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An exploratory study of private sector health care provider's use of the Archive of Imaging Data

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Abstract

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The purpose of this thesis was to gain customer information for the development of the Finnish national medical imaging service: "Archive of Imaging Data". According to the Health Data Act, Finnish health care providers have had to archive the radiologic images in Kanta by 2019 and the storing of wider range of imaging content will be mandatory by 2029. Very few private sector health care organizations have implemented the Archive of Imaging Data. The need to develop the current service has been recognized within the Kanta Services.

Within the background of this study were presented the regulations and other related topics regarding the national imaging service. Change management process for technology is presented along with Kanta's means of improve the services of the health data exchange in Finland.

An exploratory intervention was conducted in order to find out more about the situation within the private sector organizations regarding utilizing and storing imaging content. The data was gathered in an on-line survey and was analyzed by qualitative research methods.

The findings show overall that utilizing images within the health care is considered important and a lighter, less complex process to join the Archive of Imaging Data would increase the deployment of the national service of exchanging the imaging content in health care. Important is to continue to inform the private sector about the Archive of Imaging Data as the results of this study showed that there is not enough information about the service in the field.

Keywords: Medical Imaging, Health Data Exchange, Customer Information, Change Management

Contents

1 Introduction

The Finnish Kanta Services provide a nationwide social and health information system in Finland that leans on the Act on Processing Customer Data in Health and Social Care (159/2007) (Jormanainen 2023). The main services are Patient Data Repository, Client Data Archive for Social Welfare Services and the Electronic Prescription. One of the extensions of Patient Data Repository is “The Archive of Imaging Data” and this thesis focuses on the deployment and development of this service. More specifically, why the private sector’s health care organizations that produce radiologic images have not deployed the service even though it is mandatory. In addition to that, the thesis explores what customer information is needed from the private sector in order to develop the national service for smaller organizations’ use in the future. The new Act on Processing Customer Data in Health and Social Care 703/2023 mandates that all images produced within health care must be archived in Kanta by October 2029 (FINLEX 703/2023).

The Archive of Imaging Data is possible for a health care organization to deploy if they have certified information systems and have already deployed the Patient Data Repository. At the moment, there are 16 Wellbeing Counties and only 11 private sector health care providers which have deployed the Archive of Imaging Data (Kuva-aineistojen arkisto). The act 1257/2015 obligates all heath care providers to archive the radiologic images to Kanta Services by December 2019 (FINLEX 1257/2015).

According to the Finnish Radiation and Nuclear Safety Authority (STUK), there were 1350 health care organizations in Finland that had applied for the use of radiation in 2022. The social and health care reform in 2023 caused a queue in applying for the certifications of radiation when the well-being counties started and had to renew the former hospital districts permits. However, the amount of private sectors’ applications presumably has to be higher than the public sectors’ applications. Since there are 21 Wellbeing Counties in Finland that cover the

whole public sector, an assumption is that rest of the applications are applied by private sector organizations. (Venelampi 2022)

Health care is delivered across different providers nowadays. People travel and move or want a second opinion from different health care provider. Sometimes the need for specialized care demands different health systems. This leads to the need of exchanging the digital medical images in between different care providers. There are open standards and solutions available that are not unproblematic to implement but need special planning. Especially business incentive and security and privacy policies must be taken into account as well as the governance overall. (Persons et al 2020)

This thesis was in cooperation with the Kanta Services, where the problem of archive compliance has been identified and the need to develop the imaging services nationally. As a part of an investigation within the Kanta Services this thesis investigated why private health care organizations lack deployment of the mandatory service. The aim was to find out the reasons why so few have started the process and if there is not enough knowledge of the service in the private health care organizations. The information gained from this thesis will be used to evaluate the need to develop the technical interface of the national service of utilizing the images produced within the health care.

2 Change Management of technology

Organisations' need to change rapidly is a common theme of today. Both operational and strategic levels are under consistent change in order to keep up the pace of the business environment. It is irrelevant which industry an organization represents, but the pace of changes, either internal or external, is a part of every business. The change management requires high level managerial skills and ability to specify the goals and how to reach them. (Todnem By 2005)

Chance in information technology can be defined as any installation, alteration or modification of system software or applications and policies related to the delivery of the current service. The implementation of the new altered service is a part of the change. Information systems' change often focus on customer needs, market change, competition and government policies. Technology solutions are organizations' means of tackle the highly competitive market. Managing change is crucial for the product development. There are many ways to deal with the change management. The change starts often from the executive level that implies the broad strategies. It is important that the decision about the change in IT solution is interacted in between the technology experts and the business experts to avoid the unsatisfactory outcomes in the wanted product. Tactical part of the change process is usually planned by the middle management who are in charge of the costs and benefits at the functional level. Operational level work with more concrete plans as the tactical strategies have fallen down to the organizational structure. Their work is to start implementation. The tasks are more short term at the operational level, but there is a need for a link back to the business objectives in order to ensure that the final product is what was expected. In solution development are valid both the development and the decision-maker side. It can be argued which level is more important in change management but each has its place. (Jayatilleke, Lai 2018)

Technology development requires always the ability to change. The customers and other stakeholders must be taken into account with the development. By having proper change management process increases organizations' ability be successful with their business. A risk evaluation is a part of a change management process. Stakeholders' benefits are the key elements of change process in technology. It is possible that stakeholders understanding of benefits changes during the process. Predicting the steps by understanding the stakeholders' status helps in preventing major fails. Sometimes during the development new benefits may arise. (Tanilkan, Hannay 2024)

2.1 User-centered design

User-centered design is oriented in San Diego in the 1980s and has been widely used since. It offers four basic suggestions on how a design should be:

- *Make it easy to determine what actions are possible at any moment.*
- *Make things visible, including the conceptual model of the system, the alternative actions, and the results of actions.*
- *Make it easy to evaluate the current state of the system.*
- *Follow natural mappings between intentions and the required actions.*

These offers make the user the center of the design and the designer ought to facilitate the task to benefit the user. The users' involvement to the development process is inevitable. The stakeholders are not only the end users but also the people that manage the users have their opinions too. Then there are the people that are affected of the use of the products, the tertiary users, which are to be taken in to account, too in the development process somehow. After the stakeholders have been identified is there a need to perform tasks and analysis of their needs. (Abras, Maloney-Krichmar, Preece 2004)

Technique	**Purpose**	**Stage of the Design Cycle**
Background Interviews and questionnaires	Collecting data related to the needs and expectations of users; evaluation of design	At the beginning of the design project

	alternatives, prototypes and the final artifact	
Sequence of work interviews and questionnaires	Collecting data related to the sequence of work to be performed with the artifact	Early in the design cycle
Focus groups	Include a wide range of stakeholders to discuss issues and requirements	Early in the design cycle
On-site observation	Collecting information concerning the environment in which the artifact will be used	Early in the design cycle
Role Playing, walkthroughs, and simulations	Evaluation of alternative designs and gaining additional information about user needs and expectations; prototype evaluation	Early and mid-point in the design cycle
Usability testing	Collecting quantities data related to measurable usability criteria	Final stage of the design cycle
Interviews and questionnaires	Collecting qualitative data related to user	Final stage of the design cycle

	satisfaction with the artifact	

Table 1. Involving users in the design process (Abras et al 2004)

Usability testing is another phase of the development. There is empirical measurement on the users' needs and iterative design. Th system designers are a part of the testing as pilots are launched to make sure the product meets the needs of its' users. Usability engineering provides an approach for iterative testing: iterative conceptual model evaluation with feedback from the stakeholders. (Abras et al 2004)

2.2 Agile methods and SAFe methodology

Agile development is commonly used in software development. The methods offer a quick development and rapid respond to changes in the process. It is argued that agile methods would be suitable for small organizations mostly. (Jayatilleke, Lai 2018) Agile management and development are designed to specialize in change and adaptation. Frequent deployment makes practitioners update their way of thinking while observing the solution in use. It has been studied that the projects that have highly involved customers in the planning of the benefits are more likely to be successful with benefits but also with cost, scope and time (Tanilkan, Hannay 2024).

SAFe methodology (The Scaled Agile Framework) is an agile platform to guide the organizational changes and to deliver results. It provides principles, roadmaps. competencies and presentations for the organizations which use the methodology. SAFe promotes alignment, collaboration and delivery across the different teams of the organizations. The method enables the organizations to manage projects and multiple groups to get feedback. The key elements of SAFe are value streams and release trains. Value streams are the processes that add value to the customers, either internal of external. The release trains (ARTs) are the teams of development that are under a value stream. SAFe principles are:

1. *Take an economic view to allow for optimal lead time while providing the best quality and value.*

2. *Apply systems thinking into all facets of development.*

3. *Assume market and technical variability by preserving choices and encouraging innovation.*

4. *Build incrementally with fast, integrated learning cycles that facilitate customer feedback and reduce risks.*

5. *Base milestones on objective estimation and evaluation of working systems to ensure there is an economic benefit.*

6. *Make value flow without interruptions by limiting the amount of work in progress, decreasing batch sizes, and managing queue lengths to enable continuous flow.*

7. *Apply cadence (timing), synchronize with cross-domain formation to recognize business opportunities and allow for corrective action as needed.*

8. *Unlock the intrinsic motivation of knowledge workers to reach their unseen potential.*

9. *Decentralize decision-making to become more agile and effective.*

10. *Organize around value to ensure development responds to the needs of customers, providing them with new and innovative solutions.*

(Alexander 2023)

SAFe main competencies are team and technical agility, agile product delivery, enterprice solution delivery, lean portfolio management, organizational agility, continuous learning culture and lean-agile leadership. These elements are able to provide the knowledge to achieve business agility. (Alexander 2023)

2.3 Digital health care and interoperability

Digital health care technology is used as a means of decrease the problems of health industry in many countries for the last decades. For instance the USA and the UK have invested billions in their national digital strategies. Even if the many countries have their own problems with their digital transformations, are some similarities in them established. There is substantial pressure with these public transformations to have quick respond to the problems in the society but usually the full benefits take long time to materialize. There is always the balancing with the variety of local solutions and the competition in between them. The era of patient centered care with data integration across primary, secondary and social care is now. (Cresswell et al 2020)

The Kanta Services were implemented in 2010-2018 based on the need to have a nationwide structure for patient data and service. The laws behind are Act on Electronic Prescription (61/2007) and the Act on Processing Customer Data in Health and Social Care (159/2007). The complexity of the new infrastructure has taken a large-scale and costly input involving different stakeholders from public and private sector. (Jormanainen 2023)

The implemention of two of the Kanta Services, The Electronic Prescription and the Patient Data Repository were supported and established by the Finnish Institute for Health and Welfare (THL). THL is responsible for the official approach of the services of Kanta. The deployments, the enforcement, technical specification and the production are managed by the Kanta Services. (Jormanainen 2018: 381)

The first deployments of the Archive of the Imaging Data were in 2018 and they were public health care organizations. Until now there are only eleven (11) private health care organizations that have deployed the Archive of Imaging Data. (Kuva-aineistojen arkisto) There are a few organizations that are interested in starting the process but their information system is not certified yet. This is an assumption that involves many other organizations as well.

The Client Data Act regulates the health data exchange in Finland. In the Act is explained the purpose of the Patient Data Management Service, held also by Kela's Kanta Services. It possesses the information that a patient has been informed about the national Kanta Services in which their health data is stored. (FINLEX 703/2023) The data sharing via the Kanta Services is controlled by patient's consent and denials, set in the Patient Data Management Service. The decision on and the setting off consent or denials can be done at an appointment in health care or browsing in patient's own MyKanta –web pages that the patient can control by himself of herself. These consents or set denials affect the exchange of images as well as the other patient documents. (Tiedonhallintapalvelu; Jormanainen 2018: 387)

Kela carries out the processing of personal data in accordance with the EU's General Data Protection Regulation (GDPR) and other legislation regulating the processing of personal data. (Privacy policy)

2.4 Change management in Kanta Services

Finnish Institute for Health and Welfare (THL) is in charge of steering the Kanta Services nationally. Kanta Services are a part of Kela, The Social Insurance Institution of Finland. STM and THL with Kanta Services plan the roadmaps for development of the national health data archive. The Client Data act is providing the legislation for the development. Kanta's responsibilities as developing the service of Imaging Data are updating the technical and functional specifications and implementing technical changes as well as describing customer

understanding. The deployment process and support of Kanta Services are on Kanta's account, too. (Kalima et al 2021)

2.4.1 The benefits of the service of the Archive of Imaging Data

According to THL there are many benefits when archiving the images nationally. For the patient, the images archived nationally empowers them to participate in their care more when they can view or download the image reports in MyKanta. The patient is also capable of setting a denial of data sharing in between two organizations. For a health care organization, the benefits are retrieving patients' previous images and imaging documents to compare. The Archive of Imaging Data enables the data sharing among different professionals in order to make the right diagnosis for instance. It also decreases the manual recording of data. The society benefits from the Archive of Imaging data as it stores the images and the organizations do not have to archive the imaging data by themselves which potentially cuts costs. The access to the patients' previous images can reduce overlapping imaging and radiation load. (Kalima et al 2021)

The Act of Secondary use of Health and Wellfare Data regulates the use of data recorded in Kanta. The secondary use of data allows for instance research conduct. For the secondary use, health data is given according to 37§ without personal data. (FINLEX 552/2019)

2.4.2 Training for the implementation

The implementation of a new service requires always input on the training of the staff. The basic knowledge of the subject must be quarantined before the production use of a new system. The support along the learning is important for the health care workers. The health workers play a significant role in implementing a new information system. (WHO 2019: 36; Jormanainen 2021)

Kanta is responsible for support the health care organizations for it's services' implementation. The means of promoting the deployment are a wide range of activities. The main information source of Kanta Services is shared in kanta.fi -

web pages. In addition to that the implementation and adoption support has included help desks, educative and guiding videos, written guidelines and presentations, newsletters, national conferences, other seminars and meetings for focus subject matters and regional support. The coordinating function has also granted state subsidies to provide partial funding for breakthrough pilots. (Jormanainen 2018; Events and training)

Information systems' support is inevitable and regulated by law. The information systems are responsible for informing the buyer organization of the system's interoperability factors, data security and operations in general. (FINLEX 703/2023)

3 Purpose, aims and research questions

The Kanta Services were first implemented by the The Ministry of Social Affairs and Health (STM) in 2007 in cooperation with many stakeholders from the health care industry and state funding was involved. The implementation has been launched in stages. The Archive of Imaging Data is an extension of Patient Data Repository, one of the main services of Kanta that was implemented first in 2013. By 2015, all public health care providers had deployed Patient Data Repository and in 2016 started the private sector organizations to join. In PDR are stored patients' health data like test results and reports and other information of medical care. In order to exchange the data between two organizations, the patients' consent has to be assured and applied. (Jormanainen 2018: 389)

This thesis concentrates on gaining more customer information from the private sector's health care practitioners regarding imaging. The need to develop the national service of Archive of Imaging Data has been recognized.

Images in health care have been used as diagnostic assistant but nowadays even more when the use of mobile device has increased. The quality of the

images varies and the need of standards that affect medical decisions has to be acknowledged.

In May 2023 Kanta held an event about the imaging for the private sector's representatives. The main information gained from the event was that more support is expected to the private sector and easier deployment process including technical aspects are the keys to increase deployment. (Events and training)

3.1 Implementation of Kanta Services

The technical architecture of the Kanta Services is mostly based on on HL7 V3 and CDA R2 interfaces. The Imaging interphase is carried out by extending that base with IHE XDS interfaces and DICOM studies. XDS interface integrates the customers to the national domain and enables to storage and manage of DICOM studies. For the imaging studies like study reports and documents, the specifications are same as with the other documents in Patient Data Repository which is in active use nationally. (Technical Specifications: 8-9)

3.1.1 National Code Service

The Client Data Act contains the directions for THL to maintain the National Code service that shares the information about the required specifications for the information systems attached to Kanta. Kanta Services are responsible for the technical implementation of the National code service. (FINLEX 703/2023)

The Code Service is responsible for the quality of the health data structures nationally. Data Structures are for instance code sets, classifications, vocabularies and register information. The common use of the nationally set data structures forms a comprehensive use of health information. All the standardized data structures required by the electronic data systems are published free of charge on the code server as well as the central code sets of the statistical and register data collection. (Koodistopalvelu, Jormanainen 2018: 384)

3.1.2 MyKanta

MyKanta is a citizen's view to their own health data in Finland. MyKanta shows documents and prescriptions recorded in Patient Data Repository regardless of whether done in public or private health care. The access to one's own health information is by web browser with an electronic identification like mobile certificate or banking credentials. Of imaging related data, citizen can view their own imaging referrals, imaging studies and reports via MyKanta. In MyKanta user can monitor which organizations have viewed their information. MyKanta enables the user to maintain the consent and denials that affect to the person's health data exchange via Kanta. (Jormanainen: 2018)

3.2 Deploying the Archive of Imaging Data

The health care organizations have had to archive the radiologic images related to patient's care to the Archive of the Imaging Data according to the Act on Processing Customer Data in Health and Social Care 1257/2015 by December 31st 2019. This excludes for instance visible light images, which are lined in the Act on Processing Customer Data in Health and Social Care 703/2023 (The Client Data Act). In the new Client Data Act that will be executed 1st of January 2024, are listed the new information contents that will be mandatory to health care providers to archive to Kanta Services. The obligated date to archive other than radiologic images is by 1st of October 2029. The new contents to be archived nationally in Kanta Services are video and audio recordings, visible light images, oral health care images and other images produced within the health care. From 2021 there has been a possibility to archive nationally the ECG-records for those organizations that have already deployed the Archive of Imaging Data. (Kuva-aineistojen arkisto; FINLEX 703/2023)

There are several technical requirements for the organization in order to deploy the Archive of Imaging Data. The overall principles of the Kanta architecture ought to be relied on. All the archived imaging data must be in DICOM format. The archived images are linked to the imaging documents that are archived to

the Patient Data Repository. This link is one of the reasons that the organization using the Archive of Imaging Data must have already joint the Patient Data Repository and the principles of the Patient Repository are expected to be implemented by the specifications. (Technical Specifications)

The deployment and implementing of the Archive of Imaging Data takes time and effort from the health care organization. They have to plan and carry out the technical architecture, do the testing and then undertake the administrative measures like accept the service description with the Kanta Services. They have to pass the deployment test. The test is run by the health care organization's representatives for instance physicians and project co-ordinates, the PACS' and the Electronic patient record systems' representatives and technical and customer support from Kanta Services. The customer organization will send a report of conducted deployment test to Kanta. After all these steps the organizations can start the production use of the Archive of Imaging Data. (Kuva-aineistojen arkiston käyttöönotto)

The Client Data Act requires the information systems representatives to transparently guide the health care organization to implement their system. In order to connect the system to national Kanta Services, must the security, data protection and usability requirements be ensured. (FINLEX 703/2023)

3.2.1 Certification process

The information systems that are required in order to deploy the service of Archive of Imaging Data must be A-standard certified. The organization has to have in use at least an information system that has passed the testing of archiving the imaging documents to Patient Data Repository and a certified PACS-system (Picture archiving and communication system) that archives the imaging material. A viewer is also inevitable to do searches and view the images from another health care organizations' register via Kanta. This is one of the main benefits of the Archive – sharing data. (Kuva-aineistojen arkiston käyttöönotto)

The Client Data Act contains the demand for the information systems and transmission services to have passed class A certification in order to be able to join the Kanta Services. The certification process includes joint testing that is coordinated by Kanta. The information systems have to be implemented according to the national definitions. All amendments to the Client Data Act must be updated to the information systems as well. (FINLEX 703/2023)

PACS is digitalized archives consisted of one or more computers in a network that enable image storage and exchange. PACS stores the images in high quality and ageing does not affect that. PACS are suitable because the queries are fluent and the required space is limited. (Mustra, Delac, Grgic: 2008) PACS suppliers must do the joint testing with an EHR (Electric Health Record) or EMR (Electric Medical Record) since the combination of them will be the one to be able to production use of Archive of Imaging Data. The joint testing is mandatory when there is a new system to be in production or if there are new functionalities to be supported with the system. Sometimes new legislative amendments require joint testing. (From testing to production)

3.2.2 Preliminary information about the challenges of deploying the Archive of Imaging Data

The short of new deployments or certifications of new systems to the Archive of Imaging Data are the key aspects to study the current state. Within Kanta, there have been recognized the fact that there must be valid reasons behind the slow progress of deployment among the private sector. The list of A-standard certified PACS systems is short which means that either many organizations do not have a certified PACS or PACS at all in their use. From the certified PACS' representatives Kanta has gained information about the organizations that use their systems but have not deployed yet the Archive of Imaging Data. (Kuva-aineistojen arkiston tilanne)

Kanta's info event for the private sector about imaging services in May 2023 revealed that many private sector's representatives had not been aware of the regulations and demands on joining the Archive of Imaging Data. The feedback

from the participants was that the information should be given in legible form and the on-line events should be held regularly.

The most common use of Kanta Services is within the private sector's health care providers in addition to public municipalities' health stations. More than 50% of the practitioners in those actors did queries via Kanta every day. The need for easier queries came up in 50% of the practitioners responds. (Vehko et al. 2021)

There is a hypothesis that the same organizations that produce certain content would utilize similar content in their operations to compare the results and to produce high quality care for their patients.

3.3 Data exchange and standards

Below is described the main standards that affect the Archive of Imaging Data.

3.3.1 DICOM standard

The Standard for Digital Imaging and Communications in Medicine (DICOM) is a non-proprietary format to exchange medical images. It was found in 1983 by groups of American College of Radiology and National Electrical Manufacturers Association in order to find out how to connect displays from different manufacturers. The DICOM standard Version 3.0 was released in 1993. That version uses network connection instead of point-to point connection between imaging system connections. The previous versions had problems with the modern communication networks which do not use dedicated channels. The DICOM standard is maintained by the DICOM Standards Committee. Each year new the development aims to support new modalities and ways to represent data among different systems (Lipton etc. 2012). (Mustra, Delac, Grgic 2008; About DICOM; Lipton, Nagy, Sevinc 2012)

The DICOM standard is used internationally to interchange digital medical images and related data within branches like cardiology, mammography,

radiology, surgery, endoscopy, dentistry and pathology. It was developed to standardize the interchange of medical images. DICOM provides a comprehensive protocol for imaging studies to be exchanged, saved and viewed. It has been planned to cover all aspects of medical imaging. (Mustra, Delac, Grgic 2008; Pianykh 2012; Hannula 2020 s 25-26)

Web services can connect different information models in disparate systems. The interaction happens over a network and the service provides interphase language, description language, that uses simple object access protocol (SOAP) messages. The messages are generally extensible markup language (XML) communicated through HTTP. The web-based services provide interoperability with lower costs that traditional DICOM and HL7. Web based imaging services need a proper structure in order to be functional. The needed elements are content discovery, metadata retrieval, object retrieval and transformation services. The web is becoming more and more common platform for enterprise access to data. The typical web browser can place constraints regarding the type of data that is provided. Additional services may be provided to enable renditions of images. (Lipton, Navy, Sevinc 2012)

DICOMWeb offers a standard for web based medical imaging. It can be implemented as a proxy to existing DICOM Message Service Elements in order to access systems that support DICOM. (DICOM)

3.3.2 XDS standard

Cross Enterprise Document Sharing (XDS) is defined by Integrating Healthcare Enterprise (IHE) that is concentrated on finding profiles for data sharing in between different systems. XDS does not limit the documents' form to textual information but is able to handle any type of text, formatted text, images and structured clinical information. An XDS Affinity Domain is a group of healthcare organizations that have agreed a common set of policies and share a common infrastructure like a national EHR system, regional organizations or specialized care. (IHE 2023)

In Finland IHE's XDS is chosen to be used for the transmission of the images from the Archive of Imaging Data. The images like x-rays and documents attached to those images are retrieved from XDS repository of the Archive of Imaging Data. The Patient Data Repository registers all imaging study documents in the XDS registry of the Archive of Imaging Data which enables the retrieval for the imaging documents to the workstation that is a XDS consumer. The retrieval is performed in accordance of XDS specifications. The query of images or imaging documents requires patient's identity code provided. Timeframe and study code are possible to provide in order to narrow down the results. The consent management is carried out while the ongoing query to exclude the restricted data. The practitioner sees the metadata of the search results in the viewer and the actual imaging study or its objects are retrieved to the viewer with a specific transaction, RAD-69, via the XCA-I initiating imaging gateway. (Technical specifications: 32-36)

3.3.3 HL7 standard

Standards help to define how the information is packaged in such form to establish the exchange from a party to another. Health Level 7 standard has been spread widely in Finland. All health care providers must form the documents according to these specific standards in order to make them possible to be exchanged, retrieved and integrated. The HL7 standard defines the structure and data types that ought to be in the health information shared from different system to another. (Jormanainen 2023 s. 28-29)

HL7's Clinical Document Architecture Release 2, CDA R2, is the form of document that is used as the imaging documents liked to the imaging studies archived to the Archive of Imaging Data. The CDA R2 documents are in XML form and can contain various types of clinical information. (Heikkilä 2020) The common idea of CDA R2 is to simplify the structure of the document and entry each component individually. (HL7 Finland 2015)

HL7 CDA and V2s are the most popular standard in the health care industry in the world for data exchange. There is a possibility to adopt a newer standard alongside with the HL7; FHIR. (Ayaz et al. 2021)

3.3.4 FHIR standard and RESTful architecture

HL7 has produced health care data exchanging models over 20 years. The newest specification is FHIR (Fast Healthcare Interoperability Resources) that can be used in stand-alone data exchanging standard or with other generally used standards. FHIR promotes integrity of the health information and simplifies the implementation. It uses existing logical and theoretical models to data exchange between different applications. (FHIR; Ayaz et a 2021; Lehne et al. 2019)

FHIR allows external software to access and search for clinical information from the electronic medical record using internet standards. This is relevant to medical imaging as well. Kame and Nagy suggest in their research that in radiologic imaging FHIR provides a patient centered system that does not have balance in between different platforms like PACS and EHR. Tools like DICOMWeb and FHIR can medical imaging be embedded with the other clinical information of the patient. FHIR server offers a way to unify the needed health information into a single platform. (Kamel, Nagy 2018)

The basic building block of FHIR is a Resource. FHIR resources aim to define the information contents and structure that are set as the core information like patient, practitioner, condition or device. Most resources are mapped to several different formats. One of them is DICOM. All resources have at least one example within the specifications in order to help the implementers to follow the design rationale. (FHIR, Lehne etc.: 52-53)

FHIR standard is mostly used in scientific literature when topics are data models, mobile and web applications, medical devices as well as EHRs. The literature has increased from 2013 to highest at 2018. The focus with the literature were found mainly in the United States but also European countries

like Germany and Austria had several research possibly to improve their health data exchange nationally. (Lehne etc 2019:57) FHIR's most important objective is to easier implementation without losing integrity of the health data. With FHIR, the access to clinical data can be granted by standardized browser applications. (Ayaz et al. 2021)

Within Kanta, the first FHIR based specifications are about to be used in Patient Repository, Client Data Archive for Social Welfare Services, Prescription and Personal Health Record. Kanta has been gathering customer information from the system developers about the FHIR interface (From testing to production). It is yet to be decided whether FHIR interface will be utilized within the exchanging of the images nationally.

FHIR along with REST (Representational State Transfer methodology) are a part of European Health Data Space's specifications. (EU) REST is lighter technology compared to SOAP-based (simple object access protocol) web services that Kanta's imaging service is supporting at the moment. REST is solution that many service providers are moving toward because of it's simpleness and resource-centric conceptualization instead of service-centered approaches. (Parra et al. 2014) REST does not interact with messages or operations but with resources. REST defines protocols to well-known operations. REST is more scalable than service-oriented architectures and it serves an uniform interface that can integrate with devices with low processing capabilities using lightweight format. (Lipton, Navy, Sevinc 2012)

As mobile technologies are increasingly important components in health care especially in telemedicine but also in the active care, the protocols for communicating with image repositories such as PACS are not suited to exchange data with mobile devices yet. There are possible ways to integrate the applications to PACS. The interface with the gateway is accomplished using Hypertext Transfer Protocol (HTTP) requests following REST methodology (Valente, Viana-Ferreira, Costa, Oliveira:2012)

3.3.5 Interoperability

WHO has defined interoperability as the ability of multiple information and communication technology systems and software applications to communicate with one another, exchange data and use the information that has been exchanged (WHO 2019, Jormanainen 2023:16).

Health care data is represented by many sets of vocabularies, terminologies, and codes which grow and change over time. As a result, it is important for the data exchanged to be equally understood by the sender and receiver, which is known as “semantic interoperability “. Semantic interoperability relies on standards but there are still many barriers to overcome with like the complex systems that the health care organization have and that are not compatible for exchanging the data. The terminologies and classifications ought to be relied on. (Mello et al. 2022; HIMSS 2013)

3.4 European Health Data Space

European Commission has presented a regulation to set up the European Health Data Space (EHDS). The EHDS builds upon other legislations as the GDPR, the Regulation 2017/745 (Medical Devices Regulation, 2017/746 (In Vitro Diagnostics Regulation) and proposed acts like Artificial Intelligence Act Data Governance Act and Data Act and EU Directives 2016/1148 (NIS Directive) and CBHC Directive. The main points to the EHDS regulation are to support the individuals to take control of their own data, to increase the use of health care data for research and innovation and to enable the data exchange within the EU. EHDS is one of EU’s main priorities within the area of health. (EHDS: 1-3)

EHDS has named some categories as priorities when it comes to European wide interoperability of the health care data. Different categories have different stages at standardization of the data and that is why the implementation of the data exchange varies in complexity. Images and image reports have been

selected as one of the most relevant categories for the Members States to easy access and transmission. Other prioritized categories are patient summary, electronic prescription and dispensation, laboratory results and reports and hospital discharge. The target is that by 2030 all EU citizen would have access to their own electronic health data by EHDS. This requires the use of common European electronic health record exchange format. Commission Recommendation (EU) 2019/2437 provides the foundations for a common European electronic health record exchange format.

The requirements for the EHRs promote patient safety, supporting generally accepted forms of data in exchange with other parties and compatible with the EU's adjusted infrastructures. The EHR must have a functionality for entering structured personal health data in commonly used and machine-readable format in order to be communicated from system to system. There are requirements for the security aspects for the EHR as well. For instance the health care professional must be identified by name and profession (EHDS: 2-3) Since Finland is a member of EU, should the EHDS recommendations be validated within the national development of the health data exchange.

3.5 Different Imaging content in health care

According to the National Conceptualization of the new contents in the Archive of Imaging Data, THL has pointed out the guidelines for the utilization and interoperability of the images in health care. The Ministry of Social Affairs and Health (STM) gave commission to THL to define the road map and follow up-plans to different specialities' contents in 2021. The conceptualization was exploited when making the new law 'Act on Processing Customer Data in Health and Social Care 703/2023'. (Kalima et al 2021:9) The technical development and decisions were ruled out from the conceptualization with gaining customer information about the new contents' utilization. This Thesis can be used as one of the means of carrying out Kela's Kanta Services part of the development.

The roadmaps for some new imaging contents have been planned already by THL alongside of the Kanta Services. In kanta.fi web pages are informed the published timetable for intraoral imaging, optometric imaging and ECG-reports (as laboratory workflow). The production use is possible for these contents in 2024. (Scheduled health care services)

From planning to the national production use of new imaging content can take several years. The specification process takes time and effort. In order to implement the utilization of the new content need the organizations be aware of the current situation, work with their information system so that they build their solution according to the future use. This complexity of the supply of the extensions or integrations of the systems is noted as one of the challenges with the development of the national health data exchange services within Kanta's customer support.

3.5.1 Radiologic images

From 2018 it has been possible to archive radiologic images to the Archive of Imaging Data. Radiologic images contain images as x-ray examinations, ultrasounds, oral x-rays, computed tomography (CT), magnetic resonance imaging (MRI), angiographies and transilluminations. All radiological imaging uses the same principles as storing the images nationally to the Archive of Imaging Data. The workflow contains a radiologic referral to the imaging unit. The images are taken and attached to the referral and imaging study archived to Patient Data Repository with a Study instant UID, an identifier and link between the documents and the images. After imaging, the report on the images is liked and stored using the same identification. (Technical Specifications)

3.5.2 Visible light imaging

The visible light images are primarily taken at the appointments and that differs from the x-rays' process. Visible light imaging is a growing segment among health care imaging. (Kalima et al 2021) Photodocumentation and medical

video documentation and audio recordings are subset for visible light imaging. The expanding and predominant use of smart devices lowers the threshold at producing medical photographs at the point of care. Even the patients can do so. Health care providers usually use the visible light images for as a diagnostic document or progression of a disease, consultation purpose or as a guide procedure. The quality of the images may vary depending on the source and the training. It is uneasy to monitor the quality without national guidelines. (Petersilge et al. 2021: 385-6)

Visible light imaging is challenging the current process of archiving images nationally. Typically, there is not a statement made about visible light images. The visible light images are often attached to the patient data as a part of another statement or summary. In the conceptualization is mentioned that so far the plan is to archive the visible light images to the Archive of Imaging Data even when recognizing the difference both in technical archiving and the limitations in the health care practitioners' permits. (Kalima et al 2021:16)

3.5.3 Optometric images among the visible light imaging

Fundus photography of the eye and other optometric images are possible to archive in Kanta by the end of 2024. The format is DICOM as the other content is so far in the Archive of Imaging Data. The fundus photography is visible light imaging that are taken either in policlinic or most often in an optician appointment. The first category of the visible light imaging to archive nationally is the optometric imaging including the fundus photography. The requirements are similar as with the radiologic images; same workflow and DICOM standard images. (Kalima et al 2021:17)

3.5.4 Oral imaging

By now, nationally there are few oral x-rays archived since the process of archiving is (certified) PACS based and need of referrals and at least image document is inevitable. Those organizations that have deployed the Archive of Imaging Data could have stored their oral radiologic images according to the

usual x-rays' procedure. The roadmap for the archiving of the oral images is underlining that the PACS and RIS systems in dental care ought to be certified by 2029 and after that the deployments of the Archive of Imaging Data can be fulfilled. Concerns about implementation is the fact that there are not just DICOM format images but for instance jpg or bmp are commonly used. (Kalima et al 2021:18-19)

In dental health care the most common images are intraoral images that are visible light images. The decision to need an intraoral image is usually made while the patient is at the appointment and that procedure differs from the procedure of the oral x-rays. X-rays have referral made and according to that are the images taken and the report of the image is usually written by radiologist afterwards and connected to the image. Oral imaging has new specifications made about the numbering the tooth that is under observation. Therefore, the organization that have already deployed the Archive of Imaging Data can start to store intraoral images, too, if their system is updated with the specifications. The official roadmap for archiving the intraoral images is in 2024. (Kalima et al 2021:18-19)

3.5.5 Signal reports

From 2021 can the organizations that have deployed the Archive of Imaging Data store ECG. The workflow and the format for the ECG reports are the same as with the radiologic images. If in PDF format, should the ECG be encapsulated into DICOM format before storing to the Archive of Imaging Data. (Technical Specifications)

Within the national roadmap for the imaging content, ECG and other signal report are to be archived by the first of October 2029. In order to archive the private sector's signal reports requirements for the systems need to be ensured. (Kalima et al 2021: 44)

3.5.6 Mammography screening

According to the Client Data Act the responsibility of the health screening, like mammography, is addressed to the Wellbeing Counties starting from 2023. This means that the images formed by the mammography are required to archive nationally. THL conceptualization on the new imaging contents suggest that the utilization of the mammography images increase as the recording policies are first implemented. Up to now the organizations have outsourced the screening to private sector actors that have not joint the Kanta Services and the data is not available nationally. (Kalima et al 2021: 21) Since the screening is outpointed to the Well Being Counties, public sector, does this not apply the private sector unless the Wellbeing Counties have outsourced the screening to private sector.

3.5.7 Digital pathology imaging

The use of digital pathology images is not widely active within the health care but in the future could the consultations of the samples be by digitalized images and sent electronically. Digitalization of the pathology images can be time-saving and it enables for instance the use of Artificial Intelligence (AI) as with the help of making a diagnosis. The digital pathology images (Whole Slide Imaging) are significantly large in size. This affects the storage capability. (Kalima et al 2021: 18)

3.6 The study objectives

The study objectives of this thesis are:

1.Why have so few private sector health care providers deployed the mandatory service of the Archive of Imaging Data?

2.Gaining customer information to support the technical solution for the new information contents' deployment in the Archive of Imaging Data.

This research aimed to gain more customer information on how can the Kanta Services promote the deployment of the Archive of Imaging Data among the private sectors' heath care providers and find out more means of improve the service in order to increase the archiving and utilizing the images nationally. Especially the technical interface that at the moment requires a combination of certified information systems needs evaluation since it that has been identified as expensive and arduous for the small organizations to deploy. This Thesis will concentrate on the conclusions on why have not the private sector organizations deployed the Archive of Imaging Data yet and which factors occur that could be used in the development of the service regarding the new archived contents by the Client Data Act especially. The results of this study can be conducted for further research within the Kanta Services.

4 Methods

This research was conducted aiming to proceed in the development of a national service according to the legislations. In this Master's thesis was qualitative approach. Qualitative research aims to provide evidence for understanding events that happen and design future research. It is important that the research is sound to provide trustworthy evidence and perspective of the research participants. (Fossey et al 2002)

4.1 Exploratory intervention

An exploratory investigation was conducted regarding the development and future of the Archive of Imaging Data. There was a semi-structured survey planned that was sent to private sector representative in order to gain crucial customer information. The data included numbers and proportions of the gathered data from the survey. Among the data were respondents' open comments too.

The Thesis was conducted in co-operation with the Kanta Services. An on-line survey was planned and sent to private health care organizations' either

administrative or other personnel that utilize or produce images in their work. The questions in the survey were be both open-ended and close-ended and the results were analyzed by using qualitative methods. The open-ended questions were analyzed by the themes that were recognized in the responds. All the questions in the survey were planned in co-operation with the other specialists that work with the development of the Archive of Imaging Data. The questions in the survey were composed based on the presumptions of the situation with the private sector's health care providers. The survey was executed in Finnish.

5 Sampling

The survey consisted of background questions to confirm the sample to correlate the population. The latter part was where more detailed information was asked about utilizing and storing different imaging content and whether the organization needs them to either to view or produce. First was asked how many health care professionals within their organization either produces or view listed contents. Then after there were questions where statements were given and the respondent had to choose from "very important", "rather important", "not important" or "does not apply to our operations". Likert scale is a tool to find out more than just a yes or respond in a closed-ended question but to determine if the respondent confirms the statement or not. This used scale started with a strong approval to less strong and ended up to disagreement and decline of the statement. (Nemoto, Beglar 2014) The questions were if according to their operations it would concern the organization to either view the listed contents that other organizations have archived or if it would be important for other organizations to be able to view their recorded images via Kanta. In order to utilize the service of Archive of Imaging Data, there is both the archiving process and the viewing of the images. These elements were both recognized in the survey and asked separately according to the different contents of images.

The respondents that were taken into account was (n=) 151. Among the final results there were 4 respondents with very limited information and no responses

to the background questions and that is why they were ruled out from the analysis. All together the response rate was 0,1.

5.1 The respondents' background information

The largest group as respondents' reception activities as a branch were limited reception activities with 74%. The second largest group was 13% and was wide range of reception activities. 7% were producing mainly imaging service. The other options were laboratory services 2%, and the category "other services" where the respondents could add their organization's specialization in writing. The reception activities are represented in Figure 1.

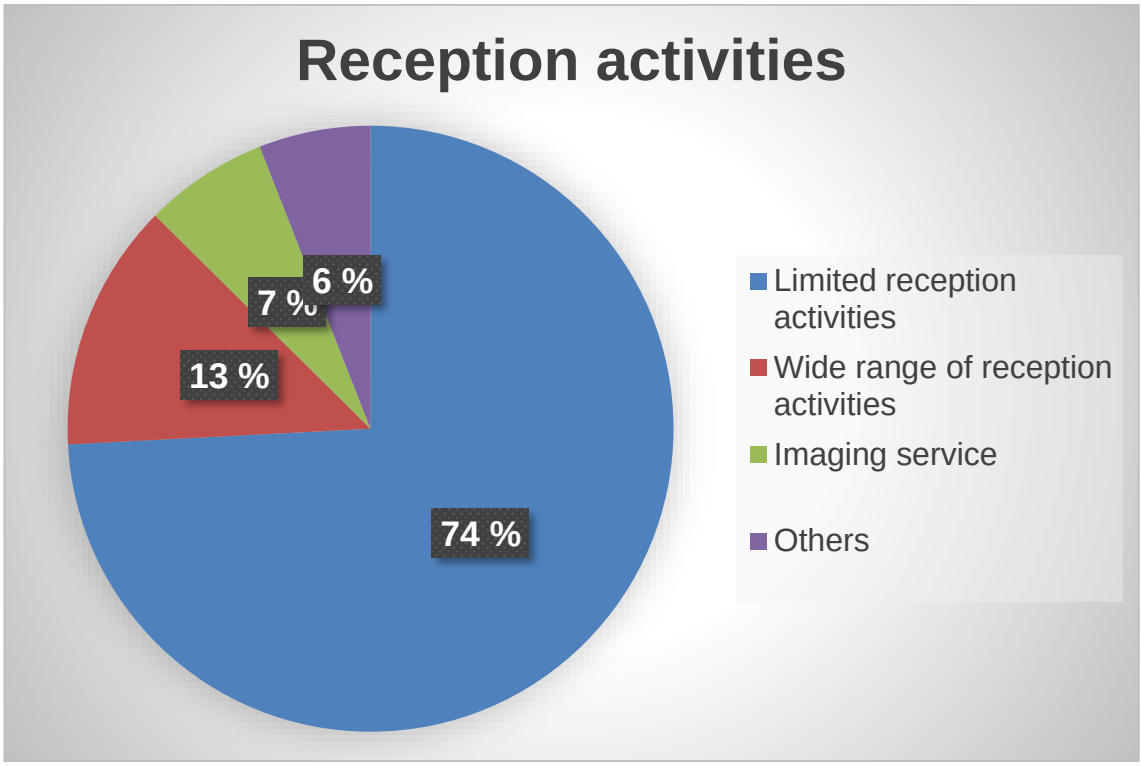

Figure 1. The respondents' organizations reception activities.

There was an open question among the background information gathered whether the respondent wanted to specify the branch of their organization. It was answered by 64%. The responds were filtrated first by the words 'dental' and or 'oral'. The responds were 19% (n=29) oral health care providers among the respondents. Using 'therapy' as a filter the result was 19% (n=29). Within

therapy branches were physiotherapy 13% (n=19) and psychotherapy 4% (n=6) and (just) therapy 1% (n=2) speech therapy 0,7% (n=1) and occupational therapy 0,7% (n=1). Other were general or specialized health care providers including both nursing and doctor's appointments by 16% (n=24), optometric branch 5% (n=8), occupational health care providers 8% (n=12). The rest of the answers were not easily categorized according to the branch they represent. Only assumptions could be made considering the images they value or produce by looking at the later answers to the questions. 36% of the respondents had not elaborated the open question. In Figure 2. are shown the most represented branches within the survey.

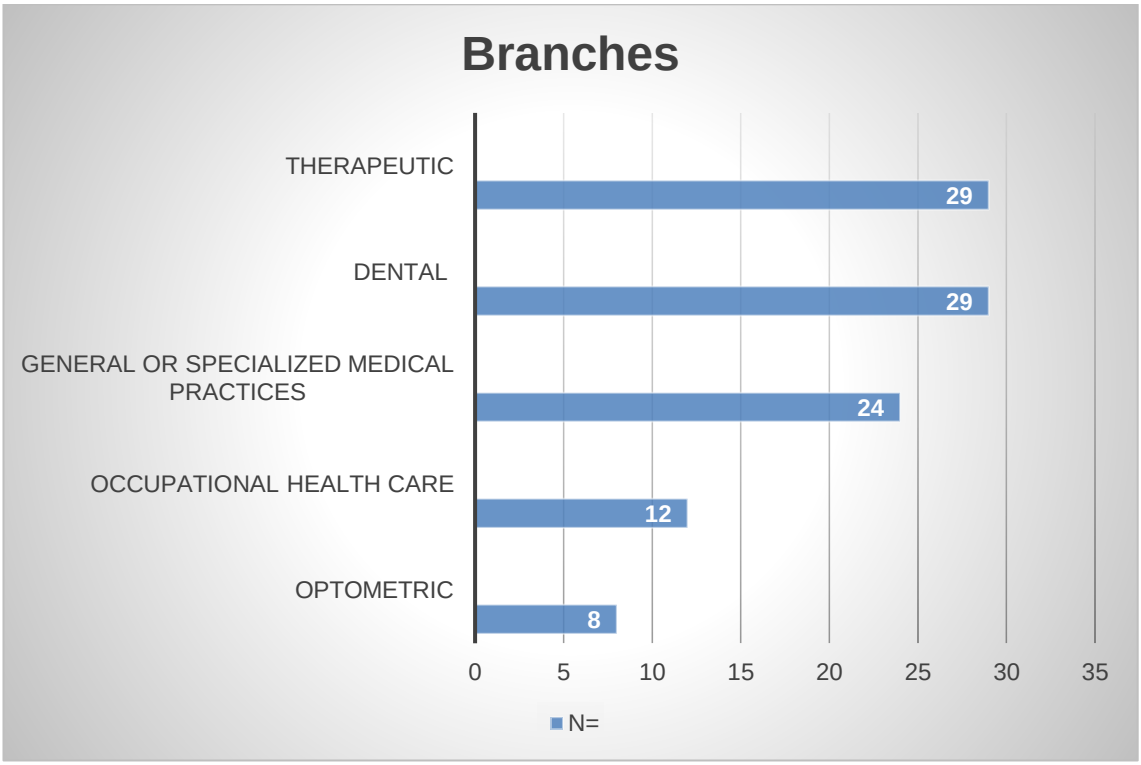

Figure 2. Different branches that were represented in the survey.

A high share of small private sector organizations as the respondents was validated as there was a question of how large businesses the respondents are a part of. Especially, how many health care practitioners (further on as HCPs) their organization have as employees. The options were 1-10, 10-50, 50-100 and 100-1000 HPCs.

74% of the respondents are from organizations that has from 1 to 10 HCPs. 19% has 10-50 HCPs and the third largest group with 1000 or more HCPs was 3%. Only 1% responded that their organization has from 50 to 100 HCPs. This finding is interesting since the presumptions on the difficulties in deploying the Archive of Imaging Data have been identified with the small private organizations in particular.

6 Data collection method

An online-survey is a data collection method. The most important factor about the data collection method is the quality of the data. Rich and complex data is a key to a broad study research. The quantity is also a matter in a data collection, but ought never to be the main focus. The criteria to a valid data for qualitative research are that the data produces enough information throughout the dataset. (Ponto 2015)

Sampling is important to plan beforehand. The target population needs to be set and the sampling frame is all the cases included to the research. Sampling ought to represent the whole population from which could be drawn generalizations in existing theory or study objectives. Sampling types can be divided in two groups, probability sampling and non-probability sampling. There are several more specific types under the main groups. Before choosing the precise type, it is important to choose from the broad type of technique. Non-probability techniques are most often used with sampling in qualitative research where a real- life phenomenon is studied. Quota sampling is one of the specific sampling techniques. In quota sampling the participants are chosen on predetermined characteristics. (Taherdoost 2016) The main goal of sampling is to gather a representative sample of the population. That is why it is important to identify the population of interest correctly, including all the characteristics of the population. (Ponto 2015)

Constructing a survey need an understanding of the relations in between the sample size and the complexity of the population. Not only the size of the

sample matters but also the aims of the research. The larger the sample the smaller the biases possibly are but there are limits to that while the sample grows. (Taherdoost 2016) Survey as an instrument of data collection is a broadly used form of collect information within the questions asked. The standardization of a survey as a method is not easy since there is no reassurance that the questions are understanded the same way, or that the respondents have the knowledge to answer rightfully all the questions. (Collins 2003)

Survey questionnaires are a legitimate approach to research a phenomenon of interest. Like other research, has survey research potential for errors but there are ways to reduce the errors. The means of avoid the bias are for instance are pre-testing of the survey, user friendly survey-design and clearly identified population of interest. (Ponto 2015)

The survey of this thesis was sent to 1430 administrative personnel's email addresses that represent a private sector health care organization. The list of receivers was gathered from Kanta Services' customer information register where the filter was appointed to private sector organizations who have deployed the Patient Data Repository besides the self-employed. Among the list were also the participants of a Kanta's info event for the private sector about the Archive of Imaging data (Kuva-aineistojen arkiston info yksityisille palvelunantajille) held in May 2023. The info was appointed to private health care provider's that were interested in deploying the Archive of Imaging Data. In addition to the list of gathered contact information and as agreed beforehand, the link to the on—line survey was sent to share amongst Hali and LPY, registered associations that are both cooperation organizations for the private health care sector. The survey was open from the 25th of August to the 10th of September in 2023. There was a reminder message sent to the receivers to respond to the survey 5 days before it was closed.

The survey was built with Questback Essentials -system into an on-line survey. Kela as an organization guides that all questionnaires that are in cooperation

with Kela, use Questback tool for on-line surveys. The execution was built by a specialist in Kela, according to the directions that I provided. The on-line survey was tested and corrected by Kanta's specialists.

7 Data analysis

The data was analyzed by qualitative content analysis. QCA is a means of categorize a collected data into themes or categories. In QCA the researcher is free to decide the level of the data analysis but it is important to compare back and forth with the whole data in order to come up with a theme of category. Previous knowledge and researches can affect positively to the conclusion about understanding the phenomenon of the research. The categories of themes are the final products of a QCA. Creativity is a useful tool for researcher to clarify the data analysis. (Vaismoradi, Snelgrove 2019)

The coding of the data of the open questions was done by first with an overall look of the responds' resemblance. Then there was an iteration of the rising themes or set of words that the answers brought up. The predeterminated coding sometimes needs to be divided into sub-codes. The coding of the data enables the data to become manageable parts that tells a complete storyline of the results. (Stuckey 2015)

With the analysis of the open-ended questions was used themathic analysis. By categorizing the sample by themes that are common to each other of reflect each other's characters is possible to define new themes or conclusions. It is possible to help categorize the themes by using tables or charts. (Saaranen-Kauppinen, Puusniekka 2006)

The material of this thesis' questionnaire was collected and analyzed by using Excel. Excel as a tool provides filtrations as the data from the survey was gathered to the tool. The proportions could be filtrated by the respondents' choices in close ended questions and the results could be calculated as percentage of the sample. To categorize the open comments by themes was it

necessary to underline the key words that the respondents had written in their responds. The theme that was most relevant was considered at the analysis if there were many different aspects that the respondent commented.

8 Results

The results of the study are presented by the order they were asked in the survey.

8.1 Why have the organizations not deployed the Archive of Imaging Data

7% (n=11) of the respondents had joined the Archive of Imaging Data already. 92% (n=139) had not yet deployed the service. There was one respondent that did not fill in the question. It is possible that not all HCPs know whether their organization has or has not deployed the Archive of Imaging Data.

93% of the respondents has less than 50 HCPs in their organization. This applies to the concerns about the challenges that may become from the multiple systems required to deploy the Archive of Imaging Data. Yet, the most common reasons that the respondents answered to question ‘why they have not yet joined the Archive of the Imaging Data’ is by 46% “do not produce radiologic images”, 32% “do not have enough information” and by 24% “do not have a PACS system”. There was possible to apply multiple options to the question.

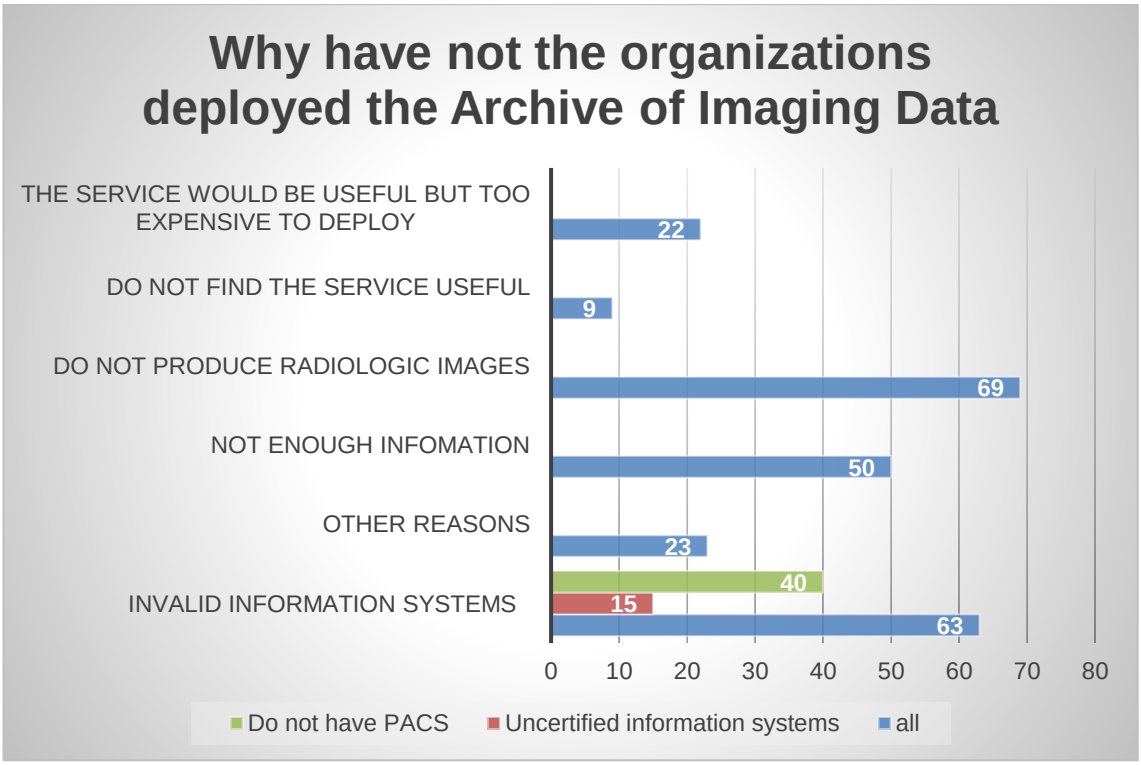

Figure 3. The reasons the organizations have not deployed the Archive of Imaging Data.

Within the question there was also an open part where the respondent could fill out more specific why they have not joined the national Imaging Service under the respond “other reasons” (n=23). The most common were related to “not enough knowledge” (n=5) or “not need for the images within their provided service” (n=5). Other answers (n=13) concerned the updates of the organizations’ information systems and that the process of deploying the service is on already.

As the Figure 3. shows, 46% (n=69) applied that they do not produce radiologic images and that is why they do not have deployed the service. This population especially is the one that is under observation when it comes to the possible new technical interface in the Archive of Imaging Data, at least if they produce other images or content that need to be archived nationally by 2029. Of the 69 respondents that do not produce radiological content, 22% (n=15) still utilizes radiologic images and ultrasounds 19% (n=13) within their work even if they do not produce such images. 33%(n=23) think it would be either very important or

rather important to be able to view other organizations' radiologic images and 25% (n=17) other organizations' ultrasounds.

25% (n=17) of organizations that do not produce radiologic images needs to view visible light images and video material is relevant to view for 13% (n=9). 17% (n=12) of these organizations need to view drawings within their operations. When it comes to utilizing other organizations' visible light images, 26% (n=18) thought it was very or fairly important with visible light images and 16% (n=11) with videos.

The utilizing is not mandatory but the archiving nationally other than radiologic contents is by 2029. 30% (n=21) of the organizations that do not produce radiology still produces other imaging content. The largest group of produced content is with visible light photodocumentation 17% (n=12), 9%(n=6) ECG, 9% (n=6) videos and 9% (n=6) drawings. 6% (n=4) were producing optometric imaging which, like videos and drawings, are under the category of visible light imaging in general. Only ECG of these is not categorized as visible light imaging, and what is possible to archive nationally already, if the system requirements are met. The procedure is the same as with the radiologic imaging. The visible light content is to be decided yet whether the workflow with the archiving is going to be the same or is there another possible set of specifications needed. The roadmap for archiving the optometric images is published already. In the Figure 4. is represented the number of respondents that do not produce radiologic imaging but are going to have to archive their other produced content by 2029. The roadmap for archiving the visible light images excluding the optometric images is yet to be decided.

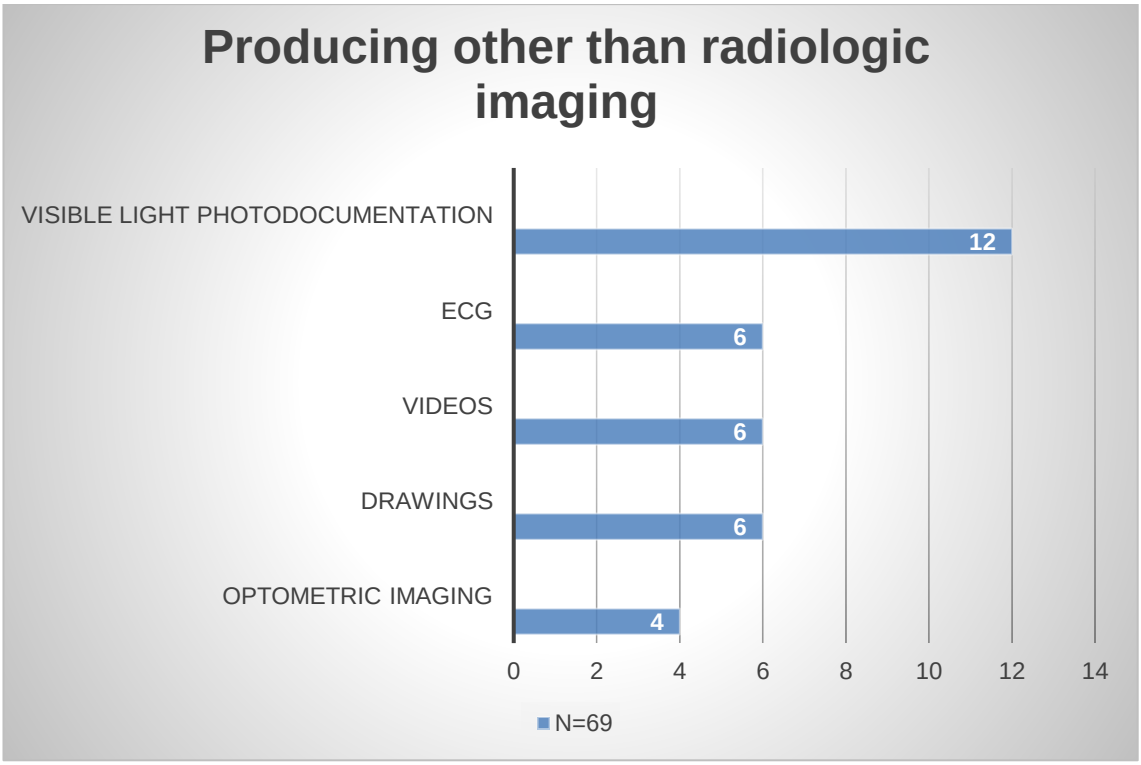

Figure 4. Producing other than radiologic imaging.

8.2 Utilizing the Images

Utilizing nationally archived images demand at the moment a certified viewer and other related systems' combination attached to the Archive of Imaging Data. In the Figure 5. there are underlined the numbers that appeared the highest in the survey to questions about the utilizing and producing certain content currently and if it was important to be able to utilize them nationally via Kanta.

Content	**Utilizes (n=151)**	**Produces (n=151)**	**Important or (fairly important) to view other organizations' content**	**Important or (fairly important) that others can view your content**

Radiologic images (other than below)	41	12	30(+13)	12 (+6)
Ultrasounds	32	16	25(+11)	10 (+8)
Mammography screening	13	6	17(+3)	7 (+3)
Oral radiologic images	56	48	38(+20)	25 + 25
ECG	24	14	20(+10)	16 + 6
EEG	7	4	12(+6)	3 +2
EMG	10	5	15(+8)	4 +4
Other signal reports	13	9	9(+9)	4 +9
Optical imaging	14	12	8+(9)	4 +9
Visible light photodocumentation	38	32	18+(21)	14 + 16
Digital pathology samples	6	2	5(+6)	1 + 3
Drawings	17	12	11+(8)	4 + 6

Table 2. List of different imaging content's utilization.

From Table 2. can be observed that all listed content has been in use in the respondent's organizations. The underlined contents were in most asked categories the same modalities. Oral images, both x-rays and visible light, were among the most used. ECG and ultrasounds in addition to traditional x-rays were also in the highest categories of utilization. Visible light photodocumentation is also considered as valid content category for most organizations.

Table 2. shows that all content got more support when it comes to view others' images than that their own stored images were to retrieved from Kanta to other organizations' use. The private, often small organizations may benefit from other organizations' stored data more as their own operations may not hold the comprehensive information about the patient.

8.3 Utilizing of oral images

Oral images, both radiologic and other were among the highest at all questions. The level of utilization of imaging within the dental health care is high already, locally as Figure 5. shows: 37% (n=56) utilizes oral x-rays and 25% (n=38) other oral images. 38% think it would very important or fairly important to be able to view other organizations radiologic oral images and 29% other oral images. These were among the highest categories of utilization and the potential for the national use of images is suspected to be high as the archiving them to Kanta become possible.

8.4 Utilizing of visible light images

Visible light images are another category that has high numbers in each question. In the survey the video and audio contents were asked in different categories but as well as drawings, could video and audio recordings be added to the visible light category. 25% (n=38) of the respondents' organizations view visible light images like photographs. 26% think it would be important to view others' visible light photos. Drawings, video and audio recordings all got

support when asked of the importance of being able to exchange the data via Kanta.

8.5 Utilizing of radiologic images

Radiologic images are concerned as valuable to many operations. Especially the utilizing of other organizations' radiologic images is considered as important by 28% of the respondents (very or rather important) even not all of them produce themselves. Ultrasounds that are a part of the radiologic content, were utilized currently by 21% of the respondents. 24% thought that it would be very or rather important to be able to utilize other organizations' ultrasounds via Kanta.

8.6 Producing imaging content

As a comparison to hypothesis that the same organizations that produce certain content would utilize similar content, was an analysis made of from the respondents' answers in the questionnaire. Below in the Figure 6. is presented the numbers that show the results of this data. 51% (77) of respondents produce and utilize exactly the same content of images that they produce. 7% (n=10) produce and view partially the same contents. 13% (n=20) of the respondents do not produce themselves the imaging content they need to utilize. Only one (n=1) produces content that they do not consider to be valuable to view by others. 28% (n=43) of the respondents' organizations do need neither to produce or view of any content at present.

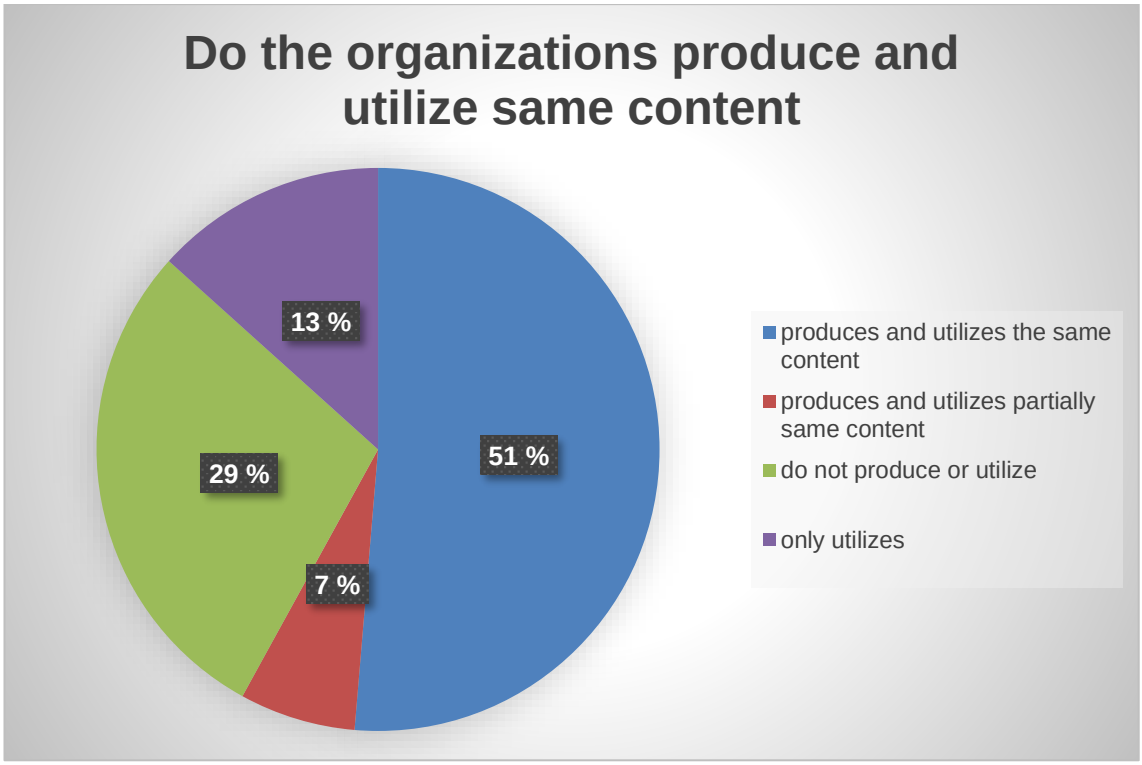

Figure 5. Organizations produce and utilize same content.

The Client Data Act requires the health care organizations to archive (other than radiologic) images and other contents in Kanta by October 2029. The other utilization via Kanta is up to their need and their systems' capability but not mandatory. Producing images and other content was asked of the respondents by first how many HCPs produce listed contents and then how important it was that the other organizations would be able to view their archived contents. The Table 2. shows that the most important content considered to be able to be exploited by other organizations are oral images, ECGs and visible light images.

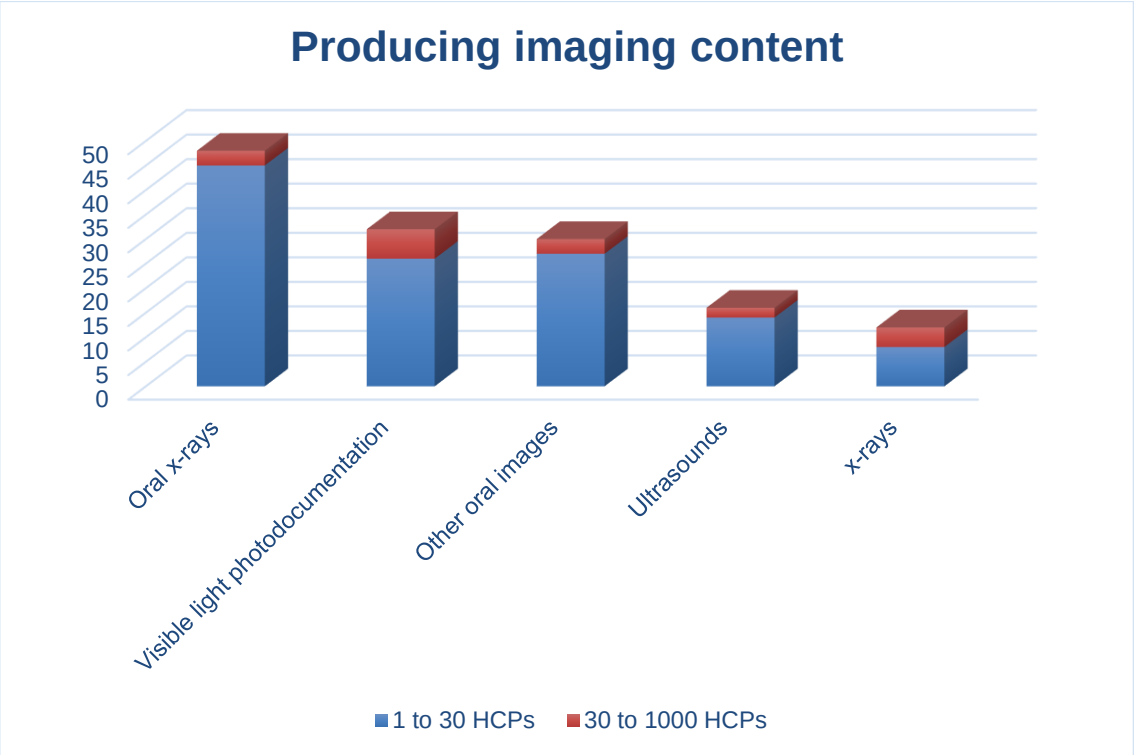

Figure 6. Producing imaging content.

In the Figure 6. are observed the contents that had most responds on the producing aspect. Noted was the fact that in all categories mostly less than 30 HPCs produce certain content which means that for those HCPs ought the certified systems' configuration be made in order to be able to archive in Kanta. The most produced content was oral x-rays that 30% of respondents produce. The next highest number had visible light photodocumentation by 21%. Other oral images were produced by 20%, ultrasounds 11% and x-rays 8%. In addition to the observed contents in the Figure 6., ECG was produced in 9%(n=14) of the organizations and Optometric images in 8% (n=12) of the organizations. The rest of the modalities had less producers but all listed modalities had producing organizations, even the digital pathology images (n=2).

According to the responds, 58% (n=88) of the organizations produce at least one of listed imaging content currently. This population includes the potential clients of the Archive of Imaging Data within the next years. At the moment the deploying process to join the Archive demands a lot of support, advanced

preparations and time not only from the client organization but also from Kanta's specialists and production system. If the same proportion of all the private sector's health care organizations that the survey was sent to (n~1500), produce imaging content and are obligated to join the Archive of Imaging Data by 2029, would the amount of organizations joining be approximately 870. This would hypothetically cause a dramatic change in the production of the Archive but also requires many changes within the processes of the deployment not to mention the management of the customer information that are manually gathered at the moment. Currently the production carries of 11 private sector's images and of 16 Wellbeing Counties' images. Even if the big Wellbeing Counties probably take the largest share of the medical images in Finland, would this matter of expanding affect many aspects in Kanta.

8.7 Where are the images and other content stored at present

54% (n=81) responded to an open-ended question "where are the images and other contents recorded at the moment?". The responds were sorted by themes that rise from the written sentences. There were various methods of recording the images. According to the responds not all HCPs know necessarily the process of recording the data and are not involved with the decision making when it comes to the data recording.

The most common respond was that the images and such content were recorded to the organizations' own EHR system (n=29). 7 out of the 29 respondents claim that the images were recorded to the EHR as an appendix. PDF file was mentioned as one example as the form of the appendixes.

21 respondents replied that in their organization the images and other contents are recorded in their imaging system. Systems were referred as PACS, or by the product name of the imaging system. Only one (n=1) respond was that they archive the images both to their PACS and nationally to the Archive on Imaging Data. (Diagora, DTX, Romexis)

12 out of 81 responds reveal they record the imaging content to a cloud-based server. The filter “cloud” was used in Excel and in addition to that the names of the information systems had to be investigated by visiting their web pages. The aim was to find out whether the system was cloud based or a local database system. (Sidexis, Commit, Optomed saas, Tietoevry saas, Planmeca Romexis)

External hard drive was (n=6) used as well to record the imaging content. 5 out of 6 respondents explained that their organization has another platform to store the images so the external hard drive was not usually exclusive to the other.

Imaging content was archived in local database in 10 of the responds. In these responds were not mentioned more specific the system or form of the content.

Four (n=4) were representatives of organizations that give the images to the customer to take with, for instance burnt in a CD or in an electric format.

Other responds were that the imaging content is not recorded at all, paper archive, computer memory, and not producing any imaging content so there is no need to record them.

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Other responds were that the imaging content is not recorded at all, paper archive, computer memory, and not producing any imaging content so there is no need to record them.

This is the potential for the storage of the images and such content for the Archive of Imaging Data as it nationally has to have the capacity to store all images produced within the health care. At the same time the costs from storing would be addressed to Kanta Services from the health care organizations.

8.8 Comments about the process of deploying the service

Open comments of the process of deploying the Archive of Imaging Data were received from 31 respondents. The comments were from one sentence long to multiple sentences that contained various aspects or opinions on the deployment of the Archive of Imaging Data.

Themes	**N=31**
More information needed about the deployment	5
Important to join the service	6
Easier deployment process	5
The project is time consuming and (or) expensive	3
It would be important to view others' images	4
Private-public sector collaboration needed	4
The deployment is not relevant for the organization	3

Images as PDF-files	1

Table 3. Themes from the open comments of the deployment.

In Table 3. is represented the themes that could be shown from the comments about the joining the Archive of Imaging Data. Among the comments was valid information about the respondents' organizations' situation with the imaging. Especially the physiotherapy organizations think it would be useful for them to view the MRI's or x-rays of their patients in order to provide high-quality care for them. There were also several comments about the system suppliers lack of knowledge about the national services and about the fact that when the information system has to develop more component is the prize of the service always higher for the health care organization to buy. The information about the development of the national services were requested to the health care organizations not only to the system suppliers. Some respondents suggest to channel the cost of the deployment of the service to the Wellbeing Counties. There was a comment also if the nearby Wellbeing County has not joined the service, may the benefit from deploying the Archive be limited for a small private health care provider.

The need to develop the national service is inevitable. At the moment only radiologic workflow is in production use in the Archive of Imaging Data. By 2029 there are many other imaging modalities that need to be able to archive in Kanta. Making new specifications take time and effort in addition to evaluate how are the new contents to be archived. Kanta's responsibilities are the technical workflows and architecture design, the deployment process with it's support and the joint testing. From this Thesis' findings there are many things to consider in order to fulfil the Client Data Act's demands. The health care professionals need to be involved when developing a service that they use for the patient care. The findings of this thesis show that the HCPs have the need to utilize more of the imaging content via Kanta.

8.9 Need for more information about the deployment of the Archive of Imaging Data

According to the findings there were responses on short of knowledge about the Archive of Imaging Data. “Not enough information about the deployment” was the second most popular respond when asked the reasons why the organizations have not deployed the Archive of Imaging Data yet. In addition to that the short of knowledge came up in responds for the open questions multiple times as well. As described in the background Kanta’s responsibility is to inform the organizations about the legislations by training for instance. It is also a part of an organization’s own accountability to follow national instructions on utilizing health data. The third party are the system developers that ought to follow the legislations in Finland concerning the health data exchange and make sure their customer organizations know the regulations and how to use the system.

The correlation of the three parties, health care organizations, their information systems and the national authorities may need evaluation in the future. As stood in one of the open comment of the deployment to the archive, is it more of the health care organization’s responsibility to demand their system supplier to provide mandatory part to meet the regulations or the system’s liability to build new extensions and sell them to the organizations as mandatory? Also, the information about the development is often given to the system suppliers by Kanta since they have the technical understanding. The organization’s administrative personnel must be taken into the decision making and information about the development of the national service. Therefore, Kanta could have regular events for the private sector organizations about the Archive of Imaging Data and its’ development. The resources within Kanta must be evaluated as there is gap of information needed among the client organizations. The means of informing the clients need futher observation.

According to the numbers of this study show that there is, at least potentially, a great amount of organizations that ought to deploy the archive of Imaging Data by 2029. The process of the deployment needs renewing as it was considered

as complex and time consuming by the respondents. Easier deployment is not only the system's capabilities but the administrative protocols that at the moment take time and effort. In small organizations it is possible that the same staff handle the administrative and the patient care. A smooth deployment process with minimum time from the field of care could motivate the organizations to the process according to this Thesis' results.

The dental care organizations are motivated and a large group of private organizations to deploy the Archive of Imaging Data within the next years. As the data shows, are the oral images valued to be utilized via Kanta in the future. In order to make the organizations to deploy, ought the information about the specifications drift to the system suppliers of the dental organizations, too. Cooperation is needed in between Kanta and the private sector organizations and their system developers.

There was a high demand of utilization of the visible light photodocumentation. The roadmap for some of the visible light images are yet to be decided but it is anticipated according to this study. The Digital Pathology images were in rare use still but mammography screening seems to be valid for some organizations. These contents need a plan nationally of how to store and utilize them by 2029. Optometric organizations like opticians would value the utilizing of optic images taken elsewhere. The deployments of the visible light category of imaging content starts with the fundus images. The joint testing for the opticians' systems is expected and required as only organizations that have already deployed the Archive of Imaging Data can start to store fundus images in 2024.

9 Discussion

According to the survey's results the utilizing of various images in health care is considered important. Mostly the images that represent their own branch are valued to view but also many find valid to be able to utilize other general information like patient's previous ECG. Interesting is that many organizations that do not produce any images seem to find crucial to be able to utilize other

organizations' images via Kanta. At the moment there are no organizations that have joined the Archive of Imaging Data such as a viewer of other organizations' images. This is something that is valid to observe nationally whether it would be worth supporting in order to increase the utilization of images stored in the Archive of Imaging Data.

Common use of Kanta Services is within the private sector's health care providers and an easy retrieval of patient data is expected. This applies to the Archive of Imaging Data as well as the respondents insist on quick query on specific patient's images within the open questions. This is not possible necessary currently since the retrievals of a patient's image queries take time depending on the search criteria and the available data and because of the features of the used standards. There are different standard possibilities for the retrieval of imaging content for the future development.

The PDF or such files are requested by many respondents to be able to view from their EHR or web server via Kanta. An inexpensive possibility to join the Archive of Imaging Data as a utilizer should be appraised by Kanta in which the demand of several information systems would not be necessary for the organization. As described in the purpose and aims of the study, would a modern FHIR-based metadata retrieval and a RESTful architecture be one way to bring the images to nationwide use. This evaluation needs more research if it would be possible to have such an alternative interface to the existing architecture of the Archive of Imaging Data. The current architecture in production work for those joined already.

The European Health Data Space is regulated data exchange service for the EU Members. As Finland is a Member of EU, should national health data services adapt to those regulations regarding the EU. Medical imaging is named a category of EHDS priorities to be accessible for other Member States. This needs to be acknowledged when developing the interfaces of imaging exchange in Finland. Interoperability standards are mostly open and

international. To enhance Finnish exchange of health care images should be considered to go hand in hand with the goal of EHDS an it's processes.

9.1 Recommendations for future studies

From this Thesis' findings can draw conclusions about the need for both information but also easier facilitations of the imaging service are required by the private health sector. In order to develop the technical architecture is further research needed. By interviewing the representatives about their situations with their system development and plans to proceed the utilization of the images could be next part of the technical development. The different branches represent similar kind of process with the utilizing of the imaging content so the interviews could be by group interviewing.

Another aspect is to inform better the private sector about the Archive of Imaging Data. The current methods may need deeper observation since there is not enough knowledge of the national regulations at present. Evaluations about the methods used now could be processed and consider if some need changing.

As an obligatory service for the health care providers but also for the system developers, has the supervisory authority been rather quiet. There could be a reason to research the supervision of following the legislations of the Client Data Act in the future.

10 Main results

This study reflects the current state of the private sectors' situation of the medical image utilization. The Archive of Imaging Data is not widely used by the private sector at the moment. The most common reason to private health care organization to not have deployed the Archive of Imaging Data is that they do not produce radiologic images and the law at the moment does not apply to them. Yet there were more than half of the respondents that referred that their

information systems were invalid for the deployment. The knowledge of the process of implementing the Archive of Imaging Data is not high and there is a lot of work to do within Kanta Services to respond to that need.

The results give proper feedback from the private sector for the development of the service as the Client Data Act requires them to archive the other than radiologic images by 2029. For the future the technical development would increase the utilization of the Archive of Imaging Data as the deployment would not demand too much resources from the organization. Easy directions and informing of the clients and their system developers may be the keys to enhance the utilization of the national service. The benefits of the Kanta's imaging service as the other services are for all heath care and citizen and that is why the customer information is valid in all phases of development.

11 Critical assessment

The study was conducted according to Kela's guidance and according to Metropolia's guidelines for master's thesis.

11.1 Reliability and Validity of the collected Data

The Data gathered was adequate to make some assumptions of the private sectors state about imaging. The response rate (0,1) could have been higher. There is no information about the respondents if they are from Kanta's current client lists or from the registered associations that may have not deployed any of Kanta's services yet.

The data collected had representatives from all the imaging categories that the official roadmaps for Kanta's deployment have been recognized. The private sector representatives were from very small to large organizations which could imply that a wide scale of private sector organizations in size was included to this study.

In general, the data gathered was consisted with the presumptions of the situation of private sector's imaging from the preliminary information that Kanta had from system suppliers, the Info Event in May and other client encounters.

12 Trustworthiness and ethical considerations

Within the survey there was not any personal information of the respondent. Even the name of the organization they represented was left out of the questions. The list of whom the survey was sent to was collected from Kanta's register. Privacy Policy for Clients using the Kanta Services points out that the use of the register is allowed when making research that aims to develop the services. (Privacy policy)

The thesis report was submitted to turn-it-in service that checks that the report is free from plagiarism.

13 Limitation of study

The survey was supposed to have an easier layout with a table that the respondent could mark in one table the different questions about the list of imaging content but due to technical matters with the on-line survey were the questions separately. This may have added time to respond the survey inconveniently and possibly caused the decrease of the interest to apply the survey. There were a few inconsistent responds among the data which can also imply that the survey was either too long or hard to follow. Better pretesting of the survey may have reduced the limits from the time consuming. It could have increased the amount of respondents, too.

14 Conclusions

This thesis was conducted to find out why have the private sector not deployed the Archive of Imaging Data and to gain more customer information about the

private health care organizations that utilize medical images in order to develop of the national service of exchanging medical images. Three main things rose from the study: there is not enough information about the national service and its' requirements, and on the other hand even if having knowledge of the possibilities that the national Archive of Imaging Data could bring to the private sector organizations, the complexity of the deployment is hard to implement according to the current specifications. Thirdly, not all organizations produce radiologic images which are currently mandatory to store nationally but the ones that do have difficulty to meet the standards of the deployment. There is definitely a demand for development and an easier layout for the archiving and exchanging of the medical images in Finland.

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Appendices

The survey

The first questions were about background information.

1. How would you describe your organizations' activities as a health care provider?
()wide range of reception activities
()limited reception activities
()laboratory
()imaging services
()other services, what ? _____

2. How large is your organization by the amount of the health care providers?
() 1-10
() 10-50
() 50-100
() 100-1000
() over 1000

With these starting questions were meant to categorize the respondents either by the size of the organization of by the branch or activities they represent.

3. Have you already deployed the Archive of Imaging Data?
()yes
()no

If the respondent replied "no" to this question was the next question number 4 and if they responded "yes", was the 4th question skipped since it concerns the reasons why they have not joined the Archive of Imaging Data.

4. What are the reasons that your organization has not deployed the Archive of Imaging Data?
()The systems we have are not certified
()We do not have a PACS system
()Invalid electronic information system/no system at all
()The service would be useful but the expenses are high
()The service is not beneficial, why? ____
()Do not have enough information about the requirements of the deployment
() W edo not produce radiology
()Other reason, what? _____

There was possible to fill in multiple options. The open comment had limited space approximately for a couple of sentences.

The next section of the survey listed different types of imaging content as below.

Radiologic images
Ultrasound
Mammography screening
Oral radiologic images
Other ora limages (inc visible light images)
ECG
EEG
EMG
Other signal reports
Optometric imaging
Photodocumentation
Video recording
Audio recording
Patology
Drawings

5. question was to respond how many of the organization's health care practitioners, first utilizes the listed content and second, produces them, at the moment. Each content was to respond from scale:

()1-5
()5-10
()10-30
()30-100
()100 or more HCPs

6. question had the same list of different imaging content as in the question 5. and the respondent was asked **if it would be important that the other organizations would see their produced content via Kanta?** Secondly **if the respondent thinks if it would benefit their organizations to be able to utilize other organizations' specific content via Kanta?** The scale was:

1. Very important
2. Rather important
3. Not important
4. Does not apply to to our operations

The survey had two more following questions that the respondent could apply in their own words. There were not limitations in word account.

7. Where are the images stored currently in your organization?

8. Other comments about the deployment of the Archive of Imaging Data.

The cover letter of the survey

A survey to private sector health care organizations regarding the development of the Archive of Imaging Data.

Dear representative of a private health care organization

With this survey we are gathering customer information about the deployment of the Archive of Imaging Data, one of the national Kanta Services. Especially the private sector health care providers' utilization of the imaging service is our target of gaining customer information. According to the situation in the organizations we aim to recognize the challenges with the deployment of the Archive of Imaging Data and to clarify the need to develop the service.

The need to develop the service has been recognized within the Kanta Services and there is an investigation launched in order to make the national imaging service approachable to the private sector as well. Archiving the radiologic images has been mandatory since 31.12.2019. According to the new Client Data Act archiving other imaging content than radiologic will be mandatory by 2029. Both private and public sector health care providers are under the legislation.

This survey is a part of a Master's Thesis for Health Business Management studies. The research permit has been granted. All the gathered data is processed confidentially. When complete, the Thesis will be published in www.theseus.fi. The instructor of the Thesis is Product Owner Sanna Perälä.

This message has been sent to private sector health care organizations' representatives. Some of the contacts were gathered from the client registration of the Kanta Services. In addition, the survey was sent to Hali and LPY registered associations to share.

Please feel free to share the survey to a person that is involved with the imaging in your organization.

You need approximately 10 minutes to apply to this survey. The survey is open until 10.9.2023.

LINK to the survey

email: kanta@kanta.fi

Thank you for your respond!

Best Regards, Kaisa Huitti, Kanta Services