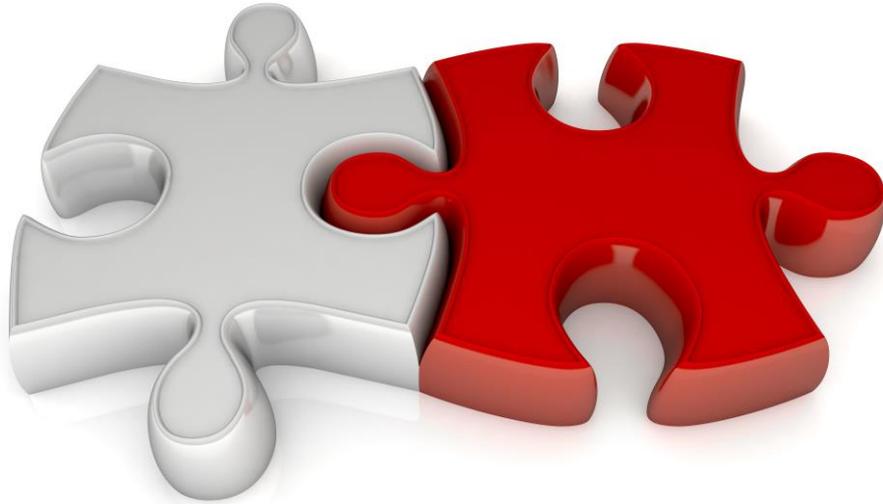




UNIVERSITY OF GOTHENBURG



Standardization of Interoperability in Health care Information Systems

*Bachelor of Science Thesis in the Program Software Engineering &
Management*

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Glossary

- DICOM - Digital Imaging and Communications in Medicine
- EHR - Electronic Health Record
- HIP - Health Innovation Platform
- HIS - Health care Information System
- HL7 - Health Level 7
- ICHOM - The International Consortium for Health Outcomes Measurement
- ICT - Information Communication Technology
- IS - Information System
- LOINC - Logical Observation Identifiers Names and Codes
- SNOMED CT - Systematized Nomenclature of Medicine Clinical Terms
- UML - Unified Modeling Language
- VBH - Value Based Health care
- W3C - Word Wide Web Consortium

Abstract—This study examines the interoperability issues of Health care Information Systems, (HIS). With the evolution of big data, Internet of Things, smart devices, Value Based Health care and categorization of patient groups for outcome measurements there is a great need for better HISs which in an effective way is able to share data with each other. Standardization is one recognized way of achieving interoperability in information systems. Hence, in this case study we have researched the architectural drivers of hospital which incorporates interoperability and which interoperability characteristics can be standardized via existing health care-focused open standard.

Our results, gathered via nine semi-structured interviews and analyzed through a thematic analysis, show that HISs objectives are hindered by both design constraints and by technical, semantic and process interoperability issues. It also shows that there are open standards which are applicable to these, however this raised the question of why they in a broad scale are not. We therefore also discuss the possibility of adding a forth category to the three previous forces that in make up interoperability [15], [26]. This forth force we call interoperability climate and it is defined as: Organizations' readiness to interact with each other under unanimously defined terms. It is inspired by the "climate of innovation" and "innovation value-fit" in the theory of Innovation Implementation by Klein & Sorra [16]. It incorporates the idea of how a bad climate of innovation and low intensity innovation value-fit can prevent interoperability in HISs.

Keywords: interoperability, open standards, health care information systems, software architecture, interoperability climate

I. INTRODUCTION

There is ample room for both improvement and innovation in today's HISs [24]. A major driver for change is the adoption of Value Based Health care (VBH) [27] taking place in health care organizations today [24]. Among several improvement areas, successful adoption of VBH especially requires improved measurement of health care activities and better health care information systems [24]. Further, patient-centred health care, which is a major characteristic of VBH, requires cooperation between health care organizations as well as departments within the same organization. In such a cooperation, retrieving and sharing data becomes vital and to view rich health care data as a central asset to improve efficiency than rather a by-product of health care delivery [22].

In a transition towards VBH health care providers face major challenges to exploit the advantages of Big Data [2], [20] and Internet of Things [8]. With an increased digitalization and use of smart devices [23] health care providers have access to large volumes of quantitative, qualitative and transactional data that is both structured and unstructured [6]. Further, innovation of smart personal devices from large vendors, such as Apple and Google, are opening up possibilities for individuals to retrieve a lot of health data. Thus, patients may bring their own data and become an important source of information for health care providers [5].

General HISs today are fragmented and limited in terms of interoperability [22]. Nordenström [24] claims that health care information systems can be characterized as electronic paper journals with no more benefits than accessibility. He expresses the need for better integration of systems, devices and data sources to be able to collect, store and analyze large and complex data.

Our introduction shows that there is support for a study of the state of art of interoperability of health care information systems and challenges that Big Data and Internet of Things pose to health care providers.

The purpose of this study is to examine the architectural drivers related to interoperability in HIS. This will be done from the perspective of both health care objectives and interoperability constraints. Further it looks at existing open standards in order to determine their applicability on the examined interoperability characteristics. A driver is a force that influences the early architectural design decisions and can be divided into both objectives and constraints [1]. To analyze and describe the objectives we have used the framework of UML use cases [38]. To analyze the constraints we have categorized them according to the specifications of Bass, Clements & Kazman [1]. The list of applicable open standards that is used in this document is to a degree case specific since it was given to us by our industry partner. One of the open standard initiatives in this list is HL7 [15] which has defined a framework that categorizes interoperability as technical, semantic and process interoperability. We will use this framework to analyze the interoperability characteristics identified in this study.

In relation to the above, the research questions have been defined as:

RQ1. What are the interoperability drivers in HISs?

RQ2. To what extent can the implementation of interoperability characteristics defined in open standards improve the flow of information in HISs?

This research is carried out via a case study methodology with semi-structured interviews, following the guidelines of [10]. Our results were produced via a thematic analysis of our gathered data. Its purpose was to find and compare patterns in the data in order to find their critical incidents, i.e. to find the underlying reasons behind the choices that had formed these information systems.

Our results show that there is a great need for interoperability and some of these needs were able to be categorized and analyzed. We have shown that there are forces that strive for and against interoperability. These can in some cases be addressed by the standardization of interoperability characteristics according to technical, semantic and process interoperability. The results also show that these standards are to an extent not used today. This might be because of the interplay of a number of architectural constraints which we identified in our analysis. Therefore we suggest that an additional part could be added to the definition of

interoperability structure, apart from technical, semantic and process. A fourth category inspired by Klein & Sorra [16] which discuss the environmental factors, could describe the climate of interoperability.

In the background section we will detail our framework and findings presented in related research. The methodology section consists of information about how we performed our study. It details a description of the company of which we conducted this research with, the health care regions that we visited and the status of their HISs as well as the existing validity threats of this study. In the result section we show the drivers found as well as the related characteristics in relation to the open standards initiatives. After that, in the discussion section, we reflect over our findings and present some possible new perspectives of the health care situation as well as their implications to both research and practice. Finally, we summarize the conclusions of this research.

II. BACKGROUND

In this section we go through the definition of interoperability, how it relates to architectural drivers and how it can be characterized. After that we present definitions of open and closed standards, implementations and quality promises with a focus on interoperability before moving on to a set of existing open standard initiatives. The first reason of why we present these aspects is so that you as a reader understand the underlying concepts of this study. Secondly they will be used to elucidate our findings from the analysis. Finally this chapter will include a section about previous research related to this study.

A. Interoperability drivers and characteristics

According to [26] "Interoperability is the ability of multiple systems to use each others services effectively" pp. 19. The interoperability of software systems is therefore said to be their ability to use each other's software services, i.e. to both exchange and use data in order to reach a common goal.

The ability to exchange data between two system could be described as an architectural driver which is a force that influences the early design decisions in software architecture. Drivers are seen as either a positive or negative [1], in this study we will refer to the positive forces as architectural objectives and the negative ones as constraints. Architectural objectives are seen as the goals that system design strive towards, the goals during development. On the other hand, there may also exist constraints that obstruct development and hinder the realization of certain objectives unless they are addressed [1]. These two types of drivers are what we perceive as needed to keep track of to fully grasp the entirety of the development process. There could be numerous other drivers within this field of research but this study focuses heavily on interoperability, thus the scope of it covers only the drivers related to this, i.e. the interoperability drivers of HISs.

Pokraev [26] uses a division by three levels of interoperability to further define it as syntactic, semantic and pragmatic interoperability. In the health care domain the

same division is used, although with the names technical, semantic and process interoperability. These are defined by HL7, a widely recognized set of open standards that we will present later in this paper [15]. By definition HL7's division of interoperability is the same as Pokraev's, we will with regards to the domain of this study use the former.

Technical interoperability, also known as syntactic interoperability as defined by Pokraev [26], is the technical ability of systems to send information between each other. It is defined by HL7 [15] as the structural and syntactical alikeness which allow messages to be sent from one system to another. According to Pokraev [26] the syntactical aspects are concerned with ensuring that the message is sent between systems in the same syntactical structure, thereby allowing a correct parsing of the message.

The semantic interoperability is defined as the ability of systems to correctly interpret external messages, i.e. that the symbols, codes and meanings of messages is the same in both systems [26]. It assures that the full meaning of the message is preserved and correctly understood by the system receiving it [15].

Process interoperability, described by Pokraev as pragmatic interoperability, is the equality of real world expectations on the message. It ensures that the message has the intended effect on environment on the receiving end [26]. Health care process interoperability is defined as the degree of which the organization housing the systems use the same processes. In other words it is the ability to maintain the same work flow processes so that the messages have the same business meaning [15].

B. Open and closed standards

In this section we describe the terms open and closed standards. The definition of a standard is, according to the British Standard Institution, "an agreed, repeatable way of doing something. It is a published document that contains a technical specification or other precise criteria designed to be used consistently as a rule, guideline, or definition." [7]. It is imperative to note that there is a distinct difference between open source software and open standards. An open standard does not, by itself, imply that the source code is publicly available like open source does [4]. Instead, the conditions of a open standard is a set of common specifications of which the software is constructed [9]

Regarding what makes a standard open or closed Cerri & Fuggetta [9] has defined it as:

- 1) Closed, the standard is a secret known only to the company who owns it.
- 2) Disclosed, the standard is available to the public but under the ownership and direct control of one single party.
- 3) Concerted, the standard is defined through a consultation however the process of admission to this consultation is managed by a single party.
- 4) Open concerted, the standard is managed and defined through an open process which is publicly available.

- 5) Open de jure, a national or international standardization body is in charged with ownership and management of the standard.

Cerri & Fuggetta [9] also suggests that standard should not be referred to as open unless it is established by the above methods 4 or 5 and fulfills all five criteria below:

- 1) The specification of the standard must available to the public free of charge or at a nominal fee.
- 2) The standard must not be owned, controlled nor have special rights directed at any single party. Instead it must be under the control and ownership of an official standardization body, open group or a consortium.
- 3) The design and definition of the standard must be done in an open process where all interested parties have the ability to take part in the decision making so that a consensus is reached.
- 4) The implementation of the standard must be free for any and all interested parties and it must not include a royalty fee. If the standard includes any patented technologies these must be licensed under nondiscriminatory and royalty-free terms.
- 5) The standard must be available and possible to include, reuse or extend in other standards under the same open terms.

1) *Quality promises of open standard implementations:*

Since we discuss how the implementation of open standard characteristics can influence HISs it's also important to realize the different ways of implementing standards. According to Cerri & Fuggetta [9] there can be closed implementations of open standards and vis-à-vis closed standards used in open source. Open standards could be extended into proprietary fashioned implementations, companies and/or administrations can introduce their own requirements to the standard despite of the standards setting in and influence of its official standardization body. Establishing and upholding the openness of a standard requires a combination of action and initiative and action against forces who seek an non competitive market must be taken. Because the ambition of this strategy is to endorse several competing implementations of a single standard [9].

The use of closed standards means that communication with them can only be made by software who has the knowledge of these secretive standards, presumably software developed by the same actor that holds the standard. The overarching consequences of this is that it can enable the holder to control all development of related software and thereby control the market via an enforced monopoly [4]. The introduction of open standards would on the other hand:

- 1) Enable any company to develop software based on that standard. As long as the standard is followed, it's possible to create a solution that still can communicate with other software on the market. Thus interoperability is endorsed [18].
- 2) This could in turn also reduce the risk of technological lock-ins by minimizing the dependence on single

actors or product [18].

- 3) Facilitate a healthy competition between the companies by opening the markets to more companies [4], [18].
- 4) Provided that the standard is continuously maintained it can act a basis for long term accessibility [18].
- 5) It will also enhance the reusability of separate part of the systems since they are based on the same standards [18].

2) *Health care interoperability initiatives:* In this section we go through a set of open standards and initiatives which originated from our industry partner. The reason why we go through these is because they are used in our analysis to see how they can address interoperability characteristics. They were initially selected because they, to a large degree, fall under the open categorization of Cerri & Fuggetta [9] and therefore address the focus of our study. This list of existing open standards, deemed relevant to our study, has partially grown by us adding more standards to it. The standards we chose to compliment it with were mentioned or used by other standards in the original list. This topic is further discussed in the validity section.

- Health Level 7 is a non-profit organization who specializes in developing standards that defines the exchange, integration, sharing and retrieval of electronic health information. This messaging standard is designed to foster communication between two or more health care information systems and in this area it is one of the most recognized standards in the world [15]
- OpenEHR is a non-profit community who design specifications for health care information systems with a focus on EHRs with the goal of an efficient internal interoperability and computability. Their architecture is said to be based in such a way that integration of external terminology standards such as SNOMED CT and LOINC is possible [25].
- DICOM, (Digital Imaging and Communications in Medicine), is an open standards committee. It creates and maintains standards for the communication of biomedical diagnostics and therapeutic information that uses digital images associated with data. DICOM is therefore the largest standards used in radiology [12].
- SNOMED CT, (Systematized Nomenclature of Medicine Clinical Terms), is a health care terminology body consisting of clinical terms, definitions and synonyms used for documentation of health care information. It uses sets of numerical concept codes and textual definitions to identify and describe clinical terms, these exist in poly-hierarchical structures of relating sets [34].
- LOINC, (Logical Observation Identifiers Names and Codes), is designed to manage the storage and exchange of results of clinical care, outcome management and research which it does by the application of universal codes and identifiers. LOINC codes are thereby meant to be used in combination with a messaging standard, such as HL7, to facilitate semantic interoperability [17].

- Schema.org is a medical vocabulary standard which is intended to complement existing standards such as SNOMED. Its scope is to define a medical web structure that makes it easier for search engines to gather the right information and for HISs integration of external applications. The standard is described as an attempt at dealing with the hardships of navigating medicinal data [32].
- ICHOM, (The international Consortium for Health Outcomes Measurements), is a non-profit organization that has defined a set of standardized outcome measures based on health care scenarios. In other words a set of values which are most important to measure in order to provide patients with a good health outcome. Examples of existing defined outcomes measurements in treatment is: lung cancer, Parkinson's disease and lower back pain [36].

C. Related research

There are several studies which include the problem of interoperability and the use of open standards in health care. In the study by Blinkenberg, Federspiel & Brincker [4] the political process leading to open standards in the Danish public sector is evaluated. Similar to our study Blinkenberg Federspiel & Brincker [4] analyze the use of open standards in big public organization. However it does so with a focus of the risks associated with it versus the risks of proprietary software from an economic, political and ideological standpoint. Another study which relates is DeNardis [11] who has studied ICT standards in health care. In her conclusion she presents five prerequisites to obtain better HISs with standards. In comparison to our study which heavily focused on the interoperability, DeNardis [11] suggests emphasis on interoperability but does not investigate it further.

From an examination of the existing literature, the interoperability issue in health care seems to be one which at least a large part of the western world is trying to deal with right now. According to Reynolds & Wyatt [28] health care is a global business that represent multibillion dollar industry and in order to maximize the return of the growing investments in it we need to start addressing the problems of HIS standardizing. There are numerous sources that indicate flaws within health care information systems, the reason of which originates from different aspects; it has been argued not only from an economical and/or ideological standpoint but by individuals directly affected by the lack of communication within the health care systems. This is an issue since it could cause problems in terms of lock-ins, high costs and customers losing data. In an overall perspective, the use of proprietary software may affect the market in multiple ways; not only does it prevent the potentially dynamic emergence of new software but it will also risk obstructing a free-roaming market. In turn this can hinder other companies from producing products at lower costs and better quality which could also share the current software standard [4].

There is an apparent need for interoperability in health care [11]. Its factors are described as multidimensional and com-

plex [21], [22] and there is little unity among interoperability standards to use [11]. We argue that our study which seeks to investigate these architectural interoperability drivers to see how they can be addressed by open standards therefore is well-founded.

III. RESEARCH STRATEGY

The methodology for this study is a case study, following the guidelines of Creswell [10]. The reason for choosing a case study is because we wanted to examine and learn about a real world problem which is context specific and also as we have presented quite complex; it not only involves pure software engineering issues but also factors such as political, economical and legal. We therefore deemed it to necessary to explore our questions on the level of the actors.

A. Case description

This study was performed in collaboration with Findwise AB and the case itself is mainly focused around regions in the public sector and their HISs.

Findwise is an IT consultancy firm with offices in Sweden, Denmark, Norway and Poland. They were founded in 2005 and is specialized in building search-driven findability solutions for intranets, web, e-commerce and applications [13]. Findwise acted as supervisors in the study and facilitated with connections, office space and knowledge in the subject.

The participants we have conducted our data collection with are Region Skåne, Region Halland and Västra Götalandsregionen. These are three big counties within the southern and western parts of Sweden. In total these three counties are in total inhabited by circa 2.3 million people and have a total of 30 hospitals and 339 health care centers [39], [29], [30]. As a part of the public sector the three regions has the highest political decision-making within the counties. Apart from health care they therefore also manage public matters such as public transport, infrastructure, industry, culture, etc.

The HISs of the three regions, analyzed in this study, are often large and complex. To a degree they are based on a legacy of systems designed under proprietary licensing and they are therefore not, even within the same health care institute, interoperable. The base idea that drove the initial design of these systems was a migration from old paper journals to the new electronic ones. Because the same structure of the old journals was kept in the systems problems with text handling arose leading to a lack a searchable structure and redundancy in information storage. A root to some problems faced in HISs is that there is a very wide spread IT governance, meaning that a lot of people have the authority to decide on the IT strategy. This has lead a great diversity and separation of systems, every hospital or health center have been purchasing their own from separate suppliers.

It is in and around these situations that our study takes place.

B. Data collection

The data collection was carried out through retrieval of qualitative data; including interviews of IT people and hospital and/or county managers. The interviewees are people who work within three different counties in Sweden; Västra Götalandsregionen, Region Halland and Region Skåne.

Interviewee	Region	Role
Lars Lindsköld	VGR	Project manager
Marcus Österberg	VGR	Development manager & Information architect
Petter Wolff	VGR	IT strategist
Mats Lööf	VGR	Medicinal advisor & Informatics
Ulf Malmqvist	Region Skåne	Operations manager R&D
Alexander Büller	VGR	IT-strategist
Torgny Nilsson	Region Halland	Hospital logistics manager
Fredrik Stegmark	Region Halland	Administrative director
Hans Gyllensten	VGR	Enterprise architect & Senior IT architect

TABLE I
INTERVIEW SUBJECTS AND ROLES

The two criteria sets seen below are the required properties that the case company and the interviewees must fulfill in order to be selected for this study. They are included for two reasons. First of all to give you as a reader an idea of our case we have analyzed and the people we have interviewed. Secondly they were used as a guide for communicating the same thing to our gatekeepers. In other words, when we communicated with these rather big organizations we often had to do it through a person who was in charge of their public relations. Therefore we sent them these guides so that they can get us in contact with possible respondents or choose interviewees for us. This negated the possibility of researchers biased in term of interviews, which is discussed further in the external validity section. Case organizations and respondents will also be conveniently sampled according to suggestions from our industry partner, who has a solid knowledge of relevant organizations for our study.

Criteria for choice of case company:

- Has to be a large region in the public sector or a hospital.
- Preferably similar situations exists in all organizations when it comes to HISs, so that relevant comparisons can be made.

Criteria for choice of respondent:

- Has to have an experience of at least two years in the field.
- Has to have some knowledge of ICT and VBH.
- Has to be of a significant position in the organizations so that trust can be put on his/her statements of their situations and strategies.

C. Interviews

The interviews ranged from 1-2 hours and were recorded and performed face to face based on a semi-structured interview guide. We chose semi-structured interviews because we had limited knowledge of the topics going in to this study and we wanted to let the interviews flow more freely in terms of what our interviewees regarded as objectives, obstacles and standardization needs. Since we wanted to gain more knowledge and coverage of relevant respondents our interviews would always end with the question: “Do you think that there is someone else in your organization with knowledge of this that you believe we should talk to?” There was of course a limit to how many we could interview, so this only continued until we arrived at a saturation, i.e. we got the “same” answers as the previous respondent and no new knowledge was gained.

In order to address the first research question we used these guiding questions:

- What is your definition of interoperability in relation to hospital information systems?
- What are the interoperability objectives?
- What are the interoperability constraints?

Then to get answers to the second research question we instead used these guiding questions:

- How does the internal and external communication in your region work?
- What standards are used?
- Is there a need for additional standardization? and if so how?

D. Data analysis

After data had been gathered we started a thematic analysis to categorize the findings. The purpose was to find and compare patterns in the data in order to find their critical incidents, i.e. to find the underlying reasons behind the choices that had formed these information systems. Focus was to find the aspects related to our research questions.

The drivers that we identified in the form of goals that the organization was striving towards were structured as scenarios using the UML use case pattern [38]. They are, as all of our results, based purely on information gathered during our nine interviews and are therefore not validated against any documents or verified a posteriori. This will be further discussed in the next section.

The architectural constraints that were road blocks to the theoretical development were during our analysis categorized according to a list that originated from Bass et al. [1]. The original list featured development, technical, business & economic, contractual and legal constraints. We supplemented this with political constraints since we found a considerable amount of data that indicated a constraint not categorized under the previously mentioned.

The standardizable interoperability characteristics that could play the biggest part for realizing the drivers were categorized in the analysis using the framework of Pokraev & HL7 [26], [15]. The data from the interviews related to

this was divided into subcategories of the characteristics. These subcategories were identified by the strategy of finding critical incidents, e.g. data structure being a subcategory of technical interoperability.

E. Validity threats

To address the validity of our results we have used the guidelines of Runeson & Höst [31]. We chose these because they are applicable to our study in the sense that they are designed to address the most prominent validity threats of qualitative studies. Runeson & Höst has categorized the threats as:

1) *Construct validity*: A point to consider in terms of this validity is the possibility of background affecting our view of the issues. We are two students from a very technically oriented program, conducting a technical study. This means that we could have seen mostly technical explanations to causes which might have broader reasons. We have been aware of this and have tried our best to be objective in this sense.

Another point worth noting is that concepts like interoperability can be hard to define exactly what it means in various situations and open standards a term that is thrown around too easily [19]. We had all ready realized this before we started interviewing and took action to prevent it, still this might have caused some misinterpretations.

2) *Internal validity*: In this case the casual relations of both our first and second research question is of note in terms of internal validity. First of all there is no complete assurance that our drivers are completely covering the entire picture. There might for example be more factors affecting how open standards are implemented. There might also be a threat to the fact that our objective scenarios are only validated in the interviews and not verified a posteriori. Secondly we have not covered all existing standardization initiatives but only the ones relevant in our specific case. Our study has only reported on what we have been able to gather from our analysis the gathered data.

3) *External validity*: One common discussion when it comes to the validity of case studies is the ability to generalize the finding. We cannot and have not stated that our findings are representative of the entire health care domain. Instead we have presented the picture which represent an image of the specific regions of our case. Our findings can therefore be seen as an indication or a representation of a possible wider situation.

Another point discussed by Runeson & Höst [31], providing validity to a study, is the random sampling of individuals. We used a so called gatekeeper for the selection of subject for our interviews. Of course this did not provide us with a purely random sampling but at least it eliminated the possibility of researcher biased in selections.

F. Reliability

To ensure the reliability of our study we have included our interview guide and our strategy around how we conducted our research. Further our respondents are from three different organizations and out of the six who were from the same organization, (Västra Götalandsregionen), four were from one office. However these four answered similarly to the rest which were from other organizations or offices. Therefore we argue that the risk of answers influenced by internal communication is not great.

IV. RESULTS

In this section we present our result, addressing each research question in order: the architectural drivers and the standardized interoperability characteristics that were identified throughout the interviews.

The drivers are presented in their two distinctions; architectural objectives and constraints. Our results show six objectives that influence the architectural decisions in HISs and via scenarios we have also shown how their realization is affected by the lack of the interoperability characteristics technical, semantic and process. Additionally, in the other half of our results regarding drivers, we have identified seven sets of prominent constraints that can affect how interoperability can be achieved and according to Bass et al. [1]. These are divided into development, business & economy, cultural, technology, legal, political and contractual. They represent the architectural design constraints that must be taken into consideration during software design [1]

In the second part of the section, we detail what and how standardizable interoperability characteristics can help improve the flow of information of HISs. This is done by an analysis of each interoperability characteristic along with a comparison of existing open standards. The results show that there is a significant number of standards that in theory could address these characteristics, but that they to an extent are not applied in today's HISs.

A. Interoperability drivers

The six interoperability related objectives represents a picture of what the health care institutes are striving for during designing HISs. To be able to see why and how these architectural drivers, in the form of objectives, are related to interoperability we have designed example scenarios in a use case style according to UML [38]. Considering the purpose of this study, the scenarios are not on a low technical level but an abstract one. The motivation for this is that their purpose is to on a high level show how HISs are interacting and how they in theory could be redesigned to address their interoperability issues. These scenarios and their respective main flow steps are based on information gathered and validated during our interviews.

The seven architectural constraints that we identified represent factors that hinder the transition towards higher flow of information between HISs. They were found multiple times but in different constellations, depending on the region.

Architectural objectives

Possibility to transparently present work flow:

The possibility of tracking the work process of health care practitioners is something that we were able to identify as a great need from our interviews. Because of a lack of interoperability in the health care system, the data which could be used for process analysis and improvement, research and decision support is often not available.

Scenario 1: A practitioner wishes to check when a medicinal tool was cleaned

Description: To negate any possibility of contamination a practitioner needs to check whether or not his tools have been cleaned and if so when they were cleaned.

Main flow:

- 1) The practitioner searches for the tool in on his terminal.
- 2) The system connects with the necessary components and queries the status of the tool.
- 3) The system gets a response and displays the data.
- 4) The practitioner checks the status of the tool.

In this case, from what we have gathered from the interviews, this scenario could fail in step no. 2 and/or 3 since there is seldom any incentive to document this data, there is seldom a unified way of documenting it and the technical possibility for systems interaction seldom exists.

Streamlining of bookings:

Booking systems are often a part of the EHR system in HISs and can in some cases be described as a basic calendar function for date and time. There is not always information about the actual patients, their condition or previous medical records referenced in them. It has therefore been expressed that there is a need for automatic and smarter booking systems. To visualize this objective and see what impact it has on the structure of the HIS we have designed this scenario:

Scenario 2: Effective patient booking

Description: After a consent has been given the health care practitioner makes a booking which includes references to patient data.

Main flow:

- 1) A practitioner starts the process of creating a new patient booking.
- 2) The patient has given his/her consent to the intersystems exchange of his/her personal data.
- 3) The booking system automatically queries all relevant systems for the relevant patient data.
- 4) A booking with the patients relevant medical information is created.

As the previous scenario, this one would in most cases fail on either the second or third step. There is seldom an effective way for patients to give their consent for a systematic exchange of data and without it, it is therefore often prohibited by legislation. Further, the technical

connections that are required to accomplish the third step do not exist in most cases, even though it has been expressed in the interviews that these communications are necessary. In this particular case, it might be because the laws aggravate an all ready difficult situation.

Effectively follow the patient through the health care process:

The possibility of integrating patient data in the booking systems so that the physician is able to see the medical conditions and previous visits of the patient. This type of information exchange has been identified to be lacking in different cases. In our example scenario we present a situation within a hospital with several facilities but these needs could be existing between systems within facilities and also between systems in separate hospitals, regions and even countries.

Scenario 3: Track the patient care

Description: Health care practitioners wishes to follow the patient through the health care process to ensure that the most efficient processes are used.

Postcondition: The patient has given his/her consent to the inter systems exchange of his/her personal data.

Main flow:

- 1) A patient moves from health care facility A to health care facility B.
- 2) Upon arrival patient data from health care facility A is retrieved.
- 3) Since the semantic structure of the data is the same in both A's and B's system the data is interpreted correctly by B's system. Practitioners in B can therefore see which medicine the patient is currently taking, what the latest lab tests showed and how his/her latest visit was.
- 4) Because A and B also follows the same health care process in terms of which tests, medicines, etc. to use facility B can continue the process where A left off.
- 5) All data from this process is structured and stored in such a way that it can be queried at a later stage so that it can be used in research, for example.

Again this scenario of the driver to follow the patient through the health care process would not go through as the means of interoperability in a broad sense rarely exists. This quite clearly shows the three parts that is said to make up interoperability in information systems. In step no. 2 there is a need for a technical solution that would allow data to be transferred from facility A to facility B, the so called technical interoperability. Step no. 3 is an example of the need for the next part of interoperability, namely the semantic. Lastly the 4th step shows how the importance of having the same processes to achieve a high grade of interoperability.

Streamlining of text handling:

The interviewees expressed that the systems is in need of a improved functionality in terms of text handling. The facilitation of record documentation will improve the overview of the current records and give a better overall structure within the administrative health care aspects. The possibility to create and manage views from the text will make the right information available and improve the sorting and analysis of patient records. Structured records will also allow for successful imports and exports of data from other systems.

Due to the importance of patient handling for health care personnel, less time should be spent on administrating and looking up patient records. There are many possibilities to provide functionality of transfers to patients records, this by streamlining the use of dictaphones through automated text-to-speech and text analysis. This would also allow the use of business intelligence systems that would help interpret input and/or diagnoses to give suggestions of actions.

Scenario 4: Artificial Intelligent text handling.

Description: A doctor uses the help of an AI for decision support in his/her health care process.

Main flow:

- 1) A Patient has a long history of diseases and therefore also a substantial journal. This patient is now at a hospital because of yet another illness.
- 2) The hospital system queries all other systems for relevant patient information.
- 3) Since the patient data is structured in a standardized way, the doctor can use an AI to asses the patient medical history for decision support in this process.
- 4) The doctor treats the patient with with the help of the AI.

Again, the picture of interoperability problems in similar. Because of the semantic and technical deficiencies the scenario would probably fail in step 2 and 3.

Categorization of patients for outcome measurement:

Numerous interviewees as well as Porter & Teisberg [27] and Nordenström [24] have talked about the possibility of patient centered health care; the methodology of grouping patients based on treatment scenarios. The different scenarios would have multiple distinct steps, each with a measurable treatment outcome to track the progress of the patient. This method would track the quality of patient in relation of costs and thus better detect potential areas of improvement. By incorporating this approach of patient handling in multiple health care services, a deepened communication between entities would exist which would include an improved patient tracking and handling on a process level.

Over time, new data would be gathered which would in turn be applicable for measurements and research.

Scenario 5: Treatment of a patient categorized in a patient group

Description: A doctor treats a patient according to information gathered from a group of patients

Main flow:

- 1) A patient has a difficult disease which is hard to diagnose and treat.
- 2) The doctor queries the system for patient groups with similar symptoms.
- 3) From the results of the query the doctor can with the support of a calculated probability diagnose the patient.

As a reappearing pattern in this section the lack of technical, semantic and also process in this case. Apart from the, in most cases, not existing possibility of sending and interpreting the data there is also a need for standardized processes in this scenario. Without the use of the same outcome measurements practitioners cannot compare data from other regions, hospitals or departments with their data.

Facilitate the integration of external innovations:

From our interviews we have been able to identify some the same needs which is discussed by McAfee & Brynjolfsson [20], Nakajima, Shiga & Hata [23] and Chui, Löffler & Roberts [8]; the need of new and smart health care innovations. An example of how this is starting to happen right now is the HIP, (Health Innovation Platform), which is an open platform where any one can use their open source code and API to build their own eHealth solutions [14].

Scenario 6: Integrate an external innovation

Description: A external actor implements an eHealth solution to a HIS.

Main flow:

- 1) The external actor has developed an innovative new smart phone application that gatherers health related data such as diet, exercise and sleep cycles.
- 2) A hospital considers this data could be useful in their research and health processes and therefore moves to integrate it.
- 3) Since the application is based all ready on the communication standards that the hospital uses it is integrated.

A problem which has been expressed in our interviews is that there first of all is tough to integrate these solutions to more than a few systems because of the fact that they are often using different types communication, structure and semantics, much like the some of the above examples. Therefore these health innovations, even though they are needed, they are adapted to single systems and therefore cannot be implemented at a larger scale. A second problem that has been discussed in some cases is the organizational resistance to new innovations, which seems to stem from a number of architectural constraints to the interoperability which is not only semantic, technical or process related.

Architectural constraints

Even though there exist a promising outcome for open standard characteristics, it's important to put into consideration the constraints, or influencing forces, that affect its implementations. The ones we have been able to identify are:

Development:

The HISs that are used today have to a large degree become so big and complex that copious amount of time and money is needed just to introduce new updates; the day-to-day work done is to a large extent spent on maintenance. This hinders the development of new features.

From our point of view, there seems to exist a lack of Agile thinking in some areas of HIS development; the programming is not necessarily done in a continuous manner and the backlog that exists keeps growing. It's also been stated that all development is done in the same manner, irregardless of size; it doesn't matter if the development is about a large journal system or if it's a small adjustment, it all goes through the same types of steps. Due to the fact that integration of new functions may need to be consolidated from management departments, making the time it takes to introduce them significantly longer. An example of a consequence of this that we found was that these hierarchical steps are ignored. Some developers have decided to ignore this step and just implement the functions that are needed without management knowing. This type of shadow IT will further prevent the possibility of a clear overview of the software architecture.

Business & economy:

Due to the complexity and size of the currently used HISs, the money that is spent on the systems is to a majority on maintenance instead of further development. The allocated budget for health care IT is sometimes relatively small. All new function needs are implemented in a short-sighted manner; putting out fires is prioritized in order for the system to keep functioning. This has formed some HISs in such a haphazard way that maintenance costs may be much higher than one of a meticulously structured system. To prevent this, it has been considered necessary by some to buy a new complete solution that has been properly structured from the beginning. This is however an economic undertaking too big for the majority of health care institutes and can still put them in the same monetary situations as they are trying to escape.

Cultural:

Another factor which we've identified that is a bit vague and hard to define but might be of the same caliber as the others is the culture of hospitals. From several interviews we've heard examples of how the culture present in the health care institutes can have a negative effect on strategies. The hospitals of the regions are self governing and can therefore in many ways oppose the hierarchical decisions or guidelines. At the same time as the doctors themselves

are the ones who has the final say on patient treatment and can therefore also oppose hierarchy. We are not stating that this is a bad decision tree, however knowing this whilst also realizing that there is a culture where people feel the need of assert oneself we can see that problems can arise.

Technology:

We also have technical factors which to a large extent stems from the early evolution of electronic journals which we have discussed in previous section. The systems are often old, there are often no complete diagram or knowledge of all systems and their connections. The fact that they been frequently patched and altered with under the circumstances of a lacking IT governance has been a large contributor to this issue. Further we have been able to identify that a technical debt has been accumulated because of lack of documentation, lack of collaboration and a lack of alignment to standards.

Legal:

A law in particular have been identified to be design constraints namely patient data act (2008:355), 2 § which states that the purpose of the law is that: Information handling within health care should be organized in such a way that it caters to patient security and favors cost efficiency. Personal information should be formed and handled in such a way that the patients and any other registered should have their integrity respected. Documented personal information should be handled and kept in such a way that unauthorized people cannot access them [35]. Whether or not this law is justified and/or correctly structured we can not and will not comment on. What can comment on however is that it affects HISs by limiting the way that they are able to communicate and share information.

Political:

Political aspects have been a large contributor as to why the HIS environment is where it is today. One big factor here is that are so many different visions involved when deciding the evolution of the HISs; how future actions should be prioritized, who should decide on difficult design implementation choices, whether to buy a new system or further develop the existing resources. On top of this, health care decisions are made on numerous levels, such as from politically self-governing counties and municipalities, multiple organizations within regions as well as separate hospital boards. These groups have their own way of seeing how HISs should evolve and this has played a major role in why the systems look, behave and are structured so differently.

Political actions have also influenced decisions for HIS investments due to their own self-interests, putting the IT of health care on lesser priority. One example of this is the fact that if a company providing software is under legal scrutiny, the parties involved will choose to distance themselves from them in order to not project a bad political image. All in all, there are many political factors that play

a role which can easily be forgotten when thinking about HIS development. One important example is that it isn't a political failure in the public eye when someone decides to buy a costly, intricate system that has been proven to work, even if it's only limited to its own proprietary premises. What can be delicate however is the decision to spend money on steering the development of systems towards new open standards that may have been less tested in the field; there exists a risk of implementation failure, yielding no results from the money spent. People have a tendency to emphasize this type of immediate failure rather than an overly expensive purchase made 5-10 years ago, the penalties of which become clearer today.

Contractual:

To an extent the systems are designed after the needs of the suppliers instead of the need of the user. A supplier might not necessarily feel a need to integrate their system with other systems which are developed by their competitors. From their perspective it could be beneficial not to integrate with other providers; this would thereby influence their customers to adhere to their products. On the other hand, if we were to look at this from the perspective of the health care providers a very important criteria is as simple as just to have the system up and running without problems as soon as possible and therefore criteria such as this one might be neglected. Often what the hospitals end up using is what Cerri & Fuggetta [9] would have categorized as closed implementations of closed standards.

B. Standardizable interoperability characteristics

From what we gathered from our interviews and analysis the interoperability characteristics defined by Pokraev [26] and HL7 [15] could be standardized and in turn provide a better flow of information in health care. There is, however, a multitude of factors that influence the standardization direction for each hospital. This might be due to the constraints, we have summarized, that can fall upon each unique situation.

Semantic:

The need for semantic standardization is a very important aspect of HIS interoperability; it is the matter of communicating in the same type of semantic structure. During the interviews, it was expressed that different hospitals used very disparate means of documentation. Semantic interoperability means to methodize ways of using determined expressions so as to invoke an understanding between entities. By using the same codes for health care connotations, a concept can be identified between different entities even when the meaning of it is handled differently between the two. This would also help bridge transfers of records between systems of different languages since the code would still identify the same concept.

As we have seen earlier there are standards who in different ways promise to solve this issue of differences in semantics of health care information. One example of how the

terminology issue, as we have seen, could be solved is using the SNOMED CT standard [34]. Another examples of how this type of semantic interoperability could be achieved is via LOINC [17]. From our interviews we have noticed that everyone seems to be in agreement that SNOMED CT is the way to go when it comes to standardizing the terminology of health care. However none of the regions in Sweden we visited had systems who support it even though Sweden is a member of its organization which thereby allows hospitals and health care centrals to use it.

When trying to examine why these standards aren't used at a large scale we found no direct answer. Some have been planned for in both Region Skåne and Västra Götalandsregionen but an implementation would be too big, costly and complex to accomplish.

Technical:

Even though there may exist a semantic interoperability and there still lies a great emphasis of maintaining standardized transfer protocols and data structures. The interviewees talked about multiple ways that they needed to parse data from different systems so as to be able to extract all data. Due to the multitude of older existing systems still being used, they have also used tailored point-to-point integration so as to bridge communication to the newer implementations. The desired goals were expressed to have predetermined connection types as well as a stable and structured overall architecture which could easily incorporate new systems.

In terms of data structure, there were many times that the interviewees expressed areas of improvement. In order to better analyze and handle patient records, both from within sections and between hospitals, there needs to be a standardized way to structure records and other concepts in the first place. It's also important to note that are existing certificates that can be used for secured communication protocol.

There are also certain existing contracts that need to be followed for certain sections of health care regions, therefore it's important to have systems that can facilitate these needs in a streamlined fashion. During the interviews, HL7 was mentioned multiple times and several subjects declared the standardization of technical interoperability through integration of larger standard frameworks; by imposing a set of technical rules across multiple regions, the consequences would be that the regions would strive towards a unified system structure.

Even though there seems to be a somewhat unified desire to implement a more detailed and standardized data structure, there were also many explained factors that were standing in the way. The use of HL7 standards has already started in Swedish health care administration but is at the moment only used in smaller scales.

Apart from HL7 there are three other open standards, which we have covered in our report, that could possibly solve this issue, namely DICOM [12], OpenEHR [25] and Schema [32]. DICOM is said to provide a well-tested and widely used standard [3] however as it mostly covers the sharing

of images and videos it does not, by itself cover any other drivers. Interestingly, neither Schema nor OpenEHR are present in the regions at a large scale, the reasons of which have been vaguely mentioned at best.

Process:

There is a need for a standardization of the health care processes. How the work flow of health care practitioners is executed differently in separate health care facilities can have an impact on systemic interoperability. Like Pokraev [26] and HL7 [15] defined as the third leg of interoperability, Pokraev [26] called it pragmatic interoperability whilst [15] called it process. This type of interoperability is not by itself technical, but our study have shown it may affect technology anyway. In our particular case it is due to how interoperability can be used once technical and semantic is secured. An example of how it can be problematic is if hospital A deems a critical blood sugar value of patients to be 4.0 whilst hospital B does not, in their process 3.0 is instead though of as the critical point. Note that even if these particular values in this examples is far from real world examples they do illuminate a possible situation in the real world.

Examples of how this type of interoperability could be standardized, and is to an extent all ready being standardized, is through initiatives such as Value based health care[27] and ICHOM [36]. It has been expressed that this is the way to go when it comes to how the health care process should be standardized, which is inline with what Nordenström [24] and Porter & Teisberg [27] discusses. The problem however is one that is almost comparable with a moment 22. You might not be able to standardize according to, for example ICHOM, unless you have secured that the health care process can follow the standard. Vice versa you might not be able to follow the process of outcome measures unless you previously have standardized your data in such a way. Further it has been brought up during our interviews that these standards as of now only categorize some treatment scenarios and that these in most cases only incorporate single and easily defined illnesses. In cases where patient experience more complicated diseases or a multitude of simpler ones standardization is more difficult and has therefore not been fully achieved yet.

V. DISCUSSION

Provided that Value Based Health care and standardized outcome measurements is the future of health care [27], [24], [36] it is clear that open standardization of patient information is crucial to its success. This is something that must be realized by a consensus of involved actors. Health care practitioners should in some cases realize how their work flow could be changed according to the above theories. Administrations and politicians should realize the need and potential outcomes from open standardization. Suppliers of both open and closed systems needs to use these existing standards and finally the standardization committees and

consortium’s needs to realize the evolution of Value-based health care and patient categorization so that their standards adhere to it.

A. Interoperability climate

The overarching problem might not be as simple as actors failing to realize the importance and potential value in this change. Largely it might instead stem from a combination of all or several points brought up in our section of architectural constraints. To us it seemed as though a fourth standardizable leg of interoperability was emerging which we have chosen to call ”interoperability climate”. The idea came to us from the theory by Klein & Sorra [16] which is called ”Innovation Implementation”.

To ensure a higher rate of implementation success, there needs be effectiveness on two different key fronts; climate of implementation and innovation-value fit. Implementation climate is a term that is used to describe how well the innovation will be implemented in regards to organizational preparedness [16].

Innovation-value fit describes how well the innovation corresponds with the employees’ vision and beliefs. These values can be split into two subcategories: low- and high-intensity. High-intensity values define strong and high-priority views that the employee has regarding desired and undesired actions. Low-intensity values define views that are of less importance. The innovation-value fit will be good if the innovation is regarded as compatible with the organization member’s values [16].

The combination of implementation climate and innovation-value fit influences how well the innovation implementation will pan out. In order to effectively complete implementation it’s important to have good conditions on both of these characteristics [16]. The model implementation effectiveness can be seen in figure 8.

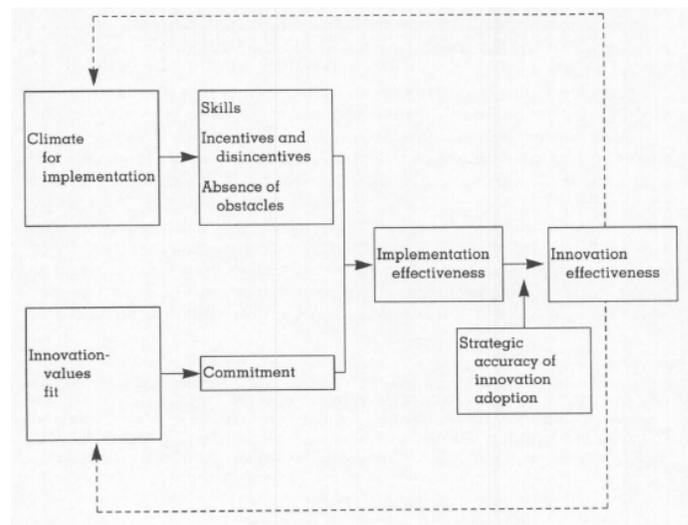


Fig. 1. Determinants and consequences of Implementation Effectiveness [16]

If we apply this theory to the situation in health care we can see that the climate for innovation is quite poor. Largely this is due to reasons such as the ones we have brought up in the section of contextual factors. The organizations are seemingly not ready for changes because of the general unpreparedness that exists; there are disparate levels of preconditions and backgrounds which makes the existing situation incompatible to cardinal changes on a broader scale. If we on the other hand look at incentives and disincentives to change, everyone we talked to were pretty much in agreement on that a change was needed. Disincentives however seem to be created through the complexity of the previously mentioned organizational road blocks; the lack of IT governance over the maintenance of large legacy systems could demotivate people into thinking that a change is going to be so hard that no clear way forward can be seen.

In turn this no clear way of achieving the change brings us to the second half of this theory [16]. Because this might lead to the different visions and beliefs in the organization which is covered by the innovation-value fit. An example we were able to identify in terms of how there might be different opinions in regards to how our interviewees described their perception of the so called three R group. This group consists of representatives from the three biggest regions in Sweden: Stockholms läns landsting, Västra Götalandsregionen and Region Skåne. Their objective is in broad terms to solve this issue we have been discussing throughout this paper by implementations of a new unanimous system in all three regions. Whilst most of our interviewees argued that there was a huge risk in this solution since you might end up in the same closed and locked-in system again, some instead argued that it might be the only way out.

In light of this we would argue that, at least in this situation, in order to achieve interoperability one must discuss the climate of it. Interoperability climate could be defined as: Organizations' readiness to interact with each other under unanimously defined terms. It incorporates the idea that in order for systems to effectively communicate, the climate for innovation must allow for interoperability and the innovation value-fit must be of an equal level in the environments of the systems so that there is an equivalent idea on how to achieve technical, semantic and process interoperability.

The integration of software based on open standard may require and impose a large organizational change, meaning that it can be very important for managers to take those aspect into consideration; how ready the organization is towards the change.

Based on the conclusions we have made from our data collection we have created a model to show the criteria needed to achieve interoperability. This model could suggestively be used as a guide for determining the various shortcomings of interoperability that could exist in organizations. Its structure could act as a communicator in and between organizational entities to help them effectively describe the present state of each interoperability tier. Regions and hospitals could use it for both deciding their readiness for interoperability as well as communication of a common goal. See figure 9. From

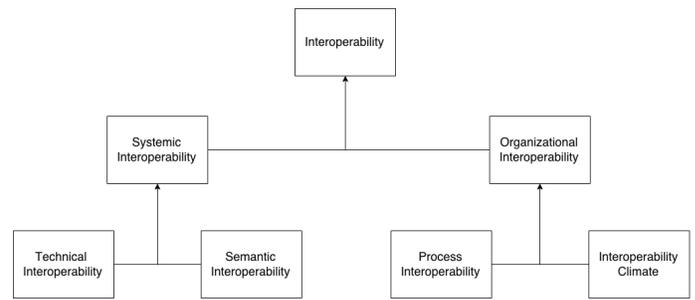


Fig. 2. Proposed substructure pyramid of interoperability

our perspective there seems to exist a division into the two subcategories systemic and organizational interoperability. Systemic interoperability is the ability for multiple systems to send, receive and interpret messages. It focuses on the characteristics and criteria of the message; not only how the message is structured and sent but also the readiness of the systems to receive and handle its contents. Organizational interoperability is the definition of how the organizations strive towards a unified path; the streamlined and synced work flow as well as the level of readiness towards new innovations that exists.

B. Implications to research

Our study has showed that there are many artifacts that can make or break interoperability in HISs, but there is still room more a lot of more research in the field. Researcher could take our approach and dive deeper into the objectives of our architectural drivers, to see more exactly how they can differ from our results in a different setting and examine, possibly in practice, exactly how they can be addressed with an open standard or a combination of them.

We also strongly believe that there is a need for more studies on how our constraints can be addressed, both in separation and in combination. Separate constraint studies could for example investigate the long term effects of open systems. Our results show some of the long term effects of closed systems and that there is a willingness to try open systems instead. However since this idea is fairly new, the long term effects on large systems might not be mapped out yet. Another example of a study is the evolution and management of legacy systems in the public sector. This study could focus on how a lack of IT governance can spawn different dialects in systems and/or completely different systems with concepts such as shadow-IT. Our study has also showed that there might be a lack of Agility in the HIS development processes, a study on how to scale agility in large political organizations with a lot of bureaucracy we believe is a crucial step in solving some of the issues discussed in this report.

Additionally, as we mentioned, a study on the combination of constraints in terms of how they affect change might be needed. A deeper analysis in the interoperability climate is regarded by us as a possible further research; to present more concrete examples in the field of HIS from a climate and

innovation-value fit perspective. Even though our model of climate interoperability is not yet shown to exist in every situation, it does show that there is a need for change management studies in this area since none was found in the literature.

An example of a prominent change management theory which might complement Innovation Implementation by Klein & Sorra [16] is the continuous change versus episodic change by Weick & Quinn [40]. It could for example incorporate the study on the episodic change of a swifter introduction of a new and unanimous system versus the continuous change of agreeing upon the usage of standards and work to implement these in a more long term fashion.

C. Implications to practice

The same categories discussed in the implications to research can also be discussed and maybe applied in practice. The problem of interoperability in health care has roots in several factors but through the use of open standards and with the regard of climate interoperability and change management we believe it can be solved. For decision makers, we therefore find it important to take into consideration the influences regarding climate and innovation-value fit.

One big problem that we see is the fact that there seems to be certain decisions being made without the consent of the people most influenced by the changes. Our suggestion for the regions is to try to maintain a continuous direction towards a unanimously used technology base before striving towards innovations used for specialized health care. This could stabilize the implementation climate, allowing for use of new systems in a wider range of hospitals. As seen in

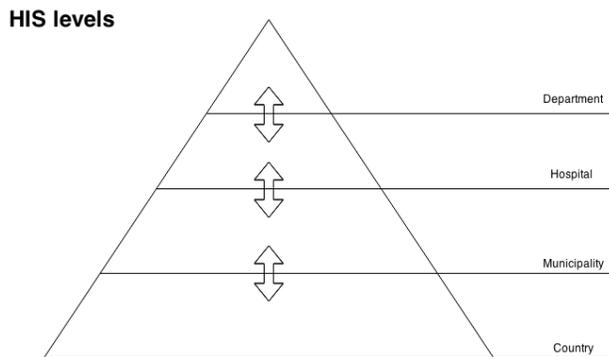


Fig. 3. Levels of technological adaptation for HISs

figure 10, an optimal way of maintaining interoperability across a region and/or country could be by having an HIS base at all health care services, setting the same premises for all systems. The technical base would suggestively contain all data structures relevant for national/international use such as for patient and journal data. On a hospital level, certain systems are needed in order to work efficiently in a specified role, such as specializations in heart surgery. This structure with master systems as basis could allow the use of tailored systems within hospitals while still ensuring systematic interoperability.

VI. CONCLUSIONS

In order for hospitals and other health care facilities to join the evolution of the internet of things [8], combined and categorized outcome measurements [36] and Value based health care [27], interoperability is crucial. In theory, this evolution is partially categorized by the drivers in our first research question, can be accomplished by the standardization of interoperability characteristics which is described in our second research question. However the combination of all or some constraints, identified in our architectural drivers section, seem to often hinder it. Therefore we have suggested a fourth category to be added to the factors which enables interoperability, namely the interoperability climate. Inspired by the ideas behind "Innovation Implementation" which is a organizational change theory by Klein & Sorra [16] the interoperability climate is a way to describe, analyze and possibly standardize the organizations readiness for interoperability in terms of climate and the employees visions of it.

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