INTEROP COUNCIL
for digital health in Germany

Anhang

Arbeitskreis „Governance für Kernprofile“

17.03.2025

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Ergebnisse der durchgeführten Interviews

Österreich

Survey: National Governance and Usage of (FHIR) Core Data Sets*

by the Working Group of the Interoperability Council for Digital Health in Germany

* a **national core data set** is understood to be a harmonized set of common clinical and/or health care related data elements that are used across multiple use cases in order to facilitate interoperability within a jurisdiction. It may consist of *both* a technology agnostic national information model *and* a FHIR based specification derived from that model, or may be solely expressed as a national FHIR core specification.

This survey aims to gain a broader understanding of common approaches towards governing national data sets and the challenges met during the process.

About the interviewee	
Name	Anna Lin (Co-Chair TC FHIR) and Reinhard Egelkraut (Chair TC FHIR)
Country	Austria
Organization	HL7 Austria
How was the questionnaire completed? (interview, autonomous, in person)	Interview with Anna Lin (Co-Chair TC FHIR) and Reinhard Egelkraut (Chair TC FHIR), questions pre-answered by Maximilian Ossana (Member of HL7 Austria)
Interviewer	Maximilian Ossana
Organizational questions	

What is the composition of stakeholders for the creation of core data sets (information model and/or FHIR Core Specification)?	All voting members of HL7 Austria, no official regulations regarding minimum number of participants or mandatory attendance of representatives - participation on a voluntary basis but normally in the participants' own interest. Participants are representatives from the public sector (ELGA, Gesundheit Österreich), research (universities, universities of applied sciences), social insurance, hospitals and vendors that are active in the field of processing digital health data, e.g: HIS providers
Which organization is responsible for the National Core Data Set?	HL7 Austria
Is there any national legislation supporting the Core Data Sets? If so, which laws are pertinent?	No national legislation is in place regarding the FHIR Core Data Sets yet, however it will be defined as soon as the national ELGA infrastructure is impacted.
National Governance for Core Data Set Creation and Maintenance	
How is the standardisation process initiated? How and by whom (persons, projects, organizations) are requests/applications submitted? Are requests submitted or is it managed by a committee only? How formalized is this request? (Template, Jira tickets, informal verbal/written request,...)	An informal, verbal request from a member of the TC FHIR (person, organisation) is sufficient to include the topic on the agenda of the next monthly TC FHIR call and thus initiate the standardisation process.
How are requests prioritized? How is it decided which content is processed and when? Which committee decides this?	There is a discussion and possibly a vote by the TC FHIR on the request and whether there is a need to create a new base profile for a specific use case (e.g. coverage resource) However, care is always taken not to unnecessarily inflate the number of base profiles and thus avoid future problems. The management of the TC FHIR plays a key role here. Prioritisation has not been necessary to date, but this is going to change beginning this year - we're in the same situation as in Germany and will have to develop and introduce a prioritization process.

How long does a process take from application to decision? How many processes are being processed in parallel? How formalized is this process? Which tooling is used for this?	The duration is highly individualised, as the process is very informal. As a rule, it is possible to respond relatively quickly, within a few months depending on the content of the profile - balloting is carried out according to a predefined balloting plan (Content for 2025 ballots is currently in progress). So far, there have been no parallel processes, as such requests have been rare. FHIR Shorthand/IG Publisher is used as a tool; the balloting comments are collected and consolidated in Excel but experimentation with ticket tooling is in progress.
Is the same process used to update the existing core data set?	Yes, the process is the same.
What is the composition of the committee that manages the core data set (Honorary vs paid, part/full time)? What skills are required for committee members?	The TC FHIR consists of honorary members from all interested representatives of the Austrian healthcare system and is authorised to make decisions on the establishment of working groups for the creation of implementation guides, the ballot timeframe, the balloting of existing implementation guides and the removal of existing implementation guides (e.g. FHIR STU3). This is done by means of a vote of all voting HL7 Austria members on the basis of a simple majority. No formal skills are required from the committee members.
Are there ancillary/specialised committees?	There are sub-working groups that create implementation guides for specific use cases, but no other/parallel specialised committees that deal with FHIR in Austria. Projects can be started in parallel with TC FHIR, but out of self-interest these are also coordinated with TC FHIR from a certain point onwards. The TC FHIR is interested in presenting all FHIR-specific IGs in Austria in an overview, see HL7® Austria & TC FHIR® Implementation Guides
In addition to the regular process, are there also expedited procedures (aka: "Accelerators") to cover urgent requirements?	As the regular process is already very simple, informal and therefore fast, there is no need for other processes.

Is the responsibility for defining and coordinating the information model/data sets separate from the responsibility for creating and maintaining the national FHIR Core Specification? If so, who is responsible for the translation to FHIR? What is the composition of the team that manages the FHIR Specification (Honorary vs paid, part/full time)? What skills are required for team members?	No, in Austria both are handled by the TC FHIR - composition and skills see above.
In your opinion: Does the process work well? What should be changed/improved?	It does work well, the TC FHIR agenda is always sent out a few days before a meeting to allow all participants to get involved if necessary. A more formalised ballot plan should be drawn up in the future though, particularly in regard to coordination with international ballots (HL7 Europe, HL7 International).
Scope and Adoption of the Core Data Sets	
Is there a general health care information model for the country? (Please provide link to latest publication if applicable.)	Austria does not use its own general information model. For documentation in healthcare, a nationalised version of CDA is used, see the CDA Implementation Guide: ELGA-CDA-Implementierungsleitfäden | Gesundheitsportal
Does the FHIR Core Specification include a mandatory API or any other mandatory transfer protocols? If so: which and for what use cases?	No, it does not include any mandatory API other than the one specified by FHIR itself and no other transfer protocols are being used.
Where is the latest version of the national FHIR Core Specification published?	HL7 AT FHIR Core IG: https://fhir.hl7.at/index_published.html
How long has the Core Specification been active?	The first version of the FHIR basic profiles was balloted at the beginning of 2021 and published as version STU1 at the beginning of 2022.

In your opinion: do you feel the scope to be sufficient? Can the Core Specification be adopted successfully? What is missing from the Specification? Which parts are the most relevant?	The scope has been sufficient so far and the core specification is used successfully by other IGs developed in the sub-working groups as well. The coverage and/or location resources may be supplemented in the future. The most relevant are the base profiles of Patient and Organisation, Practitioner and PractitionerRole. The only profiled datatype is Address.
Is the adoption of the Core Specification measurable? Have parameters / KPIs (key performance indicator) been defined to measure success?	To date, no specific data has been collected on usage and distribution and no such KPIs/parameters have been defined.
In your opinion: Does the adoption process work well? What should be changed?	The adoption process works well so far. The cardinalities of the elements in the basic profiles should not be set too restrictively in order not to limit the possible use cases too much - experience from the past. For the specific IGs based on this, however, it should be the other way round in order to be able to validate sensibly.
Balloting and Voting of Core Data Sets and FHIR Core Specification	
At which process steps is vote held?	For the introduction and for major changes. However, all changes should always be recorded in the meeting notes.
How does ballot participation/voting work? (Rules/Tools?)	Ballot according to HL7 Austria regulation, see https://hl7.at/technische-komitees/abstimmungsverfahren-ballots-2020/
Who is eligible to vote?	All members of HL7 Austria are entitled to vote.
In your opinion: Does the balloting process work well? What should be changed?	The members are very active, the necessary quorum has always been reached so far. The system with the Excel files could be improved, especially to avoid duplicate comments for different releases (R4 and R5).
Enforcement of Core Data Sets and FHIR Core Specification	
Is conformance to the national FHIR Core Specification being assessed? If so: how? What testing tools are used?	There is currently no process for assessing the conformance to the national FHIR Core Specification itself.

Is the use of the FHIR Core Specification mandatory? If so: how is the obligation enforced?	Their use is not legally obligatory, but they are used voluntarily by all stakeholders. However, an obligation might be established as soon as the national ELGA infrastructure is impacted.
In your opinion: Does enforcement work well? What should be changed?	There is no enforcement in place yet.
FHIR Profiling	
What rules/best practices/strategies are applied when creating profiles? (e.g. closed vs. open profiling, usage of inheritance/derived profiles)	Open approach, care is taken to only use a minimal data set for the basic profiles to prevent future interoperability issues.
Is there a fixed release cycle? How are breaking changes being handled?	There is no fixed release cycle; the profiles are updated as required. After publication in version STU1 in 2022, they have just been published in version STU2 in 2025; a new ballot is planned towards the end of the year due to the needs of social insurance (patient billing). Breaking changes have never happened so far.
How strictly is terminology binding handled in general?	Terminology bindings are generally required but the binding strength is usually set to “extensible” unless the tooling enforces a “required” binding.
National Terminologies	
How are national terminologies associated with the Core Specification maintained? Are processes and responsibilities the same as for the core data sets or is it separate?	Terminologies are not part of the base profiles and are managed externally via the national terminology server, which is maintained by TC Terminology. A close cooperation between them and TC FHIR is in place.
Are national terminologies being published separately from the Core Specification?	Yes, they are published separately.
Do you have a National Terminology Server/Service or other infrastructure dedicated to the distribution of terminologies?	Yes there is, see Austrian e-Health Terminology Browser

Are the release cycles for national terminologies and the FHIR Specification coordinated?	The national terminology server has continuous delivery, thus no release cycle is necessary.
In your opinion: Does the maintenance and distribution of national terminologies work well? What should be changed?	The existence of a terminology server, which is processed independently of the basic profiles, is very helpful.

Canadian Institute for Health Information (CIHI)

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This survey aims to gain a broader understanding of common approaches towards governing national data sets and the challenges met during the process.

About the interviewee	
Name	Shannon O'Connor
Country	Canada
Organization	Canadian Institute for Health Information (CIHI)
How was the questionnaire completed? (interview, autonomous, in person)	Autonomous
Interviewer	N/A
Organizational questions	
What is the composition of stakeholders for the creation of core data sets (information model and/or FHIR Core Specification)?	Data standards experts, clinicians, patient partners, Indigenous partners, data architects, policy organizations, health administrators, digital health and terminology experts, researchers and academia.
Which organization is responsible for the National Core Data Set?	CIHI develops and maintains the Pan-Canadian Health Data Content Framework, including the Canadian Core Data for Interoperability (CACDI).
Is there any national legislation supporting the Core Data Sets? If so, which laws are pertinent?	No. Draft legislation proposed (June 2024) former Bill C72 *Connected Care for Canadians Act*: An Act respecting the interoperability of health information technology and to prohibit data blocking by health information technology vendors but died on Order Paper when Canadian Parliament was prorogued in January 2025.

National Governance for Core Data Set Creation and Maintenance	
How is the standardisation process initiated? How and by whom (persons, projects, organizations) are requests/applications submitted? Are requests submitted or is it managed by a committee only? How formalized is this request? (Template, Jira tickets, informal verbal/written request,...)	CIHI has an established standards development process that is aligned to the ISO Harmonized Stage codes. Standards development can be initiated by government funded organizations like CIHI and Canada Health Infoway with collaboration and input from external stakeholders. Requests are communicated through both informal and formal means.
How are requests prioritized? How is it decided which content is processed and when? Which committee decides this?	Prioritization occurs through environmental scanning and in alignment with other national and international standards, including the International Patient Summary (IPS), the Pan-Canadian Patient Summary (PS-CA), the United States Core Data for Interoperability (USCDI) and the Australian Core Data for Interoperability (AUCDI). Additionally, prioritization occurs through health system partner consultation, and identifying health system needs.
How long does a process take from application to decision? How many processes are being processed in parallel? How formalized is this process? Which tooling is used for this?	The development cycle for each release of the Pan-Canadian Health Data Content Framework is generally 12-18 months. This is an iterative process where the standard is expanded upon in each iteration. Each publication has an open review period during which issues can be identified for update during the next iteration.
Is the same process used to update the existing core data set?	Yes, it is an iterative process.
What is the composition of the committee that manages the core data set (Honorary vs paid, part/full time)? What skills are required for committee members?	CIHI employees manage the Pan-Canadian Health Data Content Framework (paid full time employees), though employees may not be fully allocated to development of the Pan-Canadian Health Data Content Framework. Skills such as clinical knowledge, data standards development, data architecture, terminology, use case development are required.
Are there ancillary/specialised committees?	Yes. Development of the Pan-Canadian Health Data Content Framework is a co-design process with stakeholder involvement spanning the health system. Examples include working groups, co-contributor groups made up of

	clinicians, patient partners, Indigenous persons, data architects, policy organizations, health administrators, digital health and terminology experts, researchers and academia.
In addition to the regular process, are there also expedited procedures (aka: "Accelerators") to cover urgent requirements?	Not at this time.
Is the responsibility for defining and coordinating the information model/data sets separate from the responsibility for creating and maintaining the national FHIR Core Specification? If so, who is responsible for the translation to FHIR? What is the composition of the team that manages the FHIR Specification (Honorary vs paid, part/full time)? What skills are required for team members?	Yes. The Pan-Canadian Health Data Content Framework has supporting common data architecture developed by CIHI, including an information model, metamodel, conceptual data model, logical data models and metadata. Translation to FHIR via the CA Core+ is the responsibility of Canada Health Infoway. Skills such as interpreting FHIR resources, terminology, clinical knowledge, data standards expertise and data modelling is required.
In your opinion: Does the process work well? What should be changed/improved?	It works well. To date, partners have been receptive to the co-design process and feel that this is a transparent and collaborative process.
Scope and Adoption of the Core Data Sets	
Is there a general health care information model for the country? (Please provide link to latest publication if applicable.)	Yes, the pan Canadian Health Data Content Framework developed by CIHI. Please see: https://www.cihi.ca/en/connected-care/products-of-the-pan-canadian-health-data-content-framework
Does the FHIR Core Specification include a mandatory API or any other mandatory transfer protocols? If so: which and for what use cases?	N/A – Refer to CA Core+
Where is the latest version of the national FHIR Core Specification published?	N/A - Refer to CA Core+
How long has the Core Specification been active?	The first draft of the pan-Canadian Health Data Content Framework was published in September of 2024.
In your opinion: do you feel the scope to be sufficient? Can the Core Specification be adopted successfully? What is missing from the Specification? Which parts are the most relevant?	The core specification is currently a draft specification. Adoption plans are currently in progress.
Is the adoption of the Core Specification measurable? Have parameters / KPIs (key performance indicator) been defined to measure success?	Adoption measurement, including KPIs are planned for the future as the Pan-Canadian Health Data Content Frameworks matures beyond the current draft for reference.

In your opinion: Does the adoption process work well? What should be changed?	The core specification is currently a draft specification. This will be considered in the future.
Balloting and Voting of Core Data Sets and FHIR Core Specification	
Which process steps are balloted?	N/A – refer to CA Core+ and HL7 Canada.
How does ballot participation/voting work? (Rules/Tools?)	N/A
Who is eligible to vote?	N/A
In your opinion: Does the balloting process work well? What should be changed?	The Pan-Canadian Health Data Content Framework uses an open review process. The CA Core+ is the implementation of the PCHDCF in FHIR.
Enforcement of Core Data Sets and FHIR Core Specification	
Is conformance to the national FHIR Core Specification being assessed? If so: how? What testing tools are used?	N/A - refer to CA Core+.
Is the use of the FHIR Core Specification mandatory? If so: how is the obligation enforced?	N/A
In your opinion: Does enforcement work well? What should be changed?	N/A
FHIR Profiling	
What rules/best practices/strategies are applied when creating profiles? (e.g. closed vs. open profiling, usage of inheritance/derived profiles)	N/A- refer to CA Core+.
Is there a fixed release cycle? How are breaking changes being handled?	N/A
How strictly is terminology binding handled in general?	N/A
National Terminologies	
How are national terminologies associated with the Core Specification maintained? Are processes and responsibilities the same as for the core data sets or is it separate?	CIHI and Infoway each maintain some national terminologies and classifications. Maintaining the Pan-Canadian Health Data Content Framework is the responsibility of CIHI. The FHIR CA Core+ specification is maintained by Canada Health Infoway.

Are national terminologies being published separately from the Core Specification?	Yes. FHIR CA Core+ specification is maintained by Infoway. CIHI and Infoway each maintain some national terminologies and classifications. National Terminologies are published to a terminology server, whereas the FHIR CA Core+ specification is published on Simplifier.
Do you have a National Terminology Server/Service or other infrastructure dedicated to the distribution of terminologies?	Yes, Canada Health Infoway maintains the Terminology Server that has infrastructure dedicated to the distribution of terminologies. CIHI distributes national classifications and curated value sets with maps through separate tooling.
Are the release cycles for national terminologies and the FHIR Specification coordinated?	No. The FHIR CA Core+ specification publication and national terminologies each follow their own publication cycles.
In your opinion: Does the maintenance and distribution of national terminologies work well? What should be changed?	Yes.

HL7 Canada (Baseline Profiles

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About the interviewee	
Name	Sheridan Cook (Accenture) Elliot Silver (ResMed)
Country	Canada
Organization	HL7 Canada
How was the questionnaire completed? (interview, autonomous, in person)	Autonomous
Interviewer	Patrick Werner
Organizational questions	
What is the composition of stakeholders for the creation of core data sets (information model and/or FHIR Core Specification)?	Canadian FHIR Implementer community (open for everyone)
Which organization is responsible for the National Core Data Set?	HL7 Canada (for CA Baseline)
Is there any national legislation supporting the Core Data Sets? If so, which laws are pertinent?	No?
National Governance for Core Data Set Creation and Maintenance	
How is the standardisation process initiated? How and by whom (persons, projects, organizations) are requests/applications submitted? Are requests submitted or is it managed by a committee only? How formalized	The project was initiated about 5 years ago as a grassroots, community effort inspired and influenced by early US Core, trying to get ahead of an expect surge in Canadian FHIR deployments.

is this request? (Template, Jira tickets, informal verbal/written request,...)	The project is run as a workgroup of HL7 Canada, supported by Canada Health Infoway. Alternating between “governance” (management) and “profiling” (technical) weekly 1-hour calls, each led by an informally recognized leader, the workgroups are self-directed addressing submitted tickets, responding to changes in the Canadian healthcare IT landscape, topics raised by workgroup members, and so on. We maintain an issues list within Simplifier.
How are requests prioritized? How is it decided which content is processed and when? Which committee decides this?	Work is largely decided on ad hoc basis, with the committee leaders managing tentative topic lists for the next couple of months of meetinges. Committee members may raise topics for discussion on any call, or may request a topic be scheduled for a future call. Discussion during meetings often uncovers issues to be discussed. Items from the issue list undergo an infomal triage by the technical leader, who will choose which items to address in a given meeting. Selected items are often grouped thematically (e.g., issues related to errors in FHIRpath constraints; issues around cardinality; etc.). Because of the large overlap between participants in the governance and profiling committees, issues raised in one committee are often considered in the other, although often with an adjustment of focus. (For example, a discussion on profiles maturity and retirement started within the profiling group who considered the technical issues and formulated a proposed policy which then went to the governance committee for further discussion, before feeding back into the profiling committee.) From time to time, the committees will undertake larger tasks such as reviewing our project against other jurisdictions data sets, or comparing our profiling against evolving best practices. This is usually based on initiation by the committee leaders, and largely guided by them.
How long does a process take from application to decision? How many processes are being processed in parallel? How formalized is this process? Which tooling is used for this?	We don’t officially track issue age. However, informally, I (Elliot) would expect that most issues are addressed within 18 months of submission. We attempt to provide 1 or 2 minor

	releases each year. Due to the volunteer nature of the committee, aside from the leadership meeting management/coordination, most work is accomplished during the meetings, which limits the number of parallel activities possible. An exception to this is the application of agree-on tickets and IG packaging, which are performed "offline" by the technical leader assisted by a couple of technical community members.
Is the same process used to update the existing core data set?	Yes. In fact, since the CA Baseline was based on local adaptations of US Core, most of the work since the initial IG creation, has been updates to the existing content.
What is the composition of the committee that manages the core data set (Honorary vs paid, part/full time)? What skills are required for committee members?	Both governance and technical committees are lead and composed of primarily non-compenated volunteers. However, most are employed by (and may represent, to a greater or lesser extent) organizations with an interest in development of Canadian healthcare IT standards, and so their efforts may be compensated by their employer. No specific skills are required of committee members to participate, although those with stronger knowledge of healthcare IT, FHIR, leadership, and the Canadian healthcare landscape are obviously able to contribute more. Although the CA Baseline is a project of HL7 Canada, and convened through Canada Health Infoway, membership in HL7 Canada is not required for participation.
Are there ancillary/specialised committees?	As mentioned above, the CA Baseline project consists of two committees: one focusing on governance (management, developing policy, etc.), the other on profiling (and other aspects of practically authoring the IG).
In addition to the regular process, are there also expedited procedures (aka: "Accelerators") to cover urgent requirements?	No. To date, there hasn't been a need.
Is the responsibility for defining and coordinating the information model/data sets separate from the responsibility for creating and maintaining the national FHIR Core Specification? If so, who is responsible for the translation to FHIR? What is the composition of	Within Canada, there are three parallel national efforts: • the Pan-Canadian Health Data Content Framework (pCHDCF), identifying common data elements, terminology, etc. for use nationally, independent of

the team that manages the FHIR Specification (Honorary vs paid, part/full time)? What skills are required for team members?	any implementation. This is approximately equivalent to the American USCDI. • The CA Core FHIR implementation guide, providing FHIR profiling to realize pCHDCF, with an initial focus on primary care. • The CA Baseline implementation guide intended to provide context-independent profiling for the Canadian context. As mentioned previously, CA Baseline is a self-governing project of HL7 Canada. CA Core is a project of Canada Health Infoway (Infoway, or CHI), and pCHDCF is a project of Canada Institute for Health Information (CIHI). Both Infoway and CIHI are federal government agencies with support of the Canadian provinces and territories. Separate survey responses have been submitted by CIHI and Infoway for their projects. (Various similar provincial/territorial efforts also exist.) The management of the datasets and other work products of CIHI and Infoway is separate from, and does not officially drive, CA Baseline decision making. The determination of what to include in (or exclude from) CA Baseline is driven by community feedback and committee participants. As mentioned, above these participants are volunteers and not compensated for their effort.
In your opinion: Does the process work well? What should be changed/improved?	I (Elliot) see a few issues with the CA Baseline processes. • Participation is entirely volunteer, which limits the velocity we can move at. • Because of the organic development of the committees, decision making processes are not formalized. Although this has not created significantly issues to date, it has led to a few "is that what we decided?" or "I don't think we had consensus on that"-type discussions • There is no rule, law, regulation, or other obligation to encourage or compel use of CA Baseline • The community CA Baseline effort predated pCHDCF and CA Core

	initiatives, but since their announcement, the CA Baseline community has struggled to articulate its specific value proposition, compared to, in particular, CA Core, especially as CA Core expands its scope.
Scope and Adoption of the Core Data Sets	
Is there a general health care information model for the country? (Please provide link to latest publication if applicable.)	See survey response for pCHDCF.
Does the FHIR Core Specification include a mandatory API or any other mandatory transfer protocols? If so: which and for what use cases?	No, to date, CA Baseline only includes resource profiles, extensions, value sets and code systems. There are no CapabilityStatements or transport protocols documented. In part, this is intentional, because CA Baseline is not intended to address specific use cases.
Where is the latest version of the national FHIR Core Specification published?	https://build.fhir.org/ig/HL7-Canada/ca-baseline/
How long has the Core Specification been active?	I (Elliot) believe the effort started in 2019, although the current repository only contains content back to 2020. The release 1.0.0 package was created in January 2022.
In your opinion: do you feel the scope to be sufficient? Can the Core Specification be adopted successfully? What is missing from the Specification? Which parts are the most relevant?	(Elliot) Due to the above-mentioned confusion about the relationship between CA Core and CA Baseline, and the ongoing role of CA Baseline, it is hard to determine if the scope is correct. In some ways it is too small (e.g., only profiling implantable devices, but no other kinds of device), but in some ways may be too large (we have no indication that anyone is using the implantable device profile). I think prior to evaluating whether the scope is too large or small the committees and the Canadian FHIR community need to settle on the vision for CA Baseline, and agree on its role.
Is the adoption of the Core Specification measurable? Have parameters / KPIs (key performance indicator) been defined to measure success?	We are aware that several Canadian provincial Ministries of Health have looked at CA Baseline to inform their own profiling efforts. In some cases, they derive their profiles from CA Baseline, and in others, use CA Baseline as inspiration. Our understanding of use is based on personal communications and feedback; we don't have measurable KPIs.
In your opinion: Does the adoption process work well? What should be changed?	

Balloting and Voting of Core Data Sets and FHIR Core Specification	
Which process steps are balloted?	To date, CA Baseline has operated on a consensus basis; however, we have an intent that release 2.0, will go through an HL7 Canada ballot following the HL7 International process starting this year.
How does ballot participation/voting work? (Rules/Tools?)	The concensus process has worked adequately to date, although we feel that the visibility has been limited. We have not yet attempted a structured balloting process.
Who is eligible to vote?	We expect to limit voting to HL7 Canada individual and organizational members. (Organizational members include the federal, provincial, and territorial ministries of health, as well as CIHI and Infoway.)
In your opinion: Does the balloting process work well? What should be changed?	
Enforcement of Core Data Sets and FHIR Core Specification	
Is conformance to the national FHIR Core Specification being assessed? If so: how? What testing tools are used?	To date, I am not aware of any assessments of conformance to CA Baseline.
Is the use of the FHIR Core Specification mandatory? If so: how is the obligation enforced?	No.
In your opinion: Does enforcement work well? What should be changed?	
FHIR Profiling	
What rules/best practices/strategies are applied when creating profiles? (e.g. closed vs. open profiling, usage of inheritance/derived profiles)	Because CA Baseline is attempting to be context independent, we have recently made an effort to relax our profiling—removing cardinality constraints, removing must-support flags, etc. Extensions are mostly optional, intended to indicate "if you want to capture this piece of information, we suggest using this extension." We do have several required value sets, but they are mostly on optional slices. Slicing is open. Generally, our profiles are derived directly from FHIR Core, with the exception of a couple that re-profile other CA Baseline profiles. We expect most use of CA Baseline will be as the base for other implementation guides, or to be used in conjunction with other IGs (e.g.

	IPS), therefore we try to impose as few limits as possible, while still providing value and guidance.
Is there a fixed release cycle? How are breaking changes being handled?	There is no fixed release cycle. We strive to avoid breaking changes; however, we have not been overly observant about this. We recently formalized a deprecation process that suggests keeping deprecated resources in the IG for a minimum amount of time, and only removing them on major releases.
How strictly is terminology binding handled in general?	Most terminology binding is preferred. Slicing may use required value sets in their discriminators, but in that case the slice is usually optional.
National Terminologies	
How are national terminologies associated with the Core Specification maintained? Are processes and responsibilities the same as for the core data sets or is it separate?	At the moment, terminology is a significant problem for CA Baseline. We want to encourage use of domestic terminology issued by a number of organizations, including government ministries and agencies. However, those terminologies are often not available in FHIR representations or through FHIR servers. We don't want to duplicate content from other sources in CA Baseline, for both currency and copyright reasons. One of the goals of the next release will be to improve our terminology representations. This will likely involve experimenting with different ways to represent third-party terminology (e.g., content-not-present valuesets).
Are national terminologies being published separately from the Core Specification?	Some national terminology is part of other Implementation Guides (e.g. CA Core; or the Canadian IPS variant, PS-CA), and can be accessed through IG dependencies. Other national terminologies were previously available through Infoway websites. These have recently moved to an Infoway-managed FHIR terminology server. It is expected that this move will simplify some use of third-party terminology within CA Baseline.
Do you have a National Terminology Server/Service or other infrastructure dedicated to the distribution of terminologies?	Yes, Infoway hosts an Ontoserver implementation containing national terminology, including Canadian LOINC and

	SNOMED variants, as well as HL7 v3 terminology used in older Canadian standards. It does not host CA Baseline terminology, and it isn't clear whether that would benefit the community.
Are the release cycles for national terminologies and the FHIR Specification coordinated?	No, CA Baseline is released independent of national terminology updates. Note that terminology updates themselves are not coordinated—pCLOD (the Canadian LOINC subset), SNOMED CT CA, and other terminology all have independent update cycles.
In your opinion: Does the maintenance and distribution of national terminologies work well? What should be changed?	Too many "national" terminologies, are not publicly available in FHIR format. They are locked away in legacy formats, or not easily publicly accessible. Some "terminologies" that we have attempted to use, such as Health Canada's DIN (drug identification number) are not actually terminologies, but rather identifier systems. Some content is based on very early releases of FHIR, and is not easily consumable. CA Baseline would like to be a consumer of these terminologies, but is challenged by their availability in consumable formats. It is possible that a more "official" effort could open discussions with the terminology holders and convince them to publish their own content, or to let Infoway publish it on the national terminology server, or to allow CA Baseline to reproduce it. However, the volunteer nature of the CA Baseline effort makes such discussions (and possibly resulting ongoing maintentance) difficult.

Schweiz

SWITZERLAND Survey: National Governance and Usage of (FHIR) Core Data Sets*

by the Working Group of the Interoperability Council for Digital Health in Germany

* a **national core data set** is understood to be a harmonized set of common clinical and/or health care related data elements that are used across multiple use cases in order to facilitate interoperability within a jurisdiction. It may consist of *both* a technology agnostic national information model *and* a FHIR based specification derived from that model, or may be solely expressed as a national FHIR core specification.

This survey aims to gain a broader understanding of common approaches towards governing national data sets and the challenges met during the process.

About the interviewee	
Name	Oliver Egger
Country	SWITZERLAND
Organization	ahdis ag / HL7 Switzerland
How was the questionnaire completed? (interview, autonomous, in person)	autonomos
Interviewer	SH
Organizational questions	
What is the composition of stakeholders for the creation of core data sets (information model and/or FHIR Core Specification)?	all members of HL7 Switzerland
Which organization is responsible for the National Core Data Set?	HL7 Switzerland (only FHIR CH Core)
Is there any national legislation supporting the Core Data Sets? If so, which laws are pertinent?	No
National Governance for Core Data Set Creation and Maintenance	
How is the standardisation process initiated? How and by whom (persons, projects, organizations) are requests/applications	1. Yearly development & ballot cycle. 2. Every HL7 Switzerland member (or members of wokgroups which are joint)

submitted? Are requests submitted or is it managed by a committee only? How formalized is this request? (Template, Jira tickets, informal verbal/written request,...)	3. Everyone can submit 4. Github issues created b a Google Sheet Form
How are requests prioritized? How is it decided which content is processed and when? Which committee decides this?	According to capacity. hl7.ch FHIR working group is taking that on
How long does a process take from application to decision? How many processes are being processed in parallel? How formalized is this process? Which tooling is used for this?	depending on the complexity, 1 to 6 months not many formalized via github issues github
Is the same process used to update the existing core data set?	yes
What is the composition of the committee that manages the core data set (Honorary vs paid, part/full time)? What skills are required for committee members?	Honorary, sometimes contributions thor paid projects participating
Are there ancillary/specialised committees?	terminology has been separated from the FHRI core, exchange formats are also separate work groups
In addition to the regular process, are there also expedited procedures (aka: "Accelerators") to cover urgent requirements?	not yet
Is the responsibility for defining and coordinating the information model/data sets separate from the responsibility for creating and maintaining the national FHIR Core Specification? If so, who is responsible for the translation to FHIR? What is the composition of the team that manages the FHIR Specification (Honorary vs paid, part/full time)? What skills are required for team members?	we don’t have yet a information model/data sets separate from CH Core
In your opinion: Does the process work well? What should be changed/improved?	works will, but buttom up, we do not yet have an initiative for a general information model/data set
Scope and Adoption of the Core Data Sets	
Is there a general health care information model for the country? (Please provide link to latest publication if applicable.)	no
Does the FHIR Core Specification include a mandatory API or any other mandatory transfer protocols? If so: which and for what use cases?	no, but is on the agenda

Where is the latest version of the national FHIR Core Specification published?	https://fhir.ch/ig/ch-core/index.html
How long has the Core Specification been active?	2020-04-21
In your opinion: do you feel the scope to be sufficient? Can the Core Specification be adopted successfully? What is missing from the Specification? Which parts are the most relevant?	no yes API general identifiers, linking to terminology
Is the adoption of the Core Specification measurable? Have parameters / KPIs (key performance indicator) been defined to measure success?	no no
In your opinion: Does the adoption process work well? What should be changed?	yes
Balloting and Voting of Core Data Sets and FHIR Core Specification	
Which process steps are balloted?	the resulting IG
How does ballot participation/voting work? (Rules/Tools?)	https://www.hl7.ch/de/assets/File/Technisches_Komitee/20220409_BallotVerfahrenHL7Schweiz.pdf
Who is eligible to vote?	members of HL7 and joint work groups
In your opinion: Does the balloting process work well? What should be changed?	yes
Enforcement of Core Data Sets and FHIR Core Specification	
Is conformance to the national FHIR Core Specification being assessed? If so: how? What testing tools are used?	no, just dependent IG's from CH Core
Is the use of the FHIR Core Specification mandatory? If so: how is the obligation enforced?	no
In your opinion: Does enforcement work well? What should be changed?	no
FHIR Profiling	
What rules/best practices/strategies are applied when creating profiles? (e.g. closed vs. open profiling, usage of inheritance/derived profiles)	for Core open

Is there a fixed release cycle? How are breaking changes being handled?	yearly not yet normative, breaking changes would be allowed is however tried no to do
How strictly is terminology binding handled in general?	in Core we select preferred
National Terminologies	
How are national terminologies associated with the Core Specification maintained? Are processes and responsibilities the same as for the core data sets or is it separate?	separate terminology ig governance is not the same (not balloting), governance is currently set up
Are national terminologies being published separately from the Core Specification?	yes
Do you have a National Terminology Server/Service or other infrastructure dedicated to the distribution of terminologies?	under construction
Are the release cycles for national terminologies and the FHIR Specification coordinated?	yes
In your opinion: Does the maintenance and distribution of national terminologies work well? What should be changed?	it works, however the volume is currently low

Dänemark

Survey: National Governance and Usage of (FHIR) Core Data Sets*

by the Working Group of the Interoperability Council for Digital Health in Germany

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This survey aims to gain a broader understanding of common approaches towards governing national data sets and the challenges met during the process.

About the interviewee	
Name	Michael Johansen
Country	Denmark
Organization	MedCom
How was the questionnaire completed? (interview, autonomous, in person)	Autonomous
Interviewer	HL7-Germany
Organizational questions	
What is the composition of stakeholders for the creation of core data sets (information model and/or FHIR Core Specification)?	HL7-Denmark, FHIR SIG, Facilitated by MedCom The FHIR SIG have participants from Vendors, Projects, Regions, Health Data Authority, MedCom – and develop FHIR Core specifications.
Which organization is responsible for the National Core Data Set?	HL7-Denmark
Is there any national legislation supporting the Core Data Sets? If so, which laws are pertinent?	The Core FHIR specifications are approved by the Health Data Authority (RUSA board), and registered in the national catalogue of approved standards.

National Governance for Core Data Set Creation and Maintenance	
How is the standardisation process initiated? How and by whom (persons, projects, organizations) are requests/applications submitted? Are requests submitted or is it managed by a committee only? How formalized is this request? (Template, Jira tickets, informal verbal/written request,...)	The FHIR SIG working group will suggest the content of the next release of DK Core at an HL7-Denmark meeting. All topics will be created as issues in GitHub, to keep track of the working group's work.
How are requests prioritized? How is it decided which content is processed and when? Which committee decides this?	At the HL7-Denmark meeting, the owner and FHIR SIG working group will agree on a prioritized list (backlog) of overall topics for the next release of DK Core.
How long does a process take from application to decision? How many processes are being processed in parallel? How formalized is this process? Which tooling is used for this?	Application are done informal during bi-weekly meeting in FHIR SIG, and confirmed on the meetings in HL7-Denmark taking place twice a year. Profiling of several FHIR ressources can be performed simultaneously, in case members in the FHIR SIG volunteer as author and reviewer. The process for development of Core profiles and approval are formal.
Is the same process used to update the existing core data set?	Yes
What is the composition of the committee that manages the core data set (Honorary vs paid, part/full time)? What skills are required for committee members?	HL7-Denmark FHIR SIG workgroup. All members pay yearly fee, with a discount for small organizations, and for organizations with multiple members. All participants are welcome. Development of Core profiles are done pro bono.
Are there ancillary/specialised committees?	We have had a subgroup looking into Patient Reported Outcome (PRO), and debate the StructuredDataCapture IG. We have had an educational SIG, to publish the knowledge of FHIR to the healthcare IT community

	We have developed a best-practice for tenders involving FHIR.
In addition to the regular process, are there also expedited procedures (aka: "Accelerators") to cover urgent requirements?	If the changes only result in a raise of the patch number, the FHIR SIG working group is allowed to publish DK Core after review.
Is the responsibility for defining and coordinating the information model/data sets separate from the responsibility for creating and maintaining the national FHIR Core Specification? If so, who is responsible for the translation to FHIR? What is the composition of the team that manages the FHIR Specification (Honorary vs paid, part/full time)? What skills are required for team members?	During development of Core profiles some logical models developed elsewhere can be used, otherwise the author of the Core profile also have the responsability for the logical model. Logical models are often developed by the National Healthdata Authority.
In your opinion: Does the process work well? What should be changed/improved?	We observ lack of engagement, since the profiling are done pro bono, and work is mainly done by the same few persons.
Scope and Adoption of the Core Data Sets	
Is there a general health care information model for the country? (Please provide link to latest publication if applicable.)	Logical models are only developed for each area/project/sector, so there is no overall information model.
Does the FHIR Core Specification include a mandatory API or any other mandatory transfer protocols? If so: which and for what use cases?	No
Where is the latest version of the national FHIR Core Specification published?	https://build.fhir.org/ig/hl7dk/dk-core/index.html
How long has the Core Specification been active?	Since 2021-12-18
In your opinion: do you feel the scope to be sufficient? Can the Core Specification be adopted successfully? What is missing from the Specification? Which parts are the most relevant?	Our MedCom modernization of messaging has resulted in a number of FHIR messaging IG, who all derive from DK-core. Adoption successful.
Is the adoption of the Core Specification measurable? Have parameters / KPIs (key performance indicator) been defined to measure success?	HL7-Denmark has developed a list of FHIR-projects. KPI is the procentage of FHIR IG that conform to DK-core.

In your opinion: Does the adoption process work well? What should be changed?	Process is fine, but adoption take more time than expected.
Balloting and Voting of Core Data Sets and FHIR Core Specification	
Which process steps are balloted?	We co-create and work with consensus. No ballots.
How does ballot participation/voting work? (Rules/Tools?)	We implement ballot tools in case we can't continue having consensus.
Who is eligible to vote?	Members of HL7-Denmark
In your opinion: Does the balloting process work well? What should be changed?	We prefer to get consensus during co-creation
Enforcement of Core Data Sets and FHIR Core Specification	
Is conformance to the national FHIR Core Specification being assessed? If so: how? What testing tools are used?	Yes, for some IG. MedCom use Touchstone from AEGIS.
Is the use of the FHIR Core Specification mandatory? If so: how is the obligation enforced?	Only recommandation
In your opinion: Does enforcement work well? What should be changed?	Use should be done mandatory.
FHIR Profiling	
What rules/best practices/strategies are applied when creating profiles? (e.g. closed vs. open profiling, usage of inheritance/derived profiles)	We keep the national Core profiles as open profiled as possible, and when each project derive from the national Core profiles, they can add more restrictions within the project. MedCom messaging derive from DK-core, and a number of FHIR messagetypes can derive from the uniform MedCom messaging IG.
Is there a fixed release cycle? How are breaking changes being handled?	Twice a year a new version of DK Core will be released, following the frequency of HL7-Denmark meeting. Breaking changes are handled by semantic versioning at major level.
How strictly is terminology binding handled in general?	Strict

National Terminologies	
How are national terminologies associated with the Core Specification maintained? Are processes and responsibilities the same as for the core data sets or is it separate?	The national Healthdata Authorities are responsible for the national terminology, and HL7-Denmark is responsible for the DK-core.
Are national terminologies being published separately from the Core Specification?	Yes, like SNOMED and ICD10.
Do you have a National Terminology Server/Service or other infrastructure dedicated to the distribution of terminologies?	Wish for a terminology server. Some classifications can be downloaded from webservices on the national service platform.
Are the release cycles for national terminologies and the FHIR Specification coordinated?	No
In your opinion: Does the maintenance and distribution of national terminologies work well? What should be changed?	We need a terminology server, and we need systems to syncronize classifications after same schedule.

Estland

Survey: National Governance and Usage of (FHIR) Core Data Sets*

by the Working Group of the Interoperability Council for Digital Health in Germany

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This survey aims to gain a broader understanding of common approaches towards governing national data sets and the challenges met during the process.

About the interviewee	
Name	Rutt Lindström Rutt.Lindstrom@tehik.ee Ragne Õitspuu ragne.oitspuu@tehik.ee Kerli Linna Kerli.Linna@tehik.ee
Country	Estonia
Organization	TEHIK https://www.tehik.ee/en Estonian Health and Welfare Information Systems Centre
How was the questionnaire completed? (interview, autonomous, in person)	Virtual meeting
Interviewer	Patrick Werner Christine Haas
Organizational questions	
What is the composition of stakeholders for the creation of core data sets (information model and/or FHIR **Base** Specification)?	Estonian Health and Welfare Information Systems Centre, Development Partner of national health system
Which organization is responsible for the National **Base** Data Set?	Estonian Health and Welfare Information Systems Centre
Is there any national legislation supporting the Core Data Sets? If so, which laws are pertinent?	No legislation in place, for national health information system there is legislation about which data has to be represented Link to legislation:

	https://www.riigiteataja.ee/akt/123052023044?leiaKehtiv
National Governance for Core Data Set Creation and Maintenance	
How is the standardisation process initiated? How and by whom (persons, projects, organizations) are requests/applications submitted? Are requests submitted or is it managed by a committee only? How formalized is this request? (Template, Jira tickets, informal verbal/written request,...)	TEHIK coordinates request from health insurance fund, health ministry. Working group is built (BA), can be outsourced. TEHIK creates profiles, terminologies, etc..
How are requests prioritized? How is it decided which content is processed and when? Which committee decides this?	Committee responsible at the ministry, new ideas have to presented to the committee. 2nd Layer: TEHIK decides based on resources and workload
How long does a process take from application to decision? How many processes are being processed in parallel? How formalized is this process? Which tooling is used for this?	Depends on use-case, from few month, to 1+ year. During dev phase: JIRA
Is the same process used to update the existing core data set?	Different: Changes to existing services (bugs & smaller changes) are handled faster (contract between TEHIK and implementing entity) No committee involvement
What is the composition of the committee that manages the core data set (Honorary vs paid, part/full time)? What skills are required for committee members?	TEHIK with ministry & health insurance fund. Health care profesionals are contributing on a voluntary basis, technical implementation is done by paid workers. Other government organistions , universities, patient organisations are part of the WG
Are there ancillary/specialised committees?	-
In addition to the regular process, are there also expedited procedures (aka: "Accelerators") to cover urgent requirements?	-
Is the responsibility for defining and coordinating the information model/data sets separate from the responsibility for creating and maintaining the national FHIR Core Specification? If so, who is responsible for the translation to FHIR? What is the composition of the team that manages the FHIR Specification (Honorary vs paid, part/full time)? What skills are required for team members?	TEHIK, does both, same team. Team: ~6 people, but also responsible for CDA & Terminologies

In your opinion: Does the process work well? What should be changed/improved?	Committees need to be upgraded, not enough resources to implement all accepted ideas from the committee.
Scope and Adoption of the Core Data Sets	
Is there a general health care information model for the country? (Please provide link to latest publication if applicable.)	Planned for the future. Currently done inside WG of new services.
Does the FHIR **Base** Specification include a mandatory API or any other mandatory transfer protocols? If so: which and for what use cases?	As part of policies in IG https://ig.hl7.fhir.ee/ig-ee-base/policy.html#conformance More policies for the national health data system. https://e-estonia.com/solutions/x-road-interoperability-services/x-road/ defines connection protocols for national it infrastructures.
Where is the latest version of the national FHIR Core Specification published?	https://ig.hl7.fhir.ee/ig-ee-base/index.html
How long has the **Base** Specification been active?	~ 3 years
In your opinion: do you feel the scope to be sufficient? Can the **Base** Specification be adopted successfully? What is missing from the Specification? Which parts are the most relevant?	Hard to decide: what should be part of the base profiles. Clinical part currently missing (published for the nation health information system) Base profiles are designed in an open manner, mismatch in down-stream profiles from base.
Is the adoption of the **Base** Specification measurable? Have parameters / KPIs (key performance indicator) been defined to measure success?	National infrastructure profiles are derived from base. No specific KPI. No knowledge about adoptions outside. Statistics about national profiles are available.
In your opinion: Does the adoption process work well? What should be changed?	FHIR adoption just started on the health care provider side.
Balloting and Voting of Core Data Sets and FHIR Core Specification	
Which process steps are balloted?	IG is balloted https://ig.hl7.fhir.ee/ig-ee-base/ballot.html
How does ballot participation/voting work? (Rules/Tools?)	Invitation to dev partners, health care providers GH issues were used for balloting
Who is eligible to vote?	TBD, planned as voting of HL7 affil. HL7 affiliate members can vote.

In your opinion: Does the balloting process work well? What should be changed?	Stakeholders lack FHIR knowledge, more feedback is needed from external Stakeholders in the future Need more experience in the process. Balloting can/should be part of the pilot(showcase) process/phase.
Enforcement of Core Data Sets and FHIR Core Specification	
Is conformance to the national FHIR **Base** Specification being assessed? If so: how? What testing tools are used?	Not right now. For national profiles: testing environment. No certification, but cyber security rules. Will be needed for EHDS FHIR Server validates incoming messages.
Is the use of the FHIR **Base** Specification mandatory? If so: how is the obligation enforced?	no
In your opinion: Does enforcement work well? What should be changed?	-
FHIR Profiling	
What rules/best practices/strategies are applied when creating profiles? (e.g. closed vs. open profiling, usage of inheritance/derived profiles)	Base profiles are modelled open, Not yet, will be added in the future.
Is there a fixed release cycle? How are breaking changes being handled?	No cycle. General policies/processes (also from experience with CDA) are in place: Early notices & Information about breaking changes is distributed to stakeholders. FHIR & terminologies are using SemVer
How strictly is terminology binding handled in general?	No required bindings in base, in national profiles have required bindings.
National Terminologies (https://teabekeskus.tehik.ee/et/teenused/teabekeskuse-teenused/terminoloogiaserver)	
How are national terminologies associated with the Core Specification maintained? Are processes and responsibilities the same as for the core data sets or is it separate?	Handled at TEHIK, data exchange & terminology team. External owners will be managing the content of CS &VS
Are national terminologies being published separately from the Core Specification?	Published independently
Do you have a National Terminology Server/Service or other infrastructure dedicated to the distribution of terminologies?	Authoring tools are used, VS & CS are published via Ontoserver syndication feature (or queried via FHIR API)

Are the release cycles for national terminologies and the FHIR Specification coordinated?	Independent
In your opinion: Does the maintenance and distribution of national terminologies work well? What should be changed?	Central Terminology handling worked well, csv-based authoring was not sufficient End-user want hierarchies, services, not just plain ValueSets.

Kroatien

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This survey aims to gain a broader understanding of common approaches towards governing national data sets and the challenges met during the process.

About the interviewee	
Name	Ivan Pristaš, Marko Čavlina, Antea Ježidžić Hrvoje Belani Miroslav Končar
Country	Croatia
Organization	Croatian Institute for Public Health Ministry of Health HL7 Croatia
How was the questionnaire completed? (interview, autonomous, in person)	autonomous
Interviewer	Sanja Berger
Organizational questions	
What is the composition of stakeholders for the creation of core data sets (information model and/or FHIR Core Specification)?	The core data set is mostly defined within the national eHealth program and project deliverables. The data sets that used as part of the national eHealth infrastructure are all published and freely available on the main national eHealth infrastructure (CEZIH) web page: (link). The program itself is one of the foundational pillars on the national health development program (link). The data sets however are not using FHIR standard.
Which organization is responsible for the National Core Data Set?	Most recently, there has been an increased interest and initiative to revisit the status of

	national core data set, and bring them beyond national EHR program charter. The consensus is that data flows, various clinical data repositories and workflows may sit beyond CEZIH infrastructure. That is why MoH has started the process of regulation and other legal acts to standardize clinical data collection, communication and interoperability. That is work in progress. Croatian Institute for Public Health (CIPH) is the coordinator for the standards governance and adoption; Ministry of Health runs the editorial efforts and support functions; and various national agencies are responsible for standard selection and localization within the realm of their service and authority.
Is there any national legislation supporting the Core Data Sets? If so, which laws are pertinent?	In progress. See national gazette publication, https://narodne-novine.nn.hr/clanci/sluzbeni/2024_10_117_1933.html
National Governance for Core Data Set Creation and Maintenance	
How is the standardisation process initiated? How and by whom (persons, projects, organizations) are requests/applications submitted? Are requests submitted or is it managed by a committee only? How formalized is this request? (Template, Jira tickets, informal verbal/written request,...)	We have only one example to mention here, and that is microbiology report. That is initiated by CIPH and takes FHIR as basic model, also as a part of EU-HIP project. The process will assume the creation of catalogues which will be publicly reviewed and maintained.
How are requests prioritized? How is it decided which content is processed and when? Which committee decides this?	The process is use case driven. It primarily targets the workflows that are part of the national strategy, or EU related projects. In all fairness, one can argue of course, is this the most effective approach, and will it lead to sustainable solutions – to be seen.
How long does a process take from application to decision? How many processes are being processed in parallel? How formalized is this process? Which tooling is used for this?	When it comes to national EHR program, the process is quite manual, and takes a lot of time. The issue also is that the core teams are understaffed, and quite often work in silos. Finally, the awareness of decision makers with importance of the work is very limited
Is the same process used to update the existing core data set?	No
What is the composition of the committee that manages the core data set (Honorary vs paid,	Most of the work is project based; the rest is voluntary, non renumerated.

part/full time)? What skills are required for committee members?	
Are there ancillary/specialised committees?	If the work is done within the projects, than the committee structure follows the project structure.
In addition to the regular process, are there also expedited procedures (aka: "Accelerators") to cover urgent requirements?	No
Is the responsibility for defining and coordinating the information model/data sets separate from the responsibility for creating and maintaining the national FHIR Core Specification? If so, who is responsible for the translation to FHIR? What is the composition of the team that manages the FHIR Specification (Honorary vs paid, part/full time)? What skills are required for team members?	N/A
In your opinion: Does the process work well? What should be changed/improved?	Far from suboptimal.
Scope and Adoption of the Core Data Sets	
Is there a general health care information model for the country? (Please provide link to latest publication if applicable.)	Yes. Croatia has national eHealth program, which includes infrastructure and EHR platform for connecting primary care practices with labs, pharmacies, national health insurance and public health. Over the years it has been upgraded with connectivity to hospitals and secondary care units, with services such as eScheduling, invoicing, discharge notes sharing etc. The standards that are in use however are HL7v3, CDA and IHE profiles. FHIR on this level is currently not in use. See https://www.cezih.hr/dokumentacija.html
Does the FHIR Core Specification include a mandatory API or any other mandatory transfer protocols? If so: which and for what use cases?	N/A
Where is the latest version of the national FHIR Core Specification published?	Not published yet.
How long has the Core Specification been active?	N/A
In your opinion: do you feel the scope to be sufficient? Can the Core Specification be adopted successfully? What is missing from the	There are many missing elements, unfortunately. Mostly due to resources shortage, lack of awareness of decision makers,

Specification? Which parts are the most relevant?	and impact analysis. Core data set is the means to an end, and not the end itself – and as long as the end is not quite clear, this work is difficult to maintain,
Is the adoption of the Core Specification measurable? Have parameters / KPIs (key performance indicator) been defined to measure success?	Currently not in place. The work on KPI's is expected to be done at MoH level.
In your opinion: Does the adoption process work well? What should be changed?	Governance, capacity building, and clear impacts/business case for interoperability
Balloting and Voting of Core Data Sets and FHIR Core Specification	
Which process steps are balloted?	We do not conduct balloting on national level – we are understaffed with resources.
How does ballot participation/voting work? (Rules/Tools?)	N/A
Who is eligible to vote?	N/A
In your opinion: Does the balloting process work well? What should be changed?	N/A
Enforcement of Core Data Sets and FHIR Core Specification	
Is conformance to the national FHIR Core Specification being assessed? If so: how? What testing tools are used?	N/A
Is the use of the FHIR Core Specification mandatory? If so: how is the obligation enforced?	Currently it is not, and it is not even planned.
In your opinion: Does enforcement work well? What should be changed?	To establish eHealth governanance slear strategu, action plans, mandates and resources.
FHIR Profiling	
What rules/best practices/strategies are applied when creating profiles? (e.g. closed vs. open profiling, usage of inheritance/derived profiles)	eHN recommendations.
Is there a fixed release cycle? How are breaking changes being handled?	N/A
How strictly is terminology binding handled in general?	There is no formal process in place.

National Terminologies	
How are national terminologies associated with the Core Specification maintained? Are processes and responsibilities the same as for the core data sets or is it separate?	There is no formal process in place.
Are national terminologies being published separately from the Core Specification?	No
Do you have a National Terminology Server/Service or other infrastructure dedicated to the distribution of terminologies?	No
Are the release cycles for national terminologies and the FHIR Specification coordinated?	There is no formal process in place.
In your opinion: Does the maintenance and distribution of national terminologies work well? What should be changed?	There is no formal process in place.

Niederlande

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This survey aims to gain a broader understanding of common approaches towards governing national data sets and the challenges met during the process.

About the interviewee	
Name	Karlijn de Bruin <karlijn.debruin@nictiz.nl> Zain Ishfaq zain.ishfaq@nictiz.nl Dave van Dijk Wouter Zanen
Country	Netherlands
Organization	NICTIZ
How was the questionnaire completed? (interview, autonomous, in person)	Virtual meeting
Interviewer	Patrick Werner Christine Haas
Organizational questions	
What is the composition of stakeholders for the creation of core data sets (information model and/or FHIR Core Specification)?	nationwide health organizations (nurses, practitioner, …), healthcare professionals (hospital related), architectural board (providers), software vendors Models have owners: ministry of health, authorized by nationwide health organization & internal stakeholders (NICTIZ)
Which organization is responsible for the National Core Data Set?	NICTIZ (Models & creation of core profiles)
Is there any national legislation supporting the Core Data Sets? If so, which laws are pertinent?	Yes, but still in the early phase.

	WEGIZ Law is generic, for a new use-case an addendum will be developed.
National Governance for Core Data Set Creation and Maintenance	
How is the standardisation process initiated? How and by whom (persons, projects, organizations) are requests/applications submitted? Are requests submitted or is it managed by a committee only? How formalized is this request? (Template, Jira tickets, informal verbal/written request,...)	- Process (new models / or modifications) can be started by anyone, by email or call. - Create JIRA Ticket: including specific questions
How are requests prioritized? How is it decided which content is processed and when? Which committee decides this?	NICTIZ decides on priorities (e.g. EHDS is important at the moment)
How long does a process take from application to decision? How many processes are being processed in parallel? How formalized is this process? Which tooling is used for this?	Duration depends: is there pre-existing work? , quality of request. First reaction ~ 1 month next phase: Candidate ZIB or holding area (~2 months) ChangeRequests have deadlines, usually there are done in groups to solve multiple issues at once (delay is between months and years) Corrections: handled mostly in 1-2 months From request to publishing: 3-4 years to months (depending when the request reached NICTIZ) ~ 60 tickets in parallel JIRA zorginformatiebouwsteen (ZIB) HealthInformationBuildingblock
Is the same process used to update the existing core data set?	yes
What is the composition of the committee that manages the core data set (Honorary vs paid, part/full time)? What skills are required for committee members?	4,5 Full time employees + 1-2 FHIR core profile specialists (separate team) Needed in the team: - data/information analytics skills - health domain knowledge - “people skills”, decision making, getting consensus - FHIR knowledge

Are there ancillary/specialised committees?	- FHIR affiliation board - expert communities for dedicated areas, for vendors, architects, health care professionals
In addition to the regular process, are there also expedited procedures (aka: "Accelerators") to cover urgent requirements?	Priorities are done by NICTIZ, depending on strategic priorities. Bugfixing are done quicker. Time for implementation should be still manageable by vendors Flexibility and stability the same time, to be manageable. Flexibility for smaller releases. bigger releases in larger time cycles (every 4 years).
Is the responsibility for defining and coordinating the information model/data sets separate from the responsibility for creating and maintaining the national FHIR Core Specification? If so, who is responsible for the translation to FHIR? What is the composition of the team that manages the FHIR Specification (Honorary vs paid, part/full time)? What skills are required for team members?	NICTIZ + FHIR specialists, all reimbursed. Maintenance and governance is paid, communities are not paid.
In your opinion: Does the process work well? What should be changed/improved?	please read position paper in general process works well - Process to be improved, way of implementation to be improved. for example conditions, close conditions, agreement between healthcare providers needed. - Guidance and agreement how building blocks are to be used. - Governance on clinical side, care providers need to have mandate to make decisions - International first approach, before modelling, for example australia.
Scope and Adoption of the Core Data Sets	
Is there a general health care information model for the country? (Please provide link to latest publication if applicable.)	big picture of healthcare system. No one overall model besides ZIBs, by intent. We don't want to have overarching modell, maybe for some areas it would be helpful. ZIBs don't have to much context (for specific use cases). LInk to ZIRA https://sites.google.com/site/zirawiki

	Reference architecture for ● hospitals ● for mental health ● for care ● general practitionners
Does the FHIR Core Specification include a mandatory API or any other mandatory transfer protocols? If so: which and for what use cases?	quite deep, is use case specific. Transaction models are available, pushing models TA-notified pull (Technical agreement notified pulls) notification that something is available, then you can get it. Send patient to specialists, specialist gets information, that data are available. Specialists pulls information during the visit.
Where is the latest version of the national FHIR Core Specification published?	Link 2 actual ones 2017 ZIBs (FHIR STU 3) 2020 ZIBs publications (FHIR R4) 2024 ZIB FHIR R4??? https://referentiemodel.nhg.org/frontpage general practicioners Home | HIS-Referentiemodel https://simplifier.net/nictizstu3-zib2017 Nictiz STU3 Zib 2017 - SIMPLIFIER.NET Nictiz repository of FHIR STU3 conformance for HCIM Release 2017 for package version 2.x. Includes MedMij and HL7 NL. Implementation guides (IGs) that build on the packages in this project, may be ... https://simplifier.net/nictiz-r4-zib2020 Nictiz R4 Zib2020 - SIMPLIFIER.NET FHIR R4 conformance resources for zib publication 2020.
How long has the Core Specification been active?	Update cycles of 3 to 4 years
In your opinion: do you feel the scope to be sufficient? Can the Core Specification be adopted successfully? What is missing from the Specification? Which parts are the most relevant?	the most relevant parts in the specification. Missing are measurements (weight, temperature), simple clinical measures. Not important in Crossborder exchange.

	Most of use cases covered for EHDS, maybe not aligned. Most relevant: Conditions, Medication, Lab, Procedures (EU Patient Summary is core of cores, Patient related resources are in a lot of usecases.
Is the adoption of the Core Specification measurable? Have parameters / KPIs (key performance indicator) been defined to measure success?	problematic area, no dashboards to date, depending on use cases, and national priorities, No numbers available. Depends on how you look at it. Patient summary implemented in most of hospitals, but usage not known.
In your opinion: Does the adoption process work well? What should be changed?	see current position papier of NICTIZ https://nictiznl-my.sharepoint.com/personal/dave_vandijk_nictiz_nl/_layouts/15/onedrive.aspx?id=%2Fpersonal%2Fdave%5Fvandijk%5Fnictiz%5Fnl%2FDocuments%2FChatbestanden%20van%20Microsoft%20Teams%2FArchitectuur%20advies%20zib%2Dtransitie%5Fverder%20met%20zibs%2Dde%20toekomst%20van%20zibs%20in%20databeschikbaarheid%5Fversie%201%2E2%5Fdec%202024%2Epdf&parent=%2Fpersonal%2Fdave%5Fvandijk%5Fnictiz%5Fnl%2FDocuments%2FChatbestanden%20van%20Microsoft%20Teams&ga=1 work on implementation, GP uses structured data, Insight on background of doctors to use structured data. widespread needs of GP, rising awareness of benefits of structured data at GPs. Vendors have to be convinced to implement data and usability of providing data and support process. Sharing implementation models right? Attention to usage by GP Difficult to reuse data “Chain problem”, proper registration by care provider. Each step has to go right, otherwise IOP is compromised. Start with a proper registration is not always considered. Big issues in compliance and solid agreements:

	Advice: start with less fields and do more education / communication at each step for the user. Problem / Condition / current not-current problem as starting point. Complexity for Nurses, hospitals
Balloting and Voting of Core Data Sets and FHIR Core Specification	
Which process steps are balloted?	2 things are balloted: - every pre-publication for communities - every public ballot all new things all changed things give feedback to the ZIB center HL7 validation is part of the process NICTIZ resolves all comments, then checks whether feedback is correctly implemented.
How does ballot participation/voting work? (Rules/Tools?)	balloting fatigue also: reviews are too large, prepublication postponed to publication more focussed process more focussed involvement of experts smaller reviews per ZIB and not per issue some smaller publications f ex. allergy and intolerances - working group, bigger ballot - topic specific balloting smaller rounds for re-evaluation part of the orchestration of the health care system smaller, bigger, public processes → role model open EHR archetypes review???
Who is eligible to vote?	no voting process, only commenting process everybody can comment voting by NICTIZ governance board every comment welcome, no compromises via voting, common consensus like openEHR: votes for ready to publication
In your opinion: Does the balloting process work well? What should be changed?	
Enforcement of Core Data Sets and FHIR Core Specification	
Is conformance to the national FHIR Core Specification being assessed? If so: how? What testing tools are used?	FHIR core profiles help conformance comes from quality insurance department at NICTIZ to do tests and verification together with software vendors to

	test data whether they have implemented according to core profiles. Vendors have to use the core profiles to quality assurances, no quality control of implemented software
Is the use of the FHIR Core Specification mandatory? If so: how is the obligation enforced?	
In your opinion: Does enforcement work well? What should be changed?	quality control of implemented software vendors do things to pass verification tests and don't use it in the field
FHIR Profiling	
What rules/best practices/strategies are applied when creating profiles? (e.g. closed vs. open profiling, usage of inheritance/derived profiles)	implement building blocks, every other data element ZIBs profiles are strict core profile is ZIB plus other data (observation, lab result) core profiles to accept data ● components = protocols for data surronding ● has member kind of relationships for clinical data (parent) to be completed Wolter sends best practices
Is there a fixed release cycle? How are breaking changes being handled?	in line with ZIBs FHIR R4 to R5 under discussion
How strictly is terminology binding handled in general?	required and extensible bindings inside ZIBs can be extended but with same code system alternative datasets for conditions are possible, ICD-10, SNOMED, mental health … 8 to 10 codesystem, advice to move to SNOMED implement terminologies in use, alignment as a separate process. has to be done before made mandatory. deprecated terminologies
National Terminologies	
How are national terminologies associated with the Core Specification maintained? Are processes and responsibilities the same as for the core data sets or is it separate?	There are two types of associations Fixed (for things like a status field) and Dynamic for instance with a SNOMED Expression or reference set. The fixed ones are managed within the building blocks reference the code system.

	Dynamic ones are managed outside of the building blocks and can change at any time (per month). These are managed by the Terminology center at Nictiz.
Are national terminologies being published separately from the Core Specification?	Yes inside the national terminology service. A national onto server.
Do you have a National Terminology Server/Service or other infrastructure dedicated to the distribution of terminologies?	https://nictiz.nl/wat-we-doen/activiteiten/terminologie/de-nationale-Terminologie-Server/
Are the release cycles for national terminologies and the FHIR Specification coordinated?	No not for dynamic. For fixed yes.
In your opinion: Does the maintenance and distribution of national terminologies work well? What should be changed?	Yes it does work pretty well. We do need to make more clear what are dynamic and fixed Codelists. Also implementation of Dynamic Codelist and frequent updates at vendors still pose a challenge.

USA

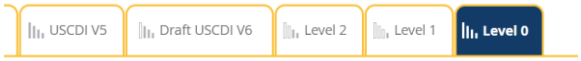
USA Survey: National Governance and Usage of (FHIR) Core Data Sets*

by the Working Group of the Interoperability Council for Digital Health in Germany

* a **national core data set** is understood to be a harmonized set of common clinical and/or health care related data elements that are used across multiple use cases in order to facilitate interoperability within a jurisdiction. It may consist of *both* a technology agnostic national information model *and* a FHIR based specification derived from that model, or may be solely expressed as a national FHIR core specification.

This survey aims to gain a broader understanding of common approaches towards governing national data sets and the challenges met during the process.

About the interviewee	
Name	Brett Marquard
Country	USA
Organization	
How was the questionnaire completed? (interview, autonomous, in person)	
Interviewer	SH
Organizational questions	
What is the composition of stakeholders for the creation of core data sets (information model and/or FHIR Core Specification)?	There is an ASTP/ONC supported Health Information technology advisory committee (HITAC) which provides recommendations to ASTP/ONC. At the bottom of that web page you can find their recommendations - for example USCDI v5 transmittal letter Beyond this HITAC, anyone can propose data elements to be considered using the ONDEC (ONC New Data Element and Class) Submission System https://www.healthit.gov/isp/ONDEC In the end only ASTP/ONC promotes a data element from proposed to included in the core

	data set. Criteria for promoting an element is designed to be objective and public. see the levels 0-2 in tabs: 
Which organization is responsible for the National Core Data Set?	ONC (Office of the national coordinator for HealthIT) https://www.healthit.gov/ Current rename to Assistant Secretary for Technology Policy (ASTP) in progress.

Is there any national legislation supporting the Core Data Sets? If so, which laws are pertinent?	• 21st Century CURES ACT (2016) https://en.wikipedia.org/wiki/21st_Century_Cures_Act
	  ○ USCDI v1 AND HL7® FHIR® US Core Implementation Guide STU 3.1.1 January 1, 2023
	
	• HTI-1
	  ○ USCDI v3 AND FHIR US Core IG 6.1.0 which will coexist with existing standards until January 1, 2026.
	
	Note, within the HL7 US Realm, we use this 'checkerboard' to guide our community. A new version will be published at the end of February 2025.

National Governance for Core Data Set Creation and Maintenance	
How is the standardisation process initiated? How and by whom (persons, projects, organizations) are requests/applications submitted? Are requests submitted or is it managed by a committee only? How formalized is this request? (Template, Jira tickets, informal verbal/written request,...)	via the ONDEC (ONC New Data Element and Class) Submission System: https://www.healthit.gov/isp/ONDEC • anyone can propose a data class or element. • The request is accessible, but also formal. • All requests are made public.
How are requests prioritized? How is it decided which content is processed and when? Which committee decides this?	The ONDEC leveling system defines public, objective criteria: https://www.healthit.gov/isp/ondec-leveling-criteria

	Non-public criteria may include national government priorities. (Note that Australia's AUCDI has a similar public, objective criteria).
How long does a process take from application to decision? How many processes are being processed in parallel? How formalized is this process? Which tooling is used for this?	A new draft USCDI is planned each January, and then a final to support it in July. For example, ASTP/ONC proposed USCDI v5 in January 2024, and published the final in July.
Is the same process used to update the existing core data set?	Yes.
What is the composition of the committee that manages the core data set (Honorary vs paid, part/full time)? What skills are required for committee members?	The members of HITECH are volunteers - on loan from their organization. Any user submitting elements to ONDEC is unpaid. Finalization of USCDI is done by ASTP/ONC employees.
Are there ancillary/specialised committees?	Not sponsored by ASTP/ONC. Industry trade groups, such EHRA, submit their own feedback and sometimes are invited to present HITECH
In addition to the regular process, are there also expedited procedures (aka: "Accelerators") to cover urgent requirements?	Yes: https://www.hl7.org/about/fhir-accelerator/ (most but not all are US focussed) The Argonaut Accelerator has supported 'initial USCDI designs'. Formal ballot process has been supported by ASTP/ONC.
Is the responsibility for defining and coordinating the information model/data sets separate from the responsibility for creating and maintaining the national FHIR Core Specification? If so, who is responsible for the translation to FHIR? What is the composition of the team that manages the FHIR Specification (Honorary vs paid, part/full time)? What skills are required for team members?	Yes. The data model (USCDI) is defined by the ONC governmental agency. USCDI is translated into the US Core FHIR specification by the Argonaut FHIR Accelerator and balloted through HL7 International. The Argonaut team is managed by part-time, paid, highly skilled and carefully selected individuals. Similarly, the US Core IG itself is authored by a part-time, paid, and highly skilled author. ● Manager skillset: pragmatic, conflict negotiation, consensus building, ability

	to understand multiple viewpoints. Ultimately responsible for both faithful translation of USCDI, and implementable, interoperable FHIR spec. ● IG Author: pragmatic, very experienced in HL7 process and as an IG author. Additionally significant input and feedback from volunteers with a primary focus on developers who will implement US Core.
In your opinion: Does the process work well? What should be changed/improved?	It took a few years to get a good rhythm - new data element publication translated to standard - but now the process is smooth
Scope and Adoption of the Core Data Sets	
Is there a general health care information model for the country? (Please provide link to latest publication if applicable.)	Yes: https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi#draft-uscdi-v6
Does the FHIR Core Specification include a mandatory API or any other mandatory transfer protocols? If so: which and for what use cases?	Yes: ● FHIR RestFul API with ● SMART-on-FHIR (for EHR integration, patient access)
Where is the latest version of the national FHIR Core Specification published?	https://hl7.org/fhir/us/core/history.html
How long has the Core Specification been active?	Since 2016 (was published as Argonaut Specification based on DSTU2 prior to 2016)
In your opinion: do you feel the scope to be sufficient? Can the Core Specification be adopted successfully? What is missing from the Specification? Which parts are the most relevant?	Incremental progress has been consistent -- we few our core as the 'floor' to build upon. We slowly raise the floor to make sure everyone is coming along.
Is the adoption of the Core Specification measurable? Have parameters / KPIs (key performance indicator) been defined to measure success?	ONC's Lantern website aggregates information about publicly accessible US FHIR Servers. The US Certified Health IT certification process largely ensures adoption.
In your opinion: Does the adoption process work well? What should be changed?	'real-world' auditing of production system would be helpful.
Balloting and Voting of Core Data Sets and FHIR Core Specification	
Which process steps are balloted?	FHIR Profiling of USCDI data elements.

How does ballot participation/voting work? (Rules/Tools?)	US Core Spec Ballot: ● According to HL7 Balloting Rules: https://confluence.hl7.org/display/HL7/HL7+Balloting ● Using the Jira Balloting Process: https://confluence.hl7.org/display/HL7/Jira+Ballot+Process ●
Who is eligible to vote?	HL7 International members.
In your opinion: Does the balloting process work well? What should be changed?	The JIRA voting process works very well.
Enforcement of Core Data Sets and FHIR Core Specification	
Is conformance to the national FHIR Core Specification being assessed? If so: how? What testing tools are used?	US Core Test Kit (based on Inferno) https://inferno.healthit.gov/test-kits/us-core/
Is the use of the FHIR Core Specification mandatory? If so: how is the obligation enforced?	The US mandate is complicated -- if you as a provider use a non-certified system you are reimbursed less by the government for any Medicare/Medicaid provided healthcare (government supported health care). 95% choose to use certified products. Health IT developer get certified because their customers (providers) want full reimbursement. One requirement on providers is patients can access data with an “app”.
In your opinion: Does enforcement work well? What should be changed?	Greater auditing on how easy a patient can access via an app should be done.
FHIR Profiling	
What rules/best practices/strategies are applied when creating profiles? (e.g. closed vs. open profiling, usage of inheritance/derived profiles)	● open profiling ● sparse use of required elements ● no derivation, core profiles are used ‘as is’ ● Strategy: **KEEP IT SIMPLE** **We are very careful to ONLY profile items everyone is committed to implementing.**

Is there a fixed release cycle? How are breaking changes being handled?	US Core release cycle is mostly annual. We do everything we can to not create breaking changes. Any breaking changes are because of real-world implementer feedback.
How strictly is terminology binding handled in general?	It's messy. We have some in the FHIR build, and some in an external value set authority center (VSAC). I wish we had a single spot but IP licensing make it complex.
National Terminologies	
How are national terminologies associated with the Core Specification maintained? Are processes and responsibilities the same as for the core data sets or is it separate?	The processes for adding/updating national terminology is the same for CORE as any other project. We might get slightly faster response times!
Are national terminologies being published separately from the Core Specification?	It's a mix.
Do you have a National Terminology Server/Service or other infrastructure dedicated to the distribution of terminologies?	VSAC is helpful, but not all value sets are in VSAC.
Are the release cycles for national terminologies and the FHIR Specification coordinated?	No.
In your opinion: Does the maintenance and distribution of national terminologies work well? What should be changed?	No. An authoritative terminology server would be helpful.

IHE International

Survey: National Governance and Usage of (FHIR) Core Data Sets*

by the Working Group of the Interoperability Council for Digital Health in Germany

* a **national core data set** is understood to be a harmonized set of common clinical and/or health care related data elements that are used across multiple use cases in order to facilitate interoperability within a jurisdiction. It may consist of *both* a technology agnostic national information model *and* a FHIR based specification derived from that model, or may be solely expressed as a national FHIR core specification.

This survey aims to gain a broader understanding of common approaches towards governing national data sets and the challenges met during the process.

About the interviewee	
Name	IHE International
Country	USA
Organization	IHE International
How was the questionnaire completed? (interview, autonomous, in person)	autonomous
Interviewer	Sven Lüttmann
Organizational questions	
What is the composition of stakeholders for the creation of core data sets (information model and/or FHIR Core Specification)?	N/A
Which organization is responsible for the National Core Data Set?	IHE International is a global organization that develops profiles for healthcare interoperability. It collaborates with national and international bodies to ensure that the developed profiles meet the specific needs of each country.
Is there any national legislation supporting the Core Data Sets? If so, which laws are pertinent?	N/A
National Governance for Core Data Set Creation and Maintenance	
How is the standardisation process initiated? How and by whom (persons, projects,	Requests for standardization can be submitted by various stakeholders, including healthcare

organizations) are requests/applications submitted? Are requests submitted or is it managed by a committee only? How formalized is this request? (Template, Jira tickets, informal verbal/written request,...)	organizations, regulatory bodies, and industry experts. IHE International has defined and structured processes for submission and review. These submissions are typically formalized through standardized templates or online request systems. The governance framework ensures transparency and traceability of submitted proposals.
How are requests prioritized? How is it decided which content is processed and when? Which committee decides this?	Requests are prioritized based on predefined criteria, which may include regulatory urgency, technological feasibility, and alignment with existing interoperability standards. The responsible committee within IHE International assesses and ranks submissions accordingly. The decision-making process involves expert panels and stakeholder input to ensure balanced and effective prioritization.
How long does a process take from application to decision? How many processes are being processed in parallel? How formalized is this process? Which tooling is used for this?	The process duration varies depending on complexity, stakeholder involvement, and review cycles. Some requests may be processed within a few months, while others requiring broader consensus and technical validation might take longer. Multiple requests can be reviewed in parallel, supported by workflow management tools, version control systems, and structured documentation repositories.
Is the same process used to update the existing core data set?	Yes, updates follow the same structured governance and review process to maintain consistency and alignment with evolving standards.
What is the composition of the committee that manages the core data set (Honorary vs paid, part/full time)? What skills are required for committee members?	Committees comprise experts from various domains, including healthcare and IT. Members may serve in paid or honorary capacities, depending on their roles.
Are there ancillary/specialised committees?	Yes, specialized subcommittees assist the main committees in developing and implementing standards.
In addition to the regular process, are there also expedited procedures (aka: "Accelerators") to cover urgent requirements?	N/A
Is the responsibility for defining and coordinating the information model/data sets separate from the responsibility for creating and maintaining the national FHIR Core Specification? If so, who is responsible for the translation to FHIR? What is the composition of	N/A, IHE does not define dore information models nor data sets. Responsibilities for development and maintenance are distributed among different domain teams and committees.

the team that manages the FHIR Specification (Honorary vs paid, part/full time)? What skills are required for team members?	
In your opinion: Does the process work well? What should be changed/improved?	Yes, the process works very well.
Scope and Adoption of the Core Data Sets	
Is there a general health care information model for the country? (Please provide link to latest publication if applicable.)	N/A
Does the FHIR Core Specification include a mandatory API or any other mandatory transfer protocols? If so: which and for what use cases?	N/A
Where is the latest version of the national FHIR Core Specification published?	N/A
How long has the Core Specification been active?	N/A
In your opinion: do you feel the scope to be sufficient? Can the Core Specification be adopted successfully? What is missing from the Specification? Which parts are the most relevant?	N/A
Is the adoption of the Core Specification measurable? Have parameters / KPIs (key performance indicator) been defined to measure success?	N/A
In your opinion: Does the adoption process work well? What should be changed?	N/A
Balloting and Voting of Core Data Sets and FHIR Core Specification	
Which process steps are balloted?	The balloting process includes several key steps to ensure transparency and consensus. Initial proposals for changes or new specifications undergo a review phase by relevant committees. Once reviewed, the proposal moves into a public comment phase, where stakeholders can provide feedback. After this phase, formal voting is conducted by eligible members. The final approval step includes incorporating accepted changes and publishing the updated specification. Each step follows predefined guidelines to maintain consistency and alignment with interoperability standards.

How does ballot participation/voting work? (Rules/Tools?)	Ballot participation follows a structured process as outlined by IHE International. Members of relevant committees and working groups review proposed changes and cast their votes through an online system or official meetings. The voting process may include predefined deadlines, discussion periods, and consensus-building steps to ensure transparency and fairness. Eligible voters must meet participation criteria, such as active engagement in standardization activities and membership requirements.
Who is eligible to vote?	Typically, members of relevant committees, working groups, and recognized stakeholders within the organization are eligible to participate in the voting process. Eligibility may also depend on organizational membership status and active participation in standardization activities.
In your opinion: Does the balloting process work well? What should be changed?	N/A
Enforcement of Core Data Sets and FHIR Core Specification	
Is conformance to the national FHIR Core Specification being assessed? If so: how? What testing tools are used?	N/A
Is the use of the FHIR Core Specification mandatory? If so: how is the obligation enforced?	No
In your opinion: Does enforcement work well? What should be changed?	N/A
FHIR Profiling	
What rules/best practices/strategies are applied when creating profiles? (e.g. closed vs. open profiling, usage of inheritance/derived profiles)	N/A
Is there a fixed release cycle? How are breaking changes being handled?	IHE International follows a structured release cycle, typically aligned with industry needs and regulatory updates. Breaking changes are managed through deprecation policies, versioning strategies, and stakeholder consultations. Prior to implementing significant changes, extensive testing, impact analysis, and community feedback are gathered to ensure

	minimal disruption. Transition periods and backward compatibility considerations are also factored into release planning.
How strictly is terminology binding handled in general?	Terminology binding is managed with varying degrees of strictness depending on the use case and regulatory requirements. In critical healthcare domains, strict binding ensures consistency, interoperability, and regulatory compliance. Loose binding may be applied in contexts where flexibility is needed for local adaptations. IHE International recommends using standardized terminologies such as SNOMED CT, LOINC, and HL7 vocabularies to maintain interoperability. Regular reviews and updates are conducted to align with international standards and evolving clinical needs.
National Terminologies	
How are national terminologies associated with the Core Specification maintained? Are processes and responsibilities the same as for the core data sets or is it separate?	N/A
Are national terminologies being published separately from the Core Specification?	N/A
Do you have a National Terminology Server/Service or other infrastructure dedicated to the distribution of terminologies?	N/A
Are the release cycles for national terminologies and the FHIR Specification coordinated?	N/A
In your opinion: Does the maintenance and distribution of national terminologies work well? What should be changed?	N/A