The outlook for HL7 FHIR profiles in Sweden

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Utsikternas för HL7 FHIR-profiler i Sverige

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Abstract

The Vision for eHealth infers that Sweden should be best in the world to utilize the opportunities of the digitization by 2025. One of three particularly important areas of action to realize the vision is standardization of e.g. exchange of information. HL7 FHIR is a modern standard for interoperability within e-health. HL7 FHIR enables the exchange of information between different healthcare information systems in an easy way. The basic building blocks in HL7 FHIR are called resources. These represent healthcare entities of some kind, e.g. Patient, Medication, Care plan, and Device. A base set of resources should either together, or by themselves, be able to satisfy the most common use cases in healthcare. A set of rules about a resource’s content is called a profile, which is used for defining extensions and constraints on a resource. Profiles can be used to customize the standard to everything from a small local use-case to characteristics common for a whole country, so-called national profiles.

This master thesis project sought to investigate the opportunities and restrictions with HL7 FHIR profiling by mapping the outlook of e-health stakeholders in Sweden. The project conducted a mixed method approach. Surveys were sent out to regions, county councils and private caregivers and interviews were held with national stakeholders, industry suppliers, HL7 Sweden and subject experts. The qualitative data was processed through a thematic analysis and the quantitative data was processed through a descriptive analysis.

The results showed that there were positive views on governing and maintaining HL7 FHIR and FHIR profiling on a national level and to the establishment of national FHIR profiles. However, questions remain on how it should be done. Among caregivers there were in general positive attitudes towards HL7 FHIR as a standard for interoperability and towards a possible implementation. However, the implementation level was low and specific knowledge of HL7 FHIR profiles is yet needed.

Keywords: HL7 FHIR, FHIR profiles, National implementation, Interoperability, Health Information Systems, Standards
Sammanfattning


Nyckelord: HL7 FHIR, FHIR-profiler, Nationell implementering, Interoperabilitet, Vårdsinformationssystem, Standarder
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Sincerely,

Rebecka Hansson

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Nomenclature

County council A regional partly self-governing subdivision of Sweden
EhM The Swedish eHealth Agency.
EHR Electronic Health Record
FHIR Fast Healthcare Interoperability Resources (pronounced fire).
HL7 Sweden HL7 organization in Sweden
HL7 Health Level 7. International standards development organization.
HSAid Identifies objects in HSA
HSA Catalog with data about people and operations within Swedish healthcare
ISO International Organization for Standardization
LOINC Logical Observation Identifiers Names and Codes. Vocabulary standard.
NI National Information Structure. (Nationell Informationsstruktur in Swedish)
NLL National list of drugs (Nationella Läkemedelslistan in Swedish)
NPLid Unique numerical code on drug packaging.
NTjP National service platform (Nationella tjänsteplattformen in Swedish).
Profile A set of rules about a resource’s content
Relaxed profiles Profiles allowing much optionality (tillåtande/öppna in Swedish).
Resources Basic building blocks in HL7 FHIR, e.g. patient and medication
SIS Swedish Standards Institute
SKL Swedish association of local authorities and regions
Snomed CT Clinical healthcare terminology system. Vocabulary Standard.
SoS The National Board of Health and Welfare (Socialstyrelsen in Swedish).
Strict profiles Profiles allowing little optionality (strikta/tighta in Swedish)
Glossary

co-ordination number samordningsnummer. 50

healthcare operation verksamhet. 31, 33, 39, 48, 50

informatic islands informatiska öar. 36, 38, 47

let all flowers bloom låta alla blommor blomma. 35, 49

personal identity number personnummer. 32, 50

spare number reservnummer. 32, 50
Chapter 1

Introduction

Today, all society sectors are either in the progress of becoming or have already become fully digitized [1]. In 2016, The Swedish Government together with The Swedish Association of Local Authorities and Regions (SKL) entered into an agreement about a long-term Vision for eHealth. By 2025, Sweden should be best in the world to utilize the opportunities of the digitization in the purpose of enabling for people to achieve a good and equal healthcare. In the agreement standardization, of e.g. exchange of information, has been identified as one of three particularly important areas of action [2].

This master thesis project is about the HL7 standard FHIR, which stands for Fast Healthcare Interoperability Resources and is a modern standard for interoperability within e-health [3]. HL7 FHIR enables exchange of information between different healthcare information systems in an easy way and has implementation and base in web standards such as XML, JSON, http, etc. HL7 FHIR allows for health care workers to have the right information accessible at the right time and place when needed. In HL7 FHIR, all content that is exchangeable are defined as resources, which form the basic building blocks of HL7 FHIR. Examples of resources are Patient, Medication, Care plan and Device. The idea is that a base set of resources should either together, or by themselves, be able to satisfy the most common use cases in healthcare [4].

A set of rules about the resource’s content is called a profile. These are used for defining extensions and constraints on resources. For example, the patient resource could be extended by adding birthplace as an extra element and constrained by removing the element for attachment of a photo. Hence the result is a profile of the base resource patient that differ in the way of having a birthplace and not the attachment of a photo. The number of different variants of how a resource can be profiled seems infinite. Consequently, questions on how to use and define profiles in HL7 FHIR leads to complexity in the interoperability of healthcare applications [3].

The HL7 FHIR standard specification in itself does not provide profiles but it is up to the FHIR implementers to develop them. Thus, profiles can be created to represent anything from a small use case for an individual organization to common
characteristics for a specific country, known as national profiles. Both mentioned applications of HL7 FHIR profiles can be seen all around the world, for instance in the Netherlands and in USA. However, is FHIR also catching onto Sweden?

1.1 Objectives

This project aims to investigate the opportunities and restrictions with HL7 FHIR profiling by mapping the outlook of national stakeholders (SKL, Inera, The National board of Health and Welfare and the eHealth Agency) and other organizations of interest. To obtain a broader view the project also aims to investigate the attitude to HL7 FHIR in general among the Swedish caregivers. The goal is to establish a compilation of the status of the national implementation of HL7 FHIR, mainly implementation level of FHIR profiles. This status compilation aims to bring knowledge and guidance to interested actors within the e-health field on how to approach HL7 FHIR profiling.

The project aims to address the following research questions:

- What is the common outlook and interest of the implementation of HL7 FHIR Profiles for e-health stakeholders in Sweden and are there opportunities for improvement?
  (a) What is the common knowledge of HL7 FHIR and FHIR profiles among stakeholders?
  (b) What is the common perception about the strengths, weaknesses, opportunities and problems of HL7 FHIR profiling?
  (c) When do stakeholders plan to implement HL7 FHIR and FHIR profiles?
  (d) What are the views on governing and maintaining HL7 FHIR and FHIR profiling on a national level?
  (e) What are the possibilities of establishing common national HL7 FHIR profiles and what room may be left for organizations to create their own (derived) profiles for their specific needs?
  (f) What are the conditions at regional levels, is there enough knowledge and interest among the county councils, regions and private care givers of Sweden for an implementation of HL7 FHIR profiles (and FHIR in general) to be possible?
1.2 Demarcations

- The project is focused on Sweden and the experts, stakeholders and suppliers that are most relevant to the subject. However, the result is applicable to other countries as well.

- There are many questions and aspects that could be addressed when it comes to implementing HL7 FHIR. However, this project will focus on the questions concerning HL7 FHIR profiling in particular.

- A selection of experts and industry suppliers was made in order to limit the number of interviews.
Chapter 2

Background

2.1 Healthcare in Sweden

The Swedish healthcare system is divided into three administrative levels: The national government, County councils and regions and Municipalities. A simplified illustration of Swedish healthcare system can be seen in Figure 2.1.

The National Government sets the general political agenda, principles and guidelines for healthcare. This is done either through laws and regulations or in agreements with the Swedish Association of Local Authorities and Regions (SKL). Examples of areas these understandings applies to are obsterics and shorter waiting times for cancer care [5].

The Ministry of Health and Social affairs is responsible to meet the goals that the Swedish parliament and government have set up. Beneath The Ministry of Health and Social affairs there are a few agencies whom serves as support for the ministry’s activities. These agencies includes for example the The National Board of Health and Welfare (SoS), the Swedish eHealth Agency (eHM) and the Swedish Medical Products Agency [5].

SKL is a member organization for all 290 municipalities and 21 county councils and regions of Sweden. Their task is to support and contribute to developing the operations of the municipalities, county councils and regions. SKL also function as a network for cooperation and exchange of knowledge [6]. SKL owns the company Inera together with regions, county councils and municipalities. Inera supports the owner’s operation development by providing competence within digitization. Inera is responsible for services such as ”1177 Vårdguiden”, ”UMO” and ”Journal via nätet” [7].

13 out of the total 21 Swedish county councils have an extended responsibility for regional development and are therefore referred to as regions. The county councils and regions are responsible for organizing healthcare to enable that all citizens have access to good care. In addition to countycouncils and regions, there are also several private caregivers whom provide healthcare to patients.
The 290 municipalities of Sweden are responsible for school health, care of elderly, care of people with physical and psychological disabilities and to provide support for people who have been discharged from the hospital and completed their therapy [5].

E-health is a part of this system, to read more about the e-health eco system and what different actors do within e-health, see Appendix A.1.

Figure 2.1: Simplified illustration of the Swedish healthcare system
2.2 Four levels of Interoperability

In the European Interoperability Framework (EIF) the term Interoperability is defined as

"The ability of organisations to interact towards mutually beneficial goals, involving the sharing of information and knowledge between these organisations, through the business processes they support, by means of the exchange of data between their ICT systems" [8].

Above is a broad definition of Interoperability. So called Technical Interoperability makes it possible to move data from one computer system to another. It is domain independent and it is care- and knowing-less of the meaning of what is exchanged. The mission is to provide the right information to the right place at the right time [3].

For the technical interoperability to be utilized, cooperation at different levels is required. Affected organizations need to cooperate and agree on how the exchanged information should be interpreted. This requires coordinated business processes at the cooperating organizations. With this background, interoperability can be viewed in 4 different levels: Legal interoperability, Organizational interoperability, Semantic interoperability and Technical interoperability [9].

Legal interoperability assures that there can be cooperation between organizations that function under different strategies, policies and legal frameworks [8] and is not about the information exchange itself [10].

Organizational interoperability is about how cooperating organizations coordinate their processes, still optimizing the own organization for external cooperation.

Semantic interoperability allows the sender and recipient to have the same understanding of the sent data. It makes it possible for computers to unambiguously understand, share, interpret and make use of data. Unlike technical interoperability, semantic interoperability is domain specific [3].
2.3 HL7 FHIR

FHIR stands for Fast Healthcare Interoperability Resources and is a modern standard for interoperability within e-health.

2.3.1 Resources

The building blocks for exchange in FHIR are called resources, which are structures that are small, reusable [3] and represent healthcare entities of some kind. The FHIR Specification defines many different types of resources, at the time of writing the number is 116 [11]. The types of resources can be categorized into Foundation, Base, Clinical, Financial and Specialized resources. For example, Clinical resource types include Procedure, CarePlan, Medication and Observation while examples of base resources are Patient, Organization, Appointment and Encounter [12]. All resources, part of the current version STU3, can be seen in Figure below.

![Figure 2.2: HL7 FHIR Resources in version STU3](image)

Figure 2.2: HL7 FHIR Resources in version STU3
Resources can be represented with JSON and XML and they all contain:

- An identity in form of an URL
- Common metadata.
- A part that is human readable
- A collection of data elements

To describe what a resource is more specifically, an UML diagram of the Patient resource type and its elements is shown in figure 2.3.

![UML diagram of the Patient resource](image)

Figure 2.3: UML diagram of the Patient resource [13]

Atop is an **identifier** for the patient. The **active** element is used to tell whether there is active use of this patient record or not. Next comes the **name** of the patient and the **telecom** element that constitutes contact details such as email or phone number. Therafter follows the **gender** and **birthDate** of the patient. The element **deceased** describes whether the patient has deceased or is alive. Next is the **address** of the patient and the **maritalStatus**. That is, the most recent civil status of the patient. The **multipleBirth** element shows whether the patient was part of a multiple birth, meaning if the patient is a twin, triplet etc. An image of the patient can be attached with the **photo** element. **generalPractitioner** is the care provider that has been nominated to the patient and **managingOrganization** is the organization that has the patient record’s custodianship [13].

**Maturity**

The HL7 FHIR resources (and profiles) are of different maturity levels, called FMM levels. These are intended to work as support for implementers to assess how advanced and stable a resource is. The levels are 0,1,2,3,4,5 and N, where 0 corresponds to draft and N, which stands for normative, means that one can consider the resource stable. Examples on HL7 FHIR resources at different levels can be seen in Table 2.1 [14].
<table>
<thead>
<tr>
<th>Maturity levels</th>
<th>Example of resources (STU3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>TestReport, DeviceRequest, AdverseEvent</td>
</tr>
<tr>
<td>1</td>
<td>Consent, Contract, DetectedIssue</td>
</tr>
<tr>
<td>2</td>
<td>Person, CarePlan, Device</td>
</tr>
<tr>
<td>3</td>
<td>Medication, Practitioner, Procedure</td>
</tr>
<tr>
<td>4</td>
<td>OperationDefinition</td>
</tr>
<tr>
<td>5</td>
<td>Patient, Observation, Valueset</td>
</tr>
<tr>
<td>N</td>
<td>None yet</td>
</tr>
</tbody>
</table>

Table 2.1: Maturity levels of resources

As can be seen in Table 2.1, no resources of the latest release of the standard, Release 3 Standard for Trial Use (STU3), are of the normative form. However, according to the Release 4 ballot, some resources will become normative, e.g. Patient, Observation and ValueSet [15].

### 2.3.2 REST API

The FHIR specification is described as RESTful since a REST API is provided to manipulate the resources. A typical FHIR URL constitutes of three parts: Base-address/Type/Id. For example:


The interactions used are Create, Read, Update, Delete, Search, History, Transaction and Operation. For example, to Create a new resource a HTTP POST command is used and may look like the following:

POST https://example.com/path/resourceType.

An HTTP POST command is also used for the Transaction interaction, that is when a single HTTP request or response is used for submitting a set of actions to be performed on the server. It may for example be a combination of other interactions. To get access of the current resource content, the read interaction is performed by the HTTP GET command:

GET https://example.com/path/resourceType/id

A HTTP GET command is also used for the Search, History and Operation interactions. A HTTP DELETE command is performed for the delete interaction to remove a resource. To update a resource to a new version a HTTP PUT command is performed for the Update interaction. [11]

### 2.3.3 Philosophy

HL7 FHIR aspires to be able to cover a majority of use cases that are common for healthcare with a built set of resources, operating either combined through resource references or by themselves [4]. The FHIR specification follows the so called 80/20
rule when designing resources. It means that the specification only includes those elements that are relevant to 80% of the implementers. The rest should be covered with applying extensions [16].

2.4 HL7 FHIR Profiles

2.4.1 Profiling FHIR resources

Conformance layer

The applicable and general characteristics of the FHIR specification leads to quite loose rules. A consequence of this is that there might be a problem of interoperability between different applications. To prevent this, a conformance layer is provided that solves specific use cases by giving details on how to use the resources and their paradigms of exchange. The conformance layer constitutes four key resources: CapabilityStatement, ValueSet, Implementation guide and StructureDefinition [17].

The CapabilityStatement resource states which types of operations and resources an application consumes or provides. The application’s particular use of the resources is described by the profiles the CapabilityStatement references to. The ValueSet resource is a specification on the set of codes, from one code system or many, that is allowed in a specific element. The ImplementationGuide resource is a document published by a vendor, institution or domain that specifies the rules on how to solve a specific use case or problem [17].

When building a profile one uses the structure definition to specify rules on how the resource type should be used. The structure definition can include either a differential statement or a snapshot or both. A differential statement informs in what way the profile structure definition differs from the resource structure definition it has been profiled on. A snapshot shows a snapshot on the profile structure definition, in other words, the resource structure definition with the applied profile rules. [17].
The profile

A profile is a set of rules about a FHIR resource’s content. Profiling of a FHIR resource can be the action to:

- Limit the cardinality of elements. That is, if an element allow input from 0 to many [0..*] (See figure 2.4), it can be limited to only 0 [0..0] - thus forbidding use of the element. It can also be limited to 0 to a particular number e.g. [0..3] or limited to only one number e.g. [1..1] etc.

- Add an isModifier flag (?)! to certain elements. This implies that the element, when it is filled in, can change the entire meaning of the resource. E.g. in figure 2.4, the isModifier flag can be seen on the deceased element.

- Add a Must-Support flag to an element. This implies that there must be support for the particular element. A Must-Support element does not need to be filled in, but if it is, it must be understandable to both the sender and receiver. That is, the receiver must be able to process a Must-Support flagged element value if it is received.

- Constrain usable data types. Some resource elements have the possibility to choose between several data types. This possibility is marked by [x] and can be constrained in a profile. E.g. in the patient resource (Figure 2.4) it is possible to choose between Boolean and Integer for the MultipleBirth element. Restricting to the use of a Boolean would mean that the profile only tells whether the patient is a part of a multiple birth (twin, triplet etc.) or not (true or false). Restricting to the use of an Integer would mean that the profile also tells in which order the patient was born in the multiple birth.
• Restrict the element content to a fixed value. E.g. require to use LOINC code when specifying a vital sign.

• Add extensions if there is something missing in the base resource but is needed in a specific context [17].

2.4.2 Derived profiles

It is not only HL7 FHIR resources that can be profiled. If there is a need to constrict across resource types it can be efficient to constrain data types. Furthermore, it is also possible to profile another profile. Thus, creating layers of profiles, so called derived profiles. The concept of derived profiles is illustrated in Figure 2.5. Profiles that are not very specific (core and national profiles) have large volumes of resources that agrees with them. For very specific profiles, a small portion of resources will agree [17].

![Figure 2.5: Illustration of derived profiles](image)

For example, a national base set of profiles would fit all the resources created in that particular country. The profiles may be further derived at regional levels to satisfy regional characteristics or needs. Furthermore, an organization in a particular region may want to develop a profile for a specific use case.

2.4.3 FHIR profiling around the world

Argonaut

The American Argonaut Project is an initiative from the private sector with the purpose of developing a specification for Core Data Services and a FHIR-based API. Thus, enabling electronic health records and other technologies to share information in an expanded way using internet standards [18]. Sponsors for the Argonaut project include Apple, Epic and Cerner [19]. Implementation guides, produced through the project, include Data Quiry and Provider Directory. These implementation guides contains Argonaut profiles, e.g. Patient Profile, Vital Signs Observation Profile, Smoking Status Observation Profile [20], Provider Directory Location Profile and Provider Directory Practitioner Profile [21].
SMART on FHIR

Another project, in collaboration with Argonaut, is SMART on FHIR [22]. It resulted in a collection of open specifications which enables integration between apps and electronic health records and other systems concerning Health IT [23]. SMART has not defined their own profiles but are adopting the previously mentioned Argonaut profiles in the US [24].

One example of a company that has implemented SMART on FHIR is Apple who uses it to integrate their health app to the consumers’ electronic health records. This is available for consumers whom are patients of a number of connected health institutions. In the app, consumers can find a view over their medications, lab results, procedures, vitals, immunizations, allergies and conditions. They are also notified when there is an update in the data and the data is protected and encrypted through the iPhone password [25].

Nictiz

The organization Nictiz is "The center of expertise for e-health" in the Netherlands [26]. Nictiz and HL7 Netherlands provides national profiles for use in the Netherlands, which are published by Nictiz in projects at simplifier.net [27]. Examples of these profiles are nl-core-patient, nl-core-practitioner, nl-core-organization and nl-core-location. These profiles are of status final, meaning that the government group have published them and regarded them fit for use [28].

2.5 Sweden and HL7 FHIR

In Sweden, there are many projects with national cooperation related to informatics, architecture and interoperability within agencies, county councils, regions and municipalities [29]. At the time of writing many are currently running. Only a few however, include FHIR.

2.5.1 StandIN

One of these projects is the 3 phase project StandIN, or "Common Framework of International Standards for interoperability and change management" ("Gemensamt ramverk av standard för interoperabilitet" in Swedish). This project was assigned to the association Swedish Medtech and is included in the governments investment on life science.

Phase 1 of the StandIN project was completed in 2016. This phase sought to identify a framework of international interoperability standards that would form a basis for the Swedish healthcare information system in the future. The project assessed 18 standards, including FHIR, to be relevant for technical interoperability. FHIR is described as of constituting an attractive opportunity because of the possibilities of download and use of technical implementations without roundabouts [30].
A master thesis project, completed and presented in collaboration with StandIN phase 1, investigated the knowledge levels of the identified interoperability standards among system providers. The result for FHIR, even though it was in a developing phase at the time (it still is), showed that a majority of the system providers had full or partial knowledge of the standard. The investigation also showed that many providers already had adopted or planned to introduce HL7 FHIR [31].

Phase 2 of the StandIN project was completed in 2017. In this phase a structure, which connects the healthcare organization needs in a process together with the results from earlier projects 3H3R and StandIN, was created. Focus in this project was put upon establishing proof of concepts and questions at issues. HL7 FHIR was identified as one suitable standard for realizing a use case, about registering life habits, which would be included in a proof of concept [2].

2.5.2 RIV-TA on FHIR

As explained in A.1.2, RIV-TA is a national framework for accessing the National Service Platform, NTjP. During spring 2018, Inera performed a proof-of-concept to evaluate the advantages with replacing the some of the current service contracts with HL7 FHIR standardized contracts. The project verified the approach with clinical building blocks in FHIR technology by reflecting today’s use of GetObservations for growth data in the service "Journalen". The proof-of-concept was evaluated from formulated acceptance criterias, which were all fulfilled. Thus, recommendation was given to proceed with implementation of a FHIR ability in the national architecture [32].
2.6 Research Methods

A mixed methods approach is used in research when both qualitative and quantitative data is collected. There are many methods for collecting qualitative and quantitative data for purposes similar to the subject of this report. This section presents qualitative and quantitative methods of relevance.

2.6.1 Surveys

Using surveys to examine knowledge levels among county councils and regions is a practicable approach considering previous reports studying healthcare related knowledge in county councils and regions [33, 34]. Previous work on knowledge of interoperability standards shows that surveys are a successful approach [31]. Therefore the investigation of knowledge levels in this project was decided to follow the previous example. However, this study also seeks to understand different stakeholder’s experience and views on the subject. Thus, use of interviews is also an motivated data inquiry method. It enables the researcher to have control over the questioning line and also to enable participants to provide information of historical form [35].

2.6.2 Interviews

Interviews comprising a concurrent mixed methods procedure collects both qualitative and quantitative data at the same time. In this procedure the two types of data are merged together with the purpose to analyze the research question in a comprehensive way. Depending on how open and closed the response options for the questions are, interview data can be of both qualitative and quantitative form [35].

2.6.3 Thematic analysis

Thematic analysis is a common qualitative research approach [36]. If audio-taped interviews are conducted, the theme identification process can start already during transcription [37]. The process involves coding interview transcripts, that is, labeling out relevant pieces. The most important codes can then be brought together to form themes or categories which are interpreted and interrelated to each other [35]. Examples of different approaches that can be used to identify themes in a thematic analysis are to search for concepts like:

- **Repetitions.** Topics occurring several times.
- **Categories or typologies of indigenous form.** Terms or phrases that may seem unfamiliar but are used in a natural way in the local context.
- **Analogies and Metaphors**
- **Transitions.** Naturally occurring switching of content.
- **Differences and Similarities**
- **Linguistic Connectors.** Causal and conditional relations can be identified through worlds like "as a result", "since", "instead of" and "if" [37].
2.6.4 Validity Strategy

Procedures used by qualitative researchers to demonstrate that the findings are accurate are called validity strategies. One of these strategies is member checking, which means that the study participant (e.g., an interviewee) receives the outcome of the informant’s involvement in the study to check that it is accurate. The procedure can involve providing the participants opportunity to give evaluative comments [35].
Chapter 3

Method

For this master thesis project, a mixed method approach was conducted, inquiring both quantitative and qualitative data. The project was initiated by the data collection design, followed by the data collection process, in which interviews were held and survey responses were collected. The collected data was reviewed and reflections resulted in new data collection. The final analysis of the data was validated before transferred to the final results. Figure 3.1 presents the steps of the method.

3.1 Data Collection Design

To answer the research questions, a large volume of different organizations, experts and caregivers needed to be reached. National stakeholder organizations (SKL, Inera, The eHealth Agency, The National Board of Health and Welfare and HL7 Sweden), experts and industry suppliers were the primary target group for research question (a)-(e) in section 1.1. Caregivers (Regions and County councils, and later also private caregivers) were the primary target group for research question (f). For this reason, the project was split into two subprojects based on the participants: I. National stakeholders, suppliers and experts and II. Caregivers.
3.1.1 Part I: National stakeholders, experts and suppliers

Research questions (a)-(e) in Section 1.1 were broken down into interview questions with accompanying subquestions. These were both open-ended and closed - to result in both qualitative and quantitative data.

Interview design

The interviews, which consisted of these questions, were held with representatives from national stakeholders, suppliers and experts in the area. A few questions were irrelevant to ask experts and representatives from HL7 Sweden. Therefore, two different interview protocols, A and B, were designed. Protocol B was used for expert interviews and was thus a subset of Protocol A. One participant requested an English interview, hence both Swedish and English versions of the protocols were produced. The Swedish version of Protocol A can be seen in Appendix B.1.

To assure that the interview questions would result in usable data, a reference group was used to test the questions before the actual interviews took place. The outcome of the reference group brought additional questions, other angles of the information and suggestions on how to improve the questions for better understanding. At least a week before every interview an introduction letter was sent to the interviewees, informing about the interview and presenting the interview questions. These were provided to the interviewees to enable preparation and acquisition of as informative answers as possible.

Surveys

For Protocol A interviews, which consisted of more questions than B, a web survey was sent out together with the introduction letter to later save time at the interview. The survey consisted of the open-ended questions 4-7 (See B.1) and all closed-ended questions. The survey responses constituted base for an elaborated discussion at the time of the interview. In other words, a sequential exploratory design was followed.

3.1.2 Part II: Caregivers

Surveys

Research question (f) in Section 1.1 was broken down into a few closed-ended sub-questions which were placed in a web survey. All surveys were created with the web-survey tool webbenkater.com. A likert scale with either 2 or 4 options was used for the questions and some of them were followed by a comment box. Two survey versions were designed. One was sent out to representatives of Swedish county councils and regions. The other was sent out to representatives of private caregivers. The survey for county councils and regions can be seen in Appendix B.2. The private caregiver survey was identical except for lacking question 2 and 3 and that the term county council/region ("landsting/region in Swedish) was replaced with your caregiver ("din vårdgivare" in Swedish). The representatives were identified and considered suitable for the survey if they had a profession similar to IT director, e-health strategist or object owner.
3.2 Data Collection Process

3.2.1 Part I

Interviews of approximately one hour length were held with one or two (representing the same organization) interviewees at the time. The interviews were audio-taped and notes were made in the protocol during the interviews.

3.2.2 Part II

An excel document was used to keep track on which of the contacted caregivers that had completed the survey, not completed the survey but responded by e-mail that they intended to and those whom had not responded at all. To maximize the response rate, a four-phase administration process was used. This included a first short-advance-notice e-mail followed by the actual web survey one week later. A third e-mail was sent as followup one week after the survey was sent and the fourth reminder e-mail was sent to all whom had not yet responded three weeks after the first send-out.

3.3 Data review and Reflection

Both interview- and survey data was reviewed simultaneously throughout the data collection process. During the interviews, several interviewees indicated on other organizations and individuals that would have relevant input to the subject. Consequently, this lead to further data collection in form of additional interviews.

Some time through the survey data collection process, several county councils and regions declined to participate in the survey. Thus, it was decided to also include a survey for private caregivers.

3.4 Final data analysis

3.4.1 Quantitative data analysis

The quantitative data was transferred to excel and processed through a descriptive analysis. Part I survey or quantitative interview answers were categorized into answers of experts, suppliers and representatives from each of the national stakeholder organizations. Part II survey responses were categorized into small county councils or regions with less than 300 000 inhabitants, medium county councils and regions with 300 000 to 1 000 000 inhabitants, large county councils and regions with over 1 000 000 inhabitants and private caregivers.
3.4.2 Qualitative data analysis

Part I qualitative data was processed through a thematic analysis. After the interviews were conducted they were transcribed. The resulting transcripts were read through and coded, that is, labeling out relevant pieces. Thereafter the most important codes were brought together to create themes or categories which were interrelated and interpreted, resulting in final narrative texts. This was done in Microsoft OneNote using different color markings. The theme identification was based on searching for the concepts listed in 2.6.3, i.e. repetitions, indigenous categories/typologies, analogies, metaphors, transitions, differences, similarities and linguistic connectors. Citations used from the interviews were translated from Swedish to English.

Comments from the part II surveys were translated from Swedish to English and summarized in tables

3.5 Validation

After the thematic analysis, the interview outcomes were sent for member checking (validation) by the associated interviewees to assure that the information was accurate. The interviewees who accepted to do the validations were also asked to leave additional evaluating input.
Chapter 4

Results

4.1 Part I

In total, 14 interviews were conducted, exploring the views of 15 experts, suppliers or national stakeholder representatives. The distribution of the interviewees can be seen in figure 4.1. This section presents the outcome of the thematic analysis combined with figures presenting the descriptive analysis outcome. In addition to the thematic and descriptive analysis, a summary of additional interview comments can be seen in Section 4.1.5.

The descriptive analysis outcome, presented by the figures 4.3-4.7, were derived from the closed-ended pre-survey and interview questions. The figures will present a maximum of 12 responses due to that a few interviews were held with representatives from the same organizations. For one supplier representative, there was limited interview time and therefore Figure 4.7 lack one supplier response.

Most of the citations have been translated from Swedish to English. Thus, grammatical adaption have been performed and possible variations in translation may occur. Some translated terms are cross-linked to the glossary, where the original Swedish terms can be found.
The interviewees are presented in more detail below:

- Expert with experience of health informatics research.
- Expert with experience of the medical profession, HIS-systems and healthcare IT.
- Expert with experience of informatics and standardization.
- Expert with experience of informatics, standardization and StandIN.
- Expert with experience of administration of standardization work at SIS (Swedish Standards Institute).
- Representatives from two suppliers of relevance.
- Two representatives from HL7 Sweden.
- A representative from Inera.
- Two representatives from SKL (Swedish Association of Local Authorities and Regions) who work in different parts of the organization. Experience of informatics, standardization and the national quality registries.
- Two representatives from National Board of Health and Welfare (SoS) with experience of medical informatics and international standardization work.
- A representative from the eHM (the Swedish eHealth Agency).

It is of importance to note that all representatives are people whom the researcher have contacted and found suitable to answer the questions. Some of the answers reflect the overall organization’s view but some interviewees have emphasized that their answers are rather their own personal views and reflections.
**Identified themes**

During the thematic analysis, 15 themes were identified from the coding. The theme identification concepts, described in 2.6.3, that frequently occurred were repetitions, indigenous typologies, metaphors, transitions, differences and similarities. The identified themes were categorized and grouped beneath 4 main themes: Knowledge, Activity, National Profiling and SWOT. A map, summarizing the identified themes can be seen in Figure 4.2. The result sections 4.1.1-4.1.4 presents the thematic analysis results in continuous text and is structured after these 4 main themes.

![Thematic analysis map](image)

Figure 4.2: Thematic analysis map over the identified themes. Connections between two themes or one theme and a main theme which is not the primary one is shown with dotted lines.
4.1.1 Knowledge

In figure 4.3 the representatives’ estimation of their organizations’ knowledge of HL7 FHIR in general and HL7 FHIR profiling in particular is presented. The diagram presents the answers to the questions “How would you estimate your organization’s knowledge about HL7 FHIR in general?” and “How would you estimate your organization’s knowledge about HL7 FHIR profiling specifically?” with the alternatives "Low, Quite Low, Quite High and High”.

![Figure 4.3: Representatives’ estimations of their organizations’ knowledge levels](image)

A representative from eHM expressed that they have good conditions when asked about the organization’s knowledge. One of the supplier representatives meant that they have very high knowledge of profiling specifically from their participation in developing a supplementation to FHIR that has been tested in a connectathon. Another supplier representative meant that in probably a year the knowledge will be very high.

Large Organizations

Some of the presented answers in Figure 4.3 were followed by comments explaining that these are large organizations, active in many areas, and that it was therefore hard to give the higher response alternatives (Quite High and High). A representative from SoS meant that it was hard to tell about the knowledge level of the organization as a whole. Further on, when it came to NI specifically, the knowledge of profiling in this area was increasing. One of the SoS representatives meant that the process of creating FHIR resources and profiles based on NI is facilitated by the similarities between NI and HL7 v3 RIM (a predecessor standard to HL7 FHIR):

“We have noticed that because NI is relatively similar to the HL7 RIM model it becomes quite simple to create both FHIR resources and profiles based on NI”
A representative from Inera meant that it is not expedient for all parts of the organization to have knowledge of FHIR or to know what it is. Although, there was an ambition to have more knowledge in some parts of the organization and that they would need to increase the competence around FHIR profiling.

Representatives from SKL means that the competence around FHIR should increase, but where (at SKL or Inera) depends on how the responsibility between SKL and Inera will look ahead.

**Importance of knowledge among County councils and Regions**

The interviewees’ answers to the question "For an implementation to be possible, is it important that county councils and regions have knowledge of HL7 FHIR generally and profiling specifically?" is presented in Figure 4.4.

![Importance for county councils and regions to have knowledge of HL7 FHIR generally and profiling specifically](image)

Figure 4.4: Interviewees’ opinion on if regions’ and county councils’ knowledge is important for an implementation of HL7 FHIR to be possible

The majority were of the opinion that it was important for county councils and regions to have knowledge of HL7 FHIR generally and profiling specifically for an implementation to be possible. One Interviewee meant that specific knowledge of profiling was not necessary for county councils and regions to have, but knowledge of HL7 FHIR in general was. Another interviewee meant that neither was necessary. Motivations to why it is necessary are summarized below:

"Yes, they must be able to give requirements on this. Thus, they need to understand what it is and in what situations one should require HL7 FHIR or not. They also need to know how profiling works in Sweden. Whether the concept which is about to be represented corresponds to something nationally common or whether they can
give the suppliers free hands.”

"Under the assumption that FHIR will be used to a greater extent in Sweden, then there is definitely a need for knowledge of county councils and regions, both in terms of FHIR in general, the profiles available and how to use the profiles available."

"Local projects must be able to use local knowledge about profiling in order for it to work"

4.1.2 Activity

All representatives from stakeholder organizations as well as suppliers could confirm that projects concerning HL7 FHIR and FHIR profiles were currently running. The work mentioned in the interviews is summarized below:

- At Inera there is one project with a terminology server build on the FHIR terminology model. Included is profiling of the resource types that FHIR uses to handle terminologies.

- A cooperative project about attention information between Inera and SoS is in progress. Attention information is the information that healthcare staff should be notified about, e.g. diagnoses, allergies and decisions that can affect care routines. The project comprises monitoring and development of FHIR profiles for attention information specifications.

- SoS is involved with the international project Snomed CT on FHIR, a cooperation between HL7 and Snomed International (IHTSDO). The project has two tracks. The first subproject is about the terminology services in FHIR. One should be able to search in different ways in a terminology or a selection from a terminology. A SoS representative explained that:

"Much of the development of those [terminology] services takes place in that project."

The second subproject is about terminology bindings to FHIR resources. The aim is to view the existing resources and examine to what extent one or several profiles could simplify the use of FHIR together with Snomed CT.

"When it comes to terminologies, the resources today are under specified. They allow anyone to use anything they want."

Part of the work has been reviewing what Snomed CT samples may be suitable for which coded values in resources and some profiles. The resource Allergy Intolerance has been viewed and also a profile called the VitalSigns profile, from which a Snomed CT variant will be produced.

- The eHealth agency will look closely onto HL7 FHIR in their work with NLL (National list of pharmaceuticals). When asked whether they will make any decisions that can influence the implementation of FHIR and FHIR profiles the
representative responded:

"I would say that since we will follow that track with NLL, which all caregivers connects to - we will certainly set FHIR resources in the form of person, profession, organization, these basic puzzle pieces. We will certainly influence it. And of course, medication."

• In StandIN 3, the combination of HL7 FHIR with different standards are examined; NI - FHIR, OpenEHR - FHIR and ISO 13940 (Contsys) - ISO 13606 - FHIR. It involves the process of life habits and to see how the standards will enter the work from business modeling to information modelling and down to technique. One interviewed expert, participating in the project, mentioned a many-to-many mapping when asked about the prerequisites to map FHIR to Contsys:

"We have started to look a little at that kind of mapping and it becomes a many-to-many mapping"

There is no specific resource that could handle one particular Contsys concept. Rather, a resource can in itself contain several concepts. On the question if a translation of FHIR would be needed, with unique, Swedish FHIR resources, to relate FHIR to Contsys, the following was explained:

"It is unfortunate if we would have to create our own base resources. However, we have discussed in StandIN that one way is to create Contsys-based resources, but then it is actually more about the purpose of showing and influencing the international standardization"

Representatives from HL7 agreed about not creating own Swedish resources:

"No. I think one should avoid it as far as possible"

"I do not think one will have to translate it. The profiles one will obtain will be Swedish, but they are based on the international FHIR"

**Time perspectives on implementation of HL7 FHIR profiles**

One supplier had implementations of different kinds, some in production and some cooperative development including international HIS providers. Another supplier representative was hoping to see a few of their own profiles become established this year (2018). For eHM, NLL should be implemented in 2020. The representative meant that:

"It is in the near future. We need to deliver the specifications a lot earlier, I suspect the suppliers will get to sample press this in the beginning of next year".
The representative from Inera thinks they will hold until the new HL7 FHIR R4 release and supposes that after the release, during 2019, activities will come from Inera.

**HL7 FHIR and the Vision for eHealth**

The interviewees were asked about what was required on a national level and of individual organizations for FHIR to contribute to the Vision for eHealth 2025. The interviewees meant that common work with HL7 FHIR and clear positions would bring Sweden one step closer.

"It is necessary to get to some kind of management organization that can take care of all that is produced and give them a national stamp. Otherwise, one creates uncertainty. The market does not want uncertainty. I think that is very important."

"There must be courage to formulate an overall strategy that states that we should arrive to a better reflection of the medical documentation, a better medical documentation in itself and a better opportunity to read it."

"I think it would be very good with a clear standpoint saying that between systems, this is the standard we use. It may be openEHR or FHIR. [...]"

"The great challenge for us to achieve this e-health vision is to agree on how we distribute the work and who does what."

**4.1.3 National Profiling**

The representatives’ attitudes to the possibility of an organization or initiative on a national level responsible for establishing and managing FHIR profiles are shown in Figure 4.5. The diagram presents the answers to the question “Would it be beneficial to have an organization or initiative on a national level responsible for establishing and managing FHIR profiles?"
The task

The representatives’ had many suggestions on what the assignment of the previously mentioned organization would be. Some suggested that it would be responsible for designing and managing profiles, as well as to be supportive to others on how to develop and use them. The following citations come from different representatives, regarding what the organization should do:

”Decide on what different profiles should look like and actually process them, establish some kind of management of these profiles and provide expertise in different domains”

”What type of efforts are required, what use cases we need to support, what resources are in question, what profiles are needed, how we should profile them, where the profiles are to be located, what the architecture around it looks like and how they can be made available to different parties.”

”Management of the profiles first and foremost.”

Several interviewees have suggested a common profile library:

”to house the profiles that are established, to have some kind of library. Also to have rules for that library that it is not just a profile but also a story about what to do with this and what the results should be.”

”We need a library where we can store all the FHIR profiles and if I am going to make a new profile I can look at what someone else has done.”
One representative meant that it is not only about HL7 FHIR profiles but about:

”[...] coordinating the development of common terminologies, common FHIR profiling, application instructions for FHIR profiles, all other services and also monitoring other standards that may be relevant. [...] If in two years, one realizes that FHIR does not hold all the way, we cannot have built an entire organization that focuses only on FHIR.”

Several interviewees believe that there is a need for international participation:

”There must be support in developing profiles and resources. But also some form of link to the international level, which I am not sure that everyone can or have the energy to run”

”In Sweden we can not only sit passively by and use. We must be able to build competence so that we can also participate and influence”

One representative also implied that before deciding who should be responsible, it is important to know what should be done. However, it is not so simple:

”Before looking at who will do it, one may think about what should be done. But it becomes a little the Chicken or the Egg, because who will then produce the plan of what is to be be done?”

The dream organization

The interviewees had split opinions about who should take on the task, when asked about what their dream organization would look like. Two interviewees suggested a virtual organization, one with the following motivation:

”I do not think it is possible to bring all kinds of people who work today at different authorities or county councils or so, then move over them, hire them and have them in a sort of line organization. I do not think that is practically feasible.”

Several interviewees meant that it should be some type of collaboration.

”I think it’s a collaboration. It’s probably not just an organization, but someone has to coordinate this and there must be some kind of decision-making body for this. There are so many actors from industry as well as from county councils and at national level. We need to collaborate around these questions. That has to be achieved.”

”I think we need to bring HL7 Sweden into the work, we must have the different organizations. There must be a will and a sustainability approach in the work with this”

One supplier representative explained that they want to take part and that they can provide important input. The ambition is to align with e.g. the national view of
profiles, on the other hand, they cannot spend too much time waiting:

"Nor do we want to wait too long for agreement on who will do what on a national level and so on"

**Built by developers, for developers - what about the clinical knowledge?**

Several interviewees stressed the importance of the clinical and healthcare operation knowledge and that the national profiling work needs this knowledge. A few also problematized that HL7 FHIR is not only a technical standard.

"[...] also healthcare organization people who can validate the implementation benefit and be able to put it in a broader context."

"Healthcare competence is needed. Both in understanding how healthcare operations can be run differently in different parts of Sweden [...] you also need the medical knowledge."

"It is important that you can feel confident to bring healthcare operation- or clinical knowledge if you detect something that could be expressed in a better way. E.g. to state what is needed to be documented and reflected."

"We must make FHIR a healthcare operations related issue as well. To actually realize that it is the healthcare operation’s needs and healthcare operation’s information that will be created and exchanged in FHIR"

"Worried about how well the resources and profiles map against the actual terms used in healthcare.[...] FHIR is built by developers for developers. How do you bring the clinical knowledge along?"

**Swedish profiles**

The interviewees’ answers to the question *Should specific national Swedish FHIR profiles be established?* are presented in figure 4.6.
The majority of the interviewees had the opinion that Swedish profiles should be established. Several stressed that Swedish profiles were needed to be able to specify unique Swedish characteristics:

"I know we need it, based on the fact that we can not use an international, Danish or Norwegian profile to represent a patient because we have unique characteristics of our patients that we need to describe. E.g. personal identity number, spare number and so on."

Other Swedish needs, that could be specified in profiles, brought up during the interviews were:

"[...] medication as well. As identification, we may use the Swedish Medical Products Agency’s national NPLid for example"

"[...] an expression of where the HSAids lands and how we express organization information."

"if you want to add a care-of address in the adress field"

"how we name things and how we handle hidden identities"

"In Sweden, we have some things concerning drugs that are not found in other countries, especially when writing recipes that have to do with subsidies and so on that no-one else does"

"We should identify actors, we should have these IDs for personal identity numbers,"
we should use these types of codes to describe lab answers or drugs. Everything that
the healthcare operations has decided must be reflected.”

Several interviewees described derived profiles to be a desirable scenario. Where
the national FHIR profiles would function as base profiles that would be built upon.
Further more, suggestions were also made to derive Swedish profiles from existing
International ones.

"In Sweden, I think you need to do the same 80/20 job done internationally by HL7,
to take care of the resources. But instead, we should apply it via a FHIR profile. [...] you
want to make a Swedish version of FHIR by creating Swedish base profiles and
then use additional profiles on top of the base profiles.”

"[...] as there are international profiles, because you can have profiles on profiles,
you should build on the international ones, but add what is needed in Sweden specifi-
cally.”

International profiles

Several other interviewees were also of the opinion that international profiles could
be a starting point:

"We should proceed from the international profiles and look to the healthcare oper-
ation needs. Possibly, make extensions on the international profiles. Would like a
LOOP there, if you find problems with the current FHIR profiles you of course want
to lift it and make changes at the international level as well. But an organization is
required to achieve that.”

"Using what is used internationally makes it easier for suppliers and almost every-
one. But it also requires that you adapt it to Swedish conditions if necessary. Then
we believe to develop an implementation guide for NI that already has the Swedish
legal, statistical requirements, etc. built in. This would facilitate the use of FHIR in
Sweden.”

"If you align with standards and have a standard strategy that maps to what the
rest of the world is doing it becomes easier to change applications, services, etc.”

Strict or relaxed

The interviewees were asked if they thought the national profiles should be strict or
relaxed in respect to how many restrictions are applied to the resource elements, mak-
ing them mandatory etc. There were quite split opinions although a trend seemed to
be keeping them relaxed in order to enable narrowing later on.

"A balance. To be useful to others, they want to know what they are getting. If
other things start to get in, it will be a bit strange. At the same time, you want flex-
ibility. I am inbetween there.”
"Have as clear and complete profiles as possible nationally but they should not be controlled about which fields are mandatory or not. In that way they can be applied in different contexts so that you can send a little information if you need and a lot if you need. But if you are going to use them locally, you can expand them, but then it will not be a national profile."

"We need to provide some kind of base profiles that are open and then one should narrow them down into specific use cases based on these base profiles."

Organizational profiles

The interviewees answers to the question "Should individual organizations be able to create their own profiles?" are presented in Figure 4.7.

![Figure 4.7: Attitudes to organizational profiles](image)

The majority of the interviewees were of the opinion that individual organizations should be able to create their own profiles. One expert warned it could be riskful and two experts stated that it should only be done in some special cases.

Derived profiles

Of those interviewees whom thought that individual organizations should be able to create their own profiles in Figure 4.7, the majority also thought that these should be based on the national profiles, if there were any.

"If there are corresponding Swedish base profiles, I definitely think so. But then it is again important that the information is returned so that there is feedback to the national level, enabling development."
Further, two interviewees meant that organizations should be able to do both.

"You might be able to do both, but you should be aware that if you do not proceed from the national profile but do something of your own, it is not certain that those things will jack into the entire eco-system later."

One national stakeholder representative problematized a situation that could arise if the use of FHIR is controlled too strictly and the national profiles does not cover the needs of an individual organization:

"[...] then there is a demand on how fast moving the management is when new needs arise. It is always like that, in which situations does common structures and innovation favor and in which do they impede?"

Similarly, one supplier representative meant that they would probably be one step ahead of the national profiling management:

"I guess we will be one step ahead of the national base profiles and then we will profile ourselves. It is possible that we would create what we consider to be national base profiles. [...] Of course everyone should be able to profile."

The other supplier representative expressed a concern about the national profiles being too controlling:

"It is great that you add some things that reflects the prerequisites in Sweden, but I would feel worried if it becomes like a great addition on top [of the resources]."

Let all flowers bloom

A saying that was recurrent in several interviews was let all flowers bloom. The interviewees referred to the effect of what happens when many, independent of each other, begin to profile.

"[...] 28,000 profiles at simplifier.net. It will be like letting all flowers bloom. The problems have more to do with the management than with the use of profiles itself."

"I do not know if there will ever be a national board for FHIR but I definitely think it is necessary. There will be a thousand flowers blooming and everybody may think that this FHIR profile is good, though we want to make this little addition for our use case."

"One can let all flowers bloom. Once again, how do we ensure that it is still a standard? One thing is the technology basically, that you have the same way to implement a technical standard. But then if we all begin to apply it in our own way, how do we secure semantic interoperability and maintain the quality of information over time? That is the greatest risk in this, as there is now such a large pressure from below [from the industry]."
4.1.4 SWOT

Discussions of the strengths, weaknesses, opportunities and threats of HL7 FHIR and FHIR profiles were recurrent throughout the interviews. Thus, SWOT was a clear theme, which is presented in text below but also visualized in table 4.1.

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inevitable need for use</td>
<td>Complexity in the profile system</td>
</tr>
<tr>
<td>Flexibility</td>
<td>Maturity level</td>
</tr>
<tr>
<td>Simplicity to developers</td>
<td>Less simple than it looks</td>
</tr>
<tr>
<td>Adaption from national to specific</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Threats</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achieve semantic interoperability</td>
<td>Weak organization/framework</td>
</tr>
<tr>
<td>Facilitate something that is agreed upon nationally</td>
<td>Overlapping profiles</td>
</tr>
<tr>
<td>Reuse competence and knowledge</td>
<td>Informatic islands</td>
</tr>
<tr>
<td></td>
<td>Unmanageable volumes of profiles</td>
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</tbody>
</table>

Table 4.1: SWOT analysis

Strengths and weaknesses

The need to use profiles is inevitable, according to several interviewees. They explained that one has to profile to be able to use HL7 FHIR, since the base resources are very relaxed.

"Without profiling FHIR becomes unusable."

Another identified strength was the possibility to adapt HL7 FHIR from national to specific levels:

"The advantage is that you can customize from national to more specific levels for different types of use cases and needs"

The flexibility was identified as both a strength and a weakness. In a similar way, the simplicity in HL7 FHIR was identified as a strength. However, several interviewees explained that it is not as simple as it might look.

"On the surface it looks simple and makes one think that it is easy to achieve semantic interoperability, which it is not. There is some sort of apparent simplicity that applies to the entire FHIR layout"

"It may be simple technically to develop against a bunch of APIs available at an arbitrary service or supplier. But if you later need to take that application and integrate it with another service or application, then I think it sets much higher demands."

Two interviewees pointed towards the complexity in the profiling system. One of them reasoned as follows:

"At the profile coding level you first have a fairly general complex type that can have
a subtype, which may in turn consist of a further subtype. Depending on where you choose to profile a particular code, it looks a bit different as it is evaluated in different ways.”

Several interviewees meant that the maturity level was a weakness of the standard since resources are still developing, although a few have higher maturity levels and will become normative in the next release. One interviewee also suggested that the HL7 FHIR optimism could be related to the immaturity.

”FHIR is still moving, resources are still developing, Even though they have some maturity, it is still moving.”

”So far, there is a lot of powerpoint wear and the problems you will undoubtedly see, with whatever standard you choose, may not have been seen yet with FHIR. Because they have not yet been encountered, not in Sweden. Therefore, one is optimistic.”

Opportunities and threats

Opportunities put forward in the interviews were that the use of FHIR profiles could form a base to achieve semantic interoperability and that it enables the facilitation of national agreements:

”If you agree that in Sweden, a healthcare provider looks like this or a patient like this, you can create a profile for it and agree that now everyone who integrates with e.g. the national service platform (NTJP) validates against that profile.”

Several interviewees also expressed the opportunities to reuse competence and knowledge with HL7 FHIR profiles as a means. The importance to reuse HL7 FHIR profiles was also frequently discussed.

”Greater opportunities to reuse competence and knowledge.”

”[...] it is very important to ensure that those who want to work with HL7 FHIR profiles understand the point of reusing already developed profiles. So that you do not start creating new profiles every time you are suppose to produce something, because then there is not much profit.”

Several interviewees problematized not having a strong organization or framework around HL7 FHIR profiling in Sweden.

”The greatest problem is mostly that there is no one with a mandate at national level to make decisions or barely give recommendations in this area. Or that can quality review what is produced, especially.”

”The problems are more about how we can handle organizing the establishment and management of the profiles.”
"That different organizations and vendors hurry and create their own profiles and then no interoperability has actually been achieved."

Overlapping profiles and informatic islands were also identified as possible threats.

"[...] profiles that are overlapping in themselves, and we also have a great challenge with overlapping between profiles of different resources. [...] Who ensures that we do not have overlapping profiles and, in case we have it, that the information is expressed in the same way?"

"[...] that there is an inability nationally and internationally to agree on how a clinical concept should be modeled and thus how the FHIR profile for that concept should look. This, in turn, gives us informatic islands"

Several interviewees have pointed towards the challenge of handling large volumes of profiles.

"[...] a situation in which one does not succeed in describing an unambiguous, long-term sustainable model for how profiles should be named and version managed from the beginning. The result of such a situation is that you get an unmanageable amount of profiles of varying quality, which complicates the implementation of the standard and ultimately the ability to achieve semantic interoperability"

"It is easy for us to end up in a position where we have lots of profiles and it will be very confusing when to use which one.”
4.1.5 Further comments

Listed below are the interviewees additional comments finalizing the interviews or later reflections made after validating their interview outcome.

"We work a lot from the national perspective, partly because it is our mission, but also because many of us who have been working for a while have been involved in many processes to introduce other international standards and we see the work that needs to be done with investigating, developing standardization processes and so on. That work still has to be done no matter what standard you choose. We of course believe that work at the national level is preferable, to start with that and then look at the international, if necessary and when needed. But it is a lot of talk out there and in other projects that international standards should be used and I do not see any intrinsic value in that it has to be international standards. Rather that to find and reuse what’s done, which is good at an international level, but one must actually look at the conditions in Sweden. It can not be ignored. Then you can look at, for example, Denmark, what problems they have had when, for example, introducing a new core system that is not from a Danish supplier”

- Representative, National Board of Health and Welfare (SoS)

"The most important thing for Swedish HL7 and HL7 internationally is to do what our members want. The organization exists for our members. So it does not get any better than what our members require us to do and how much they engage in the context of their membership in HL7. The challenge here is that, right now, one is waiting to see who will take the next big step, whether it is going to be at a state level or Inera who does something at the county council level or if Swedish HL7 should do something like that. Swedish HL7 will not do anything unless our members actively say that we should, that is how it works.”

- Representative, HL7 Sweden

"There are not many in Sweden that have actual experience and not many in the world either, because it is such a young standard […] I also think that it is very precarious to believe that if only FHIR is in place, all interoperability problems will be solved. The core lies deeper than that. The core of the problems is that we do not have common definitions of what things are in the health information systems that the healthcare operations use. As long as you end up in a situation where you need to do mapping, I think it will be difficult.”

- Representative, Inera

"From our perspective, the adoption and support of standards is very important. I believe that it is extremely important to be able to create solutions and ultimately provide better care and increase efficiency.”

- Supplier Representative
"When it comes to FHIR, there are still a lot of unsolved questions. E.g. version management but also about how to publish the specifications. [...] Security issues must be sorted out. Thus, it is not ready, there is no model for this in Sweden, I would say. On the other hand, one could say that HL7 FHIR is the probable way forward, for what I hear is that HL7 does not develop v2 and v3 any longer and then there is not much else."

- Representative, The Swedish eHealth Agency (eHM)

"We have an incentive to build external APIs and we can get much for free by looking at FHIR and utilizing what is already available both in the form of technical artefacts, documentation and informatic thinking. So it does fill a need for us even though we completely ignore the actual interoperability part. We might implement our very own FHIR-based APIs, own profiles. We ignore any kind of further interoperability thinking and then we would still benefit from working with FHIR. You need to think about what you want to achieve nationally with your FHIR work. One may start with that."

- Supplier Representative

"When we are doing something nationally, you should also think internationally in order to do the work only once. Otherwise you will have to do it twice."

- Expert

"This is a 10-thousand-dollar question. It is very important for cost reasons, but also for patient safety reasons. [...] The FHIR profiles provides an opportunity to remove manual work with safety in the process"

- Expert

"This is different and it requires knowledge. I believe in education. Then we have to make sure that something is built so that you can learn."

- Expert
4.2 Part II

In total, representatives from 24 caregivers (21 county councils and regions and 3 private caregivers) were invited to take part in the study. Out of these, representatives from 15 caregivers chose to participate. Out of the nine caregivers that did not take part, four declined because of an ongoing procurement. Figure 4.8 shows how the respondents were distributed.

![Distribution of respondents](image)

Figure 4.8: Distribution of survey respondents

4.2.1 Attitudes to HL7 FHIR

The answers to the survey question, "What is the attitude towards HL7 FHIR as a standard for interoperability like at your county council/region/caregiver?" is presented in Figure 4.9. The majority, nine (60%), of respondents’ attitudes towards HL7 FHIR as a standard for interoperability was positive. three (20%) respondents were quite positive and also three (20%) answered that they did not know.
4.2.2 Knowledge of HL7 FHIR and profiling

The answers to the question "Is there knowledge about profiling HL7 FHIR resources within your county council/region/caregiver" is presented in Figure 4.10. Three (20%) respondents answered No to their caregiver having knowledge about profiling FHIR resources. The majority, ten (67%), answered that they had general knowledge of HL7 FHIR but no knowledge about profiling HL7 FHIR resources. One respondent did have knowledge of profiling HL7 FHIR resources and one respondent did not know.

Figure 4.10: Knowledge of HL7 FHIR and profiling
4.2.3 Adoption levels of HL7 FHIR

The answers to the question "Do you have any products, integrations or initiatives that uses HL7 FHIR for information exchange?" are presented in Figure 4.11. Three (20%) responded No while eight (53%) responded No but that they were positive to a possible implementation, and one respondent chose No but that there were plans for it. One respondent answered partially while two respondents (13%) informed that their caregiver had either products, integrations or initiatives that used HL7 FHIR for information exchange.

![Figure 4.11: Adoption levels of HL7 FHIR](image)

4.2.4 Further Comments

Two of the closed questions in the survey were followed by a comment square and at the end of the survey the respondents had a chance to add an additional comment. Comments that followed the question "What is the attitude towards HL7 FHIR as a standard for interoperability like at your county council/region/caregiver?" are presented in table 4.2. Comments that followed the question "Do you have any products, integrations or initiatives that uses HL7 FHIR for information exchange?" are presented in table 4.3. Additional comments are presented in table 4.4.
<table>
<thead>
<tr>
<th>Attitude towards HL7 FHIR as a standard for interoperability</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Small county councils or regions</strong></td>
</tr>
<tr>
<td>no systematic investigation has been performed. For that reason, one has not yet taken stand as an organization</td>
</tr>
<tr>
<td>HL7 FHIR appears to be a promising initiative. However, a Swedish profile is needed to get out of the starting pits</td>
</tr>
<tr>
<td>We adapt to what the suppliers can offer but if we need HL7 FHIR we will learn it</td>
</tr>
<tr>
<td><strong>Medium county councils or regions</strong></td>
</tr>
<tr>
<td>There is no official standpoint but we monitor the area</td>
</tr>
<tr>
<td><strong>Large county councils or regions</strong></td>
</tr>
<tr>
<td>Few people with the knowledge</td>
</tr>
<tr>
<td><strong>Private caregivers</strong></td>
</tr>
<tr>
<td>Provides greater freedom of choice and opportunities for development</td>
</tr>
</tbody>
</table>

Table 4.2: Comments about the attitude

<table>
<thead>
<tr>
<th>Products, integrations or initiatives that uses HL7 FHIR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Small county councils or regions</strong></td>
</tr>
<tr>
<td>We do not think that we have it. However, we have HL7 interfaces in some systems</td>
</tr>
<tr>
<td>With a Swedish profile and if our medical record system eventually exposes interfaces for HL7 FHIR, it would be interesting to do a PoC</td>
</tr>
<tr>
<td><strong>Medium county councils or regions</strong></td>
</tr>
<tr>
<td>There is a plan to make parts of HSA available via a FHIR based API but it is paused at the moment</td>
</tr>
<tr>
<td><strong>Private caregivers</strong></td>
</tr>
<tr>
<td>Looking forward to the possibilities</td>
</tr>
</tbody>
</table>

Table 4.3: Comments about the adoption

<table>
<thead>
<tr>
<th>Additional comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medium county councils or regions</strong></td>
</tr>
<tr>
<td>There is a need for standard, for both inter- and intraoperability</td>
</tr>
<tr>
<td><strong>Private caregivers</strong></td>
</tr>
<tr>
<td>We are often dependent on the county councils systems, sometimes we can choose ourselves</td>
</tr>
</tbody>
</table>

Table 4.4: Additional comments
Chapter 5

Discussion

5.1 Discussion of the method

The Part I interviews were conducted as planned, delivering usable quantitative and qualitative data that captured the overall common national view of the subject. In hindsight, it is unfortunate that not a larger group suppliers were included in the project to achieve a more stable ground of where the industry is in manner of interest and adoption level. However, analyzing qualitative data from 15 interviews took more time than expected, thus a few more would have complicated delivering the results of the project in the limited time frame. Furthermore, in addition to the participating suppliers, three additional suppliers were contacted but either declined or did not respond. The pre-interview surveys for interview group A had a low response rate of 2 respondents. The reason could be that it was introduced to the interviewees approximately a week before the scheduled interview together with the interview introduction letter. Had the surveys been sent to the interviewees together with the first invitation e-mail the response rate might have been higher.

One alternative to the completed method for Part I could have been to conduct surveys for all participants of interest or for several suppliers only. Then, if motivated, conducting follow-up interviews with a selection of the survey respondents.

The Part II surveys resulted in usable qualitative data accompanied by informative additional comments. Since four caregivers declined because of an ongoing procurement, using a different method approach to reach the caregivers would probably not have influenced the response rate significantly. In the early stages of the project, the ambition was to follow up a selection of the survey responses for more elaborating qualitative data. However, it was realized in later stages that it was not feasible within the limited project time frame.

In hindsight, it would have been favorable to include private caregivers in the survey send-out list from the start. Thus, preventing additional work of designing another survey.

In manner of the validity of the results, validation in form of member checking (See
Section 2.6.4) was used to ensure that the interview outcomes were accurate. The interviewees also had possibility to leave an additional evaluative comment. Thus, if larger concepts of importance in the subject, according to interviewees opinion, were left out, these would probably appear.

5.2 Discussion of the results

The following section is a discussion of the project outcome, following the order of the research questions in Section 1.1.

5.2.1 Common knowledge among national stakeholders

The knowledge of the national stakeholder organization’s was in general set at the lower response options by the associated representatives. The organization that deviated by the an answer of Quite high was the eHealth Agency. There is no apparent difference between general knowledge of HL7 FHIR and knowledge of FHIR profiling specifically, thus implying that FHIR profiles is a central part of the standard. The relevance of not having lower knowledge of profiling in particular is also supported by the implication that FHIR profiles are absolutely necessary to use, according to several interviewees in Section 4.1. The generally low knowledge can be due to the fact that the adoption level in Sweden until now is quite low. Thus, there could be a lack of experience to later gain knowledge from.

Further, the knowledge result was derived from the assessments of the stakeholder representatives. Firstly, these are large organizations, as several representatives implied, therefore it may not be justifiable or even possible for the whole organizations to have knowledge of the subject. Secondly, the representatives may not view the concept and dimensions of knowledge in the same way, thus giving subjective answers to the question. However, the result at least indicates what the view of the knowledge state in Sweden is like among national stakeholder organizations. Thus, it could reflect the confidences of having the sufficient ability to implement the standard.

5.2.2 Common perception about the strengths, weaknesses, opportunities and problems of HL7 FHIR profiling?

There was also conformity of the view on HL7 FHIR profiles’ strengths, weaknesses, opportunities and threats, See Section 4.1.4. Several of the identified strengths and opportunities were also identified as possible weaknesses or threats. Moreover, some of them can be results of each other or are associated with each other. The flexibility is what makes it possible to create profiles and adapting the standard from very open and international, to national and further on to specific use cases. If one succeeds with adapting the standard to these levels by creating satisfactory profiles, it could increase the ability of achieving semantic interoperability. However, this would require a will, motivation and a vision of how. Failure of establishing these leveled adaption of the standard could be what leads to the identified threats. Not reusing the competence and knowledge by reusing already developed profiles leads to unmanagable
volumes. Together with no functional framework of how FHIR profiling should work it could lead to overlapping profiles and informatic islands. Thus, the SWOT analysis (Table 4.1) presented in this report does not only describe the perceptions of strengths, weaknesses, opportunities and threats as separate characteristics of HL7 FHIR profiles but also visualizes the overall problematic dilemmas that concerns HL7 FHIR profiling in a larger context.

Once again, Section 4.1.4 presented the interviewees perceptions of the strengths, weaknesses, opportunities and problems of HL7 FHIR profiling. One may further regard the actual knowledge of these. Some interviewees thoroughly discussed several strengths, weaknesses, opportunities and problems of profiling, while others only mentioned a few concerning HL7 FHIR in general. Moreover, as one interviewee stated, it is too early to know about all the problems since they may not have been encountered yet. Thus, the SWOT analysis involves the currently known strengths, weaknesses, opportunities and problems of HL7 FHIR profiling. These will certainly evolve together with the implementation progress.

5.2.3 Plan for implementation

In Section 4.1.2 it is clear that the level of implementation is quite low for Sweden. On the other hand, preparedness is being built on the subject. There are projects running in all national stakeholder organizations and industry suppliers. However, for the national stakeholders, it is only on the test level as for now. There was in general no official plan for implementation except from the clear time perspective identified at eHM. NLL is due to 2020, thus the HL7 FHIR profiles they will use for NLL should be established in a near future. For Inera, there were also indications that they will have more activities in 2019, after release 4. The StandIN project is still not finished but the discussions of Contsys-based resources in purpose to influence the international standardization certainly is interesting. This aligns with the initiative, to introduce a discussion between ISO and HL7 about Contsys (ISO 13940) - HL7 FHIR and ISO 13606, taken by the Convenor in WG1, ISO TC215.

This project intended to analyze the implementation level of several industry suppliers. Since several of whom were contacted declined the resultant number of suppliers were two. Therefore, one can not with certainty draw any firm conclusions on the general supplier preparedness and implementation levels in Sweden. Nevertheless, the pressure from below, as cited in the results, is palpable to the national stakeholders. There was a slight difference between the interviewed suppliers, one had already implemented HL7 FHIR profiles in their products and the other wanted to align with the national stakeholder implementation, although could not wait too long. Reasons for this difference could be that one supplier is active at the American market where HL7 FHIR is more widespread than in Sweden. Integration with NLL, using HL7 FHIR profiles, will be required by suppliers present in Sweden. Later on, this may also be the case for Inera’s service contracts. This introduces questions about how the adaption relationships between industry suppliers and national stakeholders will take form. One of the interviewed industry suppliers meant that they may create what they figure as national profiles. If these are developed before the national stake-
holder’s, should the national stakeholder organizations build profiles that matches these? Should there also be some kind of mapping towards American profiles, which may be more present in Sweden when international suppliers are entering the market? In that case, questions and discussions on how to adapt the American characteristics represented in the American profiles to the Swedish needs become important. One obvious example is the mandatory use of LOINC in the American observation profile VitalSigns, which is contrary to Sweden’s use of Snomed CT. This may be a problem for SoS to tackle in their partaking in Snomed CT on FHIR.

5.2.4 National management of HL7 FHIR profiles

The results about the overall positive attitude towards an organization or an initiative on a national level responsible for establishing and managing FHIR profiles, seen in Figure 4.6, shows that there is no opposition against it to happen conceptually. However, there were fluctuations in the opinions on how it should be done practically, what should be done and who should be doing it. None of the national stakeholder organizations were planning to take on the role as this responsible organization. Neither had any of them planned to develop national profiles with the sole purpose of constituting a Swedish base of the HL7 FHIR standard, which later can be derived and applicable to all Swedish contexts. However, the profiles that will be developed for NLL, and maybe later for the service contracts, may very well come to be used as Swedish national profiles, though perhaps unofficially. The questions is if all Swedish needs can be included when developing HL7 FHIR profiles for a specific purpose. Many of the interviewees meant that this responsible organization or initiative should be some type of cooperation and that there are many needs, especially from the healthcare operations, that should be fulfilled in the work with national profiling.

One interviewee had the suggestion that the responsible organization should only manage the FHIR profiles but not establish them. This could be an alternative together with the other suggestions on a profile library and a national stamp. Profiles created by various organizations could thus be stamped as national profiles or profiles suitable for a specific use case. This way the concept model of derived profile levels, see Figure 2.5, would be built not only from top down but also bottom up. A stamp is used in the Netherlands by the organization Nictiz to mark profiles that are adequate for use. However, in the Netherlands national profiles have been defined by the same organization, and have later been narrowed down in derived profiles by others, top-down.

In comparison with some other countries, Sweden is behind when it comes to national work with HL7 FHIR profiles. One reason could be the differences between how standardization work is financed in Sweden and in other countries. In USA, the Argonaut project resulting in US Core profiles, was a private sector initiative involving large companies. The results in this report, Section 4.1.3, shows that at least one Swedish supplier would like to take part in this kind of work. Although, it is unknown if there are more suppliers of the same will. In the Netherlands, national profiles were established by Nictiz in cooperation with HL7 Netherlands. HL7 Sweden is a non-profit association open for all people, companies and organizations
operating in Sweden. Another factor could be that there are many e-health organizations in Sweden, touching upon the subject but from different angles and with different purposes. None have the mission to explicitly take this broad responsibility of adapting the Standard to a Swedish form, including establishment of FHIR profiles for all Swedish purposes.

5.2.5 Establishment of common national profiles and room for organizational profiles

A vast majority of the interviewees were of the opinion that specific national Swedish FHIR profiles should be established. Profiles were needed to represent several Swedish characteristics put forward, from where the need of a Swedish patient profile was the most obvious one. Suggestions were on a system of derived profiles where organizational profiles and specific use case profiles are derived from national profiles. However, there is a fine balancing in the act of defining ”good” profiles. If national profiles are too relaxed there will be a lot optionality that may complicate achieving interoperability. Even though a specific profile is satisfied, the receiving system cannot be certain about what they will receive and the sending system may be unsure of what exactly to send.

Keeping national profiles very strict, with little optionality, would increase the interoperability. However, there is a higher risk that it excludes the capability to satisfy particular needs for some implementers. Thus, the question of how fast moving the management is, expressed by one interviewee, becomes important. If there is an effective and functioning feedback system in place, the managing organization may be able to keep the profiles relatively strict and still have the will of individual organizations to use them. This would undoubtedly require a lot of work which may not be possible for the managing organization to put down. Therefore, as suggested by several interviewees, developing a set of open national base profiles could be a practicable approach. The aim should be to include as many as possible to do as much as possible commonly. Otherwise, the effect of let all flowers bloom, as referred to by several interviewees in 4.1.3, will become evident.

5.2.6 Conditions at regional levels

In section 4.2 there were no perceivable differences in the answers between the caregiver categories (private caregivers, small, medium and large county councils or regions). The overall attitude to HL7 FHIR among caregivers was positive. A few had some implementation or plans on implementation of HL7 FHIR, though the majority did not but were positive to a possible implementation. Only one caregiver had knowledge of HL7 FHIR specifically while the majority had knowledge of FHIR in general. In Figure 4.4 the majority of interviewees stated that it is important for county councils and regions to have knowledge of HL7 FHIR in general but also profiles in particular. Consequently, there are good conditions among the caregivers for an implementation to be possible, seen to the positive attitudes and the knowledge of HL7 FHIR in general. However, an increase of knowledge about HL7 FHIR profiles in particular, is of importance. It should also be noted that Swedish pro-
files and proof of concepts are suggested in the comments from the caregivers (Table 4.2 and 4.3). These are prerequisites to be able to introduce new ideas and standards.

It was important to include healthcare operation competence and knowledge in the work with profiling, according to several interviewees in 4.1.3. Furthermore, it is also important to discuss how the development of regional profiles should occur. Some caregivers may want to establish e.g. a patient profile for their regional needs. Assuming that a national patient profile will be established, the regional equivalent could be derived from it without major difficulties. However, how should a regional patient profile relate to possible supplier profiles? One caregiver may have a 100 suppliers for their occupations. Should caregivers adjust the regional profiles to the suppliers or should the suppliers derive their profiles from the regional ones? If so, will suppliers have to create new profiles for every caregiver they provide?

5.3 Future work

From the results of this project it is clear that there is need for some type of adaptation of HL7 FHIR to Swedish characteristics. National profiles may be developed for the sole purpose of performing as Swedish versions of the FHIR base resources or they may be the results of a project for building something less general, such as NLL, Service contracts or a Supplier product. Regardless of what, it is nevertheless profitable to have a compilation of all the needs that should be satisfied in a Swedish adaption of the standard. Some of the Swedish unique characteristics and needs were identified in this report (Section 4.1.3), e.g. personal identity number, spare number, NPLid, HSA-id, care-of address and hidden identities. These probably comprises a fraction of all characteristics that should be satisfied. Work could be done to not only identify these characteristics but also to examine in what ways they are best represented in profiles. For example, a probable identification approach for a national patient resource is to use personal identity number, spare number and co-ordination number as three possible resource identifiers. However, how to handle hidden identities may need to be more thoroughly analyzed. One approach to tackle this task could be to start modeling a base set of profiles in an available profiling tool.

The 80/20 concept (See 2.3.3) is central for the development of HL7 FHIR. The content of the standard should cover needs common for at least 80% of users. Therefore, to have processes to e.g. publicly (hence internationally) expose the profiles created for Swedish needs, is essential for enabling Swedish influence on HL7 FHIR at a international level. Common international cooperation is of significant importance in standardization.
Chapter 6

Conclusion

• The common knowledge of HL7 FHIR and FHIR profiles among stakeholders is relatively low.

• Common perceptions about HL7 FHIR profiling concern the flexibility, maturity levels, reusability, opportunity of semantic interoperability and ability to organize oneselfs around it.

• Apart from eHM’s (the eHealth agency’s) deadline for NLL in 2020, it has not been recognized when other stakeholders plan to implement HL7 FHIR and FHIR profiles. Although, activity will probably increase in 2019.

• There are positive views on governing and maintaining HL7 FHIR and FHIR profiling on a national level and to the establishment of national FHIR profiles. However, questions remain on how it should be done. These questions are crucial because Sweden needs a cohesive solution which means that some organization shall manage the developed national profiles. Suggestively eHM, since they are a national agency, have high knowledge (as seen in this report) and are already in the process of defining profiles for NLL, which will be used due to law.

• There is in general positivity towards organizations creating their own profiles and a majority implies that they should be derived from national profiles, if there were any.

• On regional levels there are in general positive attitudes towards HL7 FHIR as a standard for interoperability and towards a possible implementation. However, specific knowledge of HL7 FHIR profiles is yet needed.
Bibliography


Appendices
Appendix A

Theory

A.1 The Swedish E-health Ecosystem

In Section 2.1 the Swedish healthcare system was described in a broader context. Within the system there are many actors involved with the area of e-health. It can be compared to an ecosystem, involving national agencies, organizations, companies from the industry and caregivers. In this section, a selection of the central actors, projects and products of the ecosystem are explained.

A.1.1 SKL

SKL (Swedish Association of Local Authorities and Regions), together with the state, supports the development of the Swedish National Quality Registries.

NKRR - Swedish National Quality Registries

The Swedish National Quality Registries contains individual-based data concerning problems, inserted actions and results within healthcare. The registries provide knowledge of how healthcare works and how it could be improved. There are about 100 National Quality Registries [38] and some examples are registries for pregnancy, palliative care, lung cancer, and heart failure [39].

A.1.2 Inera

Inera provides a common digital infrastructure as well as many services towards inhabitants, healthcare professionals and decision makers in the public sector [40].

National Service Platform and Service Contracts

The national service platform NTjP (Nationella tjänsteplatfformen in Swedish) is a technical platform that secures, streamlines and simplifies the information exchange between different healthcare IT-systems. Operations can connect their systems to the platform and exchange information without having to establish links between each other directly. Inera develops and manages service contracts (Tjänstekontrakt in Swedish), which are technical specifications on how systems should formulate
question- and response messages. The contracts concerns different processes or functions such as scheduling and listing [41].

**RIV**

RIV is a framework for interoperability within healthcare and serves as a collection page for all information concerning the common IT architecture. Through the page one can access frameworks, technical instructions of service contracts RIV-TA, source codes etc [42].

**NPÖ**

NPÖ is a National patient overview service (Nationell Patientöversikt in Swedish) which enables healthcare practitioners to, with patient’s consent, obtain health record information registered in other county councils, municipalities or at private caregivers [43].

**A.1.3 eHealth Agency**

The Swedish eHealth Agency, eHM, coordinates the Government’s initiatives within e-health, stores e-prescriptions and sends them to pharmacies and provides many other e-health services to individuals as well as operators within healthcare [44].

**NLL**

The government have assigned eHM to develop a National list of drugs NLL (Nationella läkemedelslistan in Swedish). NLL will be a nationwide information source providing the patient, health- and social care operations and pharmacies the same information about the patient’s prescribed and collected drugs and products. The new law regarding NLL will begin to apply in 2020, thus eHM’s technical solution should be ready by then and healthcare operations and pharmacies will be able to connect to NLL. In 2022, all healthcare operations and pharmacies should be connected to NLL [45].

**A.1.4 The National Board of Health and Welfare**

The National Board of Health and Welfare, SoS (Socialstyrelsen in Swedish), is an organization with activities and duties in a range of different fields such as epidemiology, social services, patient safety and medical and health services [46].

**NI**

A part of Vision for eHealth 2025 is SoS’s work with National Information Structure (NI, Nationell Informationstruktur in Swedish), which is a framework for structured information within health- and social care. NI consists of models for processes, concepts and information and is a tool to achieve semantic interoperability. SoS continuously receives comments and suggestions from users about content in need for development [47].
A.2 Health Information Systems

A health information system (HIS) is any system that can collect, store, manage and transmit health information such as information about individuals’ health or information needed for the work and processes of healthcare organizations [48]. That is, HIS’s manages the Electronic Health Records (EHR’s) of patients but can also have functions like booking of patient visits, rooms, personnel, equipment and managing salaries and accounting etc. To reach the Vision for eHealth 2025, use of standards and common structure in the health information systems is a prerequisite [29].

A.3 SDOs and Standards

All people have experience of collaboration from their life. In school, in the soccer team or at work for example. Most people have probably also experienced misunderstandings, split opinions and uneffective double work during these experiences. These experiences of poor collaboration would probably have been more positive if the people involved would have agreed on uniform and transparent routines. This is the purpose of a standard, a common solution on a recurrent problem. Standards can be found everywhere - from the simplest screw, to the environment, data communications and healthcare.

There are two types of standards. The first one is exact specifications. These are for example needed for interoperation between bolts and nuts or computers. The second one is minimum thresholds to guarantee that materials, processes and the environment are safe and have quality. This second type of standards might be useful for the security and quality for human and institutional interoperability aspects. However, what healthcare interoperability mainly need is stringent specifications at the data and technical layers of interoperability [3].

Standard Development Organizations (SDOs) are organizations who develops and coordinates specialists who develop standards [2]. These work at international or national levels, in broad areas or with very specific industries. Examples of SDOs in digital health are ISO, CEN, SNOMED International (IHTSDO), IHE, OpenEHR and HL7.

A.3.1 ISO

The International Standardization Organization (ISO) is an international member organization with the purpose for all international standards to have a focal point [3]. ISO develops consensus-based, market relevant, voluntary international standards through their members by bringing experts together to share knowledge. ISO has published over 20 000 international standards in all kinds of industries such as agriculture, food safety, technology and healthcare [49]. Swedish Standards Institute (SIS) is a member of ISO in which they represent Sweden. SIS is a non-profit organization that runs and coordinates standardization in Sweden [50]. One recent example of SIS’s work is the participation of developing the concept standard ISO 13940:2016,
also known as ContSys, which this year (2018) was published in Swedish [51].

A.3.2 CEN

EU and the European Free Trade Association (EFTA) have recognized European Committee for Standardisation (CEN), as one of three standardization organizations, being responsible at the European level to develop and define voluntary standards. It is an association with 34 National Standardization Bodies from the European countries [52]. As well as of ISO, SIS is a member of CEN representing Sweden [50]. CEN/TC 251 was the first formal SDO in health informatics and was introduced by CEN in 1990. CEN/TC 251 works with 4 areas: Information models, terminology and knowledge representation, security safety and quality and technology for interoperability [3].

A.3.3 SNOMED International (IHTSDO)

The International Health Terminology Standards Development Organization (IHTSDO) was established in 2007 and is a non-profit international organization with base in London. In 2016, IHTSDO changed their trading name to SNOMED International which reflects the focus on their global product SNOMED CT [53]. SNOMED CT is a clinical healthcare terminology system used in electronic health record systems. It uses both a coding scheme and a multi-dimension classification since it identifies terms and concepts and enable relationships between concepts [3]. SNOMED CT improves the conditions that documented information will keep its meaning and still be safe, comparable and unambiguous when communicated and transferred between systems [54]. The international SNOMED CT release of July 2018 contained more than 300 000 concepts [55]. Moreover, in 2018 the first Swedish translated release was also published [54].

A.3.4 IHE

Integrating the Healthcare Enterprise (IHE) is an initiative established by healthcare industry and professionals to help improving the way that information is shared by healthcare computer systems. IHE gathers developers and users of healthcare information technology in an annual process. In this process, technical and clinical experts define use cases, which the technical experts then addresses by creating specifications, called IHE profiles, for communication between healthcare computer systems. Thereafter the industry implements the IHE profiles into their systems and then vendors can test the exchangeability of the systems at a conectathon. Here, IHE experts supervise the tests and if successful, grants the systems with IHE approvals [56].

A.3.5 OpenEHR

OpenEHR is an open domain-driven platform for development of flexible e-health systems with the primary focus of EHR’s and related systems [57]. OpenEHR has developed an architecture, independent of technology, that contains a reference model, archetypes and templates [3]. The reference model is the foundational part of
OpenEHR and is a information model defining the logical structure of demographic data and EHRs [57]. Archetypes are modeled as constraints on the openEHR reference model and are more detailed and specific clinical models. An example is the bloodpressure archetype [3]. Templates assembles the archetypes to build data-sets specific for a certain context, such as document or a message [57].

A.3.6 HL7

Health Level Seven International (HL7) is an international standards development organization with members of more than 50 countries, Sweden included. The HL7 mission is to "provide standards that empower global health data interoperability" [58].

HL7 version 2

HL7 v2 is the world’s most widely used standard for healthcare interoperability. The first focus for HL7 was on exchange of information about transfers, admissions and discharges which was the function of HL7 v1. HL7 v2 added the possibility to use messages in exchange of reports and orders for treatments and tests. HL7 v2 is very flexible, which may be why it has had large success. The standard is adaptable to nearly any site because of the optionality of data segments and data elements. However, the optionality also creates difficulties in the manner of conformance tests. Hence, to be sure that the optional features both parties are using are the same, a lot of implementers’ time may be spent on planning and analyzing the interface [3].

HL7 version 3

Consequently, the goal of HL7 v3 included addressing the difficulties of conformance by being a definitive and testable standard. HL7 v3 has base in the reference information model (RIM). The RIM contains the backbone classes Entity, Role and Act and the Association classes RoleLink, ActRelationship, Participation and Entity-Role. In the RIM, everything that happens is an Act (encounter, tests, consent etc.) and ActRelationship relates acts to eachother. Entities (places, organizations, persons, substances etc.) play Roles (clinic, provider, practitioner, patient etc.) and can constitute Participation (subject, performer, author etc.) of an act. A relationship between two roles is a RoleLink and Entity-Role is the association between an Entity and a Role [3].

HL7 CDA

Based on the HL7 Reference Information Model is the HL7 v3 Clinical Document Architecture (CDA). It is a standard for information exchange with the use of documents which specifies the semantic and structural characteristics of clinical documents. Common CDA documents include imaging reports, discharge summaries and admissions [59].
Appendix B

Method material

B.1 Interview Protocol A (Swedish version)
INTRODUKTION


Jag lägger ingen värdering i frågorna utan det är högst önskvärt att jag kan samla in så korrekt data som möjligt på vad som är dagsläget i ämnet. Intervjun kommer att spelas in och endast jag kommer att bearbeta materialet. År det okej att jag i min slutrapport synliggör att det du säger kommer från din organisation? Det skulle vara väldigt värdefullt om jag kunde visa vad ni på "ORGANISATION" har att säga i den här frågan. Om du vill så kan jag maila dig det bearbetade materialet från intervjun som kan komma med i rapporten så att du kan titta igenom det så att det är helt korrekt.

De frågor jag kommer ställa bör inte ta mer än en timme och jag kommer nu att starta ljudinspelnningen.

Har du några frågor såhär innan vi startar intervjun?

!!!!STARTA LJUD-INSPELNING!!!!!

FRÅGOR

1. Till att börja med, skulle du vilja berätta lite om dig och vad du gör på "organisation")?

2. Hur arbetar ni som organisation med HL7 FHIR och Profilering,
   a. Har ni blivit tilldelade något ansvar?
      i. Om Ja, Vem har utfärdat uppdraget?
b. Fattar ni beslut som kan komma att påverka implementeringen av FHIR och FHIR-profiler?

c. Har ni något projekt som avser FHIR-profiler på nationell eller organisations-nivå?
   i. **Ja**, berätta mer.
   ii. **Nej**
      • Finns det någon plan på det framöver?

3. Kunskap om FHIR-profiler
   a. Skulle du bedöma "organisationens" generella kunskap om FHIR som låg, ganska låg, ganska hög, hög?
      i. **Hög** - utveckla
      ii. **Ganska hög, ganska låg, låg** - Finns en ambition att höja den?

   b. Skulle du bedöma "organisationens" kunskap om FHIR-profilering som låg, ganska låg, ganska hög, hög?
      i. **Hög** - utveckla
      ii. **Ganska hög, ganska låg, låg** - Finns en ambition att höja den?

4. Vilka styrkor ser ni med användning av FHIR-profiler?

5. Vilka svagheter ser ni med användning av FHIR-profiler?

6. Vilka är de största möjligheterna ni ser med FHIR-profiler?

7. Vilka är de största problemen ni ser med FHIR-profiler?
8. Kan du ge exempel på några situationer, gärna med use-cases, som man bör använda FHIR, IHE profiler eller ISO standarder?

9. Hur kan de profiler som redan finns upplagda på HL7 FHIR användas?

10. Tror ni det skulle vara av nytta att ha en organisation eller ett initiativ på nationell nivå som ansvarar för framtagande och förvaltning av profiler?
    a. Ja -
       i. Hur skulle drömmorganisationen se ut, vilka aktörer skulle vara med?
       ii. Vad skulle uppgiften för denna vara?
    b. Nej - varför inte?

11. Bör det tas fram specifika nationella (Svenska) FHIR-profiler?
    a. Ja -
       i. Bör dessa vara tillåtande eller strikta?
       ii. Vad skulle vara nytta med dessa?
       iii. Vad för nackdelar kan detta ha?
    b. Nej - varför inte?

12. Ska enskilda organisationer kunna skapa sina egna FHIR-profiler?
    a. Ja -
       i. Bör dessa utgå från de nationella (derived profiles) eller kan de skapas fritt?
       ii. Bör dessa vara tillåtande eller strikta?
       iii. Vad skulle vara nytta med dessa?
       iv. Vad för nackdelar kan detta ha?
    b. Nej -
       i. Varför inte?
13. Har ni något tidsmässigt perspektiv på implementering av FHIR-profiler, när tänker ni implementera HL7 FHIR profiler?

14. För att en implementation ska vara möjlig, är det viktigt att landsting och regioner har kunskap om FHIR generellt men också om FHIR profiler specifikt?

15. Vad krävs på nationell nivå och av enskilda organisationer för att FHIR ska kunna bidra till e-hälsovissionen 2025?

16. Har du några kommentarer eller skulle du vilja utveckla något ytterligare?

17. Vem borde jag vända mig till för att också intervju om det här ämnet?

AVRUNDNING

Tack så mycket för att du ställde upp på intervjun.
Det kan vara så att det uppkommer uppföljningsfrågor längs arbetets gång, skulle jag kunna återkomma till dig per mail med dessa?
Den färdiga rapporten beräknas vara klar i januari, skulle du vilja ta del av den?

!!!!STOPPA LJUD-INSPELNING!!!!!
B.2 Web survey for County councils & Regions
Enkätundersökning gällande standarden HL7 FHIR


Du har fått en inbjudan till att besvara denna enkät som representant för ditt landsting eller din region. Enkäten tar ca 5-10 minuter att genomföra och alla data och svar kommer att behandlas konfidentiellt och anonymt. Resultatet för enskilda landsting och regioner kommer inte att redovisas, utan syftet är att skapa en generell bild över samtliga landsting och regioner i hela landet. Varken dit namn eller ditt landstings eller regions namn kommer således publiceras i den slutgiltiga rapporten av arbetet.

Den slutgiltiga rapporten förväntas vara klar januari 2019. Om du önskar ta del av den så är du välkommen att maila en förfrågan till rehansson@kth.se. Har du frågor eller funderingar kring enkäten eller examensarbetet i sig är du också välkommen att maila.

Stort tack för ditt deltagande!

Vänligen,
Rebecka Hansson
Vad heter du?

För- och Efternamn

Vad har du för befattning på ditt landsting/region?

Vilket landsting eller region representerar du?

Välj:

Hur stort är ert landsting/region avseende antalet invånare?

- Färre än 300 000
- Mellan 200 000 - 1 000 000
- Fler än 1 000 000

Välj ett alternativ

Finns det kunskap om profilering av HL7 FHIR-resurser inom ert landsting/region?

Med profilering av HL7 FHIR/resurser menas agerandet att applicera restriktioner på resurser i HL7 FHIR för att exempelvis uppfylla specifika behov

Nej

Nej, men generell kunskap om HL7 FHIR

Ja

Ja, hög kunskap

Vet inte

Välj ett alternativ

Hur är inställningen till HL7 FHIR som en standard för interoperabilitet på ert landsting/region?

Negativ

Ganska negativ

Ganska positiv

Positiv

Vet inte

Välj ett alternativ

Kommentar

Har ni några produkter, integrationer eller initiativ som använder sig av HL7 FHIR för informationsutbyte?

Nej

Nej, men är positiva till en eventuell implementering

Nej, men det finns planer på det

Detvås

Ja

Vet inte

Välj ett alternativ

Kommentar

Vill du tillägga något?
B.3 Survey questions translated to English

- What is your name?
- What is your position at your county council/region/caregiver?
- What county council or region do you represent? *(not present in the private caregiver survey)*
- How large is your county council or region with regard to number of inhabitants? *(not present in the private caregiver survey)*
- Is there knowledge about profiling HL7 FHIR Resources within your county council/region/caregiver?
- What is the attitude towards HL7 FHIR as a standard for interoperability like at your county council/region/caregiver?
- Do you have any products, integrations or initiatives that uses HL7 FHIR for information exchange?
- Do you want to add something?