MIE 2018 Datathon

International Patient Summary

MIDATA Framework based on HL7 FHIR

Mobile Health in Catalonia
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User-centred Health Data Management needs new Actions in Europe

The healthcare system is currently moving from the more traditional, reactive approach towards proactive care, supporting wellness management and the prevention of illness. As part of this development, organization-driven healthcare is changing towards a person-centered model, introducing possibilities for the creation of new services that take into account customer needs and actionable data.

In Finland, we have been studying the formation of the MyData-based service ecosystem with insights into technological, regulatory, ethical, service transformation, and business model research and development activities (The Digital Health Revolution project). The aim was to identify and analyze possible systemic change opportunities in healthcare, new innovations leading to international businesses, and the value of personal data for the citizens, businesses, and public healthcare.

It has become obvious that the usage of data in the person centric service and business development is more complex than was anticipated. Data is not always available as such, and it might not be in a usable format, thus hindering the integration of data from various sources. Today, the data is collected in the registries and information is serving mostly the organizations but not people, who are using the digital services, and who need more personalized services and digitally aided consultations. Furthermore, the holistic, integrative analysis of data is very costly, requiring specific expertise in data analytics and an in-depth knowledge and understanding of the discipline at hand.

An open business environment for data sharing is only now starting to emerge; a major challenge is represented by the identification and application of the most suitable technological solution amongst the many solutions, all of which are still under development. There is a need to develop totally new business model for the personal data access and movement between various services. New models for sharing the data between individuals, data collectors and third parties is also needed to meet EU-wide privacy regulation related requirements.

The human-centered approach in the data management has become a relevant topic when developing person-centric data-led care. The MyData principles (usable data, human centric control and privacy, open business environment) are difficult to fulfill, if not major changes in systemic level are not taken place and if citizen generated data is not integrated more efficiently in the digital service development.

More importantly new role of the customer needs more attention, since the transformation to MyData-based services in healthcare can enable empowerment of the customers. The
Empowerment will happen only if we understand expectations and individuals’ capabilities to control and interpret their own data, and ethical concerns related to data sharing. Especially, citizens’ access and management of data relevant to their health and wellbeing is challenging, since data is stored in several public and private repositories and registries with different security mechanisms and consent management structures. There are several challenges that remain to be addressed in the context of the secure end-to-end management and coordination of data. Furthermore, the EU General Data Protection Regulation (GDPR) gives more fine-grained control to the individual in use of personal data, and imposes more responsibilities on organizations. For individuals, when thinking whether to share or not his/her data, it will be important that their data is shared with privacy and security. Updated set of rights and obligations gives right to data portability, communication of data breach to data subject and transmitting data in digital format.

The digital data-led health solutions demand novel approaches and policy in Europe. The management of personal data in different fields of society could be a competitive advantage, driving the data-led economy in the future.

However, there is a lack of practical experience across Europe that are demonstrating the best practices on the data management focusing on user-centered integrated care.

One suggestion is to launch an EU data initiative that considers a 360-degree view of personal data policy enablers. This would ensure a comprehensive analysis of all interrelating decisive factors for the development and adoption of person centric data-led care in Europe. The digitalization of health and social care services require extensive changes in operating practices towards person-centric care with the innovative data management models, data value chain strategy and new value assessments methods. Also, interoperability standards have a crucial role to play, and standards organizations should provide reusable tools and components that will ease the digital transformation.

We are proposing to specify a strategic agenda towards a user-centered data management model. The strategy will support a digital health and care innovation in the context of integrated care and digital single market strategy. Through Member States and multi-stakeholder collaboration, this would drive policy, regulatory, research and innovation activities to establish a Europe-wide smart health data ecosystem in this arena.

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For further information visit the Digital Health Revolution research project and results about the major achievements driving person-centric, data-led health care at http://www.digitalhealthrevolution.fi/outcomes.html
Standards for the Digital Age

Standards are found in practically every area of our daily lives, to the point where we often take them for granted. Without standards, products might not work as expected, they may be of inferior quality or incompatible with other equipment. In extreme cases, non-standardized products may be dangerous. Customers might then be restricted to one supplier; manufacturers would be obliged to invent their own individual solutions to the simplest needs, with limited opportunity to compete with others.

The benefits of standards are many. Adherence to standards helps ensure safety and reliability. Standards enable devices to work together and provide a solid foundation upon which to develop new technologies and to enhance existing practice. Standards are frequently referenced by regulators and legislators for protecting user and business interests, and supporting government policies. Standards play a central role in the European Union’s policy for a Single Market. Standards open up market access, provide economies of scale, encourage innovation, increase awareness of technical developments and initiatives and provide the foundation for new features and options, thus contributing to the enhancement of our daily lives. Mass production based on standards provides a greater variety of accessible products to consumers.

There is wide recognition of the relevance of standards to achieving the benefits of eHealth. Today’s healthcare landscape consists of a variety of care settings and stakeholders, which use many different information systems in their delivery of care.

For many years, efforts have been made to improve eHealth standardisation activities with a view to producing outputs that are coherent and relevant. Despite these efforts there still appears to be a significant gap between those who develop and those who are expected to implement. On the one hand, the very aims and objectives of most healthcare systems across the world focus on improving continuity of care through the effective communication of patient information, supported by consistent and comparable data that can inform better decision making on matters of efficiency and effectiveness. On the other hand, the application of standards – which should address these very issues – is seen as complicated and expensive and with only limited success. As a result there remains a reluctance to invest or participate in such standardisation activities.

What to do about this?

We need to bridge this gap. Perhaps a starting point would be to set out critical success criteria for standardisation activities and their outputs:

- relevance: that standardisation activities are seen as relevant to business objectives and current activities
- openness: that standardisation is seen as an open and inclusive process which removes rather than presents barriers for progress
- engagement: that all parties contribute, from prioritisation of business requirements through development, implementation and maintenance
- affordability: that resulting standards are affordable, and demonstrating a clear return on investment
- sustainability: that the framework for development of interoperability standards is sufficiently open and flexible to allow adaptation and development as the solutions and market evolve.

Jeremy Thorp, NHS Digital, UK
The International Patient Summary Standards

Patient Summaries everywhere

Most healthcare providers already have their own version of a patient summary for use in their own organisations. Many countries have national equivalents, albeit some more extensive and/or more mature than others. So why bother to standardize? And why now? And why the need for an international solution? And, assuming there are affirmative answers to be had to all of the above, how can it be delivered?

Patient summaries (PS) are concrete manifestations of a clinician’s education and training. The purpose of a PS is to provide a concise account of a patient’s clinical history, either as an aide memoir for the author, to be used in a later consultation with their own patient, or to satisfy a request for information sharing, with subsequent review by another clinician who has to treat that same patient in a different context.

Either intention, makes the PS one of the earliest examples of data reuse; particularly if one considers the exchanged data to be an ‘extract’ or ‘view’, comprising usable and useful data from one or more pre-existing records.

Patient summaries are therefore ubiquitous. They are an important, integral, and even an inseparable part of the fabric of today’s healthcare. Given the significance and intertwined nature of the PS, any attempt to impose an international standard is likely to be both contentious and disruptive! So...

Why bother to Standardize?

Patient summaries can be made more usable, more useful and effectively safer than they are now; a necessity given their increasing role in both the continuity and coordination of healthcare. Paradoxically, the success of the PS has led to a plethora of diverse implementations that make the necessary sharing of critical information at

by Giorgio Cangioli and Stephen Kay
the point of care problematic for an attending physician, who cannot always rely upon the presence of core content unless (and not always) it is from their own system/organisation.

Standardization of the PS is not a big issue for those working entirely in a closed, uniform and single system, yet even these rarefied cases have to manage external in-coming and out-going communications with the wider ecosystem in which heterogeneous systems are the norm. But...

**Why Standardize now?**

Citizens (i.e. potential patients), patients, and clinicians, move around, perhaps much more than in the past. Certainly, patient expectations are higher, demanding the same standard of care when and wherever required. Healthcare providers and their responsibilities are subject to change, and this too requires data to be shared in a seamless way. Healthcare delivery is increasingly a team-support activity, often stretching across system boundaries, and the overwhelming complexity of the ecosystem cries out for simple solutions wherever possible.

Patient summaries are not rocket science. Yet in a time of Precision Medicine, wondrous imaging capabilities, magnificent advances in treatments and amazing analytics involving Big Data, not to mention all the PS systems already in existence, is it not ironic and, a little shameful, that we cannot yet transfer a relatively small, *agreed* dataset across system boundaries in a standardized way for the benefit of the patient and healthcare provider alike? Of course, it should be possible, but...

**Why an International Patient Summary Standard?**

The essence of the problem, and the solution, is not just technical; it is much more to do with ‘agreements’. The myriad of existing systems, if not implying a reluctance to change, surely show that they have a way of doing things locally, in their own way. Certainly, it is understood that any international solution should readily support the local/national requirement, because that is where the bulk of the day to day information sharing occurs. Furthermore, local systems constitute significant investment in practice and often have buy-in from those in the healthcare professions who champion the specific content of a PS, rightfully requiring it to meet their specialist needs.

Europe has no mandate over its Member States (MS) with respect to the healthcare domain, but it encourages and facilitates mobility of its citizens across MS and therefore initiatives, such as an International Patient Summary (IPS) for cross border care, aligns well with key European policy. Furthermore, EU-US agreements mean that such initiatives have more value and credibility if they are broadened to include partner nations engaging and participating in complementary projects such as Trillium I (2013-2015) and II (2015-2017).

**How do we deliver an International Patient Summary?**

Standardization is another form of agreement but deploys a formal consensus process. It definitely takes much longer than putting together a set of preferences for ‘my ideal PS’, which exacerbates the confusion and hinders interoperability. Yet Another PS (YAPS?) is neither required nor helpful; it is just more noise.

The Standardization consensus process, however, does imply the existence of multiple, serious stakeholders. Not surprising, there are a number of concurrent activities pursing a similar goal in the PS space and some observers have likened the approach to establishing an IPS with the attempt to change a wheel on a moving vehicle!

Fortunately, whilst difficult, it is not as bad as that. Through active, joint participation, three of the four major activities are under the leadership of the Standards Development Organisations (SDOs) and are mutually beneficial and compatible:

- The JIC Patient Summary Standards Set (PSSS) is not intended to be a standard in its own right; it is essentially an informative output that is intended to inform the stakeholders about existing or developing standards in the PS space.
- HL7’s IPS and CEN’s IPS (the IPS Projects) are intended to be normative and relatively narrow in focus, taking on board relevant detail from the PSSS and contributing to the PSSS content as the IPS Projects develop the formal standards. Furthermore, the IPS Projects are actively working together to produce a single compatible solution based on agreements made at the Oslo workshop organised by eStandards back in 2016.
- The fourth project is the eHealth Digital Service Infrastructure (eHDSI) initiative for cross-border health data exchange, which builds directly on the outputs of the epSOS pilot with a view of providing implementations for European MS by 2019.

All four initiatives (the JIC PSSS differs from the others in that it includes extra items reflecting
homecare requirements but those are outside of the IPS Projects’ current scope) rely heavily on the guidelines for a PS dataset, version 2 being published by the European eHealth Network (eHN) in November 2016. This fact goes a long way to support the harmonization efforts of CEN TC 251 and HL7.

**CEN IPS Project**

The CEN IPS project will produce two standards; the first being a domain model for the IPS focussed on the use case of cross-border unscheduled care, and the second, a Technical Specification (TS), which will offer specific guidance for IPS implementation within the European context.

The first, prEN 17269, specifies “the core dataset for a patient summary document that supports continuity of care for a person and coordination of healthcare”. It also contains the conformance rules that have to be applied to a derived model in order to comply with this standard. Joint participation has enabled a consistent approach with HL7 and eHDSI, and prEN 17269 provides a means of deriving conformant implementations.

prEN 17269 does not overstate or undervalue its contribution, i.e., “due to its nature therefore, readers should be aware that the compliance with this standard doesn’t imply automatic technical interoperability. Technical interoperability enabled by this standard can be reached with the conformity to standards indicated in the associated technical specifications.” An underlying standard (ISO 13940, Systems of Concepts for the Continuity of Care, 2016) underpins the given IPS scenario providing concepts and terms to support the goal of interoperability. The accompanying CEN TS will provide practical examples, showing how other standards (e.g., CDA, EN 13606 and FHIR representations) may use the prEN 17269 IPS to achieve technical and eventually semantic interoperability for the IPS.

The CEN IPS project team passed prEN 17269 to CEN Central Management in the beginning of February for translation and subsequent launch for ballot end of May. The CEN IPS Technical Specification is currently under development with the expectation that it will be completed by the end of this year.

**HL7 IPS Project**

The HL7 IPS project will deliver two implementation guides (IG) specifying how the IPS core dataset can be represented through the HL7 CDA R2 and the HL7 FHIR standards.

The first guide (the IPS CDA IG) has been already successfully balloted and it is expected to be published as Standard for Trial Use (STU) shortly. This guide defines a set of CDA templates built on pre-existing CDA templates (HL7 C-CDA CCD (Continuity of Care Document); IHE PCC (Patient care Coordination); eHDSI, formerly known as epSOS) to be used for building an IPS document. These templates have been specified and published in ART-DECOR® (https://art-decor.org/art-decor/decor-project--hl7ips-) to facilitate the templates’ formalization and reuse.

The FHIR IPS implementation guide – based on FHIR R3 - has been recently released for the STU ballot (May 2018 HL7 ballot cycle) (http://hl7.org/fhir/uv/ips/history.html). The same conceptual content in both the CDA R2 and FHIR specifications, i.e. the IPS core dataset, has been used.

Both the guides share the same design principles in order to facilitate the alignment between CDA and FHIR implementations, without however attempting to provide or require capability for automatic transformation of instances from one standard to the other. Both guides provide support for multi-languages translations; give a strong attention to implementers; and specify the building blocks (CDA templates; FHIR profiles) used for creating an IPS document. Even if the intended use of these “building blocks” is the IPS document; there is a growing interest in looking at them as a library to be reused in other situations, as investigated for example by the European Trillium II project (https://trillium2.eu).

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A call for action by Farmácia Latina

Pharmacists’ Contribution to ensuring Healthcare Sustainability and Accessibility in Europe

On March 21, 2018, I had the unique privilege to participate in the panel “The application of new technologies and IT in health” moderated by Duarte Santos, Board Member of ANF, the association of community physicians in Portugal, with Cláudia Monteiro de Aguiar, Member of the European Parliament (PT, EPP), Ilaria Passarani, Secretary General, PGEU, and Terje Peetso, Head of Sector, eHealth, Well-Being and Ageing, DG CNECT of the European Commission.

My statement highlighted the key role of community pharmacies in safeguarding the health of communities, particularly in southern Europe. After presenting the Trillium II project on scaling up use of patient summaries, I addressed the potential role of patient summaries in improving productivity and quality of the community pharmacy services. The topic of how data-driven service innovation can best serve community pharmacies in the interaction with general practitioners and hospitals was raised: Where are the limits of big data and artificial intelligence in serving community pharmacies: skills, law, trust, standards, codes of Conduct? My argument was for design thinking: empathize, define, ideate, prototype, test, implement (understand, explore, materialize).

In Europe, community pharmacists have a unique responsibility for the health and wellbeing of citizens as pharmacists are often the first and last point of the patients’ interaction with national health systems. By offering highly skilled healthcare professionals in a familiar environment, community pharmacies play a key part in ensuring that healthcare is both accessible and patient centred. Beyond ensuring timely accessibility of medicines to the population, community pharmacists can provide an increasing number of added-value healthcare services. The network of 160,000 community pharmacies in Europe presents a unique opportunity to provide improved access to health screening, early interventions and disease prevention programmes for all citizens.

Community pharmacists reported that their expanded services include vaccination/immunization in Portugal, Ireland, the UK,
Screening programmes for type 2 diabetes through community pharmacies are common: the Italian pharmacy owners’ association (Federfarma) in collaboration with partners including Italian Chamber of Pharmacists (FOFI), Cross-Party Parliamentary Group on Diabetes and Italian Society of Diabetologists (SID), organised a diabetes screening campaign during International Diabetes Week in 2017. Community pharmacies routinely deal with minor ailments so that formal primary care settings can focus their efforts on more complex cases, improving the efficiency of healthcare services and facilitating access to care. Portugal presented the pilot-project USFARMÁCIA, where collaborative models of public health intervention between pharmacies and primary care centers, allow general practitioners and pharmacists to exchange information in pre-agreed therapeutic areas with agreed intervention protocols.

Medication non-adherence costs the European Union €125 billion annually. Community pharmacies help make patients be and feel empowered through information and education, understanding why their treatment is needed and how to take their medication. Studies showing that pharmacists’ regular interaction with patients improve adherence, reduce adverse effects of medicines use, leading to better outcomes and contributing to a cost-effective health system, were presented from France, Italy and Spain. Italian pharmacists contribute to improving clinical outcomes and cost-effectiveness of prescribed medicines, reducing medicines waste and improving patient outcomes by improving adherence through targeted consultations with asthma patients. France launched a medication review programme to support 3.9 million elderly patients with multiple chronic conditions, following on programmes supporting asthma and thrombosis patients. In Spain, project ADHIERETE supports adherence in chronic disease patients aged 60 or above.

Community pharmacists in Europe expressed their strongly commitment to digital transformation. In Spain, Portugal and Italy, a firm commitment has been made to increase the use of the electronic prescriptions in the National Health System helping to improve patient safety and the sustainability of the wider health system. In France, community pharmacists maintain patient medication records (Dossier Pharmaceutique), which display all treatments (prescribed or over-the-counter), dispensed to a patient during the previous four months, regardless of the pharmacy in which they were delivered. In Portugal, about 90% of all prescriptions are electronic.

A call to action by Farmácia Latina for all healthcare stakeholders was presented in the event:

- Promote the services available in community pharmacies through public awareness campaigns and in national health strategies. In this regard, we call upon the authorities to:
  - Recognize the role of community pharmacies in improving access to disease prevention and health promotion programmes;
  - Embrace the added-value pharmacies provide by improving access to screening services;
  - Recognize the enduring role of pharmacists in self-care and health literacy;
  - Acknowledge the growing scope of practice of community pharmacists in vaccinations.

- Support services that aim to improve patients’ adherence to medicines, developing programmes that will support pharmacists’ capacity to communicate with patients helping to ensure the sustainability of national health systems. Support professional services for medication review with follow up and reconciliation of medications at the time of the hospital discharge;

- Promote and support technological projects encouraged by national professional organizations towards innovative professional services developed by pharmacies, providing better pharmaceutical assistance to citizens and improving the efficiency of national health systems;

- Fully involve community pharmacies in national health strategies, recognizing the crucial role they play in the lives of patients;
HL7 Poland organizes first Polish Connectathon on its own Tukan Platform

The current developments of Polish eHealth projects challenge our health IT community to a significant extent. The pilot of central ePrescription system, the official recommendation of IHE profiles use and continuous development of the Polish National Implementation Guide for HL7 CDA – all of them are shaping the national perspective of eHealth for the next years to come. Polish vendors, for the first time, have also shown quite substantial interest in HL7 FHIR. The existing and planned regional platforms face new challenges resulting from common expectation to interoperate in practice.

**Tukan** is an online platform, produced and managed by HL7 Poland, dedicated to the Polish healthcare IT community, where national specifications for interoperability are published together with a set of testing tools supporting their implementation. The platform consists of selected IHE Gazelle components, XDS.b simulators, ART-DECOR environment, schematron based HL7 v3 validator and FHIR server. The most commonly used service is HL7 CDA validator, that covers conformance to the CDA data model as well as to the national IG specification (PIK HL7 CDA). The Tukan FHIR server is being used as a validation tool for all basic FHIR resources and a source of HL7 defined value sets. Several national dictionaries have been also shared there in the form of FHIR Terminology Services.

So far, the Tukan project has no public funding and all necessary work is being delivered by members of HL7 Poland. Most of the key competence and resources come from three companies: Lux Med, Comarch Healthcare and HIT Inn. Lux Med is the biggest Polish private medical provider with almost 200 proprietary facilities and about 1.600 more of cooperating partners. Since 2010 more than half of all clinical documents issued at Lux Med

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**Catherine Chronaki**
Secretary General, HL7 Foundation

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Promote strategic alliances between pharmacies, patients and scientific associations, and dialogue with the pharmaceutical industry, and universities, recognizing potential synergies;

Ensure the **long-term financial viability of healthcare** systems by recognizing the cost-effectiveness of pharmacy interventions.

Clearly patient summaries have a crucial role to plan in the new suite of services promoted by community pharmacists. HL7 and its members need to actively engage with community pharmacists to respond to their expanding standardization needs in the spirit of co-creation, governance, alignment advocated by eStandards.

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For more information

- Trillium II Project: [www.trillium2.eu](http://www.trillium2.eu)
- Pharmaceutical Group of the European Union: [www.pgeu.eu](http://www.pgeu.eu)
have electronic form, conformant to the HL7 CDA standard. Comarch Healthcare is a specialized branch of one of the leading Polish vendors with strong presence in the global market. Comarch Healthcare offers a suite of products conformant to HL7 CDA and the IHE XDS.b profile. HIT Inn, owner of the iEHR.eu portal, is a small consulting company highly specialized in implementation of interoperability standards and profiles.

The Polish community of Health IT vendors and their clients, medical providers, has been always rather hermetic and isolated from international activities. Due to strong promotion and educational activities around HL7 standards and IHE profiles, interoperability standards started to be reflected in the requirements for the regional eHealth platforms and the central, nation-wide services, like ePrescription. Organizations behind those projects strive for reliable tooling to verify the quality of implementation of standards and integration profiles. On the other hand, there is a growing interest from vendors to get verification and validation support in the software development process. For that reason, Tukan platform development have been focused on providing components to organize connectathon-like events and the platform is ready to be used as environment for peer-to-peer testing. Tukan is also recommended by the Polish national eHealth agency (CSIOZ) as the reference testing platform. According to official statement, the next ePrescription-related, projectathon-like event will be held on Tukan platform with cooperation with HL7 Poland.

The Tukan platform is based on software components originating from various sources:

- open source release of IHE Gazelle components,
- development tooling of Polish National Implementation Guide of HL7 CDA,
- ART-DECOR platform software components,
- HAPI FHIR reference implementation for FHIR STU3 standard,
- Central Authentication Server (CAS) software components.

IHE Gazelle based components are used to support basic communication platform to allow secure, SSL-based, IHE ATNA conformant service endpoint publication. We have adopted Gazelle Proxy component together with the External Validation Services Front-end (EVSClient) to support peer-to-peer testing with robust message validation functionality. Having the connectathon event organization in mind, we have set up the Gazelle Test Management application to allow testing entities registration and test instances configuration in the connectathon-like manner.

From the technical perspective, having extensibility and scalability in mind, all Tukan platform services are deployed as isolated, Docker-based containers in the Linux environment. The platform itself is the main repository of the container images. Any service can be easily replicated to many computing nodes if needed, and effortlessly deployed to other infrastructures, including various cloud service providers.

The currently running services of Tukan platform are:

- Forum for platform users,
- Central Authentication Server (CAS, incl. LDAP server),
- PL CDA validation tool,
- FHIR STU3 server (including terminology services).
- IHE Gazelle Security Suite,
- IHE Gazelle Proxy,
- IHE Gazelle Test Management,
- IHE Gazelle External Validation Services Frontend (EVSClient)
- NIST XSDTools 4,
- ART-DECOR environment (including current version of Polish National Implementation Guide of HL7 CDA and other local projects).

The first connectathon on Tukan platform is planned for autumn 2018 and will cover multiple profiles, standards and specifications for healthcare interoperability.

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MIE 2018 Datathon: Data, Process, Winners, and Prospects

Building on the lessons learned in first European DataThon at IHIC2018 that used Synthea [1], a synthetic health dataset of one Million fictitious but realistic citizens of Massachusetts, US (see relevant article), the MIE 2018 DataThon used synthetic census data from Norway, Sweden, Denmark, and Finland with the double aim to offer hands-on FHIR training and to validate the use of patient summaries in the health journey of asthma patients.

The condition of asthma was selected for several reasons:
- asthma is the chronic condition that appears earlier in life and has been extensively studied,
- asthma patients strive to control their asthma with medication and lifestyle choices,
- environmental conditions can affect status of the asthma,
- allergies and intolerance are frequently associated with asthma,
- moreover, the DataThon offered the opportunity to explore if and how the International Patient Summary (IPS) could serve the needs of asthma patients and their care givers with a window to the patient’s health information linked to data sources across the care continuum.

Reviewing UptoDate (Asthma Management 2015), GINA guidelines (GINA Guidebook 2018), Lung Health in Europe (ERS 2013), and other scientific resources under the guidance of the international clinical advisory board, an asthma patient pathway was created and adjusted with risk factors, to facilitate the creation of the synthetic population.

Following the eStandards methodological approach of Co-creation, Governance, Alignment [2], our objective was to validate the International Patient Summary (IPS) Resources that the European Project Trillium II released in late 2017 [3]. These resources formed the basis for the HL7 IPS on FHIR specification part of the HL7 May 2018 ballot [4], which is aligned with the CEN IPS project [5] (see article on page 7f).
The MIE DataThon 2018 was a real team effort with more than 12 supporting organizations and projects. Charlie, Allie, and Harley from Ramsey systems, using public census data and other public statistics on medical consumption, conditions, allergies etc., initiated the creation of 100000 synthetic IPS records using the asthma pathway. The HL7 FHIR IPS resources did not require major adaptation to fit the needs of asthma patients. Peak flow and Spirometry exams were modeled as observations and DaCHI, DK (team of Prof Louise Bilenberg Pape-Hauggaard, Institutional member of EFMI) provided realistic, but synthetic data. Giorgio Cangioli based on a clinical case provided by Prof Mitch Blair of Imperial U, UK (MOCCHA project – collaborating with Trillium II) created a sample IPS for 14-year old asthmatic patient Danny. The FHIR resources were made available on onFHIR (onFHIR.io), a FHIR server provided by SRDC, TR.

Variations of the asthma pathway were developed to focus on different junction points of the disease such as exacerbations and emergency admissions, with support from Advisory Group members, Luis Garcia-Castrillo and Andrea Fabbri of EUSEM, the European Society of Emergency Medicine (see Figure 1). The ability to compare the health and economic impact of different health policies in the management of asthma was noted by Joao Fonsceca, PT, but due to time limitations, were not introduced to this edition of the DataThon.

The MIE 2018 Datathon, offered the challenge of combining the synthetic FHIR IPS resources with web services to pollen levels in atmospheric data from the Copernicus web services to pollen levels in atmospheric data from the Copernicus web service [6] and medication side-effects through VigiAccess® [7]. VigiAccess® web services offer access to aggregated data of suspected medication side effects based on reports of Adverse Drug Reactions (ADRs), so called Individual Case Safety Reports (ICSRs), collected by national drug authorities in over 110 countries and spanning over more than 100 000 different medicinal products to VigiBase®, the global database for ADRs of WHO, maintained by the Uppsala Monitoring Centre (UMC).

The MIE 2018 Datathon lasted two and a half days.
from the Nordic countries interested to experiment with FHIR resources, but marketing efforts was ineffective as the event was in direct competition with the Vitalis exhibition and other MIE 2018 events.

**Results of the MIE 2018 Datathon Competition**

The MIE 2018 DataThon closing session was hosted by HL7 Sweden on Wednesday April 25 in the afternoon. Three working solutions were demonstrated, and participants voted for the winner using sli.do. Tom Kane, chair of the EFMI WG LIFOS on open source software served as rapporteur in the MIE 2018 DataThon closing session.

Three of the four teams presented their project goals and achievements during the MIE 2018 DataThon:
- A team with members from San Francisco, Mozambique, and Taiwan created dashboards to present the status of asthma patients.
- A team from Germany and Qatar explored use of the FHIR IPS resources in the Emergency Department, accessing and updating them.
- A team from Portugal used the UMC API to retrieve further information on medication in the patient summary of child with asthma.

None of the teams had prior knowledge of the data available and their accomplishments were remarkable given the short time available.

**The Winners of the Competition**

The winning team, Duarte Ferreira and João Almeida from Portugal (see Figure 4) presented a prototype of the ADRS Sniffing App, a health professional app that could be used by pharmacists. They received 15 votes. ADRS Sniffing aims to help healthcare professionals consider possible ADR events.

Whether in emergency situations, prescriptions assessment or pharmacovigilance causality assessments, this application allows to connect a patient’s active medication and reported respiratory ADRs worldwide. That could provide improved clinical decision support to healthcare practitioners taking care of asthma patients. Using the Vigiaccess® API, the application retrieves from VigiBase aggregated data about ADRs for each medication prescribed to the patient. Afterwards it processes the data and displays it in a simple web page, listing the respiratory ADRs found for each medication. Both researchers at project NanoStima@CINTESIS (www.cintesis.eu), João is a pharmacist active in IHE Pharmacy, and Duarte is developing integration tools for HLTSYS.pt.

The team presented graphically their data flow – the way they captured and used data. Their final product was demonstrated as it would appear on a mobile phone.

**Second Place**

The team in the second place with 20 votes comprised Edson Nunes, David Mugume and Eudson Bambo from Global Programs in Mozambique collaborating with Patric Prado from University of California San Francisco. Global Programs for Research and Training was established in 2016 in Maputo, Mozambique with the goal to enhance data use at all levels of the health system to support data-driven decision making for HIV/AIDS care and treatment focusing on national surveillance systems, health information systems, data quality improvement, and data management and use. Prof. Yi-Ju Tseng from Chang Gung University in Taiwan interested in the FHIR standard joined the team. The team developed dashboards to explore the information offered by the data. The web application presented the population of asthma patients along different dimensions as the age distribution of asthma patients, as well as prescriptions of inhalers and emergency hospitalizations over time.

**Third Place**

The third team comprising Julian Sass from the Faculty of Health Care, University Hochschule Niederrhein in Krefeld, Germany and Abdelkader Lattab from QCRI, Qatar. Julian does research in Health Information Systems, Semantics and Interoperability, focusing is on HL7 CDA, FHIR, SNOMED CT and LOINC. Abdelkader has been actively involved on processing data in real time using distributed stream computing platforms such as Apache Storm. His work also focuses on building mobile health apps for intervention for weight-loss among children with obesity or weight loss and diabetes.

The aim of Germany/Qatar team was to follow the clinical story of Danny, a young asthmatic patient
in the emergency room, where they need to access the IPS and update it with new findings. The tools used was an XML editor and REST client. The team succeeded in accessing and processing the IPS resources in FHIR. Following the story of Danny in the Emergency department, they created an allergy resource and updated IPS medication component with the newly prescribed medications.

They found that working with FHIR resources was straightforward and compared very favorably with their prior experience with the HL7 Clinical Document Architecture and the CDISC Operational Data Model formats. The team showed examples of JSON and XML FHIR transactions and spent the day learning the technical details of FHIR IPS. They are very interested in implementing FHIR in future projects in Qatar and Germany and felt that the DataThon provided a unique hands-on training opportunity.

Panel Discussion and Takeaways

The closing panel (see Figure 5) of the MIE 2018 DataThon brought members of the Advisory board to stage to discuss key takeaways with the MIE 2018 DataThon participants and to identify next steps:

- Prof Rianne Oostenbrink, MD of Erasmus University, Netherlands,
- Doug Frisma, MD of AMIA, US,
- Petter Hurlen, MD, Secretary of IMIA Board, Akershus U Hospital, Norway,
- Russell Leftwich, MD, Member of HL7 International Board,
- Helén Seeman Lodding, MD, Member of HL7 Sweden Board, and
- Alfred Winter of Leipzig University, Germany, Secretary of the EFMI board.

Figure 4: The winners of the MIE 2018 Datathon, Duarte Ferreira and João Almeida, created the ADR Sniffing App that combined data from the IPS with Adverse Events retrieved via web services from the WHO Pharmacovigilance Center in Uppsala.

Figure 5: The closing panelists for the MIE 2018 DataThon
The panel and participants agreed that strong points of the MIE 2018 DataThon was how it allowed participants to leverage public health dashboards, information to care givers, and links to other databases. Participants noted that the input from clinicians on the meaning of data during the DataThon was essential.

Regarding key takeaways from the event and thoughts for improvements of future events, several suggestions were put forward:

- HL7 FHIR DataThons provide an excellent opportunity to educate on interoperability standards taking a hands-on approach and demonstrating innovative ideas centered around health data.

- The MIE 2018 DataThon was appreciated for its focus on data standards and that was contrasted to the objectives of hackathons or connectathons. The DataThon encouraged people to think about diverse sources of data imagining how to use data creatively shared or accessed from different healthcare stakeholders (e.g. UMC Pharmacovigilance data), shifting thinking from technical connectivity issues to health policy, evidence-based design of health services, etc.

- The focus on specific clinical settings, i.e. pharmacy, by the winning team that designed a tool of potential value to pharmacists assembling data from different sources, was welcomed.

- Participants suggested that data and resources made available to potential participants before the start of the DataThon, would give them more time to experiment and familiarize themselves with the data.

- Panelists discussed the challenges related to data quality, how to overcome issues of data collection and curation, and the need for de-identified datasets to enrich the synthetic data sets. Getting the balanced right between focus on a concrete problem to solve with appropriate data sets and a more open-ended DataThon where participants explore a wide area of interest, is critical. Panelists shared that it may take one week to design a data case study idea, and then 6 months to aggregate and clean the data before the idea can be explored in a DataThon.

- Developing a shared synthetic data resource to which DataThons would contribute data sets and project ideas would further enrich future DataThons building human capital and advancing knowledge.

- DataThons offer the setting to explore questions of infrastructure, data provenance, information governance, security and privacy.

“With HL7 FHIR, technical interoperability is the least of our problems”, noted one of the clinical advisory group members.

**Next Steps**

The MIE 2018 Datathon was undoubtedly a success offering total FHIR immersion, connecting health data resources in FHIR to Pharmacovigilance data from the Upsala Monitoring Center, and validating the IPS concept for chronic patients suffering from asthma, being admitted to the emergency room. Several improvements were noted and ideas for the next DataThons have been proposed, which will hopefully bring closer researchers, standard developers and entrepreneurs. We are all excited with the idea of DataThons look forward to sharing lessons learned to ensure that future events best cater to the participants’ interests and skills, making DataThon events productive and effective, to build-up standards competencies and advance health data literacy.

Catherine Chronaki, HL7 Foundation

Giorgio Cangioli, HL7 Foundation, HL7 Italy

José Costa Teixeira, HL7 Foundation

Allie Short, Business Analyst, Ramsey Systems

Harley Johnson, Ramsey Systems

Charlie McCay, Ramsey Systems

Tom Kane, European Federation of Medical Informatics WG Chair LIFOSS

For further information

- [1] MITRE Foundation, Synthea, SyntheticMass of realistic but fictional residents of the state of Massachusetts, https://syntheticmass.mitre.org/about.html


- [3] Trillium II resources on simplifier: https://simplifier.net/TrilliumII


Impressions from the MIE 2018 DataThon: A good Place to meet

The HL7 FHIR DataThon took place during MIE 2018 in Gothenburg April 22-24, 2018. It was a rewarding event both for the young researchers and experienced clinicians.

The young researchers with background in computer science were given the task of exploring and use FHIR specification in a given clinical domain; treating asthma patients. The clinicians in the advisory board were given the task of explaining clinical thinking and clinical work as a supplement to the specifications. However, it soon evolved into a dialogue where the clinicians learned as much from the computer scientists’ reasoning, eagerness, and need to understand clinical care in order to develop good and useful results, as the scientists learned from the clinicians.

Essential in the dialogue was the need to understand the difference between data and information, but also what clinical information is and how it is used in patient care. After all, clinicians treat patients, not information. While standards and models used in computer science is intended as “one-for-all”, clinicians treat people where no two individuals are identical. We can standardise technology, but not humans.

This is possibly one of the reasons for the success of FHIR, it has an element of pragmatism where the definitions are based on the most essential clinical needs and a sound balance between what needs to be standardised from a clinical perspective, and what should preferably be left out. Clinical information is used in context, and the context is often essential to convey meaning between clinicians. Consequently, communication standards do not only describe the individual data items, but also the necessary information context for communication between clinicians.

Future work in this area must take into account the nature of clinical information and the professional language of clinicians. It can be supplemented by models, ontologies and other formal methods of describing data and knowledge. Such constructions can, however, never replace the need for individuality and precision that is represented by the clinical language. After all, humans are individuals, and no two patients are alike.

Hopefully, the DataThon will be an annual event and a good place to further explore the borderland between computer science and clinical care with mutual benefits for all participants.

Petter Hurlen, MD MSc PhD
Senior Consultant, Akershus University Hospital, Norway.
HL7 Hellas had the great honor to host the International HL7 Interoperability Conference, IHIC 2017, from 22-24 October 2017 at the Technopolis City of Athens, Greece. This was the second time that the Conference was hosted in Greece, the first being in 2008 in Heraklion, Crete. HL7 Hellas with the support of HL7 Germany and HL7 International co-organized the conference and was under the auspices of the Hellenic Ministry of Health.

IHIC events address both practitioners and scientists since they are dedicated to evaluate HL7 specifications against alternative solutions, investigate standards harmonization as well as future directions and needs, new principles, methodologies, and tools. Thus IHIC events complement HL7 Working Group Meetings where the main concern is the specification of interoperability standards.

The focus of the 17th event in the history of the International HL7 Interoperability Conferences was the digital transformation that health systems around the world are currently facing. This year IHIC included the organization of an HL7 FHIR® Datathon, which was the second of its kind in the world, and the first in Europe.

The program of IHIC 2017 started on the 21st and 22nd of October with seminars on standards and on various issues of interoperability in health by distinguished international speakers. Nine tutorials, of two hours each, covered topics related to IHE, IHE XDS, IHE Gazelle, CDA, ART-DECOR, Snomed CT, Security and Privacy, and FHIR®. More information at http://www.ihic2017.eu/content/tutorials

On October 23, the 1st European HL7 FHIR® DataThon "Healthcare Informatics in the Age of
FHIR® was held. A hands-on lab using tools to use the HL7 FHIR® standard for reviewing and searching for complex health data. DataThon was not a formal tutorial, but instead a hands-on working session where participants used FHIR® to explore informatics topics with simulated clinical data. The event was an opportunity for researchers, analysts and implementers to actively participate in developing FHIR® solutions and exchange data using FHIR interfaces. During the DataThon, FHIR® was used to explore data stores and see what information and opportunities FHIR can uncover. Participants were mainly current and future FHIR developers (programmers, analysts, architects etc.), including also some participants from the medical domain and academic research. The feedback from the more than twenty participants was very positive regarding the actual chosen topics of the event. More information at http://www.ihic2017.eu/content/hl7-fhir-datathon. The results of the DataThon were included in a report sent to the Ministry of Health in Greece for future consideration.

October 23 and 24 were two days filled with prominent speakers presenting all current international standards and interoperability developments. The conference was organized in four thematic blocks. The first conference day begun with the welcome addresses from the scientific program committee, the local organizing committee, HL7 International Chair and CEO, and two keynotes highlighting the situation and strategies for the Greek eHealth Program.

The four thematic blocks included keynotes by Ed Hammond (HL7 US), Bernd Blobel (HL7 Germany), Gora Datta (HL7 US), and presentations from excellent speakers of international scope and high scientific level from Australia, Austria, France, Germany, Greece, Italy, Poland, Portugal, UK, and the US.

The conference program of the second day was concluded with a Workshop and Panel “FHIR: An Implementers’ Guide”, presented by Charles Jaffe (HL7 International, USA), Robert Hausam (Hausam Consulting, USA), Russ Leftwich (Intersystems, USA), and Rik Smithies (NProgram, Birmingham, UK). More information at http://www.ihic2017.eu/content/program

Twenty-two papers were submitted to IHIC 2017, and the quality of submissions to the conference was very high. After a careful international review by independent reviewers, ten contributions were accepted as full papers published in an IHIC 2017 Special Issue of the European Journal for Biomedical Informatics (https://www.ejbi.org/
Six submissions were classified as Reports and five as Report Abstract. Both groups were published in the IHIC 2017 Proceedings book (ISBN 978-960-99062-3-4).

The J. W. Dudeck Award for the best new work of a young scientist under 35 years old went to the French Abderrazek Boufahja for his excellent work “On the evaluation of HL7 CDA R2 Documents Richness and Validation Reliability”, coauthored by Eric Poiseau (France).

The conference had 95 delegates from 11 countries and achieved its goals of playing the role of a link between science, research and practice to exchange experiences related to HL7 and interoperability in the domains of health and social care. We thank everyone involved in its success: IHIC 2017 attendees, authors, speakers, reviewers, session chairs, tutors, panelists, sponsors, organizers, members of the organizing committee and the co-chairs. More information at www.ihic2017.eu

The organization of IHIC 2018 will be held in Portsmouth in the UK on July 11-12, 2018. For more information on IHIC 2018 visit the conference web site at http://ihic.info.

Dimitrios G. Katehakis
Secretary General, HL7 Hellas (EL)

Nikos Kyriakoulakos
Director of Standards, HL7 Hellas (EL)

Alexander Berler
Chair HL7 Hellas (EL)

The Andalusian Health Service EHR

The Andalusian Health Service (SAS) serves a population of 8.5 million with a workforce of around 100,000 employees, 1500 thousand primary care facilities and 40 hospitals. SAS makes extensive use of IT for clinical information management. The EHR system, code-named Diraya (knowledge in Arabic), is available region-wide at any point of care.

Diraya is an integral EHR covering all relevant aspects of care: primary, emergency (ER and mobile ICUs) specialized care (outpatient and inpatient), appointment scheduling, nursing, surgery planning, e-prescription, lab testing and diagnostic imaging.

The architecture of Diraya follows a standards-based approach where the different applications exchange information through clearly defined interfaces. Applications are domain-specific and as decoupled from the rest of the eco-system as possible.

Diraya features a two-layer structure: some applications have a regional scope and others are hospital-centric (the information they record is still retrievable region-wide though). Thus, services such as the MPI, appointment scheduling, primary care, the main EHR registry, LIMS, RIS, e-prescription run at a regional level whereas applications like the clinical workstations run at the local-hospital level.

The EHR is structured as a single-registry with federated storage. A single regional application maintains the health record tree for each person. A patient’s record includes references, including the episode of care, for each of the documents and objects that are stored elsewhere in the applications that created them. These documents are requested individually as needed from any of the clinical applications that display patients’ health records. This setup aligns with the model described in the XDS IHE profile.

The exchange of information between the elements that comprise the EHR is managed through an Enterprise Service Bus (ESB). This infrastructure also follows the two-layer topology: one level for intra-hospital communication and one level for region-wide communication. Information exchange is modeled on a Service Oriented Architecture based on standard SOAP Web Services and HL7 messaging (v2.5 XML).

In addition to the standard web-services portfolio based on HL7 v.2, SAS is currently rolling-out
a wide-ranging REST API based on the FHIR standard. Using FHIR significantly reduces development, testing and deployment times, especially for mobile and modern web-based applications built around JSON. This is particularly relevant for the MSSPA initiative, which provides a framework for mobile developers that want to create patient apps around the Diraya eco-system.

All governance and standardization aspects related to the exchange of information fall under the responsibility of the Technical Office for Interoperability (OTI), a department of the Deputy Direction for Information Technology and Communications.

OTI defines all of the web services and exchange modes for all integration needs. The process begins, in line with SOA principles, with an analysis from the point of view of the business needs. From there, an OTI integration analyst, consulting with the business specifier and the endpoint developers, validates the final proposal. This may simply entail the consumption of already-existing services or the development of new services and interfaces.

Development follows a contract-first approach, no coding takes place on any of the end points until the final technical interface specification is provided by OTI (WSDL for web services, REST/JSON definition, error handling requirements...).

For integrations that match already existing profiles, for example the addition of a new departmental application in a hospital, OTI has a procedure for testing, validation and certification of the consuming application. Once a particular version of an application has successfully undergone these procedures, OTI certifies the product for that integration profile. Any other hospital that wants to deploy the same application only has to perform some technical/communications testing, saving significant time and development costs.

OTI maintains a catalog of certified applications/profiles. Hospitals now include this certification as an element in tender contracts for new software purchases for the cost-saving benefit of using an already-certified solution vs one that has to integrate from scratch.

The evolution of the interoperability strategy comprises several main goals: streamlining integration processes and requirements, evolving interfaces so that direct consumptions mostly use REST solutions and the SOAP-ESB approach is reserved for more complex orchestrations (multiple subscribers, transformations, etc.).

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Andalusian Health Service

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National Directory of Laboratory Tests

In order to ensure interoperability of medical information systems in the Russian Federation with the active participation of HL7 Russia, the National Directory of Laboratory Tests (NDLT) was developed. The Directory includes 14,276 unique laboratory tests and continues to evolve. At this stage, there is an active work on the creation of laboratory profiles.

The level of informatization of healthcare in the country is related to the ability of medical information systems to interact with each other. Interoperability of medical information systems is based on the use of standards for the exchange of electronic health information, among which the widespread international standards HL7 v.2.x and V. 3, CDA, FHIR, OpenEHR, DICOM 3.0 and others. Regardless of the standard chosen, in order to ensure the process of receiving/transmitting medical information, developers need well-structured reference directories focused on the relevant subject area.

Work on the creation of NDLT was carried out under the leadership of chief specialist of the Ministry of health of the Russian Federation on the introduction of information systems Professor T.V. Zarubina. In creating the directory of the active participation of leading experts of the Association of specialists and organization of laboratory services “Federation of laboratory medicine” (www.fedlab.ru) under direction of the chief specialist MOH for clinical laboratory diagnostics, Professor A.G. Kochetov. For collegial discussion of emerging issues and decision-making on the basis of the National Association of medical Informatics (www.nami.su) an ad hoc NDLT working group was established, which included interested specialists.

The main unit of information in NDLT is a laboratory indicator (test), which can be defined in the clinical diagnostic laboratory on the analyzer or manually and the result is presented in one of four options: quantitative, ordinal, qualitative value or a simple text description. Each laboratory test has a unique NDLT code and is determined by the superposition of the main “axes”: the type of biomaterial, measured analit and its characteristics, method of measurement, type of result scale and time characteristics of the study duration. The NDLT code allows you to compare laboratory tests with each other. For quantitative tests, you can build linear trends to estimate the dynamics of their changes. A similar principle is laid down in the international code of clinical and laboratory terms LOINC, unique codes of which are used in the exchange of laboratory results in many countries of the world.

The structure of the directory of laboratory tests includes the full and short name of the laboratory indicator in Russian, the name in English, a separate field for storing alternative names and related concepts. For NDLT laboratory tests, it is possible to map with the codes of the national nomenclature of medical services (NMS) and LOINC. The structure and example of filling the NDLT laboratory tests is presented in Table 1.

Filling the NDLT went in stages for each major section of laboratory diagnostics. First, produced the primary content of the section on the basis of existing regional reference laboratory tests „UDLT“ (Department of health of Moscow) and „LATEUS“ (Saint-Petersburg), as well as guides provided by the developers of MIS and LIS: „Asclepius“, LLC „Laboratory „ACROSS-Engineering“ and LLC „Bregis“. The content team combined all the uploaded data, selected the appropriate records, and eliminated logical duplicates and inconsistencies. Then, a mapped-group conducted a comparison of a prepared list with the nomenclature of medical services and LOINC.

The NDLT expertise was attended by leading specialists of clinical laboratory diagnostics, the candidates depending on their specialization were selected by the leadership of the Federation of laboratory medicine. The tasks of the experts included:

- Evaluation of the correctness of the full and short names of laboratory indicators, checking the correctness of synonyms of the full and short names.
- Assessment of the correctness of the selected LOINC codes and nomenclature of medical services.
Checking the correctness of the formulation of analyses, sample names, their time characteristics and methods.

Adding unaccounted laboratory indicators that were not in the list.

Elimination of any defects that have arisen during the stages of filing and mapping of the NDLT.

The first public version, the NDLT 1.0, was published on January 11, 2017 and contained 13,232 unique lab tests. At the time of writing, users can access version 3.6, which increased the total number of tests to 14,276. The increase in volume is conditioned by the intensive development of microbiological and immunological sections of the Directory. All laboratory parameters are divided into 14 groups of laboratory tests.

As a result of the development of the NDLT, five related reference directories were published on the portal of the Ministry of health of the Russian Federation:

- Laboratory test reference (14,276 entries),
- Laboratory groups (14 entries),
- Bacteria reference book (9,111 entries),
- Fungus directory (558 entries),
- The units dictionary (497 records),

however, their number will gradually increase. The lab tests directory is the primary directory in the

### Table 1: Description of the structure and an example of filling NDLT

<table>
<thead>
<tr>
<th>Field</th>
<th>Example of filling</th>
</tr>
</thead>
<tbody>
<tr>
<td>id</td>
<td>1012856</td>
</tr>
<tr>
<td>Full name of the test</td>
<td>Скорость оседания эритроцитов по Вестгрену</td>
</tr>
<tr>
<td>English name of the test</td>
<td>Erythrocyte sedimentation rate by Westergren method</td>
</tr>
<tr>
<td>Short name of the test</td>
<td>CO3 по Вестгрену</td>
</tr>
<tr>
<td>Alternative names</td>
<td>ESR по Вестгрену</td>
</tr>
<tr>
<td>Analyte</td>
<td>Erythrocyte sedimentation rate</td>
</tr>
<tr>
<td>The characteristic of the analyte</td>
<td>rate</td>
</tr>
<tr>
<td>Dimension</td>
<td>linear rate</td>
</tr>
<tr>
<td>Unit of measure</td>
<td>mm/h</td>
</tr>
<tr>
<td>Specimen</td>
<td>Whole blood</td>
</tr>
<tr>
<td>Method</td>
<td>Sedimentation on Westergren</td>
</tr>
<tr>
<td>Time characteristic</td>
<td>one-stage</td>
</tr>
<tr>
<td>Scale</td>
<td>Quantity</td>
</tr>
<tr>
<td>Status</td>
<td>Actual</td>
</tr>
<tr>
<td>Group</td>
<td>Hematology</td>
</tr>
<tr>
<td>NMS code</td>
<td>A12.05.001</td>
</tr>
<tr>
<td>LOINC code</td>
<td>4537-7</td>
</tr>
</tbody>
</table>

NDLT group, but some of its fields can be populated with formalized values from related directories. In addition to the already published reference books, there are reference books of laboratory specimens, reference books of the time characteristics of the sample, the type of the measurement scale and the status of the laboratory test (Figure 1).

The mapping of laboratory tests using domestic NMS reference and LOINC causes the connection with the current versions of these directories. The process of mapping proved to be quite difficult. As a result of careful work with NMS codes only 5,537 tests out of 14,276 (38.8%) were compared. A total of 618 NMS codes were used, of which 380 (61.5%) are repeated at least twice, and 10 NMS codes are repeated more than 50 times.

In the process of mapping with LOINC 5,541 unique codes were found, which is 38.8% of the total number of the NDLT laboratory tests. However, the results varied greatly in different groups of laboratory tests. Only 34 suitable LOINC codes were found for 5697 toxicological tests, which is 0.6%. 732 LOINC codes (58.3%) were found for 1256 immunological tests. In the group of biochemical studies the result was much better: it was possible to compare about 97% of tests.
Many experts rightly considered such tests obsolete and were categorically against their inclusion in the NDLT. But, since, until now, these tests are performed in a number of laboratories in the country, it was decided to add them as "outdated". So in the NDLT in a field „Status", besides "active" and "outdated" tests, there are now the „new" indicators which are used to mark tests that are recently introduced or still being introduced in clinical practice. At the moment, there are 435 (3.1%) new and 88 (0.6%) outdated laboratory indicators in the NDLT.

S. L. Shvyrev
Federal Research Institute for Health Organization and Informatics of Ministry of Health of the Russian Federation, Chair HL7 Russia

HEALTHeID Project: eIDAS for the eHealth Digital Services Infrastructure

eIDAS (electronic IDentification, Authentication and trust Services) is an EU regulation on / a set of standards for electronic identification and trust services for electronic transactions in the European Single Market. It was established in EU Regulation 910/2014 of 23 July 2014 on electronic identification and repeals directive 1999/93/EC from 13 December 1999. It entered into force on 17 September 2014 and applies from 1 July 2016 except for certain articles, which are listed in its Article 52. The question how the eIDAS applies to cross border eHealth services in Europe and in particular to the eHealth Digital Services Infrastructure is addressed by the HEALTHeID, a project recently funded by the European Commission.

The HEALTHeID aims at developing, testing and delivering to the European Commission and the Member States (MSs) a reference implementation of an eID connector, linking the National OpenNCP-based National Contact Point for eHealth (NCPeH) to the eIDAS node and the relevant attribute providers. Connecting the national eIDAS) Infrastructure to the national NCPeH will enable secure access to cross border eHealth Information Services (CBeHIS). The services concerned are “Patient Summary” and “ePrescription” Services, which are currently being deployed by 16 Member States (MS) supported by CEF funding – CEF eHDSI.

In this context, the action will pilot, a cross-border health data exchange between Member States,
leveraging on the eIDAS Network of Nodes, the national eID Schemes as well as the national eHealth infrastructures. All the resulting eID solution components will be made available as Open Source Software components to the eHealth Digital Service Infrastructure (eHealth DSI) and its National Contact Points for eHealth in order to incorporate them into the eHealth DSI reference implementation.

The action builds on the piloting level achievements of the project Electronic Simple European Networked Services (e-SENS), funded by the EU Programme CIP-ICT PSP. Services from the European Commission will be involved in the pilot scenario definition, design and implementation through technical meetings and workshops in order to secure a seamless testing and integration with the current version of eIDAS reference implementation.

Finally, HEALTHeID will provide a solid basis for the design and development of a reference implementation transferable to other Member States and to the eHealth DSI. Alignment, both technical and timewise with the deployment of the eIDAS nodes will be secured through the direct involvement of consortium partners representing national competent organizations.

HEALTHeID is a 14-months project lead by SPMS (Portugal). The consortium is composed of 13 entities (SPMS, AMA, HMAR, IDIKA, AUTH, POLITO, Caixa Magica, gematik, LISP, VYSCOZINA Region, ATNA, RC and IRD) from 7 countries (AT, CZ, DE, GR, IT, LT, PT), including Competence Centres, National Authorities, Academia and Enterprise, representing the national authorities responsible both for the NCPeH (National Contact Point for eHealth) and the eIDAS node.

Diogo Martins
International Projects Coordinator
Directorate of Information Systems
Shared Services of the Ministry of Health (SPMS), Portugal

For more information:
- eIDAS: https://ec.europa.eu/futurium/en/content/eidas-regulation-regulation-eu-ndeg9102014
- eSENS: https://www.esens.eu/
- eHealthDSI: https://ec.europa.eu/cef-digital/wiki/display/EHOPERATIONS/eHealth+DSI+Operations+Home
- CEF Common Blocks: https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/About+CEF+building+blocks

Patient Summary Standards Set

The first release of the Joint Initiative Council’s (JIC) Patient Summary Standards Set (PSSS) has been published. The intent of the PSSS is to provide guidance about health informatics standards, standards artefacts and profiles that meet agreed criteria, to meet a specific Use Case.

Finnish national Personal Health Record is built on HL7 FHIR

by Konstantin Hyppönen and Juha Mykkanen

FHIR was selected to become the backbone of the national Personal Health Record (PHR), extending the widely used Kanta services. Kanta normally contains data stored by healthcare professionals, such as prescriptions, health records, lab results and the like. The data may be accessed by citizens through the patient portal, MyKanta pages. The goal of the new Kanta PHR is, in simple words, to enable the opposite flow of information: individuals should be able to store their own data, and if they wish, make the data available to healthcare professionals. Such data may include measurements performed at home, answers to questionnaires and online health surveys, or information about medications purchased over the counter.

Developers and specification writers

FHIR is commonly and rightly praised for being developer-friendly. The modern REST approach and the availability of open source libraries are the most frequently mentioned things. What was also important for Finnish adoption was the existence of the developer community which was easy to reach and ready to answer questions. Even though some open source libraries were not entirely of production-grade quality, it was still easier to develop the missing blocks rather than to start from the scratch. Availability of developers of similar systems in other countries to get consultancy on technical matters was also important.

HL7 Finland was established as an HL7 Affiliate in 1996. HL7 standards have been the workhorse of the Finnish national e-Health solutions for more than a decade. In regional and local solutions the use of HL7 (mainly CDA, Medical Records) was prevalent already before the national solutions (Kanta services, www.kanta.fi/en) entered the scene around 2010. That is part of the reason why the decision of using a new and upcoming HL7 FHIR standard was accompanied with excitement rather than uncertainty and doubts in 2015.
FHIR has been easy to learn for semantic experts and specification writers familiar with CDA, even though tools and notations are different. The knowledge of healthcare-related semantics is as important for designers of FHIR profiles as it is for designing CDA implementation guides. Still, it was important for semantic experts to participate in FHIR-related trainings and get familiarized with profiling tools. To support the growing community of FHIR experts, HL7 Finland is organizing a FHIR profiling course this year. Finnish PHR profiles and implementation guides are currently published on www.simplifier.net. In Simplifier site, Finnish PHR is the most popular project at the moment.

In addition to FHIR, other standards were used for authentication and authorization (OAuth 2.0, OpenID Connect, JWT, JWK, etc.). The work performed by the Smart-on-FHIR and Argonaut projects was important to consider, and the implementation guides from these projects were used as a basis for many design choices. However, more standardization efforts are clearly needed on the authorization protocols for various types of healthcare apps.

**Profiling is important**

We have found it interesting and perhaps even alerting to hear opinions that FHIR should work right out of the box without any profiling or implementation guides needed. Perhaps the opinions are based on the fact that some EHR systems offer FHIR interfaces which have concise documentation and are easy to use. The fact is, however, that such documentation already constitutes a “profile”, only that it is not structured or published as a StructureDefinition.

Because our goal was to build a platform that is open to use by any certified application, we considered it crucial to have a well-defined data model (set of profiles and implementation guides), to support the interoperability of the apps. Feedback from software vendors in the early phases of the project emphasized clear and definite documentation and instructions of data structures. In addition, rather strict validation of data stored by the platform has been supported by the vendor community.

**Summary**

The Finnish PHR project was launched in 2015, and the central system enters production in 2018. This is not a particularly rapid journey. The main reasons for the slow pace, however, do not lie in the selected technology and standards. Instead, they are due to the complexity of the environment in which the nationwide system is being developed. More information about Kanta PHR may be found at www.kanta.fi/phr.

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TIC Salut Social Foundation is a public agency within the Catalan Ministry of Health, whose aim is to facilitate the transformation of health and social assistance models through ICTs.

Catalan’s decentralized healthcare model integrates multiple healthcare providers’ systems into one single public network. Within that ecosystem, there were several challenges to overcome. One of them was to integrate mobile data into the PHR of patients in order to aggregate not only the clinical information coming up for common healthcare procedures but also data generated by patients using their own devices or health-related apps. This ecosystem lets professionals follow up the illness of their patients viewing that information directly in their workstations and the data generated is stored in EHR which can be shared within all information systems in Catalonia. The standards used in both Catalan PHR and EHR are based on HL7 specifications, as the shared documents are represented using Clinical Document Architecture (CDA) R2 standard.

In that ecosystem an mHealth hub, called AppSalut was created: AppSalut is an app marketplace to support transformational change in the healthcare system. By the prescription of an app, patients report outcome and experience measures and the mobile data adds value in the healthcare decisions. TIC Salut Social Foundation is coordinating this project with the support of the Department of Health of Catalonia.

According to the healthcare demands coming next century, the integration of secure mobile health and social data into the PHR will be the first step to guarantee an ecosystem to monitor patients with disease and foster self-care management.

The AppSalut website (www.appsalut.gencat.cat) is a marketplace for apps related to health and social welfare area. The apps published pass an accreditation innovative process based on: contents and functionalities, security, usability, and technology criteria, ensuring patients and healthcare professionals have access to secure and high-quality apps.
The apps are recommended to their patients by health and social welfare staff. Mobile data is collected onto the Digital Health Platform (DHP) repository of the marketplace for practitioners’ revision who ultimately decide if the information needs to be integrated into the patients’ PHR.

In order to achieve the aims, AppSalut project has followed these steps:

- Create the **accreditation model of health apps** with a 110 criteria grouped in four areas: content and functionalities, security, usability and technology.
- Create a **Committee of Experts** who checks all the criteria of apps in examination.
- Develop the **Digital Health Platform (DHP) repository** and the **AppSalut website** with two types of profiles (professionals and patients).
- Define a **mobile health subset of variables** in order to guarantee the **interoperability** between the data stored in the DHP.
- Perform a **pilot stage** with professional and patients in a real environment.

After testing in a pilot with 120 users (patients and professionals) during the last quarter of 2017, it was found that the platform works well, and the data flows correctly in accordance with international standards. In terms of usability, the platform is accepted although improvements are needed for further scalability of the project to other centres.

All data generated is stored in the Digital Health Platform, a repository of mobility data (clinical and non-clinical data). All the data is standardize following the SNOMED CT standard as a common reference terminology which let feasible the communication and the understanding of this data within the information systems. Although the Digital Health Platform has its own communication protocol based on JSON, TIC Salut Social is working in moving the architecture to **HL7 FHIR** in the near future.

AppSalut project is the first initiative which combines three key elements: An accreditation model for health and social apps; an AppSalut website to marketplace apps; and the integration of standardized secure data through DHP into patients PHR. With this innovative initiative AppSalut contributes to decreasing the economic burden in the Catalan healthcare system by fostering patients’ diseases self-management, collecting meaningful health mobile data to support decision makers and finally reducing the number of visits.

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For more information:

- SNOMED CT – Download area: [http://www.ticsalut.cat/estandards/terminologia/cens-de-catalegs/13/snomed-ct](http://www.ticsalut.cat/estandards/terminologia/cens-de-catalegs/13/snomed-ct)
Towards a European Health Data Space

On April 25, the European Commission (EC) adopted the Communication “Towards a common European data space” [1] and a companion paper “Guidance on sharing private sector data in the European data economy” [2] as part of a set of policy and legislative initiatives to unlock the reuse potential of different types of data, including health data. The document notes the importance of an Open Data approach and Application programming interfaces (APIs) that are user-friendly and well-designed, while underlining the importance of data quality levels assured over time. The value of the EU data economy was more than €300 billion in 2016, and with favourable conditions and investments in ICT, may increase to €739 billion by 2020, representing 4% of the overall EU GDP (see Figure 1).

Figure 1: Data is a driving force in the digital single market [6]

A related study commissioned to Deloitte [3], characterises the barriers that prevent the full deployment of the European Data Economy:

- Technical barriers: e.g. data interoperability and portability;
- Legal: contractual e.g. ‘data ownership’ and access to and (re-)use of data, and non-contractual e.g. extra-contractual liability;
- Other: e.g. skills, competition, pricing.

Note, as an aside, the inconsistency of this analysis with the European Interoperability Framework [4]. Data interoperability and portability are not merely technical barriers, as interoperability also refers to semantic and organizational layers, in addition to the legal layer identified by the report cited above.

The EC communication released on the health sector the same day [5] builds on the midterm evaluation of the digital single market [6] and stresses the fact that citizens hold the key to unlocking health information (see Figure 2). It is paramount, says the communication to agree on precise specifications for access and exchange of health data for research and public health purposes, addressing, for example, health data collection, storage, compression, processing and access across the EU. This effort will build upon the ongoing work of standardisation bodies, national initiatives and initiatives by health professional societies, considering, among other things, the link with electronic health records. Specifications for a common European electronic health record exchange format need to be agreed upon, based on open standards, considering the potential use of data for practice-based research and other purposes, while addressing citizens’ access to electronic health records and implementation of health data protection safeguards in compliance with the General Data Protection Regulation (see Figure 2).

Making this happen requires the active engagement of all relevant digital health stakeholders and the eHealth Stakeholders group set up by the European Commission has a key role to play. Note that this exactly what the eStandards Compass and Roadmap is all about [7].

In addition, the health sector needs to embrace the development of specifications for secure access and cross border exchange of genomic and other health datasets within the internal market for research purposes. This is to facilitate interoperability of relevant registries and databases in support of personalised medicine research. Moreover, further support for the development and use of the eHealth Digital Service Infrastructure will enable new services for people, such as the portability of personal health record data using the specifications of the European electronic health record exchange format, and the use of the data for public health and research. Noted that personal health record or personal health related
data are much richer and more detailed that the data explicitly recorded in typical professional health and care settings. The Commission will be monitoring cross-border interoperability of electronic health record systems and, once in place, the adoption of the European electronic health record exchange format across the EU.

These activities will increase the quality of data, standardise data collection, promote interoperability of European disease registries (such as the cancer and rare disease registries supported by the Joint Research Centre) and advance the analysis of data using of high performance computing and modelling. The Commission will explore with scientific representatives and clinical groups how best to stimulate demand for data aggregation, addressing incentives and concerns, such as safeguarding data protection compliance, for the further processing of health data.

At the same time, knowledge and skills of citizens, patients and health and care professionals in using digital health solutions will be promoted in collaboration with health professional organisations and academia. This combination of digital skills and health skills is key to the effective use of the abundance of digital information and services available today and in the future.

HL7 FHIR is very well positioned to be the basis for a European EHR exchange format and HL7 Affiliates should work together with CEN/TC 251 national member bodies and IHE national deployment committees to build the technical competences that will fuel interoperability. The eStandards roadmap [7] provides an excellent basis to make it happen, with a health compass mindful of the needs of health systems, the workforce, and citizens, and the market.

Setting up sustainable processes that engage all relevant eHealth stakeholders from local communities, to the regional and national level and looking at standards as the enabling means to create the European health data space under the FAIR (i.e. findable, accessible, interoperable and reusable) data principles will no doubt drive health innovation for healthier people and more resilient societies.

Catherine Chronaki, HL7 Foundation
Robert Stegwee, Chair CEN TC251
A universal model for digital continuity of care

The International Patient Summary (IPS)

International Patient Summary (IPS) is one of the main items on the roadmap of cooperation on e-health between the EU and the US. This project of a universal model of patient summary has been carried out by HL7 International and CEN TC251 working together in close cooperation.

A patient summary useful at various geographic scales

The IPS template of patient summary is useful in the context of EU cross-border e-health services. To that end, the IPS project has leveraged, extended and modernized the assets produced by the European preceding initiatives epSOS (2009-2013) and EXPAND (2014-2015).

IPS also draws the lessons learned from the cross-continent e-health pilot project Trillium Bridge, carried in 2014 by EU and US. On top of this project, IPS has refined the multilingual and multi-terminological capabilities to be supported by an international patient summary.

Last but not least, IPS has operated a synthesis of the state of the art of templated information models for patient summaries, utilizing the two main sources IHE International (with templates published by the PCC and PaLM domains) and HL7 International (with the Consolidated CDA publications). This enables the IPS model to address also the needs of care coordination at the national level, especially in countries having a national EHR or PHR. This also makes this model useful at the local territory level (regional health information exchange).

A multivalent patient summary focusing attention on the essential

The IPS model of patient summary fulfills these objectives:

- **Minimal and non-exhaustive**: An IPS-conformant patient summary is not intended to carry the entire content of a medical record, but to extract from one or more records the key information relevant for continuity of care.

- **Specialty-agnostic**: An IPS-conformant patient summary aggregates the pieces of information that are useful for future unplanned care delivered to the patient, irrespective of the specialties involved.

- **Condition-independent**: An IPS-conformant patient summary is not focusing a priori on some specific health conditions, but rather, focuses...
the attention of future caregivers to the patient’s current condition and current needs for care.

**Readily usable by clinicians for unscheduled care:** An IPS-conformant patient summary is an efficient helper to any new clinician encountered by the patient.

The IPS standard specifies the metadata of a patient summary, such as the main language used in the document, the provenance of the document, the patient and other participants. The human-readable content of the patient summary may include multiple translations in alternate languages, and its machine-readable content may provide multiple mappings for coded information. These capabilities ease the usage of this document across countries speaking different languages and using national code systems mapped to a backbone international terminology such as SNOMED CT and LOINC.

The model of the international patient summary specifies three required sections, four recommended sections and six optional sections (see Figure 1).

For each section, IPS specifies the minimum dataset expected both in human-readable and machine-readable form, as well as the associated semantics specified as bindings to standardized value sets.

**An open and extensible model, built upon the most relevant international standards**

The main reference terminologies used by the IPS value sets are SNOMED CT, LOINC, UCUM, the Standard Terms from EDQM, some code systems maintained by HL7 International, and a couple of others.

The IPS dataset is implementable by two standards able to represent an electronic document:

- IPS may be a CDA R2 document template: The CDA implementation guide of IPS has successfully passed two ballot cycles, the latter in January 2018. This implementation will be published as an STU before summer 2018.
- IPS can also be implemented as a FHIR document. The FHIR implementation guide is published in the April 2018 ballot. Comments are to be returned no later than May 7th.

The business content of IPS is identical irrespective of the chosen implementation (CDA R2 or FHIR). IPS document model is both open and extensible. This means that a medical summary built upon this model may add additional sections, or data elements without losing its conformity to IPS. This enable IPS to be used as a foundation for building further refined or extended clinical document.
models, for instance within the context of a national or regional library of clinical document models.

**Organization and tooling ensuring sustainability of the IPS standard:**

The IPS project is carried by a core team of international experts (Figure 2) under the sponsoring of the Structured Documents Working Group of HL7 International, in cooperation with other HL7 Working Groups and with the CEN TC251. The specifications have been built over the past two years, using weekly conference calls, as well as the quarterly working group meetings of HL7 International, plus two out-of-cycle meetings organized in Paris at Phast’s head quarter, in March 2017 and 2018.

The specification is built in a machine-readable manner, leveraging state-of-the-art tools available for this purpose:

- The ART-DECOR platform in which are maintained the IPS datasets, CDA templates and value sets (https://art-decor.org/art-decor/decor-templates--hl7ips-)
- A mediawiki which combines the textual specification with the formal templates imported from ART-DECOR. (http://international-patient-summary.net/mediawiki/index.php?title=IPS_implementationguide_1)
- Forge used to profile the FHIR resources used by the FHIR IG (https://simplifier.net/Forge)
- The FHIR implementation guide mechanism.

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Phast – Large scale semantic interoperability manager  
IHE International – Technical co-chair of PaLm committee  
Interop’Santé – Chair HL7 France

Welcome to the International Patient Summary

**What is it?**

The International Patient Summary is a 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.

**Visit international-patient-summary.net**

International Patient Summary  
This is the wiki hosting the Implementation Guide for the International Patient Summary, an HL7 project.  
An International Patient Summary contains the following data:

- General information about the patient (e.g. name, birth date, gender)
- A medical summary consisting of the most important clinical patient data (e.g. allergies, current medical problems, medical implants, or major surgical procedures during the last six months)
- A list of the current medication including all prescribed medicines that the
CAPABLE: Empower Citizens to active Use of their Health Information

The aim of the recently funded project CAPABLE is to create a tool that enable citizens to actively utilize their clinical and personal health information to manage medication, improve nutrition, and facilitate personal health services coordination. Our approach will enable the citizen to play a truly, active role. Communication is fundamental in CAPABLE, and HL7 FHIR will be essential if the tool we plan to create shall enable citizens to select and share relevant, necessary and sufficient, context preserved information to support them in their health care trajectory and share information according to personal discretion and situational preferences.

The objective of CAPABLE is to enable citizens to actively utilize more of their clinical and personal health information for essential health care management activities, demonstrated by a tool that help manage medication, improve nutrition, and coordinate services. To reach the objective CAPABLE will develop a tool and assess its efficacy through a large-scale feasibility study to find the best balance between challenges to a) integrate and transfer health information (interoperability and portability), b) be accessible to all (universal design), c) supplement data from official sources with personal data and notes (patient generated information and personalization), d) support ease of understanding (health literacy), e) handle information in a safe and controlled way (information security), f) coordinate and administer health information (privacy and ethical considerations), and g) offer advice or warnings (safety).

The recent EU General Data Protection Regulation on Data Portability (GDPR) has given European citizens the right to request a digital copy of all digitally stored information about themselves – including health information. In Norway, current and future solutions like the “national core record” and the “patient medication list” encourage the citizen to access subsets of their health information. However, the national initiatives do not sufficiently support citizens if they like to manage and utilize their health information actively in a safe and secure way or share it with the caregivers of their choice. The ambition of CAPABLE is to support the individual’s imminent right to transfer and manage personal data. This is a contribution to truly patient-centred health care, making a personalized and universally designed digital tool that enables the patient/citizen to utilize their health information in a structured, understandable, accessible and active way.

The CAPABLE tool, to be developed in this project, will bring innovation in empowerment of citizens to assemble and manage their health information, adapted to personal preferences and capabilities. Our main task is to demonstrate that a personalized, digital tool based on universal design principles enables citizens to manage their own health information in a safe, confidential, transparent and secure way. The demonstration of the tool is medication, nutrition, and personal coordination by collecting, complementing, managing and sharing health information and services. Fragmented information for these activities cause shortcomings that cost our healthcare system billions.

The tool will be developed in close collaboration with user organizations, interest groups, service providers and health care professionals. R&D challenges includes usability & accessibility, digital health literacy, interoperability, privacy, security, trust and technical infrastructure, and reasonable trade-offs between these topics. We will build upon results of previous research efforts by consortium members, including safety and security, universal design, nutrition, medication management and electronic health record development.

The project is a 3 year innovation project (September 2018 – August 2021) funded by the Norwegian Research Council, and partners are from Norwegian hospital and municipalities, R&D institutions, SMEs and user organizations, as well as Nordic R&D institutions and HL7 International Foundation (Europe).

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Interoperability at stake

How to shift Focus from Technology to Data Quality

In times of rapid technology development and the fact that we now live in the epicenter of the information society we need to be careful – careful not to underestimate the need for data/information quality and harmonization [1]. Otherwise, the possibility to create value for the patient and care providers will be lost in favor of “cool” technology driven apps and gadgets. This potential risk will be that the great functionality within these apps/gadgets will be created based on a “generic” dataset, a dataset just created for demonstration. The big challenge we have in the healthcare market is, that the dataset we are using is created based upon the vendors’ data models and they are rarely harmonized due to various reasons into a recognized information model used for Data Curation. If we specifically look into the big challenges to get data/information quality (DQ and IQ) out of an infrastructure where there is no functionality for harmonizing nor for data/information quality control, its huge. As an example, we could go to the world’s biggest information/data infrastructure, the Internet.

Figure 1: Extension of Nauman and Rolker Model for building quality related meta data of an Information Source [3].
The rapid growth of the Internet as an environment for information exchange and the lack of enforceable standards regarding the information it contains has led to numerous information quality problems. A major issue is the inability of Search Engine technology to wade through the vast expanse of questionable content and return "quality" results to a user’s query [2]. So how can we define data and information quality (DQ and IQ)? It’s hard to put up an exact definition but we could say it depends on various factors, see figure 1.

In figure 1 we can see that the information quality context depends on the user, the information and the retrieval system. This is one of the reason that the focus in a DataThon needs to be on the dataset and its origin and not just on how the technical solution looks like. Furthermore, there is other aspects of DQ and IQ to consider as well, these dimensions reveal a complexity that is one of the main reason for us in healthcare to find it so hard to unite among a common negotiated harmonized information model, dataset, see figure 2.

We need to be aware of these challenges when it comes to evaluate the result in a DataThon so that the interoperability won’t be at stake but in favor of the value creation that everybody is looking for. It’s very important to create function and value creating apps, gadgets etc. but that should be done out of a reality that healthcare staff experience every day. We will also look into how the generic dataset used at a DataThon could be aligned with the major datasets used in Swedish healthcare.

So with this said, an app or a gadget could look amazing and show outstanding functionality but will not in the real world create any value at all and in the worst case even prohibit the creation of value. Data Curation needs to be used and fully understood if data from healthcare should work over organizational borders as well as in conjunction with the Industry.

Looking into the results from the DataThon at MIE/Vitalis 2018, we would like to analyze if we succeeded in creating a framework that can be used as a role model for apps/gadgets using healthcare data that could connect to real world datasets and by that generate value for our patients, caregivers and the industry.

Mikael Wintell
Chair HL7 Sweden
Chief Standardization Officer at Region Vastra Gotaland, a public funded regional healthcare provider in Sweden

References


A new season for HL7 Italy is starting. New collaborations are establishing for the standardization of the Italian healthcare system. The long journey, started several years ago, for the creation of an informal collaboration platform involving the several actors interested in the standardization of the social and health services (e.g. SDOs, national and regional agencies; vendors), is proceeding.

New opportunities have been opened up after the workshop organized by HL7 Italy in July 2017, involving representatives from regions, Italian ministries and national agencies. The workshop discussed the role of HL7 Italy in supporting the standardization for the national EHR-S (Fascicolo Sanitario Elettronico). After this workshop and approved by the official working group, a collaboration between HL7 Italy, Regions and AgID (Agenzia per l’Italia Digitale – http://www.agid.gov.it) was started, with several concrete results achieved this year already. AgID, moreover, accepted the invitation to be part of the board of HL7 Italy.

A second task in which HL7 Italy was engaged was the relationship with the other SDO member organizations: after the Statement of Understanding signed with LOINC Italia (http://www.loinc.it), also UNINFO (http://www.uninfo.it) was approached. An initial agreement has been eventually reached this year, recognizing the mutual representation of HL7 Italy and UNINFO as first step for a tighter cooperation to better support the standardization of the social and health services.

Finally, new opportunities appear on the horizon: very recently, HL7 Italy has been contacted by the Italian Agency for the digital transformation of the Public Administration for inputs about Resource Oriented Architecture experiences and standards in eHealth, for the preparation of the National Development Plan of eHealth (3-years plan). Thanks to the collaboration among the HL7 affiliates, contacts have been established with European FHIR implementation initiatives to support this assessment.

Fascicolo Sanitario Elettronico

In Italy the operationalization of the Social and Healthcare services is substantially done by the regions that have the responsibility to realize the policies and laws defined nationally. For this reason, Regions have implemented several regional EHR-Systems, with a common framework, defined by law, but autonomous and self-consistent. The scope of the Fascicolo Sanitario Elettronico (FSE) initiative (the National EHR-S) is to make all these systems interoperable and to allow citizens to “track and consult the whole history of his/her own health life, sharing it with health professionals”. The project include 17 (of 21) active regions; 11 of them subscribed for the interoperability services; and so far 11,545,785 records have been created with 36,835,693 reports stored. In this first phase the aim is to allow the sharing of a set of HL7 CDA documents, including Patient Summary, Reports; discharge summaries; and so on... The responsibility for the realization of the FSE is shared among the Ministry of Health, Ministry of Economy and Finance, Regions and AgID. The communications among the regional platforms is ensured by the National Infrastructure for Interoperability based on IHE XD* profiles.

The standardization of the FSE’s documents

All the documents are shared in HL7 CDA Release 2 standard and the governance of the project is defined by law. In fact, within the rules that regulate Italian EHR, there is the provision to establish an active monitoring working group (WG). This WG endorsed specific thematic groups to specify the data set for the documents that have not been defined yet. The thematic groups include regional representatives and are coordinated by the Ministry of Health and AgID. To translate these data sets into technical specifications and to reach standardization an informal agreement among regions, AgID and HL7 Italy was arranged.

The following Chart provides an overview of the type of collaboration established.
The thematic groups define the data set and the specifications (based on HL7 CDA R2 and on pre-existing HL7 IT specifications) for the clinical documents (step 0, [5]). All the CDA templates specifications are informally evaluated by HL7 IT, and informal feedback is provided to the thematic groups. Based on the maturity level of the document, HL7 IT may decide to ballot this specification following a “fast-track” process [6], in case of successful ballot and reconciliation of comments the document is published as HL7 IT specifications (Step 1). The successfully balloted documents replace then the CDA specifications produced by the thematic groups and it is published by both HL7 Italy (www.hl7.it) and by AgID as the official specification for the FSE (https://www.fascicolosanitario.gov.it/Standard-documentali).

Following this approach the Hospital Discharge Summary and the Emergency Encounter Report have been published this year. Informal comments have been provided for Prescription and Dispensation documents, their standardization is still on going. The Radiology Report has been recently balloted and it is in the reconciliation phase. Other specifications (e.g. Pathology Report, Vaccination certificate) will be balloted in the next months.

A formal joint group is being established to maintain these specifications, with the aim to move all of these templates in ART-DECOR® (Step 2 and 3).

Future plans include the formal and durable establishment of the collaboration team comprising the regions, AgID, HL7 Italy, for the definition and maintenance of the specifications; and for assisting their implementation through also supporting services (e.g. validation).

Giorgio Cangioli, Chair HL7 Italy

Stefano van der Byl, AgID

References

[1] UNINFO is the branch of UNI, the Italian CEN/ISO member body, competent, among the others, for Health informatics (CEN/TC 251 and ISO/TC 215)


[4] Laboratory Report and Patient Summary are not yet part of this set.

[5] For the more recent documents a stricter co-ordination with AgID and HL7 IT has been realized also in this phase.

[6] It is a special path for balloting documents in HL7 IT foreseen by our GOM. This applies only for materials provided by institutions of national relevance. In this case the balloted documentation becomes an HL7 IT document, preserving its provenance.
The eStandards Roadmap for collaborative and sustainable development of health informatics standards has been included in the EU Innovation Radar. The eStandards Roadmap has been produced in collaboration between CEN/TC 251 Health Informatics, HL7 International Foundation and IHE Europe, together with partners in the eStandards consortium. It describes how we can move towards co-creation of reusable standardised artefacts in health informatics that are easily deployed in eHealth solutions and maintained on the basis of deployment experience in practice. We call these artefacts eStandards, as they constitute the health informatics standards for the information age and support the much needed innovation in eHealth and large-scale adoption of eHealth solutions. The eStandards Life Cycle, as depicted below, is at the core of our view on collaboration.

Our aim to support innovation in eHealth has been recognized by the EU Innovation Radar, by including the eStandards Roadmap in their collection of outstanding EU-supported innovators and their innovations. Their assessment of the eStandards Roadmap includes dimensions such as innovation potential and innovation capacity. Together we have been able to demonstrate that standards in health informatics, when approached from a collaborative and sustainable perspective, are able to bring together a community of organisations that are both knowledgeable about what is needed to propel eHealth innovation and are capable of making such innovations contribute to the daily practice of personal health management and professional health care.

For interested parties we are happy to organise a webinar to get you started on this exciting innovation journey using health informatics standards.

Robert A. Stegwee  
Chair, CEN/TC 251 Health Informatics.

For more information:
- eStandards website: www.estandards-project.eu
EU State of Play on Patient Access on eHealth Data

In May 2014, the eHealth Network adopted a Multi-Annual Work Plan 2015-2018 that focused on four main areas: Interoperability and Standardization, Monitoring & Assessment of Implementation, Global Cooperation & Positioning and Exchange of Knowledge. The Joint Action to support the eHealth Network (JAseHN) is the current program working on these areas. One of the work streams within JAseHN was to provide an analysis of the current state of play in Europe regarding patients’ access to their electronic health record (EHR) data. This study involved conducting desk research before creating and distributing an online survey to all Member States (MS). 29 out of 30 countries responded to the online survey. Results provided insights into policy, EHR systems in place that are offering patient access, available functionalities and information within such systems, digital literacy and digital health literacy aspects.

Results

Although a country may not currently provide online access for patients to their EHR information, the subject can still feature in national or regional policy. Twenty countries indicated the existence of policy with regard to online patient access to EHR information at a national level, one country at regional level and six countries at both national and regional levels. Programs that implement such policy fall into two main categories: programs with the objective to create patient portals and secondly, programs with the objective to create standards for patient portals.

Three countries indicated the absence of any EHR system and survey results for the other 26 countries pointed to a large variety in programs, pilots, projects and systems in place to provide patients with access to their EHR data at national, regional and local levels. For example: seventeen countries have a national EHR system of which fifteen are currently offering patient access and nine countries have multiple EHR systems in place, most according to a regional breakdown.

In order to attempt a comparison between countries the functionality and services available to
patients was explored in the context of nationally organised systems only. Results show that the presentation of static information to patients is the most common feature of these systems with interactive features having a heavier associated technical burden yet to be implemented as standard. This could be said to represent a two-phase approach in developing services to patients around accessing EHR information.

Results showed that citizens can mainly access their medication overview (twenty countries are offering this information) and patient summary (nineteen countries are offering this information). General practitioners’ referrals and test results are also available to patients in some systems.

Lastly, the survey enquired as to the ability of patients to access the systems (digital literacy) and the ability to understand the data being made available (digital health literacy). Results suggest that digital literacy appears to be addressed in terms of general digital skills policy without any specific eHealth focus. In addition, there appears to be less awareness on the importance of improving the digital health literacy of patients.

**Conclusion**

Results show that there are almost as many different approaches to providing patient access to EHR information as there are EU Member States; there is no way of ranking progress of MS and no obvious patterns emerged. We can say however, that almost all countries are directing attention to offering patients access to their data, but further work is required. Based on this study a recommendation report for the eHN members was created and is awaiting approval at the upcoming May 2018 eHealth Network meeting.

_Elise Peters_
_eHealth Advisor, Nictiz_

_Linda Keane_
_Strategy and Operations Manager, Irish Computer Society/ICS Foundation_

The full report with all results can be found on https://www.jasehn.eu or you can contact Linda Keane (linda@ics.ie) or Elise Peters (peters@nictiz.nl).
MIDATA – A Trust Promoting Framework based on HL7 FHIR

The Swiss Federal Institute of Technology in Zürich (ETH Zürich) and the Institute for Medical Informatics from the Bern University of Applied Sciences (BFH) have built together a personal health record framework named MIDATA. The particularity of this framework is to put the citizen at the center of the purpose and governance.

MIDATA is a citizen owned and governed, not-for-profit cooperative. The cooperative acts as trustee of the citizen’s data. MIDATA users can actively contribute to medical research and to clinical trials by providing access to sets of their personal data in a pseudonymous or anonymous form.

and distribute mobile applications, which can be for-profit. Thus, an ecosystem can emerge were profit can be generated from value added services for collecting and visualizing data, while the management of the data always remain a not-for-profit activity.

To design this interface, HL7 FHIR has been chosen for four main reasons:

- The evolving FHIR standard defines the syntax of the messages exchanged between the mHealth apps and the server
- The semantics of the information to be stored and managed by the server can be defined.
- Its use gains momentum and as it is open, any third party able to use it can connect its application to MIDATA.
- For authentication/authorization the SMART on FHIR framework is well suited for mHealth apps and the server.
MIDATA architecture and the use of FHIR

The MIDATA server, operating as «secured cloud services», is composed of a layer, handling the identification and authentication of the users and also handling the access management. Past this layer each data element is stored as a single object (in JSON Format), the syntax and semantic is defined by FHIR. These objects are stored encrypted in a NoSQL database (MongoDB).

SMART on FHIR is used as a simple and standardized way to connect apps to MIDATA. Third party SMART on FHIR compatible apps may then be registered as apps on the MIDATA Platform.

The FHIR API is used as the layer above the MIDATA query engine and consent management. Each instance of FHIR resource is one record. MIDATA categorizes the records into a tree to allow easy sharing. Placement of a record in a sharing tree is dependent on the FHIR resource type and the underlying coding, e.g. separating vital signs from fitness data.

MIDATA currently uses the FHIR resources shown in Table 1.

To implement the FHIR API MIDATA has chosen the open source project HAPI FHIR for the FHIR data structures and the FHIR API provided by the RESTful server. The “JPA/Database Server” provided by HAPI is not used, as it is replaced by MIDATA's own query engine that provides encryption and access management backed up by consents.

Table 1: FHIR resources currently used in MIDATA

<table>
<thead>
<tr>
<th>Allergy/Intolerance</th>
<th>Consent</th>
<th>Media</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appointment</td>
<td>Device</td>
<td>MedicationStatement</td>
<td>Questionnaire</td>
</tr>
<tr>
<td>AuditEvent</td>
<td>DocumentReference</td>
<td>Observation</td>
<td>QuestionnaireResponse</td>
</tr>
<tr>
<td>Basic</td>
<td>EpisodeOfCare</td>
<td>Patient</td>
<td>Task</td>
</tr>
<tr>
<td>Communication</td>
<td>Goal</td>
<td>Person</td>
<td></td>
</tr>
<tr>
<td>Condition</td>
<td>Group</td>
<td>Practitioner</td>
<td></td>
</tr>
</tbody>
</table>

Lessons learned

FHIR fitted very well in the MIDATA architecture. It was not necessary to change any other basic concept of MIDATA to integrate it. The FHIR resources provided a basis for the data model that could be used in the MIDATA architecture. It also helped to specify which information should be indexed from the resource.

The FHIR API is easy and well suited for app development; apps can easily be adapted to FHIR API. This has been verified by a research institution, which was able to connect its existing mobile application to MIDATA within a day. The FHIR resources are basic building blocks, which have to be extended for specific use cases. The big community behind FHIR helped finding suitable and interoperable solutions for the first use cases.
But nevertheless it is an additional initial effort to use a standard instead of a custom proprietary API and the necessary know-how is not yet widespread.

Serge Bignens, Alexander Kreutz, Oliver Egger

eHDSI Semantic Task Force

The challenge is to coordinate national and EU-level development in an environment where healthcare issues are regulated by member states, but not centrally by the European commission. A directive (2011/24/EU) provides the legal framework for this initiative: Article 14 of this directive motivated a cooperative network of EU member state representatives to define and pursue a common direction in eHealth development across Europe. This „eHealth Network“ (eHN) as a political body, supported by the JAseHN project (a multi-national EU-funded activity), consented a strategy to develop cross-border eHealth service for two relevant use cases for unified communication across European countries. The eHN provided guidelines for ePrescription and a patient summary that are designed to link the various national infrastructures in order to enable patients to use their health data in other countries across Europe.

As part of the overarching Connecting Europe Facility (CEF) the eHealth Digital Service Infrastructure (eHDSI) aims at connecting EU member states for health data exchange, building on results of previous EU-funded pilot project epSOS and EXPAND. The effort is based on establishing a single „eHealth national contact point“ eHNCP in each country, thereby linking the various existing national infrastructures and enabling cross-border exchange of health data. The eHDSI „Semantic Task Force“ was created. Domain experts from EU member states work jointly with a team funded by the EU commission, they formed three working groups to address semantic, organizational and architectural challenges. Those working groups meet regularly and take part in the co-creation and evolution of crucial assets (e.g. Clinical Documents, reference clinical vocabulary) that are the foundational elements of the semantic interoperability aimed for cross-border eHealth services.

In close collaboration with experts from IHE and HL7 the Semantic Task Force adapted the specifications in order to meet the eHDSI requirements and also to meet the specific challenges of the member states in connecting their respective national systems to a cross-border exchange scenario. Besides the aforementioned central terminology server, establishing a common platform for specification of data structures was a major task. With active support of European HL7 and IHE experts ART-DECOR became a central tool and platform for the refinement of specification as well as for the automated generation of validation tests and also for the import and export of terminology assets like value sets and code systems. The coordination of European projects with strong participation of national experts provides a viable path to connect national healthcare infrastructures by aligning local, regional, and national developments with international cross-border use of health data.

Christof Geßner
Chair HL7 Germany

To establish a robust and sustainable European maintenance and development process for the transformation of semantic assets the eHDSI „Semantic Task Force“ was created. Domain experts from EU member states work jointly with a team funded by the EU commission, they formed three working groups to address semantic, organizational and architectural challenges. Those working groups meet regularly and take part in the co-creation and evolution of crucial assets (e.g. Clinical Documents, reference clinical vocabulary) that are the foundational elements of the semantic interoperability aimed for cross-border eHealth services.

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Christof Geßner
Chair HL7 Germany
MedMij, a project driven by the Dutch Patient federation, Dutch Ministry of Health and the Dutch national health IT standards organization Nictiz, aims to facilitate citizens of The Netherlands to be able to store and share their own personal health data in one personal health record. Sharing of health information, like activity measurements, blood pressure and lab results, between mobile apps, a personal environment and an electronic health record (EHR) demands a simple yet powerful standard to connect the many involved IT-systems.

After consultations within the market, it was clear that leading parties in health IT wanted to have a limited set of open standards in MedMij, to reduce costs and to be up and running fast. With a broad support of vendors from both personal health records and electronic health records, HL7 FHIR was chosen as the main interoperability standard.

What is FHIR?
FHIR stands for Fast Healthcare Interoperability Resources. HL7 International started working on FHIR back in 2011, when it became clear that the health IT market was longing for a modern, internet based application programmers interface (API). FHIR defines how applications exchange building blocks (the resources) of medical data. For instance, a mobile app where a patient can fill in the home pain score after a visit to a hospital, uses the FHIR API to store the pain score directly into the hospital EHR. Or the other way around, the hospital system asks the pharmacy system and the personal health record for both the medication prescription and the medication administration. FHIR works exactly the way popular internet platforms work: they make use of REST calls over https to exchange data.

What are the advantages of FHIR?
Nictiz defined and communicates the following advantages of FHIR as interoperability standard for MedMij:

- FHIR makes use of open internet standards like https, REST, json and xml. This makes FHIR easy to understand for developers coming from all industries.
FHIR facilitates the use of customized building blocks for exchanging information between applications. In this way, MedMij is able to outline the data models, that needs to be exchanged between different health IT systems, in a digital and easy to publish way.

FHIR builds upon existing terminology systems like SNOMED CT, LOINC and the Dutch medication standard, which helps vendors and users of personal health records to understand how data is coded and what the meaning of the data is.

**Why is FHIR cost reductive?**

MedMij is not a platform or application itself. MedMij simply defines the appointments to which vendors of IT-systems should adhere to. So, the success of MedMij is dependent of the willingness of vendors to make personal health records, mobile apps and EHR-systems “MedMij” enabled. For Nictiz, it is important to set standards that are open and cheap. FHIR keeps up to this promise, because:

- The learning period needed to develop and implement applications with FHIR is short. Any (web) developer will have his or her first app, using FHIR for data exchange, running within hours.
- The building blocks for exchanging data are machine readable. There is no time needed to discuss and decode human written texts about which data fields are going to be exchanged.
- There is an immense, global supporting community on FHIR, reachable via chat.fhir.org.
- FHIR comes with a large set of tools, both free and paid, to handle resources and to start programming. On top of that, for both .Net and Java, existing and proven API’s are available on Github.

**Does HL7 Netherlands play a role in MedMij?**

Yes, we do. In October 2017, Nictiz and HL7 Netherlands signed a contract which states that the HL7 Netherlands FHIR Governance board validates, approves and publishes the NL-core profiles. These profiles define the Dutch extensions and constraints to the core FHIR profiles and will be the building blocks for all FHIR enabled applications in The Netherlands. Since then, the HL7 Netherlands FHIR Governance board has developed itself as validation and approval institute for any FHIR project and/or application that sees the light in the Dutch market.

This article is a loosely translated version of the MedMij Factsheet, to be found (in Dutch) at https://www.medmij.nl/wp-content/uploads/2017/06/Factsheet-MedMij-FHIR.pdf

The translation and modification has been done by Rob Mulders, chair of HL7 Netherlands.
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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