HL7 International

HL7 EUROPE 10

HL7 Europe

Exciting future ahead: 10 years HL7 Europe

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NEWSLETTER

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HL7 Europe's 10th Anniversary: Comments of Europe's Contributions to HL7 International®

by W. Ed Hammond, PhD, USA

First, I would like to say I am deeply honored to receive the HL7 Europe's 10 Year Award for advancing HL7 internationalization and creation of HL7 Europe Foundation. More important is the recognition of the work HL7 Europe has done to make this organization a major success.

The first official connection to the international community came in 1993. I was engaged in ISO TC 215 as Convener of Working Group Two, and I was interested in strengthening the collaboration between HL7 and ISO. I believed that HL7 needed an official link to the international community. I talked first to Bert Kabbes, who was then working at Hewlett Packard. At an international meeting in Europe (maybe Geneva), Bert hosted a group who were attending the meeting for discussion about standards. Dr. Joachim Dudeck, who was attending the meeting, stated he was interested on behalf of Germany to become an affiliate. We created a document stating the terms and requirements for becoming an HL7 Affiliate, and Joachim was the first to sign. Bert, representing The Netherlands signed a few months later. Other countries followed over the next few months.

Joachim and Bert played a significant role in the growth of HL7 and the Affiliates. In 2000, the HL7 Interoperability Conference was created by the Affiliates, and the first meeting was held in Dresden, Germany. Preceding that meeting, the HL7 Board held its retreat in Dresden with Joachim being the host.

Another significant event in the growth of HL7 was the Eastern Europe Tour. With Germany having recently removed the Wall and opened Eastern Germany, Joachim had a strong interest in engaging Eastern Europe in HL7. He presented a plan to the HL7 Board and received approval and funding. He invited Kai Heitmann, Klaus Veil, and me to be part of the tour. The tour included The Czech Republic, Hungary, Croatia, Poland, and Lithuania. In each city, we met with healthcare leaders and technical persons, visited some local healthcare facilities, and each of us made

presentations. That tour was successful and all the visit sites became HL7 Affiliates.

Catherine Chronaki was interested in creating a formal group in Europe to permit HL7 in the European countries to have an official organization that could participate formally in the European Union. The purpose was to provide an organization that could compete for grants awarded by the European Union; to provide an organization that could participate with other groups in funded research; and to provide a unifying body for Europe. Although this award gives me credit for creating HL7 Europe, I was just smart enough to agree with Catherine and give her support.

The result is that HL7 Europe has become a solidifying force in bringing the HL7 Affiliates in Europe together. HL7 Europe has played an important role in the development and use of HL7 standards in Europe, both in HL7 Europe projects and in participating with other groups. HL7 Europe has created a visible standards developing organization in Europe. More importantly, HL7 Europe has become the role model for regional HL7 Affiliates around the world.

I congratulate HL7 Europe for its accomplishments. You have produced leaders that have extended the reach of HL7 into other SDOs and you are providing global leadership in many projects. I strongly believe that we should repeat the model you have created in other parts of the world. I also challenge you to reach out to other countries in Eastern and Southern Europe to strengthen the international community.

Finally, I think your most significant contribution to HL7 is that you have gone beyond an "affiliate" status. You are equally a part of HL7 International. Goodbye Affiliate. Welcome HL7 Country.

HL7 Europe 10 year Anniversary Celebration

by Frank Ploeg, Netherlands

HL7 Europe was established 10 years ago and that was celebrated with a webinar on January 18th. Catherine Chronaki, Secretary General of HL7 Europe, opened the webinar with an overview of the genesis and the milestones that HL7 Europe has achieved during the last decade.

The world in 2010 had already embraced the V2 standard of HL7 and in the hospitals there was a lot of communication back and forth using pipe delimited files, if not 'unsolicited' or on request. The vision of HL7, a world in which everyone can securely access and use the right health data when and where they need it, did mean that we would step outside the walls of hospitals, a mission that the European union propagated and carries forward.

Europe was the place where HL7 had to show its face in union. The number of HL7 affiliates in Europe has been growing rapidly, since the climate has been favorable to start working together,

among themselves but also with the European Union to help realize its goals.

In 2008 Ed Hammond stood at the cradle of HL7 Europe as HL7 Chair. With its EU Cross-border directive, the way was paved for the establishment of HL7 Europe Foundation in Brussels in 2010. The objective that the Foundation was given was to stimulate the use of the HL7 standards and frameworks, to elicit requirements, to get what the European region needed in achieving the mission of HL7, collaborating in a European context with SDOs and umbrella organizations and participating in projects that were (and are being) co-funded by the European Commission.

In the 10 years that followed, HL7 Europe participated in 15 funded projects, in three of which HL7 Europe had the coordinating role. A few achievements noted in completed projects:

Semantic HealthNet, Trillium Bridge I and II, Expand, OpenMedicine, eHGI (SeHGovIA and Joint Action), Antilope, AssessCT, eStandards, all completed projects and FAIR4Health, UNICOM, Gatekeeper, Gravitate Health, Mobile Health Hub, X-eHealth, and PanCareSurPass, the currently ongoing projects.

Not all initiatives in which HL7 Europe participated were successfully completed. Such was the mHealth Assessment Guidelines project, which nevertheless was the segway that laid the foundation for the CEN/ISO Health and Wellness Apps project. The final stage of review of the Draft Technical Specification was completed earlier this year. Meanwhile, the HL7 Mobile Health project Consumer Mobile Health Application Functional Framework (cMHAFF) has continued where Assessment Guideline left off.

The epSOS project, which may well have been the impetus for the creation of HL7 Europe, had the ambition to realize a trans-European EHR summary that would cross the Atlantic. This initiative ultimately led to the successful realization of the International Patient Summary (IPS) standards, an SDO collaboration that has led to an "active window to a person's health data across locations and jurisdictions". All this while taking into account four IPS principles articulated in the Oslo agreement between CEN TC251 and HL7 International in 2016: implementable, applicable for worldwide use, extensible and open and sustainable.

The celebratory webinar continued after Catherine's introduction with a panel discussion led by Line Andreassen, HL7 Norway and member of HL7 Europe Board of Directors. The panelists invited were Jasper van Lieshout, Enterprise Architect at the Dutch Ministry of Health, Welfare and Sport, Miroslav Koncar, President HL7 Croatia, and Kai Heitmann, Director Interoperability of the Health Innovation Hub in Germany.

The panel members were first given the opportunity to present their vision of the health Information Technology world, in which Jasper took the conversation with HL7 Netherlands about the use of FHIR in relation to CDA as an example and how to collaborate with HL7 Netherlands and answer difficult questions directly at the source. Miroslav especially praised the possibility of being able (and having to) look beyond the borders of one's own country for knowledge and expertise in order to arrive at sustainable solutions, and the importance of cooperation in Europe in this regard. Kai took this argument further by describing interoperability as a "social thing", something you realize together with your family – the HL7 family – by creating a community that is as accessible as possible in which everyone can participate and just like that a super- expert can pull on his or her coat to question it, and where that is not considered strange at all.

"Interoperability is a **social** thing"

Giorgio Cangioli – technical lead HL7 Europe – focused on how to strengthen the HL7 expert community in Europe. In the context of the re-envisioning principles of HL7 International – focus, global relevance, sustainability, agility, and community – Giorgio looked at the possibilities to strengthen HL7 Europe and to continue to provide the European community with knowledge. The domains of expertise, strategic areas and jurisdiction must connect and serve the community. In particular, the support in the field of HL7 FHIR and HL7 CDA are mentioned by Giorgio as spearheads to strengthen the value proposition of HL7 Europe.

As a bouncer with a light tone, Walter Suarez, chair HL7 International, spoke to congratulate

HL7 Europe but also to recognize Ed Hammond for the founding of HL7 Europe in 2010. But also the preparatory work by HL7 prophets of the first hour, Bert Kabbes and Joachim Dudeck, for their pioneering work in Europe in 1993 by starting to shape the first national affiliates in Europe and around the globe.

The closing speech was to Ed, who thanked HL7 for his recognition and congratulated HL7 Europe for its role and value in Europe.

Finally, thanks to the organizers, Roel Barelds, Christof Gessner and Catherine Chronaki.

Meet the HL7 Europe Board of Directors

On August 20, 2020, the new Board Directors of the HL7 Europe Foundation met for the first time. Here they are.

Giorgio CANGIOLI, PhD, Italy

Giorgio is the chair of HL7 Italy and the technical lead of HL7 Europe

Catherine CHRONAKI, Greece

Catherine Chronaki is the Secretary General of HL7 Europe and the president of the European Federation for Health informatics (2021–2022).

Mark Douglas Mc DOUGALL
United States

Mark is the executive Director of HL7 International

Christof GESSNER, Germany

Christof is the chair of the European Strategic Advisory Board and past chair of HL7 Germany, a strategic consultant at Gematik the eHealth competence center in Germany

William Edward HAMMOND, PhD, United States

Ed is chair Emeritus at HL7 International, director of the Duke Center for Health Informatics, Clinical and Translational Science Institute, Director, Applied Informatics Research, Duke Health Technology Solutions, Director, Master of Management in Clinical Informatics (MMCi) Program, School of Medicine, as well as professor in multiple departments at Duke University.

Henrique Manuel GIL MARTINS, MD, PhD, MLaw, FIAHSI
Portugal

Henrique is past chair of the eHealth Network established by the Member States and the European Commission under article 14 of the European Directive on Patients' rights to cross border care, past president at the SPMS the Portuguese eHealth competence center of the Ministry of Health, and associate professor at Health Management and Leadership at FCS-UBI, ISCTE-IUL, ISCSP-U Lisboa.

Charles JAFFE, MD, PhD
United States

Charles is the CEO of HL7 International.

Anne MOEN, RN, PhD, Norway

Anne is a professor at the Institute of Health and Society at the University of Oslo and Director UiO:eColab.

Line Andreassen SAELE, Norway

Line is the chair of HL7 Norway and enterprise architect at the Norwegian Institute of Public Health.

Julia Lynn SKAPIK, MD
United States

Julia is member of the board of HL7 International, Medical Director at National Association of Community Health Centers (NACHC)

Robert Arjen STEGWEE, PhD
The Netherlands

Robert is a member of the board of HL7 Netherlands and the Chair CEN TC251 the technical committee on health informatics

Walter Gustavo SUAREZ, MD
United States

Walter is the Chair of HL7 International for 2020–2021 and the Executive Director Health Information Technology and Policy at Kaiser Permanente

Jens Kristian VILLADSEN
Denmark

Jens is chair of HL7 Denmark, and software pilot for Trifork

EMH-on-FHIR: European Hospitals on FHIR

A critical asset and next step for European health data interoperability

Opinion Article

Henrique Manuel GIL MARTINS, MD,PhD, MLaw, FIAHSI, Portugal, HL7 Europe Board of Directors.

Giorgio CANGIOLI, PhD, Italy, Technical Lead, HL7 Europe

As patients and citizens move, health data needs to move with them. While primary care is fundamental and other community based social and health care solutions are increasingly important in the provision of health care and prevention, hospitals are, and are likely to remain, the largest health data stewards. Their interconnectedness is key to the European Health Data Space. This is not only for networks of care for people with rare conditions to support inter-hospital communication and ad-hoc research collaboration, but also as organized systematic networks – the prime example the European Reference Networks.

Hospital management and healthcare personnel are concerned with internal interoperability within hospital network. Hospitals may serve as the fine capillarity network of intra and inter regional and national health data exchange. In the EU this complements efforts to create the European Health Data Space. A new way? Or another way to think about the role of hospitals and large healthcare organizations in fostering cross-border exchange and interoperability standards.

Hospitals, and indeed large healthcare organizations in Europe have two fundamental responsibilities regarding the health data they collect and manage:

1 To share health data amongst health institutions, including cross-border, to provide responsible, safe, and easy patient care.

2 To make health data available for regional national and European secondary use, within safe and regulated means, fostering health research, policy and public health, adhering to the FAIR (Findable Accessible Interoperable Reusable) principles.

Additionally, hospitals are key to European health data interoperability also because they retain and are often the major source and driver of health IT assets production, human capacity building, and innovation. Hence, they are home for the large, and much needed Digital Health Workforce.

The KIWI (Knowledgeable, Intelligent, Wise and Interoperable) framework for future hospitals proposes Interoperability as key component. When thinking of inter-hospital connectivity, we can consider direct peer-to-peer services as these most often follow the patients' referral pathways. The emergence of the European Electronic Health Record eXchange Format (EHRxF) supporting services such as Laboratory and Radiology reports, as well as Hospital Discharge Reports, is being detailed by the X-eHealth project. EHRxF facilitates a multitude of the care pathways episodic, but also chronic and rare disease patients across Europe. This implies that soon enough, tested, refined and officially endorsed detailed guiding instructions and specifications will exist in the EU for how to exchange hospital borne health data. These arrangements are likely to influence or even be adopted by non-EU countries in Europe as well, thus allowing cross-border exchange with non-EU countries. This permits data exchange with national level infrastructures but also can be used for hospital to hospital connections.

Why is linking hospitals important?

Patient safety can be significantly improved when information is securely and safely exchanged between healthcare providing organizations in the cases where patients move from one organization to the other during increasingly longer periods of acute care. This is for example the case of oncology patients. These are often diagnosed or initially investigated for cancer in a hospital or smaller practice, and then move to a higher specialized hospital unit for final diagnosis or treatment. Along their clinical pathway, often information stays behind or follows in paper, leaving a health data trail of emailed and scattered PDF files. Even in countries with interconnected public hospital networks, the need to link and exchange data with non-public institutions may exist. For example, in some situations highly specialized clinical knowledge available in very few diagnostic or therapeutical facilities is key for quality patient care and survival. This often means patients follow a complex "path" including public, private or university institutions to secure the personalized state-of-the-art care required by their condition. In many such cases, critical information is still exchanged on paper or via emailing of scanned documents. Worst, sometimes, it is based on the health professionals memory recall, phone calls, or the requestioning tired sick patients and their next of kin.

COVID-19 had a positive impact on health system digitization. During the pandemic, patient data exchange between hospitals became more frequent, as resilience of hospital care services became evidently related to their capacity to exchange staff, patients and data. As a result, collective learning and European hospital-sector intelligence can be said to have risen where data and information flows were more abundant.

CEOs and CIOs need to be concerned?

Interoperability, not just technical but also organizational, is necessary for patient safety and better care. This is, however, not a matter only for software vendors and eHealth solution providers. Hospital CIOs and indeed the CEOs need to be concerned. Building common group with other "similar" or interdependent institutions is key for collaboration. The possibility of meaningful exchanges hospital to hospital, and from hospital in the country of affiliation of the patient (in the EU cross-border services jargon called country A) to the hospital in the country of treatment (called country B), will increase as interdependency increases. Knowing which organizations exist that are capable of seamlessly interconnecting their health information assets, may prove invaluable.

It is high time, that a landscape map of FHIR interoperability capabilities is established, which while pointing to supported technical FHIR resources, can serve as a proxy for organizations where it is easier to connect, with adequate security and privacy provisions that enforce the required and agreed policies.

The European Map of Hospitals on FHIR: EMH-on-FHIR

The idea proposed is simple, not new, but still valuable. Any hospital offering HL7 FHIR APIs through a FHIR Server will be able to "self-declare" their server to HL7 Europe, via an online submission form, possible indicating where and how the FHIR server metadata information can be accessed, its status (production, test, or demonstration), and what services are offered. This core information, alongside the geolocation and contact persons, will be displayed onto a map on the "EMH-on-FHIR" tab of HL7 Europe website.

In a first phase, if the FHIR server metadata information is made publicly accessible, e.g. not protected by the organization firewall, HL7 Europe will test the reported server, by getting the published CapabilityStatement and summarizing the capabilities of that server in the above

mentioned page. The CapabilityStatement is a FHIR resource documenting "a set of capabilities (behaviours) of a FHIR Server for a particular version of FHIR that may be used as a statement of actual server functionality or a statement of required or desired server implementation." This map will give a first overview of the hospitals that are potentially open for collaboration and data exchange.

Future evolutions of this service might include enhanced automatic tests based on agreed testing scenarios, following an approach like that realized by Inferno for testing conformance to the Standardized API for Patient and Population Services criterion § 170.315(g)(10), or by the FHIR ValueSet $expand Comparison Tool offered by the ontoserver. This may include the verification of selected FHIR profiles and/or implementation guides (e.g. the European EHRxF or the IPS-International Patient Summary ones), testing on specific operations, authentication methods and so on... This enhanced report will give a more detailed insight on the actual capabilities, enabling a better evaluation of what each organization can offer. The usage of this method will allow some quantification of the cross-hospital "connectivity" capabilities and eventually can also be used to give visibility to the number of transactions using FHIR standard, both internal and inter-hospital.

How and where to start

Contacts with hospital associations and network has already started. Direct participation of such European structures is key to send the message but also for top management to append the advantage of progressively knowing which hospitals can be a source of data, or at least a source of meaningful technical expertise exchange and invaluable benchmarking.

If you became interested and want to help just contact us.

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European Health Data Space: Need for large data volume standards and its piloting

The European Health Data Space (EHDS) has been put forward as important building block of the European Health Union, aiming to fully exploit the potential of digital health to provide high-quality healthcare and reduce inequalities and promote access to health data for prevention, diagnosis and treatment, research and innovation, as well as for policy-making and legislation, while championing the individuals' rights to control their own personal health data. Henrique Martins reflects what that means for HL7 Europe.

Henrique Manuel GIL MARTINS, MD,PhD, MLaw, FIAHSI, Portugal

Much has been said and discussed on what the European Health Data Space (EHDS), is, should be, is likely to be or can be. For now, that remains a mystery. Nonetheless, one that is open to our contributions and participation. The EU needs that discussion to be fertile. The European Commission, particularly DG SANTE, has promoted open discussions like the one to which HL7 Europe was invited to attend to as part of the eHealth Stakeholders Group, last January 2021.

While not all is clear, and rightly so, in a concept which is being co-created and evolving, so far two ideas that were shared are worth some detailed analysis:

1 There is EHDS 1 and 2. EHDS 1 for primary use of health data, and EHDS 2 for its secondary use. The first may inherent the old eHDSI, while the second has been, for the last one year, the predominant component of the EHDS discussion.

2 Standards are needed for both EHDS 1 and 2. If EHDS 1 is focusing mainly on cross-border exchange of health data for the purposes of direct patient care, the set of standards is very mature and definitely, since the adoption of the EHRxF Recommendation, is finally making way into guidelines, soon to be adopted by the eHealth Network in its present or future-to-be forms. The same may not be so obvious for EHDS 2.

If we accept that EHDS 2 is to serve multiple secondary use purposes, and that health data is just processed commonly from its original databases resting safely in each member state "legal, political and technical silo", the EHDS 2 is no more than a pointer system, indexing data usage "opportunities", cataloguing who needs to be contacted for what and how. This is a reductionist approach. One I personally believe to be too weak to really live up to the expectations many stakeholders are projecting but are also invited to reflect upon. On the other hand, EHDS 2 could be, "courageously" understood as a data lake, data holder, even, a data container. This "taboo" element, perhaps temporary, perhaps circumstantial, perhaps transiently, then it captures my attention for a little bit longer and risks being a world-reaching consequential endeavour.

EHDS 2 captures attention in the standards community and rightfully so, because, while epSOS 1 and 2 served the EU and indeed the world, thought the Trillium Bridge I and II projects, and its creation – the International Patient Summary – the TEHDAS Joint Action was not designed to be a technical piloting space. It has opened itself to contributions from stakeholders, including technical interoperability partners and standards development organizations (SDOs) like HL7 Europe and others, and this is good. History has shown us, however, that it was not the 2009–2019 journey to solidify a technical standard and corresponding guideline for a Patient Summary that prevented most countries to offer one to their citizens in the EU, one decade after the first European Directive on Cross-Border Healthcare was adopted. Rather it was the fact that during that same decade little legal, technical and organizational parallel efforts were stimulated, mandated, benchmarked in each of the 27 member states. This led to national legal regimes, infrastructures, clinical processes and corresponding health data outputs unfit, ill-equipped and incapable of delivering an interoperable reasonably complete patient summary. Less was the case with ePrescription and eDispensation, which saw "troika" simulation in at least 4 or 5 member states and a leading example – a permanent lighthouse - of cross-border exchange enthusiasm in the Nordics. If it was not for epSOS, however, there would be no common reference in the form a (disputable) but tangible base of standards, upon which to build some services.

Coming back to EHDS 2, bulk data transfers, direct or indirect will be needed for some common services like a common European Cancer register, or common rare disease registries, and not just a "Register of Registers", as suggested by the Parent project at some point. Even for distributed processing to occur, a minimum degree of metadata and data harmonization and standardization is elemental. Flat FHIR standard, and its inherent principles have been advocated by HL7. This could be a good basis for solid discussions on HOW TO REALLY CREATE AN EHDS, moving beyond the legislative, data protection centric discussion, and focussing on: DOING IT.

Projects with a EU wide ambition to create not just a standards based sustainable solutions but also a community, and a set or organizational frameworks, such as epSOS did in health IT pioneering ways, are needed for bulk data transfers or bulk data processing. These projects can learn from the US, which has been undergoing efforts under the Smart Health project worthy of copy, mimic, draw inspiration from. They will be different if they aggregate all, or most, member states. They will be different if they do not fail to stop "at the door" of Member States information infrastructure but approach it from up level nationwide decision-

makers. Finally, building on existing technical standards to test different common bulk data use cases, is key for public health, for research, for health management and for policy making.

Only by setting aside resources to learn and eventually improve and help existing interoperability assets such as Flat FHIR mature, can the EU be better equipped to create a EHDS that is more than a set of pointers to data holders and support a complex mechanism to manage data permits and "joint" authorizations. If bulk transfers of data with all its risks, challenges, and ghosts are not envisioned and piloted extensively in a standardized and interoperable manner in the EHDS, this is likely to happen anyway in non-standardized ways or far more obscure ways...

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The Technical CoordiNation Team (TNT for friends :-)) is a group created under HL7 Europe, as part of the 2021 HL7 Europe goal "Nurture the European HL7 Community", having as main goals:

- Facilitate the Technical collaboration among European affiliates and experts.
- Promote Capacity building within affiliates.
- Develop European Artefacts.

TNT and TNT activities are not supposed to overlap or conflict in any way with the existing groups or activities of HL7 affiliates and international.

The need of this team and the related goals have been initially presented in the HL7 Europe board of December 18th, 2020; discussed with affiliates in the ESAB (European Strategic Advisory Board) on February 22nd, 2021; and finally reported in the HL7 Europe Board meeting of March 18th, 2021.

In this initial phase a set of characteristics have been agreed:

- **Fair size:** enough people to assure the needed resources and competences, but not so big to have the majority of the time spent in organizing the team;
- **geographically balanced;**
- **focused on (few) concrete tasks**;
- **agile organization:** no rigid boundaries; participation and organization adapted based on the tasks and lessons learned.
- Rely on the group already collaborating across the on-going EU projects, but not limited to this.

The kickoff call of this team was held on Friday, March 26th, 2021 and a confluence page under HL7 Europe site was created; while a Europe stream Zulip chat was already in place.

It was decided to start informally, with the intent to learn during the process and refine and better formalize the organization of the team. The initial objectives agreed for this team have been:

- Identify and prioritize possible tasks
- Organize the TNT work
- Assure the right linkages with the EU projects and affiliates
- Propose a governance model for an EU technical community (including a governance for the Technical CoordiNation Team)

Some tasks related to these objectives have already been started, some ideas have been collected (see e.g. the ideas for collaboration page), including the collection of the identification systems used in the EU countries for patient and practitioners, a preparatory confluence page is available here, or a common specification for the European Health Insurance Card, etc.

Towards a mHealth Policy Framework


Samuel Jacinto – eHealth Project Manager at the Shared Services of the Ministry of Health in Portugal

Vanessa Mendes – eHealth Project Manager at the Shared Services of the Ministry of Health in Portugal

The increased presence of mHealth in all aspects of life is undeniable, not only for wellness promotion, but also for health management and public health. Thus, countries and regions would benefit from incorporating mHealth strategies and initiatives into national and regional policies, either as a stand-alone strategy or as part of eHealth policies.

According to WHO, mHealth or mobile Health is defined as "as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices."

mHealthHUB European
A WHO/ITU/Andalusian Regional Ministry of Health initiative

The European Innovation and Knowledge mHealth Hub (https://mhealth-hub.org/) is a project established by the International Telecommunication Union (ITU), in partnership with the World Health Organization (WHO) and the Regional Ministry of Health of Andalusia (Spain) to support the integration of mHealth programmes and services into the national health systems of European countries. The Hub project is funded by the European Commission under the Horizon 2020 program and is underpinned by a consortium of 18 public and private partners from 12 European countries led by the Andalusian Public Health System.

Among other important advances, mHealth HUB will contribute towards developing a Policy Framework for EU on adoption and assessment of innovative solutions that will pave the way towards a "Single Healthcare Digital Market" in Europe. The framework will identify relevant core components of the assessment frameworks for mobile health applications and processes for countries across EU. It will also provide the grounds for the individual countries to insert additional assessment elements at national level.

To support countries / regions / organizations to implement a mHealth strategy, the taskforce responsible for creating the Policy Framework of the mHealthHUB is developing a model for a policy framework (Fig. 1). This preliminary framework, which is in its draft version, was designed to incorporate important learnings from the on-going desk-research and interviews conducted to different countries within Europe. The desk research focuses on important examples of the application of policy connected to mHealth, ranging from projects and initiatives to examples of national strategies from across Europe. The on-going interviews have been focusing on detailed sharing of decisions, strategies, and programs among others.

The resulting combination of the knowledge acquired is a policy framework that is based on the 4 main phases of the policy cycle:

- Formulation: the identified issues and problems are addressed leading to formulation of a policy proposal.
- Adoption (or decision-making): at this stage, decisions are made at the government level (or organisational), which lead to the approval or reshape of the policy obtained in formulation.
- Implementation: the approved policy is implemented with identification of the policy network, with all key resources and actors in place to execute the approved policy.
- Evaluation & monitoring: the policy is evaluated to verify whether its implementation is aligned with the expected objectives and outcomes defined previously.

In the centre of the Policy Framework (Fig. 1), the main 8 strategic policy areas identified for mHealth that comprehend the shared expertise, experience, and knowledge of the European mHealth HUB, are highlighted:

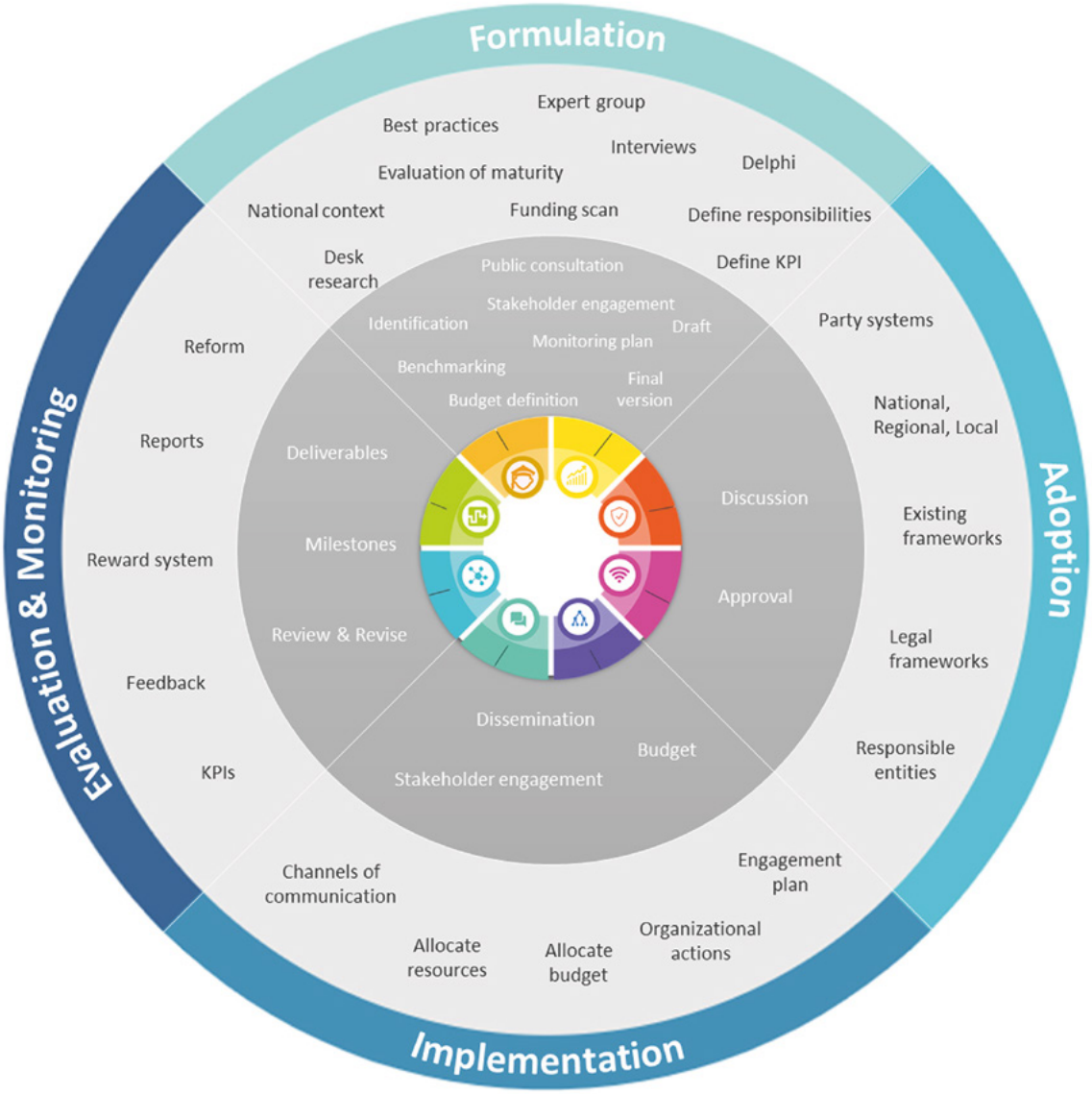
- mHealth strategies, governance models and change management
- Integration mechanisms with EHR and interoperability
- Business models, innovation funds and reimbursement
- Ethical and regulatory issues; Secondary use of data and data security
- Human centred design and patient safety; Patient empowerment, health literacy and digital skills
- Assessing the impact of innovations
- ICT infrastructure and backend technical infrastructure
- Policy for addressing countries health policies in times of emergency.

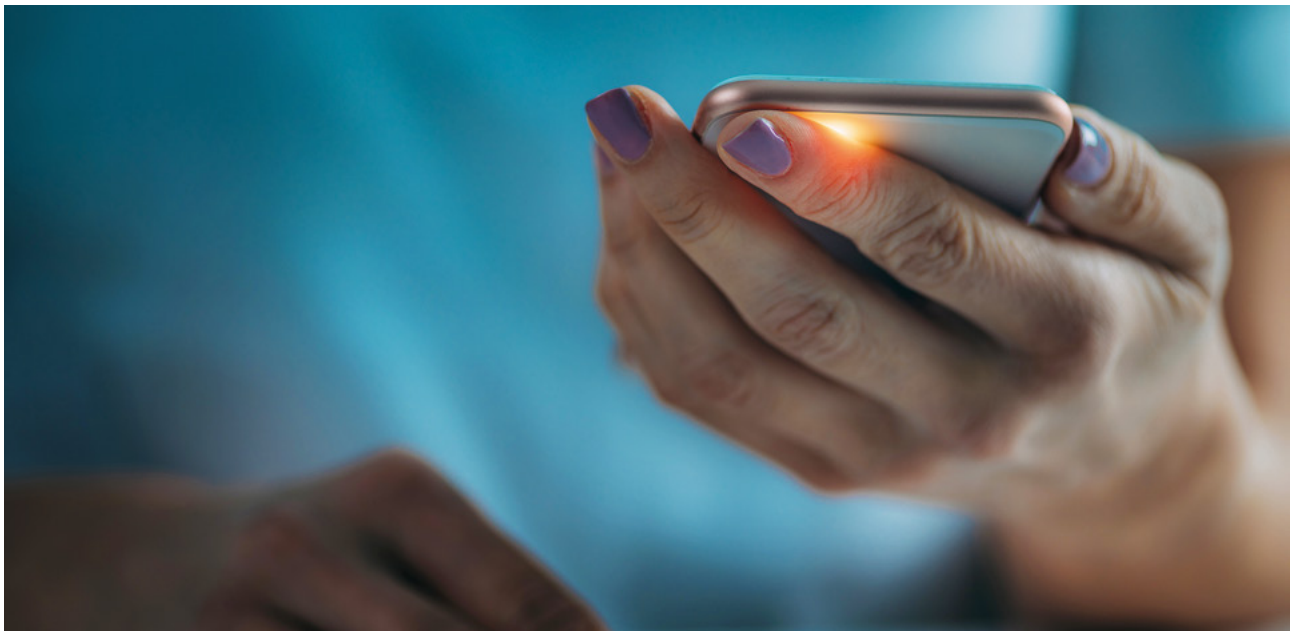
Having the policy cycle phases and the policy areas in mind, the Policy Framework will present relevant and important processes (Fig., inner circle, dark grey) and valuable insights into streams of action and direction to take, represented by their context (Fig, outer circle, light grey).

Hopefully, through the on-going work, it will be possible to build a framework and extract recommendations from reference practices that will support the development of mHealth strategies for policy makers and implementers.

Policy on mHealth were further discussed on 28th of April on the webinars series HUBTalks promoted by the European mHealth HUB.

- For more information and opportunities to engage with the European mHealth HUB, be sure to subscribe to our newsletter at https://mhealth-hub.org/news-events
- **Contact**: samuel.jacinto.ext@spms.min-saude.pt





cMHAFF and CEN/ISO:

A Consumer Mobile Health Application Functional Framework & CEN/ISO 82304-2 Quality and Reliability criteria for Health and Wellness Apps

Frank Ploeg, co-chair HL7 Mobile Health WG

The use of mobile applications ("apps") on mobile devices in healthcare is growing rapidly. Guidelines and standards with which these applications should comply have actually only been developed for devices that fall into the category "Medical Devices" and are then subject to the regulations as laid down in the EU Medical Device Regulation (from May 25, 2020, formerly the MDD = Medical Devices Directive). A great deal has been devised for all apps that fall outside this scope, but little has been brought together in an umbrella scheme.

The cMHAFF standard has been developed from the HL7 community on the basis of the Electronic Health Records – System Functional Model (EHR-S FM). cMHAFF stands for consumer Mobile Health Application Functional Framework. This standard offers a framework for testing the common foundation of mobile healthcare apps. The standard offers so-called conformance statements that an app should comply with under applicable circumstances. Based on these conformance criteria an app can be tested ("assessment") as to what extent the criteria are met. The statements have a certain weight, according to the format SHALL, SHOULD, and MAY, supplemented with IF variants for that statement that only apply in functional conditions. The areas covered by cMHAFF are product information,

security, privacy / consent / authorization, risk assessment / analysis, data access privileges, data exchange / sharing and ease of use and accessibility.

The standard currently has the status Standard for Trial Use (STU) and will be further developed into a normative standard (May 2021). The STU version is currently being tested by testing apps, but also by participating in projects such as Mobile Health Data Exchange project and Connectathon (September 2019, WGM Atlanta). cMHAFF can be viewed through www.hl7.org and can be downloaded or collected via the web guide at cmhaff.healthservice.com.

In Europe, too, the need to develop a European standard has been recognized for quite some time. In 2016, a project was started on EU guidelines on assessment of the reliability of mobile health applications. This project was stopped in 2018 without yielding a satisfactory result. Last year, CENELEC – the European Committee for Electro-technical Standardization – in collaboration with NEN (Dutch Standard) and ISO-started developing an extension to the IEC 82304-1 – Health Software – Part 1: General requirement for product safety. This project should lead to IEC 82304-2 – Health Software – Part 2: Quality and Reliability for Health and Wellness Apps. The project is being carried out under the banner of CEN / TC251 / WG2 Technology & Applications in collaboration with field experts, including the undersigned on behalf of HL7 & the University Medical Centre Groningen.

The drivers for starting this project from the EU are the promotion of digital applications to support health services due to an aging population and concomitant chronic diseases that make a claim on health budgets, the unequal quality and access to health care and the shortage of healthcare professionals.

The formal assignment is:

- Develop a CEN Technical Specification based on BSI PAS 277 that addresses the needs of Health Apps developers, purchasers and users, and the needs of those curating Health Apps Registries and Repositories.

The TS will provide apps developers with a consistent way to approach and document what they have done to deliver a reliable App of good quality:

- For the citizen, having an established and respected European quality framework in use will reduce the risk of failure of an untested low quality app causing frustration or direct harm
- For those certifying apps or selecting them for inclusion in a registry, the TS will provide an opportunity to collaborate and develop a single coherent set of criteria rather than have the wasted cost and time of developing and maintaining separate requirements independently
- The specification will not cover the processes or criteria that an app developer or publisher follow to establish whether a health and wellness app is subject to regulatory control (e.g. as a medical device, or related to information governance).

Thus, the aim and expected impact of creating a CEN Technical Specification based on PAS277 will be:

- Provide a focus for collaboration between existing national initiatives
- Ensure consistency and prevent overlap of workat different levels
- Reduce uncertainties for developers of Health and Wellness Apps, many of whom are new to the health market and unfamiliar with all the risks and issues that need to be addressed when handling health related data
- Increase users‘ confidence that the health and wellness apps are fit for purpose
- Add momentum to the EU Digital Single Market

An international working group has done significant work on the development of the specifications and criteria. As we speak, the Draft Technical Specification is about to be published and will be shared with stakeholders worldwide shortly. The cMHAFF standard is mutually aligned with the CEN / ISO / IEC specs and as such is part of the specs in an addendeum. Since 82304-2 specs are quite extensive and generic, work is underway to use the EHR-S FM profiling mechanism, where cMHAFF is iOS based, to generate specific applicable specs. The plan is that by the end of 2020 we will have the definitive normative European specifications for Health and Wellness apps.

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Supplementary or subsequent?

Clinical Document Architecture (CDA) compared with Fast Healthcare Interoperability Resources (FHIR).

Rob Mulders, HL7 Netherlands

Preface

Health Level 7 (HL7) provides standards for the exchange of data in the healthcare sector. HL7 International (www.hl7.org) provides the global standards. HL7 Nederland (www.hl7.nl), in collaboration with, among others, Nictiz, makes suitable localizations of the international standards for the Netherlands.

The most widespread standard is HL7 version 2 (HL7v2). All Dutch hospitals have been using HL7v2 internally (intramurally) since the end of the last century to exchange messages between the central EHR and the ward systems. Around the turn of the century, the need arose to exchange data between healthcare institutions (transmural). HL7 came up with HL7 version 3 (HL7v3), of which the Clinical Document Architecture (CDA) is the most successful part. With CDA, a patient record can be displayed and exchanged in a structured manner in one document.

Due to the popularity of the internet, around 2010, the need arose to replace the use of documents with an interactive question and answer game between applications. HL7 took the Internet standard Application Programming Interface (API) used by all major industries as an example and based on that, they developed the FHIR API to support workflow (question-answer interface) in the healthcare sector. Both CDA and FHIR are used in practice. Are these standards supplementary or subsequent?

1. How CDA works

CDA (Clinical Document Architecture) is the most widely used standard in healthcare when it comes to the exchange of documents. This type of exchange ("documents") has a number of very specific characteristics:

- The document (as a whole) is stored for a long time by the author and the recipient (compare: a paper transfer document or letter of resignation). The long-term storage (also called persistence) of a document as a whole is an essential characteristic of document exchange.
- The document contains a complete set of information with a particular context, for example all information that is relevant to the discharge from a Hospital. The document is shown in its entirety in its original context when consulted by a reader.
- The document contains the information in two different forms: textual (aimed at the human reader) and structured (aimed at processing by software applications).

In most CDA implementations:

- the content of the document is automatically composed by a software application,
- the document is sent to a receiving system over a network, and
- the structured content of the document is taken over by software in the receiving system.

CDA originated from the paper file

The creating system must ensure that all information, which is contextually necessary, is included in the document.

The transport mechanism is not part of the CDA standard and must be additionally implemented. Examples of software for the transport are secure email, secure FTP, IHE XDS implementations and document management systems.

1.1. Strengths of CDA (top 3)

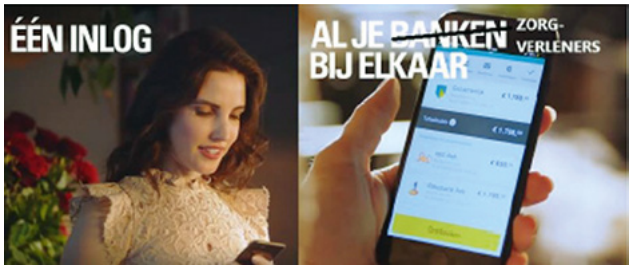
- One document with all the data for a particular context improves clarity;
- The concept of export -> document transport -> import to get data from system A to system B is easy for everyone to understand;
- CDA is an accepted standard with the main EHR suppliers.

1.2. Weaknesses of the CDA (top 3)

- The receiver depends on the generation of the document by the sender (supply driven)
- Interpretation by software is time consuming due to the average size of the document, which hinders innovations such as apps, decision support and machine learning
- The CDA standard is at the end of its life cycle. It is no longer further developed and the number of new implementations has been declining internationally for several years.

2. How the FHIR API works

An Application Programming Interface (API) is an open standard that specifies how applications enter a question and receive the answer to that

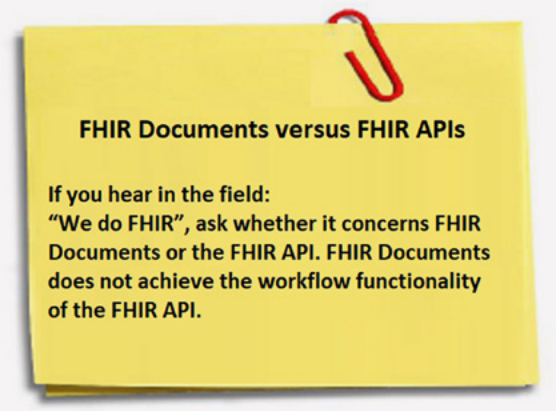


question. A well-known example is internet banking, where a web application shows balances of different banks in one overview, by requesting the balances of the banks directly from the source.

This mechanism works because the banks have agreed to open their API 24/7 to each other's applications.

HL7 has based the FHIR API on the globally used API mechanism and added what the blocks of healthcare data that are used in the workflow between applications, look like. The focus of the FHIR API is on workflow support where data is interactively exchanged between systems.

2.1. FHIR Documents



In addition to the FHIR API, FHIR supports the exchange of FHIR documents, under the name "FHIR Documents". The content of a FHIR document is built up with the same healthcare data blocks as the FHIR API. The operation of FHIR Documents is not workflow, but document-oriented. The FHIR standard as a whole contains the part "FHIR Documents" replacing the older CDA standard. The strengths and weaknesses of CDA, points 1 and 2 continue to apply to FHIR Documents.

2.2. Strengths of the FHIR API (top 3)

- The requesting application is in charge, allowing the user of the application to control the workflow (demand-driven)
- Write once, use many: applications work without modifications with all systems that have implemented the standard FHIR API

- The FHIR API uses common internet standards that are widely known to programmers (including those outside the healthcare sector), which means that the development speed of applications is high and the internet is the only infrastructure required.

2.3. Weaknesses of the FHIR API (top 3)

- Any healthcare organization that registers source data from a particular use case must implement the FHIR API before applications can use it, which requires turnaround time and investment.
- FHIR is a game-changer from supply-driven to demand-driven. Some healthcare system vendors are reluctant to open their database through the FHIR API, slowing adoption of patient and healthcare provider apps.
- The FHIR specification is relatively new. In the current release 4 of FHIR (October 2019), the definitions of the blocks of data (resources) that are exchanged via the API are not 100 % crystallized.

3. Analysis based on use cases

3.1. Type of data exchange

When looking at Dutch use cases in healthcare, it appears that data exchange can be divided into two types: exchange of documents (making a copy of the dataset, supply-driven) or exchange with the aim of supporting workflow in an interactive way (communicating real-time data blocks, demand-driven).

Table 1 shows examples of use cases with type of data exchange. By including the current progress of software at Dutch healthcare institutions (the installed base) for each type, we come to a preferred standard for this moment, with a corresponding growth path for the coming years.

3.2. FHIR API is additional to CDA

The CDA standard focuses on the document scenario and the FHIR API on supporting workflows by exchanging individual data elements. The FHIR API is therefore aimed at functionality that CDA documents do not offer at all. In that sense, the FHIR API is by definition, complementary to CDA.

Typical examples of workflow scenarios where the FHIR API offers added value are: scheduling appointments, combining parts of files from different healthcare providers, arranging repeat prescriptions and viewing laboratory requests and results. By using the FHIR API, patient participation in the logistics chain process can be improved. Analogous to other sectors that use the internet in a customer-oriented way, a reduction of the workload (and therefore cost reduction) for healthcare institutions can be achieved.

3.3. FHIR API and FHIR Documents succeed CDA

There are two scenarios in which FHIR (in addition to offering additional functionality on CDA) is also the direct successor to CDA:

- Data exchanges that traditionally use CDA documents, while the use of an API is more appropriate.
- Data exchange where the use of documents offers the best solution, whereby FHIR Documents will eventually replace CDA. The CDA standard is nearing the end of its life cycle. FHIR Documents explicitly aims to replace CDA. Documents based on FHIR Documents are built with the same set of data blocks used by the FHIR API workflow support.

An example where the FHIR API is a logical successor to CDA is the exchange between healthcare parties of the International Patient Summary (IPS). In first instance, it was logical to choose CDA for the exchange of the IPS. CDA has been a widely accepted standard since 2005, supported by major EHR / ECD suppliers. The complete IPS can be exchanged as one CDA document between two parties.

However, CDA maintains the copying of data, with negative consequences for functionality, costs and patient participation in the long term (see Appendix 1). The advantage of using the FHIR API is that each source holder remains responsible for registering their own part, while other parties in the chain can assume that they have direct and real-time insight using the FHIR API. Parties only request the part that is relevant at that time and send changes back to the source. In this way, data remains up-to-date, easier to find and available to the patient without contradictions via his / her PHR.

3.4. Developments in the market

Some countries choose to enforce the implementation of the FHIR API. In the United States, the ONC has drawn up regulations called the "Cures Act Final Rule", which obliges healthcare providers, health insurers and suppliers to open up source data using the FHIR API. As a result of this step, the market for and the range of innovative

Use case group	Examples of use cases (not complete)	Type	Advice at the start of 2021	Growth path for 5 years
Copy of the record	Switching care provider; Archiving; Establish legal burden of proof; Take a snapshot in time	Documents	CDA (installed base, decreasing) FHIR Documents (increasing)	FHIR Documents
View, edit and complete the medical record in the chain	Medical apps; IPS transfer; Observation; Medication monitoring; 1st/2nd/ 3rd line insight; PHRs	PHRs Mix of documents and workflow	Partly CDA due to installed base Partly FHIR API for introduction of workflow	FHIR API
Logistic direction by the patient	Request availability of care providers; Planning appointments; Care plan participation; Order (repeat) recipes; View notes; To file a complaint; Write reviews; Informal care	Workflow	FHIR API	FHIR API
Collect preventative data by the patient's PHRs;	Apps of monitoring tools; Sports apps such as Strava, RunKeeper, FitBit	Workflow	FHIR API Proprietary APIs from suppliers	FHIR API
Research, decision support, AI and ML	Research apps; EDC integration; Online screening and monitoring;	Online annotation; Expert systems; Personal Health Train; Cloud computing	Mix of documents and workflow CDA (decreasing) FHIR API (increasing)	FHIR API

Table 1: Based on these examples, we can conclude that in case of data exchange based on documents, moving to FHIR Documents is advisable. The FHIR API is preferred for data exchanges with workflow.

applications, both for patients and healthcare providers, has grown significantly.

In commercial sectors, APIs have boomed and promoted the standardization of data exchange between competitors. In the aviation sector, for example, KLM was quick to publish the same standard API as other airlines, because the sale of tickets and the use of the reservation system by third parties, unlike via its own website, would not have started without an API. In addition, the participation of the customer through apps that use the standardized API saves a lot of work for KLM.

Industries other than healthcare and all major IT companies have made the use of APIs over the internet a common standard. It will not be long before the benefits of using APIs reach the healthcare sector in the Netherlands.

4. Advice from HL7 Netherlands

Our advice is short and to the point: dare to take a step towards the FHIR API. If we want better data exchange in the healthcare sector (resulting in more patient participation, less workload and lower costs), then the use of a standardized API over the internet is absolutely the best way.

4.1. FHIR is supplementary and subsequent

During the analysis in chapter 3, we determined that FHIR is both complementary and successor to CDA. Additionally, the FHIR API provides workflow functionality that CDA cannot provide. Subsequently, because for use cases with documents FHIR Documents are preferable to CDA and for use cases with workflow the FHIR API is the best choice. Our advice: choose FHIR over CDA and use the FHIR API for all workflow use cases, especially if you start "from scratch".

4.2. Design a migration path from CDA to FHIR

In the long term, the FHIR API is the best choice with a view to achieve functionality in the many workflow use cases. Because the roll-out of the FHIR API in Dutch healthcare institutions has started, but has not been completed within a short time, CDA will be in service for a number of years. In this scenario, we recommend the migration from CDA to FHIR Documents and then, for the workflow use cases, make the step to the FHIR API. The use of documents (either CDA or FHIR Documents) maintains the copying of data, with higher costs in the long run, adverse functionality consequences and less control for the patient. We refer to Appendix 1 for the five biggest disadvantages of copying data. That is why it makes sense to immediately set up a migration strategy to first FHIR Documents and then the FHIR API when choosing CDA. The universal translation service as mentioned in this article can be used in the migration strategy in workflow applications where translation to FHIR healthcare data blocks is required.

4.3. Keep it simple: use the internet

It is recommended that applications with the FHIR API work over "pure" internet, just as well-secured apps do in other sectors. No additional infrastructures, network parties or central switching points are then required.

4.4. Consider a commitment to the FHIR API

As long as citizens do not act as directing patients or demanding informal caregivers, there is no incentive for healthcare institutions and suppliers to give third-party apps access to their medical systems. That is why HL7 Netherlands advises to follow the United States in enforcing the FHIR API at source-holding healthcare organizations.

The start from the Dutch government is there, as evidenced by the proposal of the Standardization Forum to put the application of APIs in the social domain on the list of "Apply or explain" standards. But in terms of data exchange, the Dutch healthcare sector benefits from less non-commitment.

Appendix 1 – The five biggest drawbacks of copying

The use of documents (CDA and FHIR Documents) maintains the copying of data. It is not without reason that the healthcare sector has worked (and works) with the fax machine for decades. Sending an A4 from the file is simple for the user, does not require an adapted representation of the document and gives both the sender and receiver the possession of their own copy of the data.

However, other industries moved away from fax years ago. Sending documents (PDFs) is also out of use for access to real-time structured data. For example, requesting the status of your package from a carrier is done online because an emailed PDF with a status is by definition out of date.

Copying data has five structural disadvantages:

- **Copied data quickly becomes obsolete:** From the moment a dataset is copied from the source, this dataset stands on its own. Updates are made in the source, but almost never in the copied dataset. Every year, healthcare providers copy data to about 100 quality registers on average. Items that are corrected in the EHR erroneously persist for years in the data sets of the quality registers.
- **Merging and deduplicating divergent data is complex**: A patient is treated for pneumonia in a regional hospital and referred to a university hospital for lung cancer research. The university hospital makes a one-off copy of the patient's file and carries out diagnostic examination, tissue collection and research during the process. In both processes (2nd and 3rd line) the problem list is adjusted in different ways. Afterwards, the patient wants to have the data unambiguously in his / her file in the regional hospital. Who is going to find out and correct the overlapping data?
- **Searching in data within copies of original documents is time consuming:** Have you ever searched for the most current address of an old acquaintance in the five different Excel address lists on your and your partner's computer?
- **Compliance with the GDPR is not feasible with copied data:** No healthcare institution

currently keeps a consistent and long-term record of which data is passed on to whom and when. If a patient wants to be forgotten, the GDPR states that the healthcare institution is responsible for the cascade of disposal at institutions to which patient data has been supplied. In practice, this is not feasible for overloaded data managers and IT departments.

- **Last but not least: the patient is not in the driver's seat:** Many of us have stopped by the pharmacy for medication, only to hear: "Sorry, the doctor has not faxed the prescription yet". The patient is dependent on a copy stroke that he / she cannot make himself. If the patient (or the pharmacy on his / her assignment) could look in the GP's system in real time, the prescription is immediately accessible after the visit to the GP. Every copy stroke creates dependence.

Appendix 2 – Four frequently asked questions about the FHIR API

Is the lead time of 5 years referred to in section 3.1 realistic?

Calculated with the lead time of implementations with the currently prevailing standards in the Netherlands, 5 years is short for a data exchange project. In the international FHIR community, however, 5 years is considered a long time. Read, for example, the experience in the New York region where workflow functionality with the FHIR API has been implemented in 8 months. Speed, simplicity and recognition for developers have been important principles in the design of the FHIR API.

How does FHIR implement the WGBO requirement to keep a medical file?

It is a misunderstanding that the Medical Treatment Contracts Act (WGBO) in the Netherlands says that a healthcare provider must save the medical file about a patient on their own computer. The WGBO says that a healthcare provider is obliged to set up a file on the treatment of the patient and to keep it for 15 years (Article 454 of the Civil Code). FHIR fulfills the WGBO obligation to set up, maintain and store the file with "resource versioning". Historical queries from source systems can be rerun, returning the same data you got back earlier. The current FHIR servers on the market are tested and certified by the ONC in the USA for this functionality. Apart from that, every user of the FHIR API is free to save acquired data if the need arises. In that case, FHIR offers the possibility to keep track of the source of the data and where the latest version is obtained.

Should source systems always be available?

Yes. Source systems that handle queries and transactions using the FHIR API must be reachable. Just like in other sectors, such as banks, airlines and telecom. In these sectors, as a citizen, we prefer the benefits of online / real-time / up-to-date over the inconvenience that a system is not reachable now and then. In the healthcare sector, provisions are currently made to give the EHR systems a high degree of availability. The same provisions must be made for the FHIR servers running on the source systems, whether within the walls of a healthcare facility or in the cloud. Smaller healthcare parties that cannot provide 24/7 accessibility themselves, can provide good availability with the help of a third party.

Does the FHIR API use a central register or switch point?

The FHIR API works over the internet. To make a transaction, the endpoint (the URL on the internet) of the system you want to communicate with must be known. A frequently heard comment in healthcare is that the patient does not know which healthcare institutions have data about him / her. This can be arranged with a central register if the central register of the source-holding systems knows and supplies the URL on the Internet. An alternative (and for privacy better) solution is that an app / PHR keeps track of the care providers on behalf of the patient and uses other source holders to supplement the list of active care providers. This could be, for example, health insurers, or public consent systems, or care providers who themselves register a treatment relationship in the patient's app / PHR. The app / PHR can then request the patient's medical data. This solution does not require a central register or switching point. USA also precedes us on this point: health insurers are obliged to make their data accessible via the FHIR API before January 1, 2021.

Approach to and Status on FHIR Profiling in Norway

Øyvind Aassve
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Norway has been amongst the early pioneers of HL7 FHIR implementation. The first interfaces were put in production at Oslo University Hospital in 2015. In the years to follow there was substantial profiling activities in individual projects and a broad range of regional and national FHIR-based services were developed by different organizations. However, different profiling choices were often made, and HL7 Norway saw early on the need for coordination of national profiling work to secure the highest degree of interoperability at the national level. These efforts to harmonize profiling at the national level have resulted in a National profiling framework.

In communicating the value of this profiling framework we often refer to the plug and play principle. FHIR should in the same way facilitate integrations for applications consuming information services by harmonizing the information structures and content of the APIs across different vendors, different geography or different care contexts. Applications exposing APIs should not implement unnecessary variations, so that small apps that need a specific set of information, do not need to develop and maintain interfaces specific to each implementation. This is also a success factor for succeeding with a platform- and ecosystem philosophy where third-party vendors are the key to deliver value-adding services and innovation.

HL7 FHIR as a standard has been adopted in a bottom-up manner compared to most traditional standards and has introduced the concept of agile standardization. Implementation of FHIR was encouraged while the standard was still in its earlier development stages. This has given a rocket start for adoption and maturation of the FHIR specifications, but time has now come for putting more attention at the necessary coordinating activities in order to achieve wide-scale interoperability. The goal is to shift the balance point between flexibility and interoperability more towards large-scale interoperability.

National profiling framework

The national profiling framework is the tool to secure the coordination and harmonization of profiles on the national level. It consists of 4 levels, the 2nd and 3rd thereof representing national profiling activities. The four levels of profiling shown in Figure 1, are:

- International resource – as described in the FHIR specification
- National base profile – fundamental adaptations of international resources to the Norwegian context independent of use-case. Base profiling consists primarily of binding to national identifiers and coding requirements in addition to defining common national extensions. By March 2020 HL7 Norway had already approved 15 national base profiles.
- National domain profile – reusable adaptations that are recommended across implementations for a given context or use-case. National domain profiles are presented in more depth further down.
- Implemented profile – the actual profile implemented by an application. An implemented profile can contain local variations of information structures or that are not deemed reusable on the national level. National domain profiles

National domain profiles

Our definition of a national domain profile is: "A national domain profile adapts international resources for a specific use case. A national domain profile shall represent information structures that

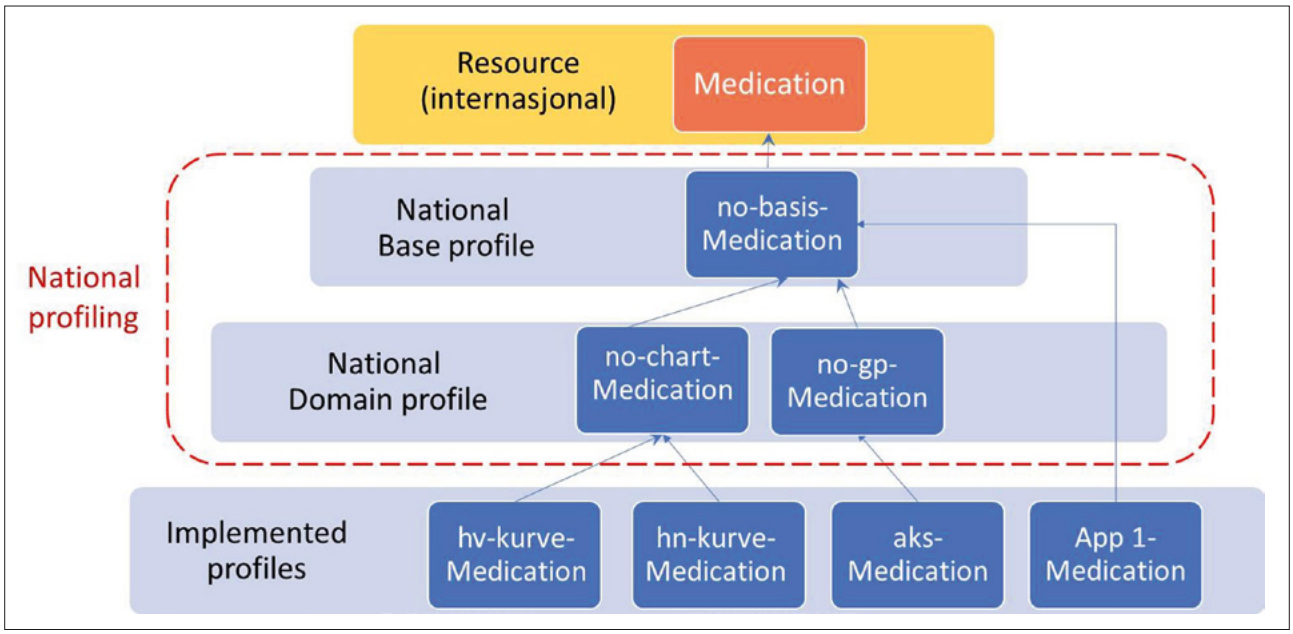

Figure 1: the four levels of HL7 FHIR profiling considered.

can be reused across implementations for the relevant use case. A national domain profile can be used directly or be further profiled for use in specific implementations."

In order to seek conformance of the national domain profiles within the broadest ecosystem possible, domain profiles should be based on international IGs where relevant IGs exist. The main reasons for this are:

- Clinical interoperability needs are not specific to Norway
- Resource efficiency (reuse international efforts, experience and expertise)
- Facilitate interoperability with the international vendor market
- Facilitate interoperability beyond national borders

The process of defining national domain profiles for specific domains should include an evaluation of what are the most relevant and leading international implementation guides for each domain / use-case in question. International implementation guides that we expect to investigate in the process of developing national implementation guides include:

- FHIR-specification (Vital Signs-profiles)
- Argonaut/ US Core (US vendor market)
- International Patient Summary (cross-border exchange)
- FHIR Point-of-Care IG (PoCG) for medical devices
- FHIR Personal Health Devices (PHD) for personal devices
- HL7 accelerator programs like mCode/ CodeX for cancer, Gravity for social determinants of health and Vulcan for research
- IGs being developed by IHE

The first national domain profiles for Vital Signs based on the profiles from the FHIR-specification and with references to CIMI-profiles for extensions are under development. However, we need to learn by practical experience over time to find what will constitute the right categorizations of domains.

Process and community

There is no central entity with resources to take responsibility for coordinating FHIR profiling at the national level. The process therefore delegates the responsibility to projects adopting new resources to develop reusable national base- and domain profiles in cooperation with HL7 Norway Technical Steering Committee and the Norwegian HL7 community. HL7 Norway arranges open quality assurance workshops with the community in the process of approving new base- or domain profiles.

As a measure to grow and educate the Norwegian FHIR community an open forum to share

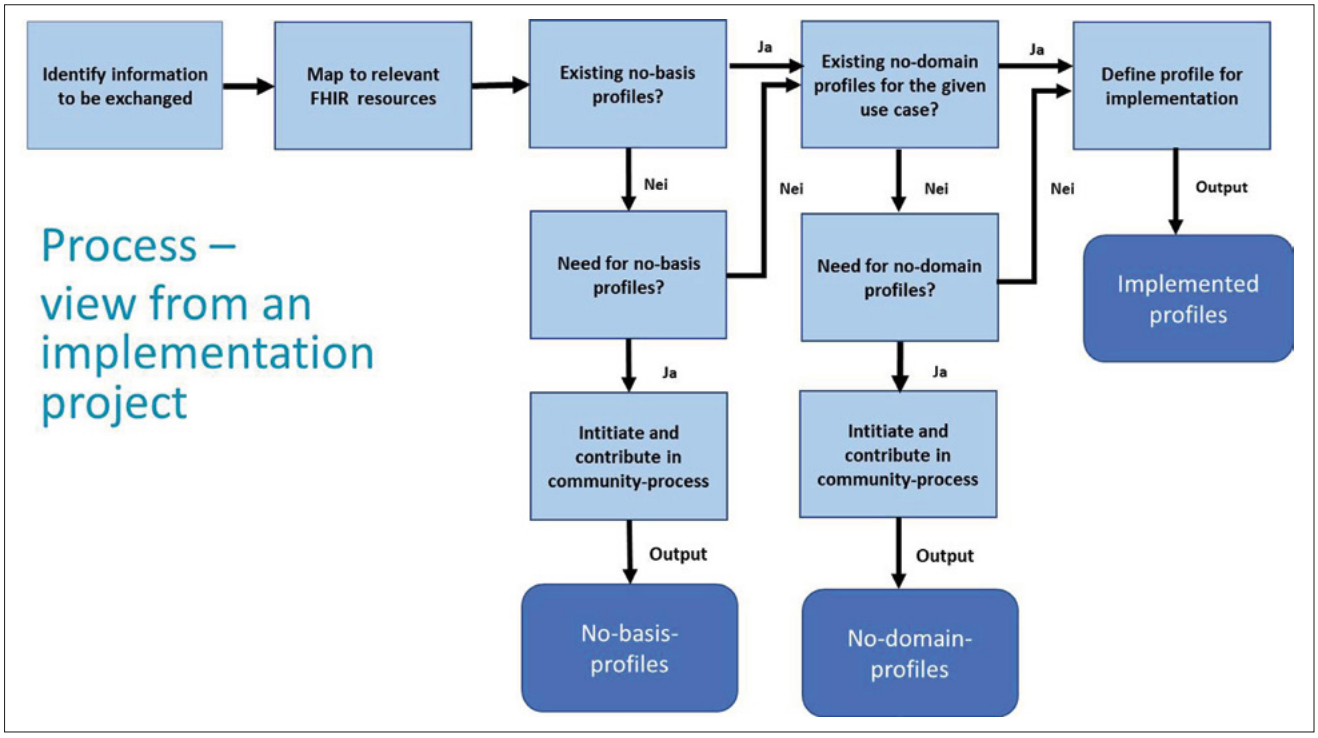

Figure 2: Process of profiling for a specific domain and use case.

experiences and discuss FHIR implementations was established in 2020. The forum meets online approximately every 6 weeks. The last meeting in March gathered more than 60 people for presentations and discussions on three projects sharing their experiences of implementing the FHIR CarePlan resource and a fourth project shared their experiences from working with FHIR for reporting to a national cancer registry. A GitHub and wiki have also been established to support the cooperation within the community.

FHIR has given us the freedom of flexibility, but with freedom comes responsibility. The task ahead is to skillfully employ the national profiling framework as a tool to identify the balancing sweet spot between top-down normative requirements and flexible bottom-up information needs for each implementation.

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- HL7 Norway – best practice wiki: https://hl7norway.github.io/best-practice/

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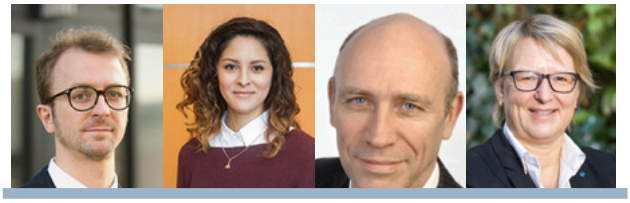
HL7 FHIR for the German Medical Informatics Initiative

The German Medical Informatics Initiative, a national data infrastructure project of German university medicine, uses HL7 FHIR for its interoperable core dataset.



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Core Unit "eHealth & Interoperability",
Berlin Institute of Health at Charité – Universitätsmedizin Berlin, Germany

The COVID-19 pandemic has reminded us again of the importance of collaborative data use in healthcare and medicine. In the past years, the German Medical Informatics Initiative has pioneered the development of common data models within German university medicine. For its core dataset, which will enable collaborative data use and access across more than 30 university hospitals, the initiative relies on HL7 FHIR.

The German Medical Informatics Initiative

The German Medical Informatics Initiative is a nationwide project of university hospitals funded with 160 million euros by the German Federal Ministry of Education and Research (BMBF). Its aim is to improve research and patient care by fostering cross-institutional data use and access. Across four consortia of university hospitals, the initiative is currently building an infrastructure of data integration centers that will enable secure and interoperable use of healthcare and research data. Functionality of the infrastructure is tested in cross-institutional use cases such as the "Collaboration on Rare Diseases" (CORD-MI), which will improve the visibility, documentation, quality of care and research in the field of rare diseases. (Other use cases aim to detect patients with poly-medication risks or improve infection control in university medicine.

Definition of a core dataset with HL7 FHIR

To ensure data interoperability across the hospitals, the initiative uses HL7 FHIR. Within the last years, health IT and domain experts defined a core dataset for interoperable data exchange, which consists of six base modules encoding information about patients, case data, diagnoses, procedures, medications, and laboratory results.

The dataset also includes expansion modules for more specialized use cases, for example, oncology, intensive care, biomaterial data or patient consent (Figure 1).

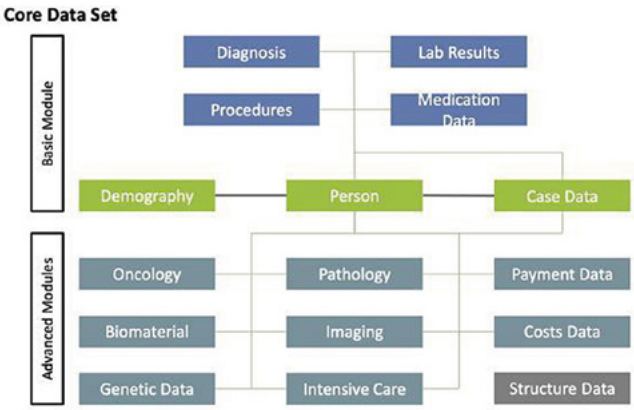

Figure 1. Core Dataset of the German Medical Informatics Initiative.

The data model of the core dataset was specified in ART-DECOR, a platform for creating and maintaining datasets, data elements and value sets. Subsequently, FHIR profiles and implementation guides were developed and published on the Simplifier platform. Where possible, the development of the FHIR profiles built on previous work, especially existing profiles of HL7 Germany, to ensure compatibility within the German healthcare landscape.

Cooperation with HL7 and organization of Projectathons

The initiative cooperates with HL7 Germany and uses HL7's formal balloting process to collect feedback for their specifications. The base module implementation guides have now completed the first cycle of 'for comment' ballots. The expansion modules are soon due a first round of balloting.

Following the example of FHIR Connectathons, the initiative has introduced the concept of Projectathons where people meet and test the developed FHIR specifications. This has now become a regular event on the initiative's calendar. Since one of the main goals of the initiative is to improve research, the focus of the Projectathons is often on data analysis and evaluation. For example, past Projectathons focused on testing the FHIR servers' search capabilities or on data preparation for research.

The initiative's decision to build their infrastructure on FHIR has led to an increase in FHIR users in Germany, and the German sub-stream on the popular Zulip platform has seen an influx of users. Moreover, numerous people working in university medicine were attending the last editions of FHIR DevDays Europe. The initiative thus contributes to the dissemination of the FHIR standard in Germany.

Links

- Data model on ART-DECOR: https://art-decor.org/art-decor/decor-project--mide-
- FHIR profiles and implementation guides on Simplifier: https://simplifier.net/organization/koordinationsstellemii

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National Terminology Server goes Dutch: a further step to interoperability

Based on an article in the HL7 Netherlands magazine by
Pim Volkert (Nictiz),
Sander Mertens (Nictiz),
Roel Barelds (Tenzinger)

Introduction

Destination Interoperability: we are not there yet. Interoperability between patient data from different sources in healthcare is not yet a reality. The vast majority of medical information is not recorded by means of a standard, which makes it hard to find a common reference. Even the data that have been recorded with a standard (for example, a laboratory result using LOINC) cannot necessarily be safely consumed by others. Where a general practitioner generally works with the "The Dutch College of General Practitioners (NHG)" Diagnostic Determinations table, the laboratory results themselves are registered using LOINC, or even via a local code table. Interpreting these different code systems (mapping) is an enormous challenge, both when it comes to retention of post-mapping information and the technical challenge.

What is a Terminology Server?

A terminology server is software that can exchange different terminologies, code sets and / or mappings via a standardized interface with other terminology servers or the content management system of applications such as EHRs or PHRs. The big advantage of a central terminology server is that the healthcare field has one central place where the various terminologies, code sets and / or mappings are stored, maintained, and distributed, and is based on a common data model.

One of these universally usable common data models is FHIR. FHIR is still rarely used in the Netherlands for terminology delivery. The focus is mainly on the exchange of patient information. Using the FHIR terminology standard, it is possible to use one model for all different systems.

In the current situation, downloads are used for the distribution of these standards (terminologies, classifications and value lists). Each terminology has its own download location, whereby an automated method of retrieval and integration into the local system is often very difficult and sometimes not even possible. Complaints are coming from the field about the required

manpower, infrastructure and time that is necessary to update a code system. Problems with version control and staying up-to-date with the latest developments are also mentioned as challenges.

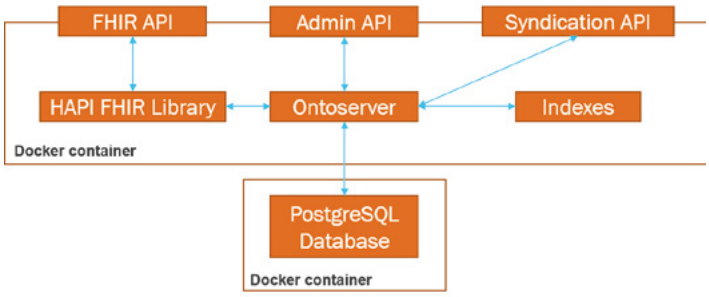

Figure 1 – High-level architecture of Ontoserver

National Terminology Server

Nictiz has started the implementation of the National Terminology Server in the Netherlands. The terminology server is based on the Ontoserver from our Australian partner CSIRO. This terminology server helps software suppliers and data scientists to keep national terminology content, such as SNOMED and the Dutch Labcode set (based on LOINC), up-to-date, and instruct potential users on how to use it. Ontoserver is a RESTful server with a Java application at its core that uses the HAPI FHIR Library. A high-level overview of the structure of the server can be seen in Figure 1. In addition, the package provides an API for server management and a Syndication API that allows content to be synchronized with other FHIR terminology servers and proprietary content, allowing advertise for use by other servers. Ontoserver is able to work with complex and extensive systems such as SNOMED and LOINC, by generating efficient indices. The database structure relies on PostgreSQL, with a Lucene index to facilitate efficient searching.

At launch, SNOMED, LOINC, the Dutch Lab codeset and UCUM will be delivered via the national terminology server. Behind the scenes we are working on expanding this offer, with the ultimate aim of being able to provide all national standard content in the Netherlands, including, for example, the value lists from Health and Care Information models (HCIMs). Nictiz launched the National Terminology Server in February 2021.

Using the Terminology Server

One of the most frequently observed barriers to the implementation of terminology is the complexity of the release model of the different terminology systems. For each system, suppliers have to get to know the file structure of the system and provide customization for the integration with their own systems. When it comes to retrieving the translation of a single code, this is quickly too large an investment. By using FHIR as the standard for terminology, this first threshold can be greatly lowered.

With Ontoserver, Nictiz offers a solution for the complex implementation of terminology. Ontoserver supports CodeSystem, ConceptMap and ValueSet FHIR resources. Via the terminology server it is possible to retrieve FHIR resources and perform operations such as $lookup, $expand, etc. Ontoserver allows you to determine the place of a post-coordination expression in the SNOMED hierarchy by finding out which concepts the expression falls under. For a comprehensive overview of all supported operations, please refer to the documentation at https://ontoserver.csiro.au/docs/.

For example, see the following example: a simple request for the term associated with the most recent version of SNOMED code 74400008:

{{url}}/CodeSystem/$lookup?code=74400008&property=display&system=http://snomed.info/sct

returns the response from the terminology server that is shown below and can be given in both JSON and XML format:

```
{
    "resourceType": "Parameters",
    "parameter": [
        {
            "name": "name",
            "valueString": "module van Nederlandse editie"
        },
        {
            "name": "display",
            "valueString": "appendicitis"
        }
    ]
}
```

Nictiz offers use of the terminology server free of charge. Access to resources on the server are linked to existing licenses. This means that if one is in possession of a SNOMED license, you can access the related resources at no extra cost.

Your own terminology server

In order to keep this solution affordable, the intention is to store the requested terminology locally for use in your product. An EHR supplier or healthcare institution can purchase its own

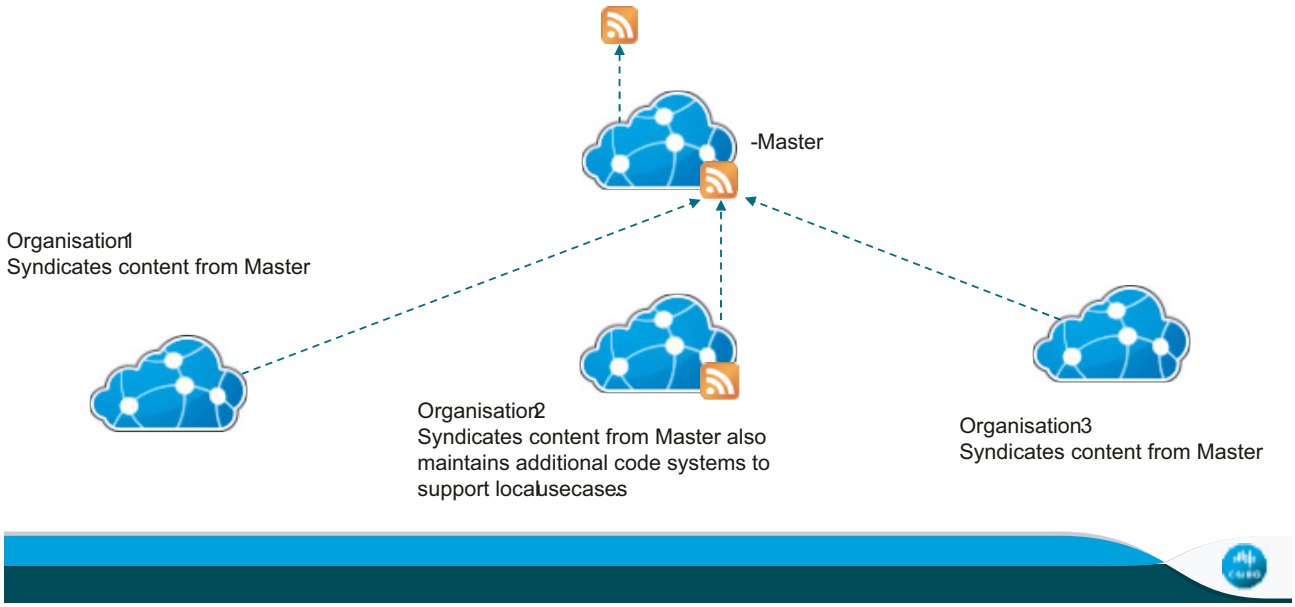

Figure 2 – Federated architecture.

license of the terminology server. This can be an instance where only the content of the original is synchronized with the syndicate through a pull system, but it is also possible, with a more extensive license, to add your own content that is not (yet) available nationally. (see figure 2).

Your local terminology server can read and retrieve the terminology on the national server via an "Atom syndication feed", so that it is always up-to-date with the national content. The syndication between two or more instances of Ontoserver is of course simple, but it is also possible to have the local terminology server communicate with the national one. A more complex syndication architecture is also possible, where your local server can combine content from multiple sources.

More information

For more information about the terminology server or to purchase your own license from Ontoserver, please contact terminologie@nictiz.nl. More information about the current state and future plans of Nictiz's national terminology server can be found at: National terminology server.

SNOMED licensees will be notified via Member Licensing and Distribution Service (MLDS) when the server is available. If you do not belong to this group and would like to stay informed, you can sign up for the newsletter via terminologie@nictiz.nl

Conclusions

With the introduction of the National Terminology Server, Nictiz wants to create an extra incentive for the structured recording of (medical) data. Due to the increasing demand for content from major National programs such as VIPP and MedMij and due to changes in the software market, the current method of content distribution by means of downloads is in urgent need of replacement. Offering a terminology service by Nictiz is therefore a logical next step.

eHealth Interoperability in Europe – 10 years of productive European projects

Karima Bourquard, Director
Interoperability IHE-Europe

Several European countries were involved ten years ago in epSOS (a large-scale pilot providing Smart Open Services for Patient travelling in Europe based for cross border Patient Summary and ePrescription services). It was the first trigger to envisage harmonization on ehealth interoperability and the first challenge. It led to understanding how much effort should be gathered over Europe in order to develop a common interoperability knowledge and skills among countries. In parallel, several other European projects worked to refine the concept of the eHealth interoperability with the support of the profiling and standard bodies. Among those projects , the **HITCH** project (2011) delivered the first inventory of testing tools, and the interoperability testing quality management system. Moreover, it provided robust inputs to the Antilope project, a major project led by MedCom and IHE-Europe. The **Antilope** project (2015) drove the adoption of standards and profiles, objects of the EC recommendation (2015) and delivered a series of materials including an overview of use cases, standards and profiles following the eHealth interoperability framework, and testing guidelines to projects and implementers.

The **Antilope** project refined the European Interoperability Framework (EIF, 2012) and provided a toolbox to support project implementers for developing their own interoperability specifications from use cases description. A set of use cases are today available on the use case repository. Other valuable assets produced were a common approach on interoperability labeling and certification processes reused by **EURO-CAS** on the Conformity Assessment Scheme for Europe (2019) in order to improve clinical data quality in healthcare. In parallel, **Value Health**, investigated new business cases related to Cross border exchange of clinical data. Finally, the eHealth Network (eHN) validated the eHealth European Interoperability Framework in 2015 to serve today as a reference in the eHealth interoperability domain in Europe. This is a major step giving a common understanding on what is interoperability.

At the same time, the community of Standard Development Organizations (SDO) s in Europe decided to join their forces (CEN, ISO, IHE, HL7, GS1, etc) in order to support the development of interoperability, standards and profiles in Europe. Starting with the **Trillium Bridge project** followed by the **Trillium II** project, extended the current cross border patient summary of epSOS/eHDSI to bridge Europe with the USA and to investigate extensions for laboratory and radiology domains (2015 and 2019). The **ASSESS/CT** project assessed the adoption of SNOMED/CT in Europe, the **OpenMedecine** project on how to overcome the issues experienced with the cross-border identification of products and last and not least the **eStandards** project (2019) focused on co-creation that involved citizens, health systems, market and workforce. Of course, other projects contributed heavily on the path that is drawing the future European eHealth interoperability landscape in order to make a solid and robust interoperability framework enable to serve the development of innovation in eHealth that includes Artificial Intelligence and big data analysis.

New projects have already started reinforcing the synergy among standard bodies with the community of implementers: the **UNICOM** project for identification of medicinal products. And the **X-ehealth project**. Based on the recommendations of the EC on the EHR exchange format (2019), the objective of this last project is to develop specifications and testing tools that support various domains such as laboratory, radiology, hospital discharge and rare diseases.

IHE-Europe with HL7 Europe as partners of those two projects will contribute actively by providing expertise on basic profiles and standards as well as testing tools and expertise in order to extend the European implementation guides with new features.

Obituary for Libor Seidl

Born on 16 February 1978, our unforgettable friend and colleague Libor Seidl passed away on 29 March 2021 in consequences of Covid-19 in the age of just 43 years. He is survived by his wife and three children as well as a big number of friends from all over the world, all challenged to master the great loss.

After finishing his master's degree in physical engineering (electronic engineering) in 2003 at the Faculty of Nuclear Sciences and Physical Engineering, Czech Technical University, Prague, Czech Republic, and engaging in some postgraduate studies at this institution, Libor moved in 2006 to Jana Zvarova's EuroMISE Center. Accompanied by short intermezzos in industry, he engaged in 2009 in parallel to his EuroMISE employment as Junior Researcher at the Institute of Computer Sciences at the Academy of Sciences of the Czech Republic. In 2012, Libor Seidl moved to the 1st Medical Faculty of the Charles University Prague, before joining in 2015 the Informatics Department at the Ministry of Health of the Czech Republic. He was the Founder and President of HL7 Czech Republic and in this position Member of HL7 Europe's European Strategic Advisory Board (ESAB) after its establishment in 2015 until his sudden death.

I've had a very special and deep relation to Libor, also based on the close collaboration with our unforgettable Jana Zvarova. I first met Libor Seidl as student attending my seminars presented to Jana Zvarova's EuroMISE Center, which was launched as result of the Joint European Project "Education in the methodology field of health care" under the European TEMPUS program. My personal meetings and educational activities with Libor got a closer relation to EFMI and HL7 in 2004, when having been invited as Keynote Speaker and lecturer at the "EuroMISE 2004 – EFMI Symposium on Electronic Health Record, Healthcare Registries and Telemedicine" and the "EuroMISE 2004, HL7 Roadshow". Quite soon after starting my lectures at EuroMISE in 2002, Jana and I established a program for jointly training international PhD students enrolled at EuroMISE and at my PhD Colleges first at the Fraunhofer Health Telematics Group in Erlangen and thereafter at the eHealth Competence Center Regensburg. In that context, we discussed the establishment of the multi-lingual European Journal for Biomedical Informatics to enable unexperienced and/or young scientists internationally publishing the results of their projects and studies with special editorial support. Both initiatives affected later on also Libor.

Libor's move to EuroMISE in 2006 including his position as EJBI Sales and Marketing Manager until he left the organization in 2011 enhanced our cooperation. This cooperation addressed the establishment of HL7 Czech Republic in 2008 as well as the preparation of many national and international seminars, tutorials, workshops and conferences. The next phase of intensifying our relations started in 2009 when he enrolled as Junior Researcher at the Institute of Computer Sciences, Academy of Sciences of the Czech Republic, dealing there with applications of international standards for interoperability of systems in healthcare. These relations have been more formalized when Libor joined the First Medical Faculty of the Charles University Prague, deployed at the Faculty's Spin-Off Application Centre. Quite soon, he was sent to my International Interdisciplinary PhD and PostDoc College at the University of Regensburg. In consequence, I became his external supervisor with Jana as the required local one. The topic of his PhD work was the interoperability between different communication standards and other systems' specifications through concept formalization and mapping. Hereby, the Czech DASTA specification and its mapping to HL7 by deploying ontologies including the new SNOMED developments and their IT-specific representation have been important issues. Highlights of our collaboration have been IHIC 2012 in Vienna, when we started publishing selected accepted IHIC submissions in the Open Access European Journal of Biomedical Informatics, and IHIC 2015 in Prague with its innovative tutorial day. Our educational and scientific collaboration resulted in a number of joined publications. Libor offered also other talents by holding a device patent for contactless monitoring of patient's vital signs. His strong dedication to his family and the three kids in combination with his new job forced Libor in 2017 to quit his PhD work, a step Jana and I regretted so much. After Jana Zvarova passed away in 2017, Libor acted as Czech Representative to EFMI, until Lenka Lhotska followed him at the beginning of 2020.

I will never forget Libor as an extraordinary friend with a great heart, so much kindness, trustworthiness and reliability. I express my sincere sympathy to Libor's wife and the entire family, but also to the Members of the Czech Society for Biomedical Engineering and Medical Informatics as well as the Members of HL7 Czech Republic. The EFMI and HL7 communities will always remember Libor Seidl with affection and respect.

Bernd Blobel, HL7 Germany

From: Memorial Colloquium in honor of Libor Seidl, Chair of HL7 Czech Republic: "Safety and Privacy by Design in COVID-19 solutions: a case for collaborative standards development" held by HL7 Europe on April 15 2021

HL7 Members and Friends wishing to donate for Libor's family please visit:
https://www.donio.cz/PomocJaneADetem

Remembering Nicole Denjoy, Secretary General of COCIR

Nicole Denjoy passed away earlier in June this year. Her influence in digital health is undeniable. In September 2020, Nicole said: "The only way to impactful and be heard in the eHealth domain is by working with all stakeholders..." and she did exactly that leading COCIR for almost two decades.

With long experience in the medical technology industry and a background in Organizational and Change Management, she took over the position of the Secretary General in COCIR, the European Trade Association representing the medical imaging, in 2005. Under her leadership COCIR opened an office in China and contributed to European Standardization with its eHealth working groups, visible publications, and annual events.

Nicole had strong views and while you might not agree with her every time, she was captivating and so charming. Nicole brought COCIR in a variety of influential fora at European Level as well as at international level. She was Chair of DITTA, the Global Trade Association representing Medical Imaging, Radiation Therapy and Healthcare IT Industry (www.globalditta.org) and lead the DITTA Industry voice in official relationships with WHO and with partnership with the World Bank since 2016. Nicole was also Vice-Chair of the Business at OECD Health Committee. As part of the Multistakeholder platform, she supported the recognition of IHE profiles by the EU.

I recall meeting Nicole around 2008 in one of the European Commission Presidency events on eHealth. I was impressed by her French flair, beautiful scars, bright smile, and elegance. When we collaborated in the eHealth Governance initiative, that resulted in the EU guidelines for patient summaries and ePrescriptions, and later eStandards that developed the roadmap for large scale eHealth standards in Europe. For our first meeting, her passion, commitment, and engagement across stakeholders made it clear that she was a power not to be underestimated. Step by step, I got to know her better, and enjoyed stimulating discussions and a few laughs with her over dinner. Last time I saw her in person was at the November 2019 meeting of the European eHealth Network. Although she had lost weight, she reported proudly on the accomplishments of COCIR and the recent publication on the European Health Data Space. However, the disease had already started its advancement. Last time we saw her was as part of the Portuguese Presidency eHealth event in June 2021. Two weeks later, she passed away, active until the end. She was happily married and a mother of three.

Petra Wilson remembers Nicole: " She was a pioneer of what we now call digital health, from when we called it health telematics where the challenges of balancing patient interests with innovation were just as prevalent. Nicole never held back from discussing the difficult issues and was key in shaping many answers. She will be missed."

Robert Stegwee, Chair CEN/TC251 shared: "Over the past 15 years, Nicole Denjoy has played an important role in promoting interoperability of health information systems and health data. She was part of the consortium that took on Mandate 403 on eHealth Standards from the European Commission, was instrumental in the success of the eHealth Governance Initiative, marking the first of a series of Joint Actions by the EU Member States and the Commission, and promoted the adoption of IHE profiles by the Multi Stakeholder Platform on ICT Standardisation. As part of the eHealth Stakeholder Group, she led the publication of the Perspectives and Recommendations on Interoperability report and engaged in discussions on business models and incentives to further the digital transformation of health and care in Europe and beyond. With her enthusiasm and warm personality, she has been a true ambassador for eHealth interoperability. Even when we didn't agree, there was always the mutual respect and the willingness to move forward."

IHE Europe announced in their site: "We are very sad to learn of the recent passing of Nicole Denjoy, Secretary General of COCIR for the past 15 years. She played an important part in the initial organisation of IHE-Europe, was a regular speaker at IHE Conferences and Seminars and a champion of interoperability on behalf of the members of COCIR. Our thoughts are with her relatives and friends at this sad time. She will be hugely missed by us all."

MedTech Europe also regrets her passing noting "MedTech Europe offers its sincere condolences on the passing of Nicole Denjoy, Secretary-General of COCIR. For more than 15 years, she has been a formidable and remarkable stakeholder in the EU healthcare community and has helped advance multiple initiatives within the medical technology sector. Our thoughts are with her family, friends and the COCIR team in this challenging time."

Elinaz Mahdavy still cannot believe Nicole has passed away! She shared, "I have known Nicole for more than 15 years. From colleagues we became friends. Nicole has been one of the most amazing woman, I have ever known in my career. She was smart, fast, a visionary, a real leader. What a pride as a woman to be able to say I have known Nicole. Behind her strong character, there was this big hearted, funny person. We laughed so much. I loved her and feel fortunate that my path has crossed hers. It's such a big loss for her family, for healthcare sector, for her friends including me. I will never ever forget her.

Rest in peace my friend."

Catherine CHRONAKI, Greece

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