patient and healthcare providers to interact in the new digital economy (mHealth, Internet of Things, cloud computing and many more)
- ■ Handling patient consent and electronic identity in distributed healthcare settings

Following good experiences from many former IHIC events, the traditional conference slot "Show me your CDA" will present CDA implementations at all levels. Meanwhile, the HL7 Fast Healthcare Interoperability Resources FHIR are gaining importance. Therefore, the question "FHIR and CDA – controversy, coexistence, or synergy?" will be discussed.

For improving the quality of specifications and implementations, but also for enlarging the community actively involved, education and training are crucial. Therefore, we will proceed in the tradition of starting also IHIC 2017 with a Tutorial Day, including one tutorial in the registration fee.

In summary, IHIC 2017 will be another success in HL7's history, if the global HL7 community, but also other interested parties are coming to Athens to actively engage in the conference. For the purpose, they should submit contributions, encourage student and young scientist to participate in the "Joachim W. Dudeck Award" competition, and share their knowledge and experiences, but also formulate new requirements and push the evolution of HL7. For doing this, please watch the updates on the IHIC 2017 Conference Website

http://ihic2017.eu and meet the submission deadline 31 May 2017. If there are still open questions, please do not hesitate to contact the authors or info@ihic2017.gr.

Bernd Blobel and Alexander Berler

Call for Papers

The IHIC is a forum for implementers and scientists to present and discuss concepts, models and implementations for innovative interoperable e-Health solutions.

The intended audience encompasses all who have developed, implemented, investigated, or otherwise used any of HL7s standards.

Implementers and Users
We invite implementers (representing healthcare providers and software vendors) to present their implementation experiences, success stories, requirements needs, assessments of standards, etc. To facilitate evaluation and dissemination of these experiences, attendees are requested to submit short practice reports, possibly also allowing that their presentations be recorded. The practice reports will be published as part of the conference proceedings, and the recordings will be made available on the conference website after the meeting.

Scientists and Researchers
We invite scientists to submit papers to be presented in the conference and be published in the conference proceedings. Selected papers will be published in the special issue "Interoperability is more than just technology" of the "European Journal of Biomedical Informatics".
The best scientific paper by a young author (< 35yr) will be awarded with the "Joachim W. Dudeck Award" (see IHIC web site for further details).

Submission and Format

Manuscripts should not exceed 5,000 words and must strictly follow the instructions for authors available at the Conference Website.

Papers are to be submitted electronically at the IHIC Submission System

https://easychair.org/ conferences/?conf=ihic2017

before 31 May 2017 (final deadline). Evaluation and notification will be 15 July 2017, camera-ready papers are due 15 August 2017.

HL7 Affiliates in Europe

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

HL7 Austria http://www.hl7.at Chair: Stefan Sabutsch	HL7 Germany http://www.hl7.de Chair: Sylvia Thun	HL7 Russia Chair: Sergey Shvyrev MD, PhD
HL7 Bosnia and Herzegovina Chair: Samir Dedovic	HL7 Greece http://www.hl7.org.gr Chair: Alexander Berler	HL7 Serbia Chair: Filip Toskovic
HL7 Croatia http://www.hl7.hr Chair: Miroslav Končar	HL7 Italy http://www.hl7italia.it Chair: Giorgio Cangioli	HL7 Slovenia Chair: Brane Leskosek EE, PhD
HL7 Czech Republic http://www.hl7.cz Chair: Libor Seidl	HL7 The Netherlands http://www.hl7.nl Chair: Bert Kabbes	HL7 Spain http://www.hl7spain.org Chair: Francisco Perez
HL7 Denmark Chair: Lene Nielsen	HL7 Norway http://www.hl7.no Chair: Line Saele	HL7 Sweden Chair: Mikael Wintell
HL7 Finland http://www.hl7.fi Chair: Juha Mykkanen PhD	HL7 Poland http://hl7.org.pl Chair: Roman Radomski MD, MBA	HL7 Switzerland http://www.hl7.ch Chair: Marco A. Demarmels MD, MBA
HL7 France Chair: Francois Macary	HL7 Romania http://www.hl7romania.ro Chair: Florica Moldoveanu	HL7 UK http://hl7.org.uk Chair: Philip Scott 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.

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