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DOI:
10.1016/j.hlpt.2020.04.001

Document status and date:
Published: 01/06/2020

Document Version:
Publisher's PDF, also known as Version of record

Document license:
Taverne

Health Policy and Technology 9 (2020) 235–246

Contents lists available at ScienceDirect

Health Policy and Technology

journal homepage: www.elsevier.com/locate/hlpt

The Contribution of Conceptual Independence to IT Infrastructure Flexibility: The Case of openEHR

Debbie Tarenskeen[a,1,*], Rogier van de Wetering[b,2], René Bakker[c,3], Sjaak Brinkkemper[a,4]

[a] Utrecht University, Utrecht, The Netherlands
[b] Open University, Heerlen, The Netherlands
[c] HAN University of Applied Sciences, Arnhem, The Netherlands

ARTICLE INFO

Article history:
Available online 17 May 2020

Keywords:
IT infrastructure flexibility
Conceptual Independence
openEHR
mixed-methods research

ABSTRACT

In the Netherlands demands on IT support in healthcare organizations are increasing. New visions on healthcare focus on patient-centered healthcare, where mutual consultation among healthcare professionals in the network becomes a standard process. Recent governmental regulations prescribe that patients must be able to access personal health records. IT flexibility is needed to allow organizations to meet new demands. In this study we focus on Conceptual Independence (CI) because CI, as a design principle, can improve the adaptability of Information Systems (IS). Software with CI operates on flexible data models that are independent of the CI based application. Therefore, it is claimed that a standalone IS becomes more flexible with CI. We extend the claim by demonstrating that CI affects the flexibility of the entire IT infrastructure. We investigate which dimensions of IT flexibility are responsible for the improvement. Multi-case study research has been performed following a mixed-methods approach in 10 mental healthcare organizations. Five have implemented openEHR, a proxy for CI, and five have not. Data has been collected with a questionnaire of IT infrastructure flexibility and semi-structured interviews. The data synthesis shows a positive effect of CI on IT flexibility, as CI increases the adaptability of IS, transparency and standardization of the IT infrastructure.

1. Introduction

In the Netherlands, as in other European countries, due to demographic changes and advances in technology, new strategies and visions on healthcare emerge. Healthcare is making a shift toward patient-centered care and this has a substantial impact on how healthcare organizations work and engage with their patients and clients. As the digitalization invades all aspects of healthcare, providers need to leverage their current and future IT investments genuinely and design applications that are future-proof and adaptable to continuously changing requirements to match clinical and administrative processes [1]. The extant literature tends to study IT applications in infrastructure as a 'black box', meaning that no particular reference is made to software or software structures or other components of the IT infrastructure. We describe IT applications as software for end users and Information Systems (IS) as a special type of IT applications, namely data-intensive IT applications. IT infrastructure is the whole of configurations of interlinked systems and IT applications in the organization. The contribution of this research is to examine the relation of software characteristics in the black box of IS to IT flexibility.

Scholars generally refer to modularity as a characteristic of flexibility to define flexibility in IT infrastructures [2-4]. However, in practice, inflexibility still exists in critical applications that rely on extensive data, such as in Electronic Health Record (EHR) systems, especially when data has to be exchanged with other IS. Synthesizing from the literature it appears that combining the functionality of IT applications has not been self-evident. According to Bygstad and others [5] silos in IT infrastructure obstruct its flexibility. These silos came into existence as past adaptations of IT applications to a bureaucratic way of working. Restructuring silos in current systems is difficult.

EHR systems store patient health information, such as laboratory results, medication lists and allergies. EHR systems allow doctors to work more efficiently and drive standardized work practices

* Corresponding author: Debbie Tarenskeen, The Netherlands.
E-mail address: d.tarenskeen@uu.nl (D. Tarenskeen).
1 Debbie Tarenskeen, Researcher at Utrecht University, the Netherlands, M MSc.
2 Dr. Rogier van de Wetering, Associate Professor at the Faculty of Sciences at the Open University (OU), the Netherlands, PhD
3 Dr. ir. René Bakker, lector Networked Applications at Center for IT and Media (CIM) at HAN University of Applied Sciences, Arnhem, the Netherlands
4 Prof. dr. Sjaak Brinkkemper, Organisation and Information. Organization and Information is one of the research groups of the division Intelligent Software Systems within the department of Information and Computing sciences at Utrecht University, the Netherlands

https://doi.org/10.1016/j.hlpt.2020.04.001

across the care continuum. However, we find that maintainability is problematic [6]. We presume that conceptual models play a crucial role in maintainability. Working with conceptual models is problematic because of the complexity of medical terminology [7]. Ignoring the conceptual models in the design of IS leads to heterogeneous, incompatible and inflexible conceptual structures [8]. McGinnes and Kapros describe the principle of Conceptual Independence (CI) [9]. The principle is defined as an alternative approach for design of IS with the objective to create flexibility in IS. They claim that CI, as a decoupling of medical conceptual models and application code, will lead to flexible IS. We enlarge the scope of CI and state that CI will increase IT infrastructure flexibility as a whole.

This study addresses the following research question: *"How do implementations of CI in IS lead to an increase in flexibility in organization-wide IT infrastructure?"*

There have not been large implementations of CI in real-life systems since the publication in 2015 [9]. Therefore, research about CI implementations affecting IT infrastructures has not been executed before.

Looking for an alternative we have decided to study a proxy, an openEHR implementation, based on similar characteristics. The openEHR is an open, flexible standard applied for modeling medical knowledge and information about patients [10]. Hence the underlying openEHR software is based on CI, as we will argue in par. 2.5. There has been one large study of openEHR and infrastructure in Norway by Ulriksen et al. [11] which concludes that information structure and installed base have to evolve together. However, these scholars do not explain which characteristics of the installed base could facilitate or obstruct IT flexibility. We fill this gap in the literature by explaining the role of the underlying software design.

We need real-life data and therefore apply a multiple case study approach with mixed-methods research.

2. Theoretical background

2.1. IT Infrastructure Flexibility

The concept of IT flexibility, in essence, refers to a shareable and reusable architecture that enables IT resources to develop and adapt system components quickly. It allows organizations to anticipate new market opportunities as business conditions change [12, 13]. IT flexibility emerges as a crucial ingredient of the deployment of digital business strategies [14, 15]. IT infrastructure flexibility has been confirmed as an influence on IT flexibility [16]. Van de Wetering and others describe the importance of IT flexibility in its relation to dynamic capabilities [1, 17].

Van de Wetering, Mikalef and Pateli [18] define IT flexibility as "the degree of decomposition of an organization's IT portfolio into loosely coupled subsystems that communicate through standardized interfaces". We apply this definition. The definition conforms to previous studies by Byrd and Turner and Duncan [19, 20]. Previous scholarship unfolded some of the key qualities that comprise IT infrastructure flexibility. These qualities are modularity, standardization, transparency and scalability [19-21]. The complementary effect of these synthesized qualities enables organizations to adapt and co-evolve with the changing conditions [22]. These dimensions can be defined in the following way, modularity, "Loose coupling" is the main idea behind modularity. With the isolation of independent components, it will be easier to replace and adapt single parts in the IT infrastructure. With transparency IT systems will behave as one integrated system with seamless accessibility to functions and data. Flexibility in this sense gives end users access to different elements in the infrastructure.

For standardization, we observe that organizations apply comprehensive standards for hardware and software. The last dimension scalability measures how well the IT infrastructure can be scaled up and upgraded when adaptation is necessary due to growing demand and an increasing number of users [22].

2.2. Conceptual models are crucial in Information Systems

Conceptual modeling has been noted as a bottleneck, specifically in healthcare, where medical specialists prefer free texts for registration of medical data [23]. In healthcare domain knowledge consists of medical knowledge. The representation of domain knowledge in conceptual models is necessary for developers of EHR systems. If, due to a growing number of independent conceptual models, the exchange of data becomes difficult, we see conceptual incompatibility [8]. Rector [7] states that difficulties of terminology in patient systems in healthcare have been underestimated and that this problem leads to specific issues in software for patient systems. He mentions ten topics where misunderstandings can arise, such as interpretations of medical specialists and observed test results.

2.3. Design principle for Conceptual models in CI

The role of inflexibility of conceptual models is often mentioned in relation to reuse of functionality. Functionality can be reused without reprogramming the application in software. There has been a large number of studies showing the difficulties in reusing functionality, because of the low-level interdependence of data structures and application code [24-27]. Expectations of Service-Oriented Architecture (SOA) to enable reuse were high. However, SOA did not solve the reuse issues, as Joachim demonstrates [28]. McGinnes and Kapros [9] tried to find a solution by separating conceptual models in the software application from the application logic. They argue that the separation of conceptual models leads to an Adaptive IS (AIS). The AIS is a system that can support any conceptual model. Therefore, CI can improve reuse and allow organizations to adapt conceptual models in IS without requiring re-programming. They describe six principles that are sufficient to achieve the separation in **Table 1** [9]. When conceptual models have been decoupled from code, Principle 1, the software contains functionality that can be reused with all conceptual models based on a meta-standard. Conceptual models conform to a standard that is understandable and machine readable. Principle 2 states that archetypical categories can initiate appropriate semantic behavior based on categories of entities, such as functionality for showing the instances of the category "Location" on a map.

If the software can operate on multiple instances of conceptual models simultaneously (Principle 3) then, the software must be able to correctly identify data belonging to conceptual models (Principle 5 and 6). Entities must be uniquely identified independent of the conceptual models (Principle 5), checks and constraints are enforced at input (Principle 4) and all data is correctly labeled (Principle 6). Thus, the principles occur together in AIS.

2.4. Conceptual Independence is a modeling approach

The design principle of CI in modeling IS can be positioned in software engineering practice, similar to Model-driven design, as described by the Object Management Group (OMG) [29]. The OMG distinguishes different layers or levels. An overview of the levels is shown in **Table 2** [30]. There are four levels of models (M0-M3), in different degrees of abstraction. The content of the models cannot be determined by the software systems but has to be input by human modelers. The meta-model of CI is positioned on M2. Analogous to Model-Driven Development (MDD), we conclude that there has to be a meta-model for conceptual models in the software.

CI, however, is not the same as MDD. MDD aims at modeling software systems, data models and behavior to generate the complete software code from its model. It does not per se separate conceptual models and application code in resulting code.

2.5. OpenEHR as an implementation of CI in the medical domain

We resort to openEHR implementations in this study, because we have no access to conceptual models in software in existing systems, except for open-source software [31]. We argue that the openEHR implementations can be approached as a proxy for CI. In openEHR flexible, extendable conceptual models exist and are termed archetypes. The archetypes have been decoupled from application logic, as in the general characteristic of CI. In openEHR the decoupling is termed two-level-modeling, where medical knowledge is decoupled from run-time knowledge and patient information [10, 32]. In theory according to Beale [32, 33], archetypes are representations of medical concepts formulated in a meta-standard, Architecture Description Language (ADL). The same IS can be used with different archetypes (CI Principle 1). Archetypes can be categorized in such a way that specific user interface presentations can be initiated (CI Principle 2). Conceptual models, as archetypes in different versions, can co-exist in one application (CI Principle 3). Principles 4-6 are present in openEHR software, such as checks on the consistency of data with archetypes (CI Principle 4) and registration of data with the different archetypes (CI Principle 5 and 6). A fundamental difference between openEHR and CI is, that CI describes principles for software design and openEHR specifies a meta-standard for conceptual models in medical domains. Therefore, we characterize CI as the underlying software design for openEHR in medical domains.

3. Research framework and propositions

3.1. Influence of CI on IT infrastructure flexibility

In this section, we formulate propositions for possible effects of CI on IT infrastructure flexibility. Usually, the six principles of CI are not observable by functional management and users as the principles have been seamlessly integrated. For discussing CI in interviews we need observable characteristics.

The observable characteristics are derived from the text of the main paper of McGinnes and Kapros about CI [9]. CI will lead to an Adaptive IS (AIS). An AIS is an IS in which the conceptual model can be adapted without reprogramming the IS. The AIS is an observable characteristic (I). Secondly, we have analyzed the 6 principles of CI in detail. Principles 1 and 2 from **Table 1** emphasize the reusability of functionality in systems with CI. “Reusable functionality” is visible (II). Thirdly, in Principle 3, the multiple conceptual models in one IS can co-exist. According to the levels of the meta-model of OMG, in **Table 2**, there has to be an observable meta-model for conceptual models, that can be distinguished (III). Finally, Principles 4-6 are not directly observable. We have argued in par 2.3 that the principles must exist in a working system with CI. The research framework in **Fig. 1** links the different observable characteristics of CI to the dimensions of IT infrastructure flexibility. Overall, we expect CI to increase IT infrastructure flexibility. We formulate one or two propositions for every dimension of IT infrastructure flexibility.

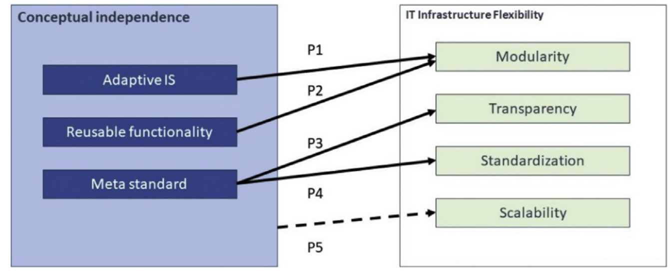

Fig. 1. Framework of the effects of CI on IT infrastructure

3.1.1. CI and modularity

McGinnes and Kapros [9] state that, if CI is implemented in a single IS, it is called an adaptive IS (AIS). We expect that if this AIS is positioned centrally in the IT infrastructure, the flexibility of the whole IT infrastructure will be enhanced because it will break open the silos, as described by Bygstad et al [5]. Proprietary inflexible conceptual models in IT silos hinder IT infrastructure flexibility, because providers are dependent on the software vendor to make functional changes to the applications. And vendors are typically inclined to postpone changes, because they affect all users in other client organizations. CI can counteract the consequences of proprietary models. Hence, we define:

Proposition 1. *Decoupling the conceptual models from application logic increases modularity in IS, therefore increases the modularity in organizational IT infrastructure.*

The concept of modularity is based on ideas of Schilling [2], Simon [34], Baldwin and Clark [3] and Byrd and Turner [19]. Modularity, defined as a structure of loosely coupled independent subsystems, will be a primary factor in the ease of changing software systems in general. We propose that reuse of functions enables isolating the functionality in software. Therefore, modularity will improve with CI and we define the following:

Proposition 2. *Because CI facilitates reuse of functionality based on the same meta-model, decoupling functionalities will be possible, not only in one IS, but in the whole IT infrastructure, thereby increasing the modularity of organizational IT infrastructures.*

Table 1
Principles of Conceptual Independence (McGinnes and Kapros [9])

Principle	Description
1. Reusable functionality (structurally- appropriate behavior)	The Adaptative Information system (AIS) is a system that can support any conceptual model. Domain-dependent code and structures are avoided.
2. Known categories of data (semantically- appropriate behavior)	Each entity type is associated with one or more predefined generic categories. Category-specific functionality is invoked at run time for each entity type.
3. Adaptive data management (schema evolution)	The AIS can store and reconcile data with multiple definitions for each entity type (i.e., multiple conceptual models), allowing the end user to make sense of the data.
4. Schema enforcement (domain and referential integrity)	Each item of stored data conforms to a particular entity type definition, which was enforced at the time of data entry (or last edit).
5. Entity identification (entity integrity)	The stored data relating to each entity are uniquely identified in a way which is invariant with respect to a schema change.
6. Labeling (data management)	The stored data relating to each entity are labeled such that the applicable conceptual models can be determined.

Table 2
Model hierarchy of OMG

Layer	Description
M3MOF	Defines a general formal language for specifying meta-models. Example: OMG's Meta-Object Facility (MOF)
M2Meta-model	Defines a language for specifying models.Example: meta-model CI, openEHR
M1User models	Defines a language for describing semantic domains. Example: a model for medical knowledge, a model for patient's health
M0Instance models	Contains runtime instances of the data in the models

3.1.2. CI and transparency

It will be easy for IT departments or organizations to connect or remove functionality to/from CI applications because of CI's open meta-model. We refer to connectivity as seen by Byrd and Turner [19] and Chanopas [35]. Connectivity will improve accessibility and use of other applications and thus advance transparency. Transparency makes the system behave in a seamlessly integrated way because users do not expect the system to reinvent or reassemble components every time a different functionality is required; cf. Star [36]. Tafti [21], Pavlou and El Savy [37] describe cross-functional integration as wide accessibility and broad use of IT resources. We expect that the meta-model of CI strengthens the connectivity of applications and thus supports transparency. Based on the above we define the following:

Proposition 3. *Because conceptual models and application structures have been separated in the IS, the accessibility of data structures and data is greatly enhanced.*

3.1.3. CI and Standardization of data as bases for interoperability

Standardization of the IT infrastructure can also aid in connecting different applications to one another. Hanseth and others [38] describe the tension between flexibility and standardization. On the one hand, standardization can increase flexibility, because of openness for further changes. However, on the other hand, standardization decreases "interpretive flexibility" by freezing semantics. Because semantics are essential in healthcare, information needs have shifted from the exchange of technical data to the exchange of meaning, the characteristic of semantic interoperability [39]. In openEHR, contrary to Hanseth's conclusion, working with flexible conceptual models opens up interpretive flexibility. Semantic interoperability is defined as enabling the users to work with and exchange meaningful information. In healthcare organizations IS will enable users to communicate about care processes in medical terminology [39]. CI decouples domain knowledge from application logic and thereby supports working with standards such as openEHR, when concepts can be extended by medical professionals with explicit attributes. We therefore define the following:

Proposition 4. *When conceptual models and application structures have been separated (CI), a meta-model of medical knowledge models leads to interoperability in general, and semantic interoperability in particular.*

3.1.4. CI and scalability

We presuppose that the upscaling of systems to service a growing number of users concerns primarily the technical attributes of IT infrastructure [40]. Scalability can be improved with technical means, such as the distribution of network traffic. The application traffic across a cluster of servers can be optimized by, for instance, load balancers, virtualization, pooling of applications and application of containers. We do not expect that a meta-model for conceptual models will affect this dimension. Therefore, scalability is mainly independent of the flexibility of concepts and models in IS [41]. Following this line of reasoning we define:

Proposition 5. *When conceptual models and application structure have been separated in the IT infrastructure, we do not expect effects on performance or scaling, because the technical infrastructure can be optimized independently of CI.*

4. Mixed-methods research in a multiple case study

4.1. Multiple case study

In this study the objective is to clarify the influence of CI, an underlying software design, on IT flexibility. Because CI is not directly visible to the IT professionals, it is fitting to carry out case studies. A case study will offer the opportunity to study the phenomenon of CI in-depth and collect information about the IT flexibility of an organization from different angles [42].

To further study the influence of CI, we compare organizations that have implemented CI to organizations that have not implemented CI in the IT infrastructure.

We had the opportunity to study CI via openEHR in the Netherlands because a group of mental healthcare organizations had started to apply modules that are based on openEHR since 2016-2017. The cases consist of the largest organizations in mental healthcare in the Netherlands. Nine out of ten are organizations with 500-800 full-time equivalent (fte) employees, one has a smaller number of employees. The application of openEHR is more common in, for instance, Norway, the United Kingdom, Australia and Russia [10]. We have divided the organizations into two groups:

- The "openEHR organizations" have 2 or more openEHR modules implemented and operational in the IT infrastructure and describe their organization in the interview as an openEHR organization (Cases C1 to C5)
- The "other organizations" have no or one module installed, and explicitly express, that they do *not* perceive the organization as an openEHR organization (Cases C6-C10).

4.1.1. Quantitative data and interviews

Lee [43] describes four problems that have to be solved in case study research. In this section we explain how these four problems have been addressed. First, the observations have to be carried out in a controlled way. Our collected quantitative data consists of scores of the IT architect or IT functional manager on a questionnaire. The questionnaire is based on an empirically validated survey of Mikalef et al. [17, 22]. Next to the quantitative data we performed interviews with IT professionals in the organization. All 17 hours of interviews were transcribed, then 885 text fragments were distinguished and summarized in English. The English statements that resulted were treated as qualitative data. We have made references to the observable characteristics of CI, see par. 3.1 in the interviews.

4.1.2. Deductions, replicability and generalizability

Lee argues [43] that deductions have to be made in a controlled way. We rely on a mixed-methods design, see the next paragraph. For replicability we compared five cases that all have implemented CI and explored similar patterns or effects. Finally, we allow for generalizability by describing how we have found the mechanisms of CI influencing IT flexibility and compare multiple cases with CI to multiple cases without CI. The sample of the five organizations that have implemented CI and the five organizations that have not implemented CI is not large enough to draw conclusions exclusively based on scores, therefore we integrate the quantitative and qualitative data.

4.2. Mixed-methods research

For deductions and interpretations of the data quantitative and qualitative data have been synthesized based on propositions. Each confirmed proposition (see 3.1) will strengthen the relation between CI and IT flexibility. Mixed-methods research is defined by Creswell and Creswell [44] as "… a research design or methodology for collecting, analyzing and mixing both quantitative and qualitative data in a single study or series of studies in order to better understand research problems". Their method consists of collecting both quantitative and qualitative data and sequentially integrating quantitative and qualitative methods. We have collected quantitative data with a questionnaire asking respondents to rate items. The data in this study were collected mostly simultaneously. In five cases one person (an IT architect) in the organization filled in the questionnaire during the interview. In three cases two persons (an IT architect and a functional management expert) did so during a combined interview. In two cases, there were two separate interviews with the IT professionals. The semi-structured interview was ordered by reading aloud each item text of the questionnaire by the interviewer. Then the interviewer asked the IT professionals to reason aloud about rating the item. Eventually the item was scored by the IT professional. At the end of the interview the interviewer specifically asked if there existed a relation to openEHR and/or observable CI characteristics, if this had not been mentioned before.

Our approach is very similar to the mixed-methods approach of Dennis in exploring the adoption of use of group support systems [45]. Dennis applies qualitative data analysis and adds a quantitative analysis to enhance understanding. In that process, he uses statistical tests on small samples and combines quantitative and qualitative data, to strengthen the results. He adds: "This mixed method of utilizing quantitative survey data with a small N to complement qualitative data has become accepted in IS research." [45].

In our study, quantitative data have been collected for assessments of IT flexibility in the organizations. We have applied quantitative data analysis by applying the Mann-Whitney U test for small samples to compare means on IT flexibility of the two groups of organizations [46]. The test results indicate whether organizations' scores differ. Also, visual analysis has been performed on the mean scores of items for organizations.

This study collects qualitative data to enrich the interpretation of questionnaire scores. We have used a qualitative analysis based on content analysis of interviews [47, 48]. Qualitative data were categorized according to items and then to propositions during the analysis process. An independent, external researcher separately reviewed the ordering of texts with propositions. Fetters and others [49] extend on methods to collect and integrate quantitative and qualitative data. We have applied "merging" for integrating data because we have brought quantitative data and qualitative data on the same items together for analyzing. At the reporting level, we have weaved data through narrative.

5. Results

In this section, we first present the total mean scores of two groups of organizations on IT flexibility, "openEHR organizations" C1 – C5 and the not openEHR organizations (referred to as "other organizations") C6-C10. Then, in **Fig. 2**, we compare mean scores

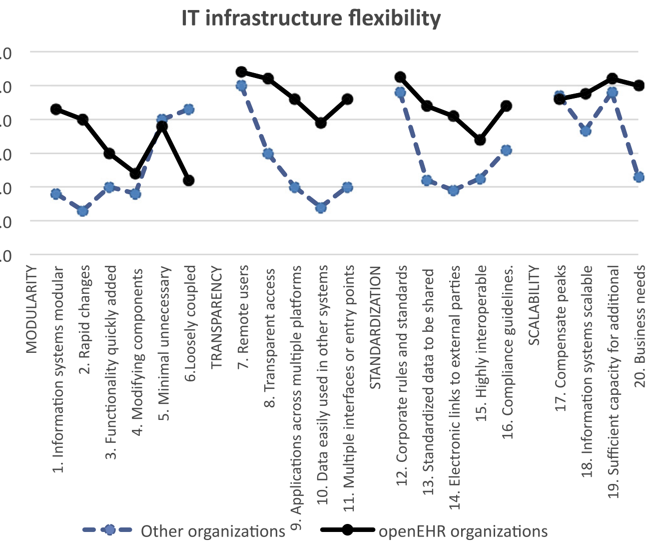

Fig. 2. Mean scores of openEHR organizations and other organizations on the questionnaire of IT infrastructure flexibility

on all items. For a complete overview of the used measures, see the Appendix. Then we will integrate these differences in a narrative with explanatory remarks from interviews.

5.1. Difference in total mean scores

The total mean score on IT flexibility of openEHR organizations is 5.2 on a scale of 1-7, and the total mean score of other organizations is 3.9. The Mann-Whitney U test in the package SPSS has been executed on total mean scores. The Mann-Whitney U test for small samples is a nonparametric test. The null hypothesis states that the distributions of mean scores of both populations are equal [46]. The hypothesis that the distribution of IT flexibility scores is the same across both groups is rejected with a significance level of 0.05.

The null hypotheses that the distribution of scores for dimensions of IT flexibility of both populations are equal can be rejected for transparency and standardization with significant level of 0.05. The null hypotheses that distributions of scores of organizations are equal for modularity and scalability have been retained.

5.2. Overall differences between groups on IT infrastructure flexibility

The visual inspection of data in **Fig. 2** unfolds that the mean scores of the group of openEHR organizations are higher for the various items of IT infrastructure flexibility. Observation of data in **Fig. 2** shows remarkable differences for groups of organizations for modularity. First openEHR organizations score seemingly higher than the other organizations on items 1-3. These items concern the adaptivity of IS. For items 4 and 5 (i.e. interdependencies in the IT infrastructure) the two groups' mean scores are about the same. On the item regarding the loose coupling of systems, item 6, the other organizations score higher. For items on transparency and standardization the openEHR organizations score higher overall. For scalability items no clear pattern emerges.

5.3. P1: Decoupling the conceptual models from application logic and modularity

In this section the quantitative data has been extended with interview data. We have analyzed the data belonging to every item

Table 3
Adaptivity and IT infrastructure flexibility

P1: Existence of AIS increases IT infrastructure flexibility			
openEHR and flexibility		other organizations: how to realize flexibility	
C1	The openEHR systems are easy to change, and this affects the infrastructure where these modules are positioned.	C6	This organization needs functionality in integrated ways to accommodate the care professional. The IT department wants to deliver independent components, but the care professional needs information systems to exchange information and operate together in an integrated EHR.
C2	Changes in the information systems are possible. It is possible to change the application infrastructure.	C7	This organization confirms that modularity is necessary for flexible systems and that the mental healthcare sector needs flexible systems. Now the systems have evolved into inflexible systems.
C3	After a history of collaboration with different vendors in the past, the organization experienced that the vendor of openEHR could execute changes in systems easily.	C8	The organization is dependent upon changes made by the vendors of the applications.
C4	This IT professional thinks the IS are not easy to change, just average. He looks at the complete IT infrastructure and does not see possibilities for rapid change, especially in critical applications (not openEHR).	C9	The organization employs full time software developers to adapt the information systems to a certain extent. The organization does not have to wait for the vendor to act.
C5	The openEHR part of the infrastructure differs from the rest of the IT infrastructure. The openEHR systems can be easily and rapidly changed.	C10	The IT professional thinks that vendors have difficulty in changing the information systems.

in the survey. We searched for reasons for the score that the organization selects. The reasons did not have to be interpreted, because they were explicitly worded by the interviewees. We have analyzed interview statements to establish if there exists a relation to openEHR. The relation exists if the interviewees mention openEHR in their reasons. Fig. 2 shows that openEHR organizations score higher on items 1-3 related to adapting IS and thus on the modularity of IS. Item 1 explicitly asks for the modularity of IS. In Table 3 comments and responses of interviewees of organizations have been summarized. Four out of five openEHR organizations (C1, C2, C3, C5) express the ease with which applications of openEHR can be changed. The following two excerpts from C1 and C5 clarify this view:

> “The openEHR part of the infrastructure differs from the rest of the IT infrastructure, the openEHR systems can be easily and rapidly changed. The information layer of the openEHR modules is more difficult to change, but it can be done. We see a world of difference between the openEHR part and the other part in our systems.”

> “The vendor of openEHR offers the functionality that we do not have in our own EHR (Electronic Patient Dossier). Our experience with openEHR software is that changes can be made, that are difficult in other software. We see that easy change is possible in new software.”

One of the organizations (C4) implemented several modules of openEHR but did not replace critical IT applications. As a result, difficulties were experienced when connecting different types of IS that is openEHR and other IS, to each other. Summarizing, four out of five confirm that CI characteristics affect the flexibility of the IT infrastructure in a positive way.

When we look at the five other organizations in Table 3, all describe that change in the IS is challenging to realize. In organization C10 reuse has not been recognized:

> "Reuse of functionality with different conceptual models probably has not been implemented in our EHR. When I look at the application of our EHR, I can conclude that the system is not very flexible, that it is difficult to change. I base this conclusion on discussions in the User Group of mental health organizations. There are not many alternatives for our EHR."

> Regarding the same topic, the informant of C8 adds:

> "No, we cannot realize rapid changes. Changes go slow, promises are not being followed up. On the other hand, we do have the possibility to develop our own forms in applications. The creation of forms is the responsibility of functional management."

A third organization (C9) employs full-time software developers and executes the changes itself and adds customized/self-made functionality that has to be maintained by the organization.

The interviews confirm that openEHR applications are easier to adapt than other IS. The other organizations complain about the lack of speed for adapting applications, except for the applications that can be reprogrammed by internal developers (C9).

5.4. P2: Reuse of functionality and modularity.

In Table 4 an overview of statements of ten organizations on P2 has been represented. In openEHR and CI reuse of functionality with different conceptual models is feasible, cf. 2.5. Two openEHR organizations (C3, C5) express a positive effect of the reuse of functionality on modularity. One (C1) openEHR organization attributes a positive effect on modularity to Data reuse and not to Reuse of functionality. The IT architect of C1 states:

> “The openEHR part of the infrastructure has been structured modularly. openEHR has technical characteristics to integrate with the software of other vendors, but these vendors are not making an effort."

Contrary to expectations, C2 and C3 score low on item 6, they do not experience loose coupling of IS and IT infrastructure. These organizations have implemented a major number of openEHR modules. C3 implemented 10 out of 15 modules, while the IT architect of C2 says that practically all have been implemented. The organizations C2 and C4 point to the effect of connecting applications, specifically connecting openEHR and not openEHR applications. IT architect of C4 gives an explanation:

> “… the problem arises when you have to migrate the data. We see that the interconnections have to be changed. Yes, changing components does affect the IT infrastructure."

Two of the other organizations see reusable functionality incidentally in applications. Also, other organizations emphasize the benefits of modularity but have not achieved modularity unless it is implemented by the vendors. The functional manager from C9 expresses a remarkable perspective:

> “In our organization you can look at modularity from two points of view. When I look at modularity from the IT infras-

Table 4
Reuse and modularity

P2: Reuse of functionality increases Modularity of IT infrastructure			
	openEHR and modularity	other organizations: how to realize modularity	
C1	This organization focuses on data reuse instead of reuse of functionality. This affects the IT infrastructure because data is easily exchanged.	C6	This organization is requiring a modular structure but needs the functionality of the integrated EHR system.
C2	Building blocks for functionality have been perceived in the IT infrastructure.	C7	In this organization the required modularity is not present. The IT infrastructure evolved: first, the EHR is selected and its functionality is evaluated. Then for missing functionality other applications have been added to complete the IT infrastructure.
C3	The reuse of functionality in the software of openEHR is recognized. The reusable functionality is used by half of the software.	C8	In this organization the required modularity is not present.
C4	The software of openEHR can process different conceptual models.	C9	This organization sees modularity as useful. Reuse of functionality is seen incidentally in a data warehouse and in architecture tool.
C5	Reusable functionality is an integral part of openEHR software. However, the organization does not apply it fully at this moment.	C10	In this organization, the IS is modular. Reuse is possible by switching modules off and on, but there is a need for more reusable modules.

Table 5
Accessibility of data

P3: Accessibility of data structures and data is greatly enhanced with CI			
openEHR and accessibility		other organizations: how to realize accessibility	
C1	ICT has been integrated completely in the care processes. The organization is now in a change process from unstructured data to a Best of Breed architecture with openEHR.	C6	In this organization an integrated solution is needed and found in the EHR.
C2	There is transparent access to all platforms and applications. If users have rights, then access is possible	C7	Remote users can seamlessly access centralized data and processes. However, data exchange is possible, but not easy.
C3	Accessibility of data has been the main reason to start with openEHR.	C8	The organization describes situations in which data is hard to access.
C4	The new EHR (openEHR) does offer access to other applications through an SSO. It is web-based.	C9	In this organization the data of one system can easily be used in other systems. This organization can manage more than one data model in the database of the EHR, because of self-made software.
C5	The organization applies openEHR, because it can integrate easily between the ETL and our own EHR for extracting data for reuse elsewhere.	C10	This organization has plans for improving data exchange. No, this is not easy.

tructure, then the systems are highly modular. When I look at modularity from the point of view of applications, the systems are not modular."

In summary, the openEHR organizations do not score lower than other organizations on modularity items 4-5, but they score lower on item 6, regarding loosely coupledness of systems. The openEHR organizations express difficulties in connecting applications, although they do not attribute the difficulties to openEHR.

5.5. P3: Accessibility of data structures and data is greatly enhanced with CI

The mean scores of the openEHR organizations on transparency, items 7-11, are higher than the mean scores of the other organizations. See Appendix. In **Table 5** an overview of statements of ten organizations on P3 has been represented.

A crucial item for transparency is item 10: Data of one system can easily be used in other systems. The mean of the openEHR organizations is 4.9 (7 points scale), the mean of the other organizations is 2.4 (7 points scale). The openEHR organizations score considerably higher. Four out of five openEHR organizations see the ease of Data access as a characteristic of openEHR modules (C1, C3, C4, C5), but three (C2, C3, C4) also experience difficulties in integrating with other IS.

Also, in C5, extra flexibility of openEHR is noted (CI Principle 3):

> “In a standard EHR there exists one process for all care workers and it is individualistic. We more often work in groups. In openEHR software you can serve different groups with the same information."

The other organizations attribute accessibility to one of the following: CITRIX, Remote desktop or they depend on the integrated EHR. But all five other organizations express difficulties in exchanging and using data of other systems and mention infrastructure solutions and technical standards for sharing data. For example, as the IT architect from C10 expresses:

> "Data of one system cannot easily be used in other systems. This is not easy, maybe if you use the raw database data, then you can access the information in other systems.”

For using data in other systems, the interviewees in C8 observe that:

> "It is complicated to work with the standard EHR when you are on the road with a client. You do not want to go through a login on CITRIX with a heavy laptop.”

Summarizing we would say, transparency has been scored higher in openEHR organizations and evaluations in interviews give explanations why.

5.6. P4: The (standard) meta-model of conceptual models in CI will lead to interoperability in general and semantic interoperability in particular

This section compares the scores on items 12-16 (i.e. standardization) for openEHR organizations and other organizations. The openEHR organizations score high on all items, the other organizations only on item 12. Looking at semantic interoperability a relevant item is item 13: the organization has identified and standardized data to be shared across systems and business units. IT professionals in almost all organizations comment on this item. The openEHR organizations have a mean score of 5.4 (scale of 7) compared to a 3.9 mean score (scale of 7) of other organizations.

Table 6
Semantic interoperability

P4: Meta model of conceptual models in CI will lead to semantic interoperability			
openEHR and semantic operability		other organizations: how to realize semantic operability	
C1	In the old EHR the data has not been structured. The main part consists of text fields (free text). Now part of the data has been structured in openEHR.	C6	The EHR offers an integrated solution for this organization. More than the software of openEHR could offer.
C2	The organization has identified and standardized data to be shared across systems and business units. But this IT professional thinks openEHR has made a start and working with healthcare data can be further improved.	C7	This organization has not identified and standardized data to be shared across systems and business units. There is one centralized EHR. It cannot serve a diversity of users as they need.
C3	The data models can be redesigned for translation and reuse, but the organization cannot exchange data this way.	C8	New regulations in the Netherlands demand that information has to be exchanged in a new standard for healthcare information, Care Information Building blocks (in Dutch ZIBs). This will be difficult for the vendors.
C4	The organization has identified and standardized data to be shared across systems and business units. openEHR is not fully applied here. Our systems were selected in order to incorporate external links to external parties. This was one of the reasons for choosing openEHR software.	C9	The organization has identified and standardized data to be shared across systems and business units. Remote users can seamlessly access the system. This organization develops part of its software.
C5	The organization has a standard for data to be shared across systems and business units.	C10	The organization works on sharing data between different business units.

The openEHR organizations declare that they are working on semantic standards. All name openEHR in this regard. Organizations refer to the new standard for information as in the Netherlands (ZIB), Care Information Building Blocks [50].

One organization, the one that has implemented openEHR fully, thinks that real semantic interoperability will still take a long time (C2). He refers to openEHR as follows:

> “In the Netherlands the ideas for ZIBs aim at the same goals (as openEHR) to provide building blocks to assemble different combinations of functionality. Too bad they have not chosen openEHR for this purpose.”

In the interview this informant reiterates that the openEHR standard is working but that the organization expects more now; it does not progress far enough. He adds:

> “In my opinion the vendor should offer more customization in the integration. Smart flow functionality. We want to work more rule-based. We are waiting for a rule engine, that has been planned, but has not been realized yet. We can add simple forms ourselves, but it is not yet enough.”

In the interviews the informants from the other organizations describe their efforts and share their problems in exchanging data between business units. One organization bases all exchange of data on the existing EHR (C6) and awaits future developments that will involve the mental healthcare sector as a network. One Other organization sees the EHR as determining and restricting the data exchange (C7), another (C9) mentions the proprietary data model to which self-made tables are added, one (C8) calls legacy software as a restricting factor. This organization expects difficulties on this item, as expressed by its representative:

> "The EHR vendors have an obligation to unlock the data in their systems in the Dutch ZIBs standard. It will be very difficult for our EHR vendor to implement the ZIB standard because of the outdated architecture. I do not recognize highly interoperable systems."

Lastly, C10 perceives an organizational gap between the functional IT department and the technical IT department, which is hard to bridge.

In **Table 6** an overview of statements of ten organizations on P4 has been represented.

Summarizing, we observe that all ten organizations are aware of semantic operability in the context of implementing ZIBs [50], but the other organizations express more difficulties in the process.

P5: Effects on scalability are not present for CI

We find differences in scalability on the mean scores of openEHR organizations when compared with the mean scores of other organizations on items 17-20. The item scores do not have higher scores for one or the other group of organizations overall. The factors that organizations mention when referring to scalability, do not involve the openEHR software. All ten organizations (openEHR and other organizations) mention different aspects or factors that affect scalability such as: a direct dialogue between functional management and technical management, virtualization of all applications, databases, and services and hardware limits. Adaptations in software and hardware are also possible as long as those are paid for. In summary, all ten organizations mention different factors than openEHR for influencing scalability.

6. Discussion, conclusion and limitations

6.1. Discussion and conclusion

For this multiple case study, results indicate that a difference is found in IT flexibility between openEHR organizations and other organizations based on a difference in total mean score and differences in mean scores on the dimensions of IT flexibility questionnaire. The statistical results demonstrate significant differences of scores of groups of organizations. The validity of the measurement relies on the validity of the questionnaire. The questionnaire contains the same items as a validated survey of Mikalef and Van de Wetering [22], therefore we presume that IT flexibility scores represent IT flexibility in the organizations. If the underlying CI design is a factor in improving IT flexibility then we expect the propositions P1 to P4 to show the influence of CI and P5 to be independent of CI. In **Table 7** the results of quantitative and qualitative data have been summarized.

Overall, the results confirm expectations that openEHR affects the dimensions of IT flexibility when performing a visual inspection. For evaluating the influence of CI, mean scores have been integrated with the detailed comments of the IT architectures and functional management. We view the results on the propositions P1-P5 that directly formulate expected effects on IT flexibility dimensions, if CI is involved. We do find confirmation for P1, P3, P4, and P5.

Table 7
Overview Propositions, combined results

	OpenEHR organizations	other organizations	Confirm*
P1	openEHR organizations describe higher IS flexibility and see that it affects whole infra	Express that change in IS is difficult, and it affects whole infra	V
P2	Extra opportunities for Reuse of functionality are present, but no general effects are seen on the modularity of the IT infrastructure	Modularity and Reuse of functionality are responsibility of vendors. Organizations observe a modular structure of applications only on a high level	X
P3	In general, connectivity and sharing data are realized. These are related to openEHR and affect transparency	Integration is realized with different technical means; the focus is on technical exchange of data	V
P4	Business unit collaboration is in progress, openEHR plays a role	Business unit collaboration described as difficult because of different factors relating to existing systems	V
P5	Scalability independent of openEHR	Scalability affected by various technical factors	V

* V = confirmed, X = not confirmed

For P2, we find that CI Principle 2 has been detected by the openEHR organizations in openEHR software. Moreover, the other organizations have not identified CI Principle 2 in IS. This difference in observed CI principles confirms our assumption that CI has been applied in openEHR but not in IS proprietary software. P2 is not confirmed by the data. The openEHR organizations observe more modularity in IS, item 1, as expected, but do not experience loosely coupled components in the IT infrastructure, item 6. The qualitative data show that some openEHR organizations realize modularity with openEHR, while other openEHR organizations do not. More research is needed here.

Despite its contributions, the present study is constrained by several limitations that future research should seek to address. First, we have not performed direct research on CI; we relied on the openEHR standard (the ‘proxy’). However, all underlying design principles of CI have been detected in openEHR software. The explanations of the IT professionals in the organizations confirm the role of openEHR. We infer the influence of CI from their remarks. Secondly, the implementation of openEHR depends on one vendor in the Netherlands, which is not the case in other countries [10].

6.2. Implications for practice and theory

Hellberg describes three strategies for healthcare organizations to enhance IT [51]. These are: technological strategy, a governance strategy, and a political/organizational strategy. The technological strategy focuses on building health portals, as the foundation of organizational IT applications. IT flexibility is indispensable for extending the infrastructure with eHealth applications. The governance strategy increases attention for management to the self-determination of the individual in improving public health, thereby focusing on the internal business processes and organizational processes. The third strategy positions ICT as a means for empowering individuals to take responsibility for their own health and thereby increasing equity for different population groups in accessing healthcare.

Our research explores the software design principles for increasing IT flexibility in IS concerning medical and healthcare terminology. In literature about openEHR and medical terminology we found that flexible domain knowledge is essential for healthcare professionals. The flexibility of conceptual models is mostly neglected in the extant literature on IT flexibility. Our contribution indicates that the way the domain model has been implemented, plays a pronounced role in the flexibility of organization-wide IT infrastructure. For theory building we advice that the mechanisms that cause the effects of CI on IT flexibility, such as the scope of the meta-model of conceptual models, should be further examined.

This research can be positioned in the technological strategy, but its implications are not independent of healthcare policy in the organization. Building IS that contain a perfect and unchangeable (hard) copy of the terminology at a certain moment in time will impede further evolution of healthcare policy. IT departments in healthcare organizations encounter dependencies in traditional EHR software, when conceptual models are integrated and encapsulated in closed software. The inflexibility of conceptual models obstructs further evolution of data models. The encapsulation leads to difficulties when meaningful data is necessary for healthcare processes. Healthcare organizations need to decide on their IT policy, specifically how much openness about “black box software” they require from vendors in order to realize IT infrastructure flexibility in organizations.

Data statement

The quantitative data and interviews that have been studied in this article can not be made public. The representatives of the organizations have asked the authors not to publish the raw data; all interviews have been confidential. The organizations have given permission to Utrecht University and HAN university of applied sciences to transcribe and analyze the data for research and use quotes from the interviews in publications.

Author Statements

Funding

HAN University of Applied Sciences, the Netherlands

Competing interests

None declared.

Ethical approval

Not required.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.hlpt.2020.04.001.

Appendix

Mean scores on IT flexibility questionnaire

Tables 8–12.

Nonparametric Tests

Test have been executed with SPSS software package with a configuration of significance = 0.05 and confidence interval = .95. The asymptotic significances are displayed.

Table 8
Mean Scores on IT Infrastructure Flexibility Questionnaire

Groups of organizations	Other organizations	openEHR organizations
MODULARITY		
1. Our information systems are highly modular	2.8	5.3
2. The manner in which the components of our information systems are organized and integrated allows for rapid changes	2.3	5
3. Functionality can be quickly added to critical applications based on end-user requests	3	4
4. Exchanging or modifying single components does **NOT** affect our IT infrastructure	2.8	3.4
5. Organizational IT infrastructure and applications are developed on the basis of minimal unnecessary interdependencies	5	4.8
6. Organizational IT infrastructure and applications are loosely coupled	5.3	3.2
TRANSPARENCY		
7. Remote users can seamlessly access centralized data and processes	6.0	6.4
8. Our user interfaces provide transparent access to all platforms and applications	4.0	6.2
9. Software applications can be easily transported and used across multiple platforms	3.0	5.6
10. Data of one system can be easily used in other systems	2.4	4.9
11. Our firm offers multiple interfaces or entry points (e.g., web access) to external users.	3.0	5.6
STANDARDIZATION		
12. We have established corporate rules and standards for hardware and operating systems to ensure platform compatibility	5.8	6.3
13. We have identified and standardized data to be shared across systems and business units	3.2	5.4
14. Our systems are developed in order to incorporate electronic links to external parties	2.9	5.1
15. Organizational IT infrastructure and applications are highly interoperable	3.3	4.4
16. Organizational IT applications are developed based on compliance guidelines.	4.1	5.4
SCALABILITY		
17. Our IT infrastructure easily compensates peaks in transaction volumes	5.7	5.6
18. Our information systems are scalable	4.7	5.8
19. Our IT infrastructure offers sufficient capacity in order to fulfill additional orders for treatment or diagnosis	5.8	6.2
20. The performance of our IT infrastructure completely fulfills our business needs regardless of usage magnitude	3.3	6.0
TOTAL MEAN	**3.9**	**5.2**

Scores on scale 1 -7 (1 totally disagree, 7 totally agree)

Table 9
Mean Scores for Organizations on IT Infrastructure Flexibility Questionnaire

ID – random	IT Flexibility score	Organization-type
1	3,52	Other
2	4,65	Other
3	4,44	Other
4	3,40	Other
5	3,56	Other
6	6,70	openEHR
7	4,45	openEHR
8	5,40	openEHR
9	4,50	openEHR
10	5,03	openEHR

Table 10
Mean Scores for Organizations on Dimensions of IT Infrastructure Flexibility Questionnaire

ID – random	MOD*	TRANS*	STAND*	SCAL*	Organization
1	3,58	2,50	3,70	4,20	Other
2	3,83	4,80	4,00	6,50	Other
3	3,40	4,25	4,80	5,50	Other
4	3,00	3,20	4,10	3,38	Other
5	3,70	3,25	2,50	4,75	Other
6	6,50	7,00	6,40	7,00	openEHR
7	3,67	5,60	4,40	4,25	openEHR
8	4,67	5,20	6,20	5,75	openEHR
9	2,67	5,00	4,80	6,25	openEHR
10	3,90	5,90	4,38	6,33	openEHR

*) Dimensions are: MOD = Modularity, TRANS = Transparency, STAND = Standardization, SCAL = Scalability

Table 11
Hypothesis Test Summary - Means

	Null hypothesis	Test	Sig.	Decision
1	The distribution of IT Flexibility Scores is the same across categories of Groups of Organizations.	Independent-Samples Mann Whitney U Test	.032[1]	Reject the null hypothesis.

Table 12
Hypothesis Test Summary – Dimension Means

	Null hypothesis	Test	Sig.	Decision
1	The distribution of MOD* is the same across categories of Groups of Organizations**	Independent-Samples Mann Whitney U Test	.310[1]	Retain the null hypothesis.
2	The distribution of TRANS* is the same across categories of Groups of Organizations**	Independent-Samples Mann Whitney U Test	.008[1]	Reject the null hypothesis.
3	The distribution of STAND* is the same across categories of Groups of Organizations**	Independent-Samples Mann Whitney U Test	.032[1]	Reject the null hypothesis.
4	The distribution of SCAL* is the same across categories of Groups of Organizations**	Independent-Samples Mann Whitney U Test	.222[1]	Retain the null hypothesis.

*) Dimensions are: MOD = Modularity, TRANS = Transparency, STAND = Standardization, SCAL = Scalability
**) Groups of Organizations are: openEHR organizations and other organizations
[1] Exact significance is displayed for this test.

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