IHE THE NETHERLANDS
Integrating the Healthcare Enterprise

IHE Guideline

The Transmural Tumor Board Review

Breast Carcinoma

based on national and international standards

Foreword

Optimal care in networks, personal integral care, joint decision making, digital exchange, reducing registration burden and the financial pressure on the care system requires cooperation and interoperability. Despite the urgency, almost every healthcare network or cooperation struggles with the lack of interoperability. Digital data exchange is difficult. Processes do not connect with each other. Systems do not "pair". Healthcare professionals do not understand IT specialists and vice versa.
The transmural multidisciplinary Tumor Board Review (TBR) is an important process where care providers from different disciplines and organizations discuss medical treatment options with each other (with or without the patient). This is to provide the patient with the most appropriate treatment possible. To achieve an appropriate plan, it is important that the patient's medical data, the medical guidelines, the knowledge, the experience of the specialists and the patient's needs and capabilities are gathered and are available for the TBR. Cooperation and interoperability at every level therefore plays a major role.

At the request from the IHE Netherlands, this document was produced in Dutch in May 2020[1] and translated on request of IHE Europe in November 2021. The authors were asked to further develop the thoughts from the "IHE Work Group on healthcare processes" into a guideline that provides concrete guidance for interoperability at the level of technical standards for TBR. The document is written for a broad public of healthcare givers, directors, policy makers, information managers and IT suppliers.
The aim is to provide a solution, based on current technological standards, to the many initiatives from VWS, IKNL, NVVR, NABON, the cooperate organizations in the Task Force Oncology and the Citrienfonds program "Towards regional oncology networks". In this way, there is room for innovation in the regional, national and international oncology networks without lock-in technical suppliers. The authors also hope to contribute with this document to the knowledge base on digital exchange, an initiative from the Citrienfonds.

By sharing knowledge over a structured approach, which is a set of the current standards, independent from vendors. We are pragmatically seeking to accelerate the necessary interoperability in the healthcare process. The aim is to speed up the digital connections with all who are concerned in regardless of which networks, by applying current available standards. We bring together relevant standards and establish the inter-relationships. The healthcare process "Transmural TBR Breast Carcinoma" has been chosen as a concrete example. For the development of this guide we have adopted the following principles: Healthcare process as a starting point for standardization, to cooperate as much as possible with the (inter)national reusable and neutral building blocks, independent from suppliers and infrastructure.

We would like to thank everyone, who was mentioned[2] and those who were not mentioned, who contributed to this document, in particular Hans Buurman (IKNL), Lidy Wijers (Hospital Alrijne), Floor Klijn (IKNL), Carla Meeuwis (Hospital Rijnstate) and Fabrizia Ketelaars (MUMC+).

November 2021
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[1] *https://ihe-nl.org/wp-content/uploads/2021/05/IHE_MDO_en_Addendum_17_mei_2020_StatusDefinitief.pdf*
[2] *See Page 62*

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1. INTRODUCTION

The transmural multidisciplinary Tumor Board Review (TBR) has been chosen as an example of a care process, to develop this document. This is because it is one of the priority processes identified by the Dutch Minister of Health, Welfare and Sport (VWS). A large optimization of this process can be achieved by using existing standards and IHE profiles[3].

Not only Board Reviews are used in oncology, but also many transmural multidisciplinary Board Reviews are used within other healthcare domains such as in surgery and healthcare for the elderly. The number of Tumor Board Reviews is increasing, as is the importance of efficient digital support for this healthcare process. The Tumor Board Review (within an institution) is not being described in this guideline. However, there are similar problems with the data exchange between information systems.

In the Netherlands, an average of 120.000 new patients with cancer are treated annually (2018, www.oncologie.nu). Each of these patients are discussed three or more times in a Tumor Board Review. That is 360.000 patient reviews for Oncology alone per year. Thanks to the application of echelons in cancer care (to adopt the level of complexity of a Tumor Board Review to the needed care), in which hospitals are divided into different expertise levels, the effective use of the available expertise becomes possible[4]. The more complex the healthcare demand, the higher the echelon and the more specialists or experts from different locations will participate.

A (transmural) TBR is a well-organized and disciplined consultation. Prior to such a TBR, the patient data is collected. For a smooth transmural TBR the relevant medical data of the patient is necessary. Therefore data exchange between different healthcare providers in a timely manner a requirement. A TBR is usually within regional partnerships but can also run outside a region, especially in the case of rare tumors. During the TBR, adequate reporting is carried out for healthcare as well as clinical studies and quality registrations. Specialists from different disciplines and organizations are brought together (virtually and physically) to discuss treatment options for the patient. Interoperability[5] therefore plays an important role here.

Collecting the required information for the TBR still seems to cost a lot of effort and is often a (too) lengthy process. This presents unwanted risk for the patient and is ineffective, particularly with the use of expensive resources. If we want to treat more patients optimally and within the same budget in the future, then flexible digital support is essential. The TBR is very important for decision-making on diagnosis and treatment. After all, it is decided during this consultation that vital, patient-related treatments are often drastic and expensive. If the use of echelons within the TBR is established, then we see improvement in the quality of healthcare that is in line with the clinical guidelines. This is also expected to save costs. It is therefore clear that for the success of a TBR, the desired information is available in a timely manner at the desired location for the right person.

[3] *An IHE profile is an elaboration of a defined set of standards for and certain healthcare processes in order to make system integration easier.*

[4] *Program to Regional Oncology Networks, Citrienfonds.*

[5] *Interoperability is the ability of organizations (and their processes and systems) to effectively share information with their environment.*

In this document we describe a working method for deploying standards. The healthcare processes are ('use cases') hereby built up from various standardized process steps (sub-processes). The information and application standards and their consistency are described in each sub-process. In order to come up with a vendor-independent but interoperable solution. In this way, the right information will be available to those involved at the right time in the process. A healthcare organization thus has the freedom of choice for applications within the framework of the standards.

In the following description, the healthcare processes ('use cases') are in the lead and made to be used as much as possible from the layer model of Nictiz[6] to structure the process and the underlying necessary standards. We make it clear how the layers can be filled in independently of each other and how they work with one another.

The different (tested) standards used in the process are systematically displayed as building blocks. It will become clear to the reader that when the relevant IT suppliers build their software according to these standards and/or IHE profiles, the suppliers or their application become interchangeable. This prevents a vendor lock-in for the customer and allows the customer to choose the best fitted functionality without being bothered by interoperability problems. This document shows that the application of standards and/or IHE profiles not only supports the smooth running of healthcare processes, but also that the use of standards can accelerate innovations.

In this document, we limit ourselves to the technical support for the transmural TBR process based on the necessary standards; HL7 FHIR, CDA, etc. and the IHE – profiles. In this document we do not go further into developments concerning legislations, decentralized healthcare infrastructures (Nuts[7]) and data governance (data ownership). We also leave the issue of patient identification (use of BSN) outside the scope of this document. The usage of multi-affinity domains (reads: multiple linked XDS environments) is explained in more detail in the Addendum as requested specifically by suppliers. The Addendum also includes a recently described profile available for public comment. This in regards to the IHE-MHDS profile, based on FHIR.

[6] *https://www.nictiz.nl/wp-content/uploads/Paper_electronic_information_for_health_and_care_services.pdf*
[7] *https://nuts.nl/*

2. SUMMARY

The multidisciplinary Tumor Board Review(TBR) is an important consultation for determining diagnosis and treatment. The TBR is frequently organized within oncology but is increasingly inter-related with other diseases. Experts from different disciplines discuss the best appropriate optional treatments with their medical point of views. This approach has increased the quality of care.

TBR's occur more than 350.000 times a year in oncology alone and the number continues to increase. This creates extra pressure for all participants in the TBR. Organizing a TBR is not easy.

Much work has since been done to make the organization of the Board Review, especially within oncology, as efficient as possible, for example by applying different echelons. Many healthcare providers have contributed to this.

A major obstacles in organizing and TBR appears to be collecting the medical relevant information which is necessary to share with the participants in the TBR. If this information is not available on time, a scheduled TBR may pass through last minute, which is very undesirable fnot only rom the perspective of patient safety and the healthcare providers resources, but also the high cost and the time-consuming organization of an TBR.

With a concrete example for the transmural TBR Breast Carcinoma is described how based on the current TBR process, currently applied technical standards and environments, the desired information can be brought together. This is based on the current implementation of the EHR's.

The Nictiz (five) layer model has been used as a base in which the 'process layer', the 'information layer' and the 'application layer' are described in detail. The "use case", the Board Review for oncology (TBR) with a concrete example Breast Carcinoma is in the lead. The process and underlying necessary standards are structured on the base of the five layers. Obstacles analysis shows that the process can be highly optimized if all data can easily be added during the request. Without retyping, structured in such a way that decision support systems can support the choice of the right echelons, the preparation of treatment proposals in accordance with oncology guidelines and that the quality parameters and different treatment proposals are easily linked. Registration at the source is essential, Natural language processing (NLP) could also contribute to the distill specific parameters from unstructured radiology and pathology reports and to establish a structured way at the time of a TBR.

The building blocks for the process ("process layer") around and during the TBR are fairly generic and widely applied for almost all types of TBR's. These process and quality control building blocks are described in the IHE profiles Cross-enterprise Tumor Board Workflow Definition (XTB-WD)[8].

[8] *https://wiki.ihe.net/index.php/Cross-enterprise_Tumor_Board_Workflow_Definition*

The most specific elements are shown on the “information layer”. The lack of information standards for a TBR is a major obstacle. By further standardizing on this layer, a lot of profit can be achieved. As the example of TBR Breast Carcinoma shows where the standard information has been fully developed. The NABON is the first to have a standard of information adapted to all professional associations. In the meantime, OncoZon is also busy with the information standard for Colorectal with liver metastases. This information model is essential if you want to exchange information institutionally. The program “Registration at the Source” has done a fantastic job in the field of data modeling. NABON has described together with the Integral Cancer center Netherlands (IKNL), a number of forms that can be used during the phases in the TBR. During the obstacles analysis it has become clear that the desire is to have these forms filled in automatically and in a structured manner as much as possible. By using these standards in the underlying layer, the “application layer”, this will be made possible.

At the application layer level, we see that when the applications uses the described standards and profiles, the desired data becomes available to other applications. The authors wrote the IHE profiles XDS from the “IHE IT-infrastructure domain” at the application level which makes the relation, the link and the integration with FHIR clear. They can after all integrate seamlessly together.

This will be confusing for a number of readers and requires the following explanation. A XDS “infrastructure” better known as a XDS “environment” consists of a framework of a number of software components / applications that can be delivered by different vendors. As indicated, XDS is an IHE Profile from the IHE-IT infrastructure Domain. This domain is called IHE-IT infrastructure domain because it does not belong to a clinical domain of IHE (such as cardiology, ophthalmology), but defines the connecting of building blocks between the different clinical domains. These connecting building blocks are hardly visible to the end user and are often embedded in the application or used as shared components.

Standards and profiles such as HL7 FHIR and IHE-XDS helps to automate the data to process in to the TBR. The standards are integrated in such a way that it is possible to support and connect components of the TBR from different applications and systems. For example, an EMR can send the TBR-form from its system via HL7 FHIR. The IHE integration profiles describe how to convert the FHIR bundles into XDS and XDW documents so that other XDS/XDW-based applications can continue the TBR process.

The authors argue that different standards whether or not included in IHE-profiles can be used alongside and/or in sequence with each other, depending on the “use case”. You are no longer obliged to take all applications from one vendor for the whole process and the absence of XDS is no longer an obstacle to the transmural TBR.

The XTB-WD profile which is included in this guide as a basic profile for the TBR’s, allows different suppliers to support TBR process simultaneously and relatively independently by using tested standards. However, the XTB-WD profile depends on an XDS environment. However, this does not have to a drawback, given the possibility that the new IHE profiles provide the integration between a XDS environment and FHIR. This has been worked out as a “IHE-XDS-FHIR-XDW Ecosystem in paragraphs 5.4.5. – 5.4.7.

Mentioned above are the different possible solutions depending on the situation and the “use case”, as long as they meet the standards used by the IHE – XDS – FHIR – XDW Ecosystem. For example, if the requestor does not have a directly connected XDS environment, the patient information can be transferred to the Ecosystem via FHIR-documents. Also other IHE profiles such as IHE-XDR or IHE-XDM can be used for transfer of images and reports.

The “infrastructure layer”, as referred to, in the (five) layer model, is then “not so exciting”. This layer exists of servers, firewalls, etc.. With the rise of internet technologies, the infrastructure become “gas-water-light” in other words “common business”. Through virtualization the location where the application and the place where data technically is stored, outside of legislations, privacy and security, is no longer of importance. According to the authors regulating the identification, authentication and authorizations (IAS) of users throughout the infrastructure belongs to this layer. Whether or not this is an infrastructure service or an application is not considered here.

By supporting the TBR and the process around the TBR with applications that meet IHE profiles and standards, the applications are interoperable, and the data can be exchanged. If the applications are interoperable, this means that the healthcare givers can choose the desired functionality with the specific applications that they want. All this fits in with the chosen organization and the “use case”.

By creating an IHE – XDS – FHIR – XDW Ecosystem based on standards, we realize optimization within the TBR with existing environments:

- A more efficient support in providing information for the TBR;
- Any healthcare provider can continue to work in their own application;
- The best functional solution(s) for the process can be chosen;
- TBR quality is expected to increase with relatively lower costs due to time savings;
- Data remains at the source (decentralized data storage);
- Among other things, the use of IHE profiles and FHIR documents makes data available regardless of the application in which it is stored.

3. INTEROPERABILITY AND INTRODUCTION IHE AND HL7

Interoperability is the ability of organizations (and their processes and systems) to effectively and efficiently share information in and with their surroundings.

This chapter summarizes the importance of interoperability and explains technical standards and profiles such as HL7 FHIR and IHE-profiles. Semantic standards have not been taken into account in this chapter, but are discussed in the "information layer" chapter. For the detailed discussion of this subject, please refer to the Nictiz website and the report on electronic information for health and healthcare[9].

3.1. (FIVE) LAYER MODEL

Nictiz distinguishes five layers of interoperability. Each layer has its own actors, concepts and standards. In addition, there are two peripheral conditional column that apply to all layers, namely legislations (law) and regulations, and security (including privacy). Interoperability is created when agreements on each of these layers are connected and meet the boundary conditions from the columns.

We use the five layers model as a tool for shaping the digital support of the TBR based on the currently available and tested standards.

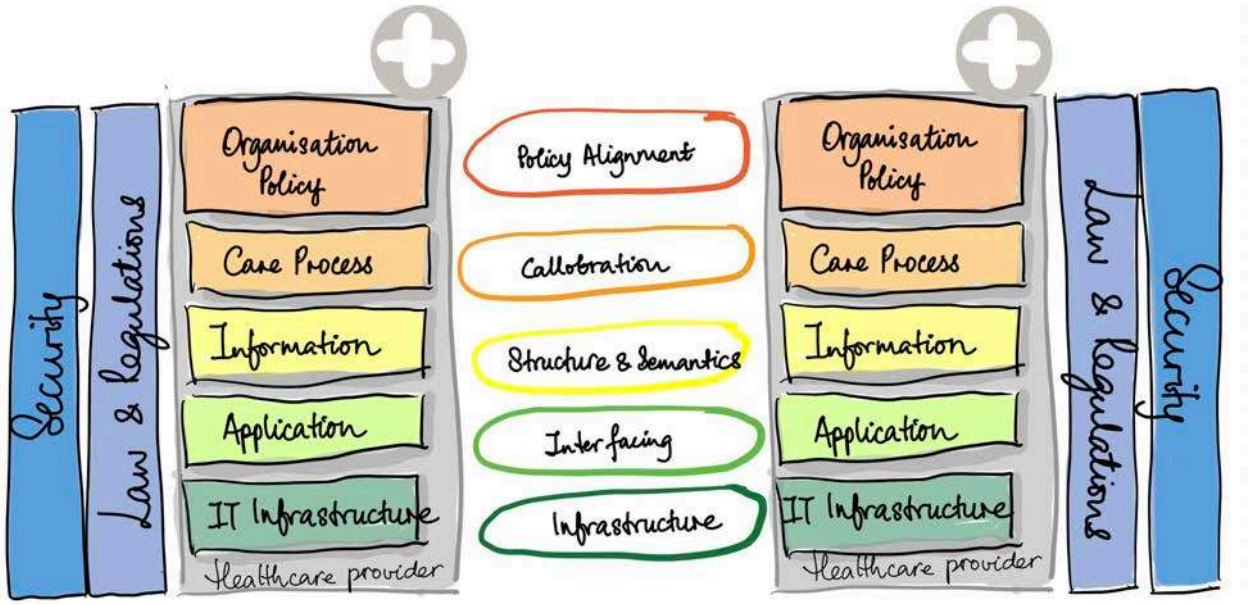

Figure 1: Nictiz Interoperability Model

[9] *https://www.nictiz.nl/wp-content/uploads/Paper_electronic_information_for_health_and_care_services.pdf*

3.2. INTEROPERABILITY

For every layer we see different actors and managers with often completely different areas of interests, such as directors, doctors, information managers and technologists. At a national level, Nictiz, the Dutch knowledge organization for digital information exchange in the healthcare, plays an important role in sharing expertise in a broad area, used as an intermediary between policy, healthcare and technology. IHE also works in its methodology from vertical coordination in order to create IHE profiles that achieve technical interoperability between systems. Solutions at a technical level must be traceable to policy decisions and not the other way around.

It makes no sense from a pragmatic and budgetary point of view to formulate a policy for solutions that cannot be made technologically. It also makes no sense to make policies whose implementation is beyond budgetary possibilities. In short, the frameworks go from top to bottom in the layered model and pragmatics goes from bottom to the top.

Technology-driven innovations are driven by technical progress/development. In recognizing clinical capabilities in newly developed technology, the healthcare process and decision-making at the organization level will have to be started first. By taking over technology-driven innovation enthusiastically, the innovations with policy and its relevance are regularly forgotten. This creates beautiful landscapes of innovations that are not interoperable within the healthcare institutions and do not contribute much to the long term goals of the healthcare facility.

This document uses the layered approach to achieve an effective and stable information-assisted organization (intra-operability) and the same layered approach to achieve interoperability between two (or more) organizational units. This is typical the case with a transmural TBR.

Interoperability requires collaboration between institutions, similar design, implementation and management strategies as within a single healthcare facility. This can only be really successful if every organization has its own intra-operability in place. In order to achieve interoperability, it is necessary that information out of the source systems can be understood and used sensibly in the receiving institution. Harmonization of collecting and storing data across institutional borders is required.

In this document, we show the TBR Breast Carcinoma “use case” per layer, how interoperability can be achieve for the provision of information in concrete cooperation within the TBR. Among other things, we use IHE- integration profiles. An integration profile describes the use and combination of proven standards per defined part (per sub-process) of the healthcare process. This is further explained in the next paragraph.

3.3. INTEGRATING THE HEALTCARE ENTERPRISE (IHE)

Integrating the Healthcare Enterprise (IHE) is an international and worldwide collaborative partnership between users and IT-suppliers in the healthcare sector. IHE is a community, it is not related to a company. Those involved in the development of the IHE domains and the working groups, work on a voluntary basis. IHE was founded in 1998 in the U.S. IHE is neutral and promotes

coordinated use of established care and IT standards such as DICOM, HL7v2, HL7v3, HL7CDA and HL7 FHIR to complete specific clinical needs for optimal patient care. This is mainly about the healthcare processes, where information exchange is essential and must flow without any problems. The first successful applications we saw was at the PACS systems in radiology (and the cd's). X-rays were carried out worldwide in a uniform manner and inseparably linked to relevant process information.

IHE process

IHE brings together stakeholders, users and developers, within a healthcare domain (e.g., cardiology, radiology, etc.) in an annual recurring process to co-create IHE integration profiles. The IHE process is an ISO-Certified Methodology[10] to identify and solve identified problems in the healthcare information exchange. The IHE-process consists of 4 steps:

1. Clinical and technical experts define healthcare processes ("use cases") where the exchange of information is a critical success factor. The "use case" in which an actual problem is encountered is thus provided by the healthcare field;
2. Technical experts make detailed specifications (IHE integration profiles) to address the communication between "use cases". Existing standards are selected and optimized. Such an IHE integration profile contains a complete description of the actors, transactions and required standards (such as HL7 and Dicom) that enable interoperability between the different systems in the defined healthcare process (the "use case');
3. The IT suppliers implement the prescribed specifications or IHE integration profiles in their IT systems/application;
4. IHE tests the suppliers systems with carefully planned and supervised events called the Connectathons.

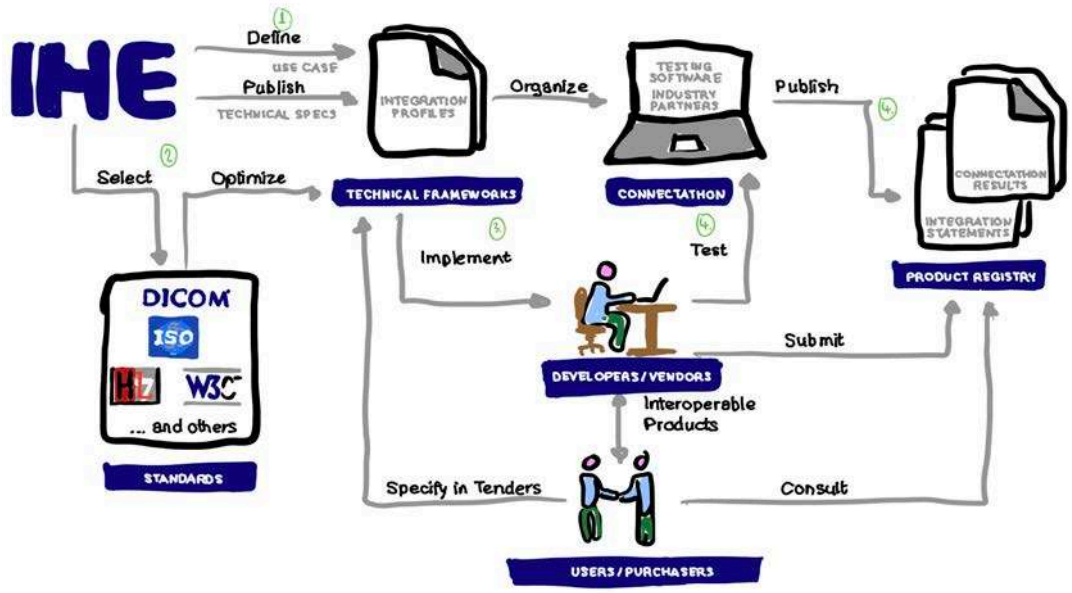

Figure 2: The IHE process

[10] *https://www.iso.org/standard/63383.html*

The results of this process are basically interoperable products based on tested IHE integration profiles. Upon positive testing of these IHE integration profiles by the supplier on the Connectathons, the suppliers may draw up an "Integration Statement". This Statement on a specific profile can be checked on the IHE website[11]. In the (European) tenders, healthcare institutions can test these statements at IHE or include them in the requirements of the tender specifications.
If suppliers use the tested IHE profiles in their applications, exchange and information flow between the different applications can run smoothly.

To illustrate, we hereby give an example of integration profiles from the Domain the "Patient Care Devices". In the IHE "Patient Care Devices" domain the data transfer is described between one or more systems that are closely connected to the patient and one or more other types of medical systems. An example in the Point of Care Infusion Verification profile (PIV) is link between a syringe pump in which the patient is administered with the medication in the hospital and the EHR of the healthcare institution. This domain collaborates and supports other domains such as with the Radiology, Laboratory and Cardiology. The sponsors of this domain are the American College of Clinical Engineering (ACCE), the Health Information Management Systems Society (HIMSS) and the Association for the Advancement of Medical Instrumentation (AAMI).

Some Integration profiles from the Patient Care Device Domain:

Tabel 1: Integrationprofiles IHE Patient Care Device Domain

Profiel	Afkorting	Beschrijving
Device Enterprise Communication	DEC	transmits information from medical devices at the point of care to enterprise applications.
Point of Care Infusion Verification	PIV	communicates medication orders to an infusion pump or pump management system.
Implantable Device Cardiac Observation	IDCO	transfers information from an interrogated implantable cardiac device to information management system.
Rosetta Terminology Mapping	RTM	harmonizes ISO/IEEE 11073-10101 nomenclature standard terms used in PCD transactions.
Alarm Communication Management	ACM	communicates alerts (alarms - physiological or technical, or advisories), ensuring the right alert with the right priority gets to the right individuals with the right content.
Retrospective Data Query	RDQ	queries archived point-of-care device observations for clinical decision support or other data analysis purposes
Infusion Pump Event Communication	IPEC	communicates clinical and technical events from an infusion pump to an information system for recording, action or presentation to a user.
Waveform Content Module	WCM	includes waveform data in IHE PCD profiles such as DEC and ACM.
Pulse Oximetry Integration	POI	guides implementation of pulse oximetry devices using IHE PCD profiles.

[11] *https://connectathon-results.ihe.net*

In the associated Technical frameworks, described in IHE_PCD_TF_Vol1.pdf[12], further details are given on a profile-by-profile basis on what should be done at the integration level and at the level of semantic content. The most commonly used standard in the IHE Domain "Patient Care Devices" profile is meanly HL7v2.

The different domains where elaborate IHE profiles are described:

- Cardiology
- Dental
- Endoscopy
- Pathology and Laboratory Medicine (PaLM)
- Eye Care
- IT Infrastructure
- Patient Care Coordination
- Patient Care Device
- Pharmacy
- Quality, Research and Public Health
- Radiation Oncology
- Radiology

3.4. HL7 AND FHIR

HL7 stands for Health Level Seven. The Global standard for secure, electronic information exchange in healthcare. The HL7's standard defines all types of data in all healthcare domains and healthcare sectors. The standard is developed and managed by the international HL7 organizations which operates in more than 30 countries. In the Netherlands, HL7 Netherlands Foundation develops, manages and aligns the standards.

HL7 is an international standard or protocol that ensures the transfer of patient information form one system to another in a correct and logical manner. Hospital systems (EHR's) must be able to share information with each other when needed. The challenge is to have a common method of sharing information, even if the patients visits multiple hospitals. Healthcare providers want to have a complete record of the patient's history, medical conditions, etc. before starting the treatment. HL7 was founded in 1987 by Donald W. Simborg, the CEO of Simborg Systems. HL7 focuses on the "application layer" protocols related to the healthcare domain. There are several variants of HL7 and the most commonly used is the HL7 version 2.x family. HL7 FHIR is the latest variant. This variant combines all the functions of HL7 version 2, version 3 and the CDA standards and offers significant improvements over existing HL7 standards. FHIR, short for Fast Healthcare Interoperability Resource, is currently being called the next big development in healthcare because of its capabilities.

[12] *https://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_TF_Vol1.pdf and https://wiki.ihe.net/index.php/PCD_Technical _Framework*

The large EHR suppliers already apply this standard. The rate at which FHIR is adopted is enormous. Especially now Apple, a key player in mobile devices, has announced that they will include FHIR in their iOS devices. FHIR does not come as an app but will be included in the operating system itself. The strongest driver in the adoption of FHIR came when the most powerful giants in the industry promised to accelerate interoperability in healthcare by leveraging the latest cloud-based technologies and artificial intelligence. This is intended to provide excellent care for patients. Major companies like Amazon, Google, Microsoft, Salesforce, IBM and Oracle signed this joint present promise in August 2018

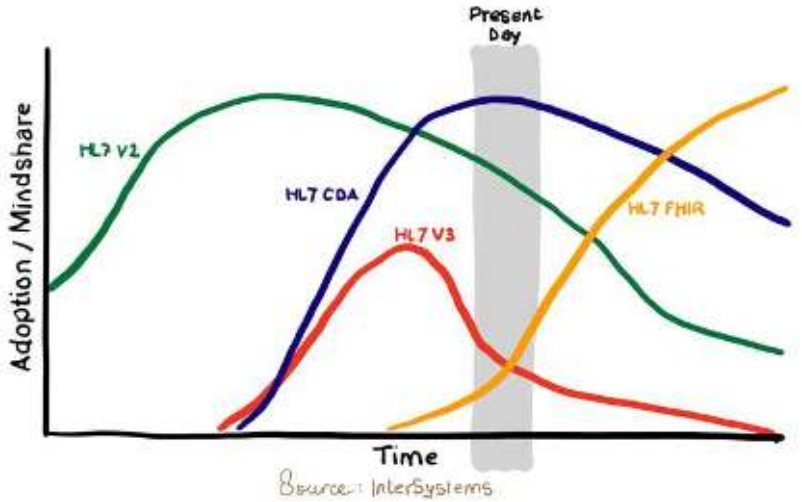

Figure 3: Adoption HL7 standards

HL7 FHIR has been developed as an easy-to-use format for sharing healthcare information based on internet standards.
The FHIR – Fast Healthcare Interoperability Resources – are developed internationally to open up, for example, EHR systems for mobile applications.

FHIR consists of reusable building blocks, called resources, that enable rapid working solutions for the exchange of both administrative and healthcare related data to be built. For example, there is FHIR resource for allergy intolerance or a FHIR resource for medication. Because the building blocks directly produce a working product, an interface can be delivered within a day. The open nature of the standard allows you to add components. The developers of the standard use the 80/20 rule, 80 percent of the functional requirements are generic, and the other 20 percent are specific to the application itself. More information about FHIR resource is available on the HL7 FHIR website[13].

Advantages FHIR

- A simple search (such as the last five lab values) immediately yields results;
- Very understandable to developers;
- Can drive healthcare innovation through short development cycle;
- Fast and secure transfer standard;
- FHIR is adopted worldwide;
- Cost saving for healthcare IT teams.

Disadvantage FHIR

- Due to different verses and implementations, vigilance and testing remain important;
- Problems with matching data and the lack of code systems are quite difficult, so that resources from a supplier are not easily linked to resources from another system (therefore there is a MedMij set of agreements in the Netherlands);
- Current iterations of the FHIR standard are not backwards compatible;
- Not all Resources are “mature” yet, which can cause many changes;

[13] *https://www.hl7.org/fhir/resourcelist.html*

- FHIR Resources are not available for all medical concepts;
- Each supplier builds own resource profiles that can make exchanges difficult (fortunately, the Netherlands has determined some profiles nationally (Medmij);
- There is no Federation (Inter-regional) concept in FHIR (Andries Hamster, 2020).

4. 'USE CASES' TUMOR BOARD REVIEW

Within oncology healthcare we have different types of TBR's depending on the type of tumor. For example, types of TBR's can be held pre- and post- operative or can be based on the complexity of the healthcare needs to be arranged. In the Netherlands we see TBR's at three different levels, adapted to the complexity of the healthcare demands, the so-called echelons. Patients with a common form of cancer are often discussed in the TBR of the local hospital, possibly with a consultant from a University Medical Center (UMC). For more complex healthcare, we see tumor specific regional TBRs with specialized expertise. For the treatment of rare tumors, a TBR can be held where specialized international expertise is requested[14] (IKNL, 2020)

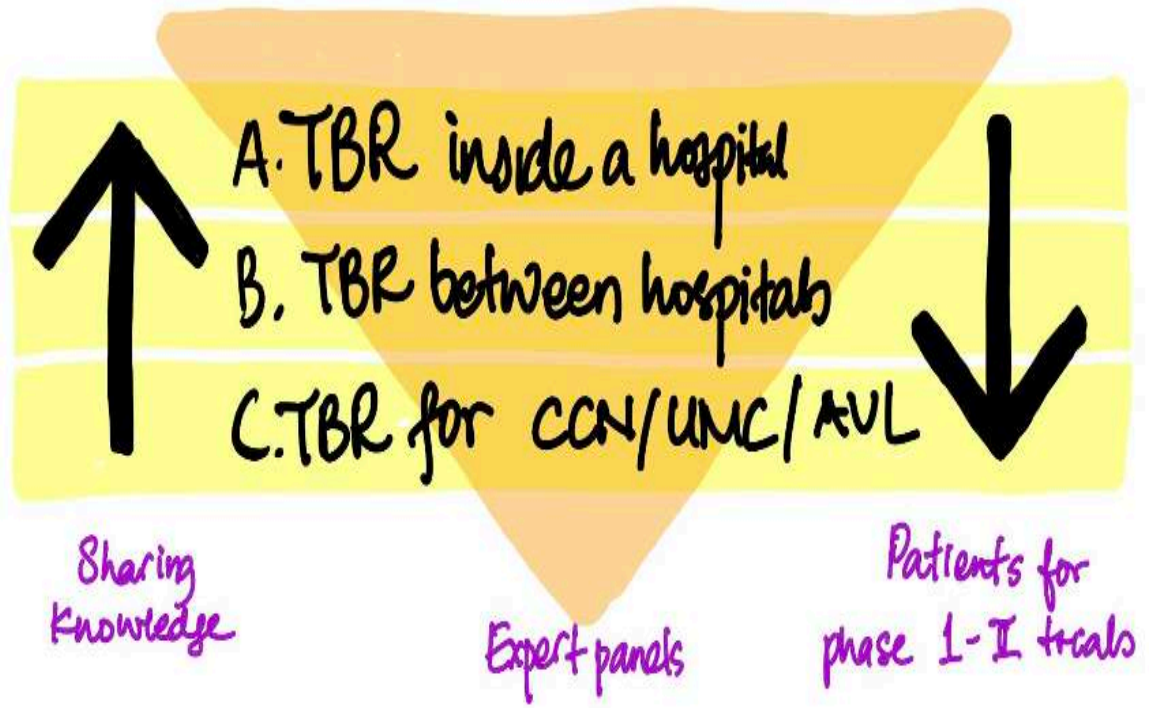

Figure 4: Echelons in the Tumor Board Review

Oncology referrals is increasingly organized regionally in networks. This leads to processes that transcend local hospitals. Expert knowledge is increasingly required for optimal assessment of a patient. A TBR team consists of a large group of healthcare providers. Specialists from various disciplines with expert panels. Geriatric expertise is also becoming increasingly important. A lot of work has already been done to set up different types of TBR's, among others, the Citrienfonds, NABON, IKNL, OncoZon, various oncological networks, many healthcare professionals and supporters. Based on their experience, through a thorough process analysis, it was determined which medical data should be collected and available for an effective TBR at the same time.

At the same time support with Digital Discussion making is increasingly being offered. IKNL has developed the Oncoguide software application for this Digital Discussion making, which provides treatment advice based on a number of relevant parameters and based on the protocols recorded in this application. The preferences of the patient are also considered (Shared Decision Making). When

[14] *https://www.iknl.nl/nkr/evaluatie-met-nkr-data/multidisciplinair-overleg*

coming up with a treatment advice for a treatment plan, the patient preferences are playing an increasingly important role. Adequate knowledge exchange between hospitals and feedback of outcomes from TBR's for improvement of future guidelines and treatments are important in this regard. This means that prior to and during a TBR, a set of the patient medical data from different sources must be available simultaneously at different locations, for different healthcare providers and experts, in a clearly legible digital form. Think of data from the ZIS/EHR/HIS, PACS, VNA – images, lab, reports, etc.. In addition, reporting and information delivery for quality improvement (IKNL, Palga, etc.) should run smoothly, preferably without additional administration burden.

Figure 5: Tumor Board Review

In this document we want to show in a technologically scalable way, how through the coordinated use of tested healthcare and IT standards described in IHE profiles, the digital data provision before and during the TBR can be achieved. For healthcare and IT standards, think of DICOM, HL7v2, HL7v3, HL7CDA and HL7 FHIR, etc..

In this guide, we have chosen a TBR Breast Cancer as an example. Based on Nictiz layer model, we take you from the "use case" TBR Breast Cancer to (transmural) technical support based on the use of international standards. We show you this in the next chapters per layer of the layer model.

The financial adjustments, laws and regulations and security that are necessary to ensure that this runs smoothly have not been taken into account in this document. We limit ourselves to currently technical standards and profiles to enable the extended data exchange.

5. STRUCTURING TUMOR BOARD REVIEW

We gratefully use the layer model as the structured tool for describing the digital support TBR process. In the report, "Electronic Information for health and care services" Are we getting better?' Dr. Michiel Sprenger[15] (Sprenger, 2019) handed his ideas and the (Five) layer model in detail at during his farewell.

Figuur 6: Interoperabiliteitsmodel Nictiz

We start from the following five layers:

1. Policy, administration and management within an organization unit, hereinafter referred to simply as "Organization and Policy";
2. Healthcare process within that organization unit;
3. Information within it: What information, how structured or coded, what coherence. What do the people within those healthcare processes provide and what do they need;
4. Applications that store, structure, process, analyze and communicate information;
5. IT infrastructure in general which provides application a foundation to work on.

5.1. 'ORGANIZATION AND POLICY LAYER' APPROACH

The first layer that needs to be explored in depth in order to arrive at a well implemented case is the "Organization and Policy layer". At this level, we find the policy frameworks and the organization (unit) or of a (regional) network organization (RSO). Additional, underlying organization architecture, security principles and design guidelines can be described here. These visions and frameworks are a compass for the projects. It is also necessary that mutually agreed objectives "SMART" are set (Specific, Measurable, Acceptable, Realistic, Time-bound).

5.1.1. EXAMPLE TUMOR BOARD REVIEW

As indicated in the introduction we take Tumor Board Review as an example. The 5 layers are almost the same for all Tumor types, except for the "information layer". Hence, we describe all layers in general, but we zoom in on the "information layer" specifically on the TBR Breast Carcinoma.

[15] *https://www.nictiz.nl/wp-content/uploads/Paper_electronic_information_for_health_and_care_services.pdf*

Organization Tumor Board Review from a vision of Oncology healthcare in a region

Every patient with cancer in the Netherlands must be able to count on optimal oncology healthcare that is tailored to her or his individual needs and wishes. This is according to the latest state of science, practice and experience expertise. In order to make this possible for all patients, independent where they start their healthcare journey, networking is needed. This patient journey starts in the first line of care, further take over by the general and specialized hospitals. So multidisciplinary cooperation is needed within each of these settings. Comprehensive cancer networks formation is the key phrase in this.

Figure 7: The OncoZon Region

In our examples we make use of the Knowledge from the developments in the OncoZon Region (Oncological network South-East-Netherlands). However, the same question also applies in other regions.

Discussing patients in a TBR is recommended in oncology guidelines, indicator sets and standardized. The quality criteria for multidisciplinary consultation[16] drawn up by IKNL stipulate that a TBR takes place at least once a week and that 90% of all patients must be discussed there. The SONCOS standards (SONCOS, 2019) described which disciplines participate in the discussion of a patient with a specific tumor.

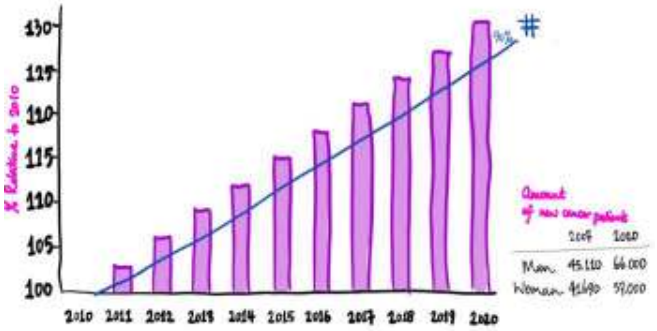

Figure 8: Number of Tumor Board Reviews in the Netherlands

The number of patients with cancer increases[17] and continues to rise. Treatments are becoming more complex and are increasingly tailored to individual patients. More and more different specialists are involved in treatments. Also, more and more patients are getting cured from cancer. They then need after care and follow-up. Healthcare for cancer patients is successful, but also complex, highly specialized and expensive. This requires a different organization for this type of healthcare. For the coming years, the challenge is to organize the oncology healthcare in such a way that the quality of care is kept at a minimum cost that can be controlled. Patients themselves want more support in the complex decisions they have to make and in dealing with their condition (shared decision making, self-management). It is important that they have an overview of the quality of healthcare providers[18].

[16] ht*tps://iknl.nl/getmedia/4dea4687-6c96-42cb-8860-72d1adb0e9f7/qualitycriteria_multidisciplinary_consultation_2016_IKNL.pdf*
[17] *http://koersboek-oncologische-netwerkvorming.nl/Koersboek.pdf*
[18] *http://koersboek-oncologische-netwerkvorming.nl/Koersboek.pdf*

In order to ensure the quality of healthcare, the basic principle is that a patient will be discussed in the TBR, where all the necessary expertise is available. Due to the increase in the number of patients, it is no longer feasible to have all patients assessed by the same team of specialists. The basic principle of the coalition agreement is to treat more patients with the same budget. This means that it is a major benefit for the patients and healthcare providers if we can organize the TBR process as efficiently as possible.

Within the process (in the next chapter) there is still a lot of efficiency to be gained. For example, by using echelons and/or by reducing administrative actions. Offering structured data and the use of Artificial Intelligence can also support decision-making. During this OncoZon region, all oncological healthcare is offered, from high-volume and low-complex care. OncoZon (Pullens, 2018) has made an inventory of how the various hospitals deal with discussing and referring colorectal patients in order to arrive at an unambiguous vision on echelons. Based on this, a proposal is locally complex, regionally complex and highly complex/second opinion.

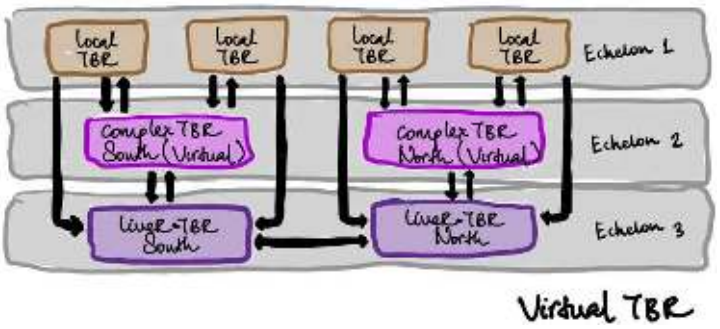

Figure 9: Echelons Tumor Board Review

Gathering the desired information for a TBR still appears to take a lot of effort and is still too often a (too) lengthy process. An incomplete patient record may make it possible to make an insufficient estimate of how complicated a condition is and there is a risk that the wrong echelon has been chosen. This means that the patient has to be discussed again (e.g., complex). This poses undesirable patient risks and is ineffective when it comes to deploying expensive healthcare resources.

The objective of the optimization is to organize more TBR's within the same financial space with better quality.
Smart objective as such:

1) Reduction of lead times by 15%;
2) Number of TBR's that are cancelled due to lack of data to 0;
3) Reduction of work of coordinator by 50%;
4) Reduction of typo error by 80%;
5) Increase quality linked guidelines by 5%.

5.1.2. CONCLUSION “ORGANIZATION AND POLICY LAYER”

Conclusion:
- The frameworks and organization of oncological healthcare in this example region has been aligned at policy level. There is shared and supported vision;
- It is clear that the demand for oncological healthcare continues to increase and that the collection of the desired information takes (too) much effort and time;
- In order to find a solution for this problem with the set financial framework and with the aim of an optimal quality of healthcare for all oncological patients, the following layers have been searched for efficiency gains in collecting the information in the process;
- The objective to treat more patients with the same budgetary scope is a requirement.

5.2. 'PROCESS LAYER' APPROACH

In this paragraph we analyse the process. To do this, we describe the current processes and define the obstacles found. We then describe the newly planned process using the identified obstacles. The identified obstacles and solutions will help us to improve and more concretely describe the objectives in the "Organization and Policy Layer". However, it is impossible to describe a new process if the technical possibilities have not been looked at. Here we see the importance of vertical and horizontal interoperability. Working with the layers model requires an iterative process where each layer is passed.

5.2.1. EXAMPLE TUMOR BOARD REVIEW

The structure of an oncology process is described in the OncoZon document "10 implementation lessons" (Dr. Gera Welker, 2019). The process begins with a patient referred to the hospital after examination during the Dutch Population Study for Breast Cancer or after a patient goes to the general practitioner (GP) with a particular complaint. In this guideline, we describe the latter. The GP is makes a diagnosis. The GP processes the patient data and the diagnoses in the GP's information system (HIS). The general practitioner then makes a referral (the referral letter) and sends it to a 2nd line - hospital. In many cases, a digital referral application is used, but sometimes the referral is emailed and/or faxed to the hospital. The patient makes an appointment with the hospital, after which the patient is received in the outpatient clinic. The outpatient staff takes over the details of the referral and enters them into the electronic patient record (EHR) of the healthcare facility. The oncologist examines the patient and requests diagnostics. In many hospitals diagnostics are being requested digitally, but there are also hospitals where this goes on paper (and again needs to be retyped). The healthcare provider (which can be nurse specialist, secretary, surgeon, internist oncologist) will then request for a TBR for the patient in an oncology diagnosis. The TBR is held within a week and a report is drawn up. The results are then discussed with the patient and together they decide which treatment best suits the patient's needs. After that, the necessary treatment is requested and performed. After the treatment, a follow-up and possibly a palliative care is arranged.

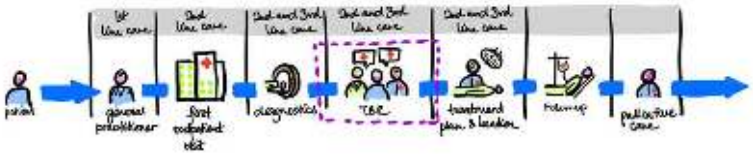

Figure 10: the oncological Process

Next, we explore the transmural TBR-process within oncology. In the recent years, a lot of work has been conducted by the healthcare providers to reorganize and streamline the TBR meeting. Although the meeting is well organized, it is still necessary to collect and to share all the patient information with all the participants in a timely matter. In addition, the information, if any, is often also provided in an unstructured manner.

In the following paragraph we describe the TBR process in which the TBR coordinator receives the request for a TBR. Not all hospitals have a TBR coordinator for the regional TBR. Additionally, the TBR process for the intramural TBR generally runs without a TBR coordinator. In the transmural TBR process we see the following steps: The referral is made by a healthcare giver or secretary, the treating physician and doctors who do the additional analyses are responsible for preparing the TBR. Both the radiologist and the treatment physician (oncologist or surgeon) can see the patient's

schedule for a TBR on the TBR worklist. The experts all prepare their part for the patient. The treating physician is only responsible for recording data in the TBR questionnaire for preparation such as questions about the characteristics of the illness and diagnosis and treatment proposal. The pathologist and radiologist ensure that the results for the TBR are identified and recorded in a report. Additionally, if a patient is suspected of oncological illnesses, the patient is also often already placed on the (intramural) TBR. A diagnosis doesn't have to already been determined.

After an oncology diagnosis has been made and a TBR has been requested, the TBR coordinator collects all the necessary information. This information comes from different systems and organizations. It often occurs regularly that the information is not yet available before the TBR starts and the TBR needs to be rescheduled. In addition, the data comes into the TBR coordinator in a different and often unstructured ways. The TBR coordinator then determines the type of TBR to be requested from the data collection. Depending on the nature of the tumor, a regular or specialized TBR is necessary (the right echelon).

After the TBR coordinator has determined the correct TBR, it will be scheduled. Participants are invited. These participants can review the patient data and prepare the patient case prior to the TBR. In the TBR the patient is then discussed and a report with the proposal treatment plan is prepared. This report goes back to the requesting specialist who discusses the proposal with the patient. Additionally, a letter from the TBR often goes to the referral (GP or referring healthcare provider from another hospital).

In 2012, IKNL, together with clinical partners, described[19] the ideal process of a lung and breast carcinoma TBR (NABON, 2012). Together with two IHE profiles, they make an important contribution to the implementation of a TBR. These profiles are the Cross Enterprise Document Workflow (XTB) profile and Cross Enterprise Tumor Board Workflow Definition (XTB-WD) profile. These profiles focus on optimally supporting workflow and clinical setting by ensuring that relevant information is present at the appropriate place during the workflow or process. These profiles provide support by using various types of statuses, the different steps of the TBR and monitor the associated flow of information, such as forms, images and reports. Application for these profiles provides pre-conditions for an efficient and standardized exchange of oncology information for different types of TBR.

[19] *(NABON, 2012; NABON, 2012)*

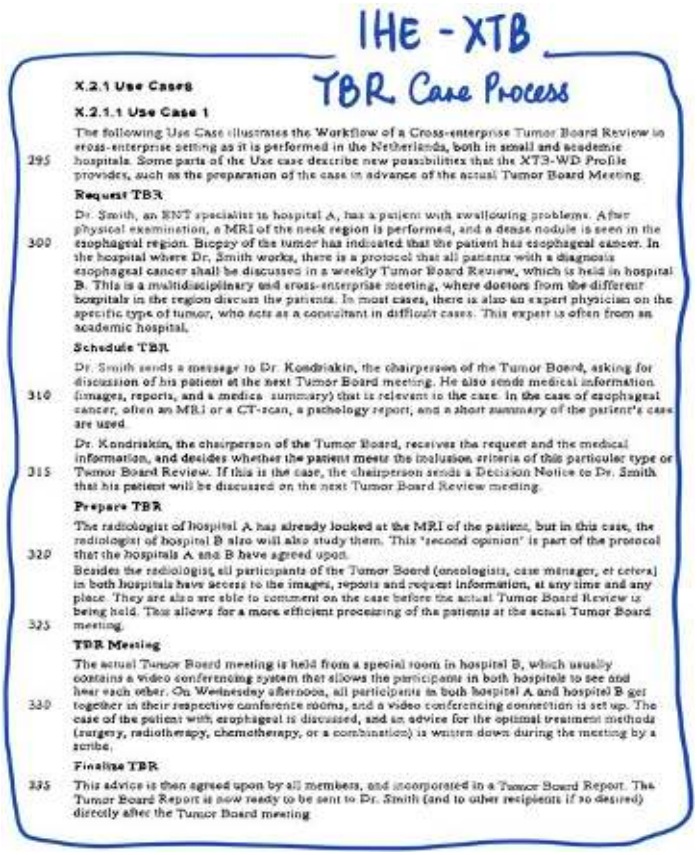

Figure 11: 'use case' 1 from the XTB-WD Profile

The TBR described in the XTB-WD profile (Committee, 2014) consists of five steps that are executed sequential, in an independent way in conjunction with each other. The delivered documents / results of a step, the output documents, are the input documents and also triggers for the next steps. The XTB-WD process is serial where a step cannot be taken back. However, the whole process can stop and start again. This makes the process relatively easy to implement. Application developers ensure that the user does not notice that the process has stopped, and a new process is started.

Figure 12: Process XTB-WD Profile

The XTB-WD profile is based on the IHE Cross Enterprise Workflow Profile (XDW)[20]. (Committee I. I., 2014) The XDW profile generally describes how to modulate a process so that a workflow definition can be stored in a standardized manner. The Workflow definition describes how and what the Workflow looks like.

The Workflow also defines which steps are available, what types of input and output documents are expected, and what statuses are possible per step. When a workflow begins, this workflow definition

[20] *https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_XDW_Rev2.4_TI_2014-10-13.pdf*

defines a workflow document which will be created per process. This Workflow document can be seen as the patient's central digitally stored history card of the process.

In this workflow document, the status and the input and output documents associated with one patient are tracked per process. In his way, the timeline of the process can be easily displayed. The workflow document can be therefore easily used for process-dashboards and quality monitoring. In this workflow document the entire process and every step is taken with all statuses, times and information used has been recorded. This document is valuable for managers who do process optimizations, and researchers can quickly find the patient's information associated with this TBR process without having to examine the entire patient's records. Thus, one workflow definition and multiple workflow documents exist per process (one per completed process).

There are many types of specific workflows and therefore there can be quite a lot of workflows definitions. The XTB-WD profile is just one of them. Some other definitions of the model processes are: "Cross-enterprise Remote Read" (XRR-WD), "Cross-enterprise Cardiovascular Heart Team" (XCHT-WD), "Cross-enterprise Basic eReferral" (XBER-WD), "Cross-enterprise Mammography" (XTHM-WD).

5.2.1.1. ANALYSIS OF OBSTACLES

To improve the efficiency of the TBR process, in order to meet the desired objectives, an analysis of obstacles is been carried out. Each process step has been reviewed to identify the obstacles that prevent TBR from being the best and most efficient. After the analysis, we can establish that many of the problems arise because the provisioning of information is not adequately organized from the beginning to the end.

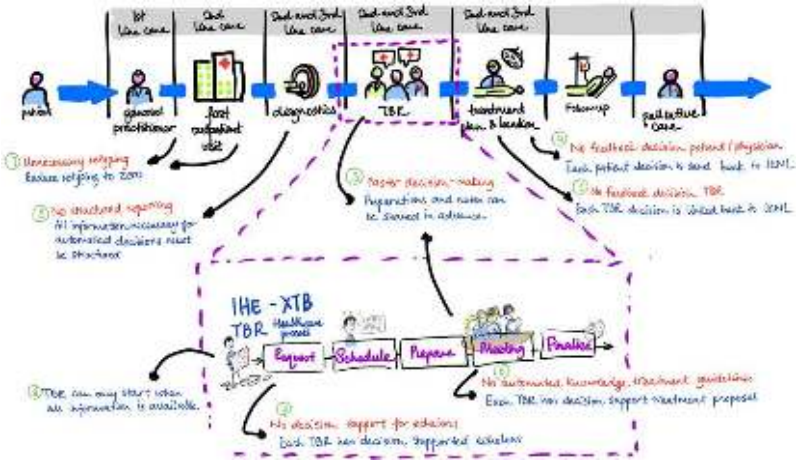

Figure 13: Obstacles analysis (and IST situation)

Table 2: Analysis of Obstacles Oncological process

Analysis of Obstacles Oncology process				
Nr.	**Obstacles**	**Consequence**	**Description**	**Objective**
1	Unnecessary retyping	Time is required for data entry and review. Additionally, there is risk of typo-errors.	Prevent retyping by registering at the source	4
2	Not structured reports According to (inter-) national agreed standards and no unity of language	Lots of time wasted in preparation, no possibility of re-use the data and automated decision support	All required fields are structured defined and unity of language in Dutch as precondition	1,3,4,5
3	Not all relevant information present has priority to plan TBR or no decision making due to missing data during TBR	Loss of time, TBR has to rescheduled, duplicate costs	All information must be present in advance	1,2
4	No feedback on treatment advice in the TBR that deviates from the national guideline	No lessons are learned from the decisions motivated by the TBR to deviate from the guidelines	Feedback on decisions sent to national working groups for adjusted guidelines	5
5	The information on possible treatments and relevant clinical studies for the patient is not always known and readily available during the TBR	Patient does not always receive the most optimal treatment	Use of decision support such as Oncoguide to provide treatment advice based on current trials applicable to this patient and treatment advice based on national guideline	5
6	No proper triage in echelon	Patient is discussed in the wrong TBR	Triage support: Patients are discussed in the right TBR	1,2,3

To optimize the process, it is important that all data can be easily added in the application and that this data no longer needs to be retyped and is structured and recorded in accordance with a (inter)national standard (unit of language), so that decision support systems can help with the choice of echelon and preparation of treatment proposals, in accordance with the oncology guidelines (SONCOS, 2019). Additionally, decisions that deviate from treatment proposals and related quality parameters must be linked back to the national guideline working groups so that they can be learned.

Figure 14: Decision support integration TBR (and Soll Situation)

5.2.1.2. TUMOR BOARD REVIEW TEAM PARTICIPANTS

In the layer process it is important to recognize who works in this TBR process (identification), what role (authorization) these people have and how many participants (licenses) will participate. For this purpose, the IHE XTB-WD profile can be used as it has already been developed. Participants can work in any healthcare facility within a region. The table below defines the XTB-WB roles. Since the XTB-WD profile is relatively general, it can be different for each type of tumor, especially considering the possible echelons. We often see that the surgeon, especially in solid tumors, is the chairman of the TBR. This can then be easily equipped in the model. The SONCOS-standards[21] (SONCOS, 2019) also describe the TBR roles.

Table 3: TBR participants conforming to XTB-Profile

Table X.1-1: Typical TBR Team Participants

Medical Rol	Function	TBR Rol	Number
<Any Specialist>	Diagnosis, (surgery)	TB Requestor, TB Member	#
Radiologist	Review of Medical images	TB Prepare, TB Member	#
Pathologist	Review of Biopsies	TB Prepare, TB Member	#
Oncologist	Chemotherapy	TB Prepare, TB Member, TBR Chair	#
Radiotherapist	Radiotherapy	TB Prepare, TB Member	#
Specialized nurse	Counselling, main contact person	TB Scheduler, TB reporting, TB Prepare, TB Member	#
Others	Psychology, (Plastic) Surgery, Case manager, Policlinic assistant	TB Prepare, TB Member	#

[21] *https://www.soncos.org/wp-content/uploads/2019/02/Soncos_norm-rapp2019-v7.pdf*

5.2.2. CONCLUSION 'PROCESS LAYER'

Conclusie
- The TBR process "Oncology" is relatively generic and therefore applicable to other specialties;
- The IHE XTB-WD profile is not only useful for the transmural TBR oncology cases in the Netherlands, but can also be used for other healthcare disciplines;
- High efficiency can be achieved with better information in preparation and during TBR;
- Objectives are realistic and achievable in terms of obstacle analysis;
- By applying the IHE-XTB-WD, we can achieve healthcare line monitoring (process and quality control);
- Complete and unambiguous information about the patient and the disease can speed up decision-making.

5.3. 'INFORMATION LAYER' APPROACH

Data is becoming increasing important. At the beginning of the 19th century, during the industrial revolution, the economic model was based on the harvesting and the collection of raw products such as iron, cotton, rubber, etc. from different colonies. Once on its own soil, the products are processed into finished products by means of highly advanced industry, after which they were sold back for much more profit to the various colonies. The same phenomenon is seen in the field of data at the beginning of the 21st century. Many companies collect huge amounts of data from consumers, among others, all over the world. This data is then retrieved by the imperial hubs, or the large IT companies such as Google, Microsoft, Amazon, etc. This results in large data lakes. These companies make this data valuable information through Artificial Intelligence (AI) and Machine Learning, which in turn can be "bought back" by companies or by the citizens themselves. The term "Big Data" is often used. This big data "movement" is currently explicitly manifesting in the healthcare. Because of the major EHR suppliers, such as Epic, Cerner, Chipsoft, Agfa, Philips, etc., as well as Apple, Amazon, Google, etc., large data lakes are created, which add value to their products through AI and machine learning. Therefore, the healthcare institutions and/or the citizens will pay for the upgrading of their EHR and PGO's, unless we can organize another route very quickly. But this falls outside the scope of this guide.

The data that is created in the healthcare process becomes invaluable due to the preservation of it and making it reusable for healthcare, education.
Therefore, it is strange that within the healthcare institutions, relatively little attention is paid to the re-usage of data. Healthcare organizations buy systems for their displays and their fantastic functionalities that can optimize the healthcare process. We leave data modeling to the EHR suppliers. As a result, the data within the EHRs is not easily accessible to applications other than those for which the EHR was created. A data lock-in has been created by the EHR suppliers that directly affects the possibility and impossibility of the re-usage of data. The healthcare institution does not have the data models of the suppliers.
PACS systems for medical images are an exception.

In the recent years, the program "Registration at the Source" in the field of data modelling has done a fantastic job. Currently, "Registration at the Source" has published a hundred Health and Care Information Building Blocks (HCIM/ZIB)[22]. Each HCIM/ZIB describes a (clinical) concept, which contains multiple data in itself with an agreed content, structure and mutual relationships. The (healthcare provision to the) patient is centralized. The HCIM/ZIB, which describes allergies, for example, is therefore by nature healthcare wide, because this HCIM/ZIB describes the patient's allergies, independently on the specialty or setting (context) in which this patient is currently receiving care.

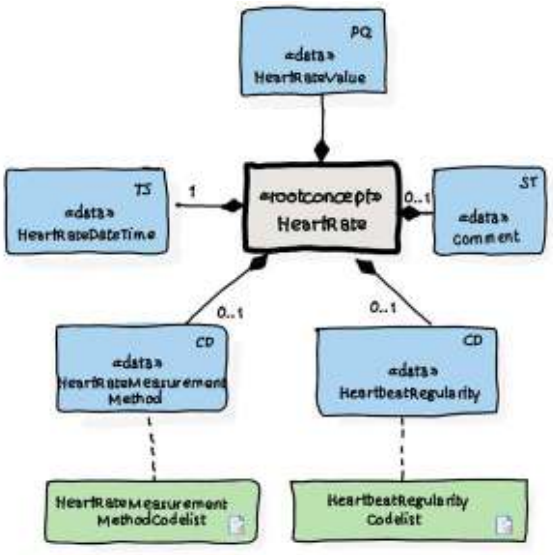

Figure 15: HCIM/ZIB HeartRate

[22] *https://zibs.nl/wiki/HCIM_Mainpage*

It is expected that more healthcare blocks will be created in the coming years. Many hospitals, Mental Care institutions, home care organizations and general practitioners have been busy implementing 26 HCIM/ZIB's of the 100 defined HCIM/ZIB's last year, thanks to various VIPP programs(Subsidies programs to speed up information exchange between patients and Healthcare providers). These 26 HCIM/ZIB's form the IHE Patient Summary and called the "BGZ" in Dutch. Despite the immense work carried out by the healthcare institutions, there are still few exchange projects completed at the moment. However, the BGZ is presented in several hospitals in patient portals. In addition, it is used within the MedMij program. The first successful exchange projects of the BGZ are expected in 2020. A hopeful development.

Figure 16: Available HCIM/ZIB's

However, we are not yet there. As indicated, the BGZ consists of only 26 HCIM/ZIB's. These 26 building blocks are hardly sufficient for a business process, making digital innovation within projects, where more information is needed from the patient, often difficult. After all, how do we deal with the other patient data?
We want to structure these if possible and necessary, so that they are of sufficient quality for reuse in the healthcare process and quality records and research. Modelling and encoding of patient's data are a knowledge intensive task. And it is precisely this knowledge that is needed that is often lacking in healthcare institutions. It is also difficult to agree on national information standards. Nictiz has set up a management process for the ZIB's[23], but this is far from adequate for all projects. Fortunately, we have already agreed information standards for various healthcare processes. On the Nictiz site[24] (NICTIZ, 2020) you can find a lot of information about this.

[23] *https://zibs.nl/wiki/HCIM_Mainpage & https://www.nictiz.nl/standaardisatie/zib-centrum/beheerproces-zibs/*
[24] *https://informatiestandaarden.nictiz.nl/wiki/Hoofdpagina*

Evolution of an information standard

As soon as an agreement is reached on the information standard, it will evolve, for example by providing new diagnostic procedures. It is therefore not enough to standardize the information. There are also agreements on what evolution can reasonably be expected, how often there are changes, and what systems can handle without breaking. The risk is that it might cost a lot of effort to standardize insights from 2020, and be stuck on that endlessly because no one can change them anymore.

From interoperability, there are a number of principles for such evolution:

- Most systems only need to have limited knowledge of the whole information standard, if they can accept, display and transmit the data;
- The standard can be expanded, but the systems that have not expanded yet, must continue to function;
- An expansion must not change the definition of existing data items.

One way of achieving this is to capture the documents in an expandable representation (for example, a CDA document for a HL7 FHIR document). Some of the information (e.g., the header) will be understood by many subsystems, and it may also be stored in a well-defined way. One can consider a CDA document, FHIR questionnaire response, or for example DICOM Structured Report or HL7 ORU. The common part can be defined sharply via HCIM/ZIB's. Some of the information will vary over time, for example by different versions of the TNM standard. At the same time, the number of subsystems that understand these nuances will be limited. Art-décor (Nictiz) supports different versions of the information standard. HL7-CDA and FHIR both have document and resource expansion strategies.

In addition, there is a need for a governance process for the information standards. The medical specialists naturally have an important vote here. At the same time, suppliers also have a fairly important role: if they implement support for certain versions of the information standards in good faith, it would be annoying if they were to be penalized by changes to the information standards they cannot process. In practice, a committee of users and suppliers will have to be set up, such as the IHE and DICOM workgroups.

5.3.1. EXAMPLE TUMOR BOARD REVIEW BREAST CANCER

In the previous chapter, the process is described in relation to a more generic transmural TBR. This showed that the process is actually quite standard for all types of oncology diseases and patients at all stages of treatment (clinical, post-operation, palliative, etc.). However, the content and participants of the TBR discussion can be substantially different. The conditions discussed are different. The participants and the echelons within TBR can be different. But the essential difference is mainly in the information used. Similarly, the "use case" Breast Carcinoma on the information layer is unique. As described above in the "process layer", the TBR according to the XTB-WD profile consists of five steps, with each step having input and output documents. It is therefore important to determine the input and output documents by step (Task). For Breast Carcinoma we use the information standard defined by the National Breast Cancer Consultation Netherlands (NABON). The information standard [25] and the defined forms [26] can be found on the internet. The TBR questionnaires will also be available in the Netherlands shortly. Additionally, the Citrienfonds has published a first fresh oncology data set. This data set can be used as a basic for each TBR oncology.[27]

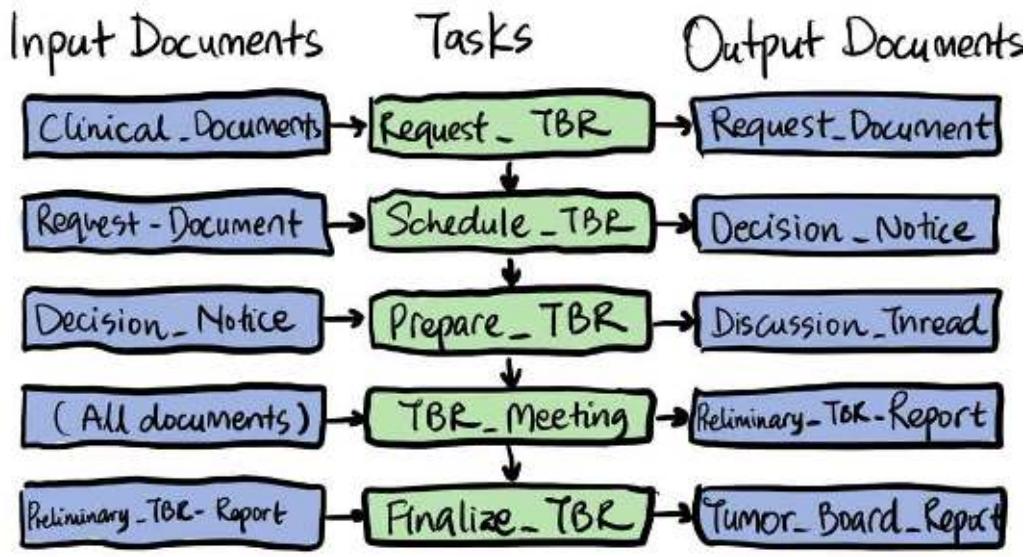

Figure 17: In- and Output in process XTB-WD

The NABON and the information standard TBR Breast Carcinoma has so far focused on the problems of data exchange for the intramural TBR. Within an institution, the problem also arises that data already recorded must be manually passed over frequently. The pilot-hospitals involved do mainly intramural TBRs for the breast cancer patients. The information standard TBR Carcinoma is therefore initially developed and intended for the intramural TBR. It can also be used for the transmural TBR, but a final check is still needed, where all the additional data items are needed for the regional or transmural TBR.

Request Transmural TBR Breast Carcinoma

In the first step of the TBR, all the necessary information is collected for the TBR Carcinoma (input documents: Clinical Documents). This step costs the healthcare provider the most time which is why it is being elaborated on in this document. Often times, a medical secretary, the TBR coordinator, is

[25] *https://www.nabon.nl/standaardisatie-epd/*
[26] *https://MDO-formulieren.azurewebsites.net/nabon*
[27] *https://www.oncologienetwerken.nl/nieuws/eerste-versie-gegevensset-oncologie-algemeen-gepubliceerd*

put in charge of this. This coordinator collects all the documentation. Often the data is delivered in an unstructured format and the coordinator may miss certain information needed for the TBR. That is the reason why an Information Standard, that contains exactly what is required to be in compliance with the guidelines for the healthcare process, is important.

Quality records have not been taken as the starting point for the necessary document information in the NABON TBR breast cancer. Only the information needed for the patient diagnosis and treatment has been included. If this information is reusable for quality records, it is taken well into account, but it is not a starting point. This is to prevent registering information in the TBR that is only required for quality records. As it creates unnecessary additional registration burden (and frustration) for the healthcare givers.

NABON has described this information standard and it is documented in the Art-Decor at Nictiz. Additionally, these information standard TBR questionnaires are designed to collect the necessary data for preparation of and during the TBR[28].

Figure 18: Information standard Breast Carcinoma in Art-Decor

The information Standard TBR Breast Carcinoma contains which data must be collected from which source. For example, for the TBR preoperative, which data is needed from the radiology report, and which data is needed from the pathology report if a biopsy has been taken? Additionally, which data should be captured by the treating healthcare giver. In each treatment phase (preoperative, metastatic and palliative) it is defined which patient's data is needed for the TBR. The TBR questionnaire supports both patient preparation and discussion in the TBR.

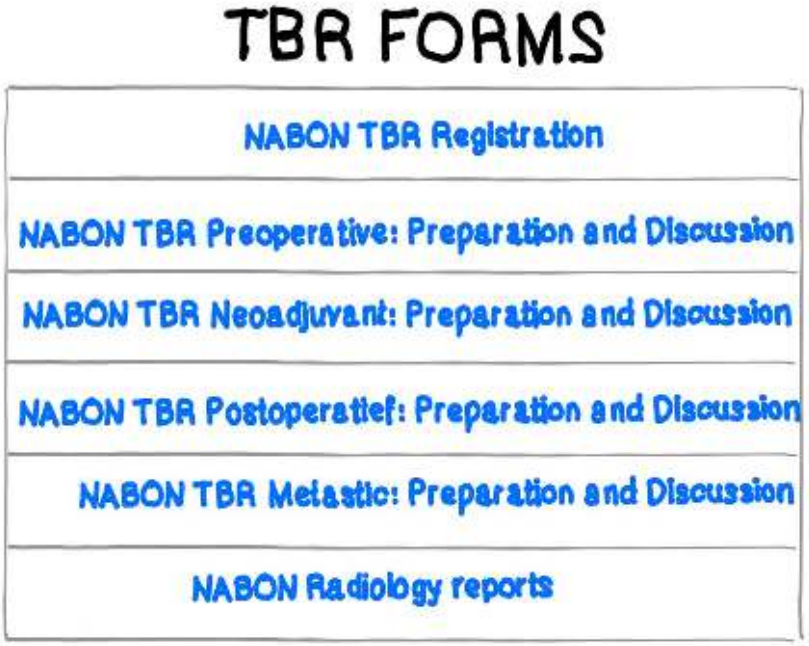

Figure 19: TBR Forms NABON

[28] *https://mdo-formulieren.azurewebsites.net/nabon*

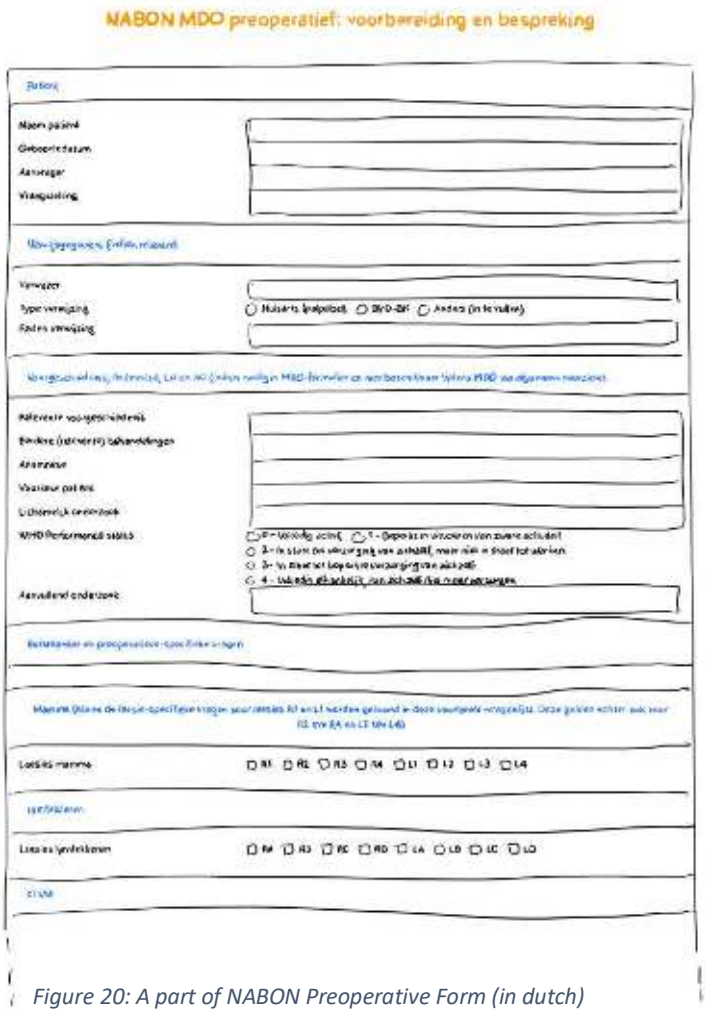

Figure 20: A part of NABON Preoperative Form (in dutch)

As in the obstacle analysis has made clear, the goal is for the form (see example) to be automatically filled in, in a structured manner as much as possible. This reduces the administrative burden and prevents errors. The required information elements must be modelled and described in the Breast Carcinoma information Standard according to "Registration at the Source". When it is possible, the HCIM/ZIB's are used, when the information required for the TBR Breast Carcinoma is too specific, it is modelled and coded by NABON and documented in Art-Decor. For example, in the diagram below, we see the Snomed-CT encodings of the WHOPerformanceStatus used in the form "NABON TBR preoperative: Preparation and Discussion".

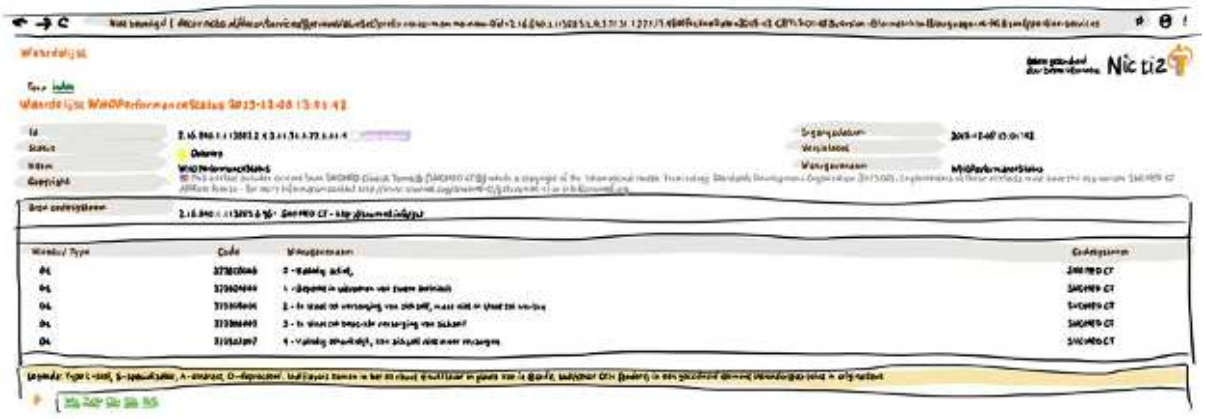

Figure 21: The Value list of WHOPerformanceStatus in Art-Decor

A part of the information from this NABON form is already defined HCIM/ZIB's from the BGZ. A large part of the information is also not available as a HCIM/ZIB. This is where we find the patient HCIM/ZIB, the healthcare giver HCIM/ZIB, treatment indication, problem, etc. However, there are also elements that still have to be modelled. Examples include, the whole WHOPerformanceStatus

as well as the TNM Classification that had not yet been modelled. These HCIM/ZIB's have since been modelled and submitted to NICTIZ as a candidate for HCIM/ZIB. However, it is not necessary to have a HCIM/ZIB available for all elements, see paper Mirte TIlme of IKNL.[29]

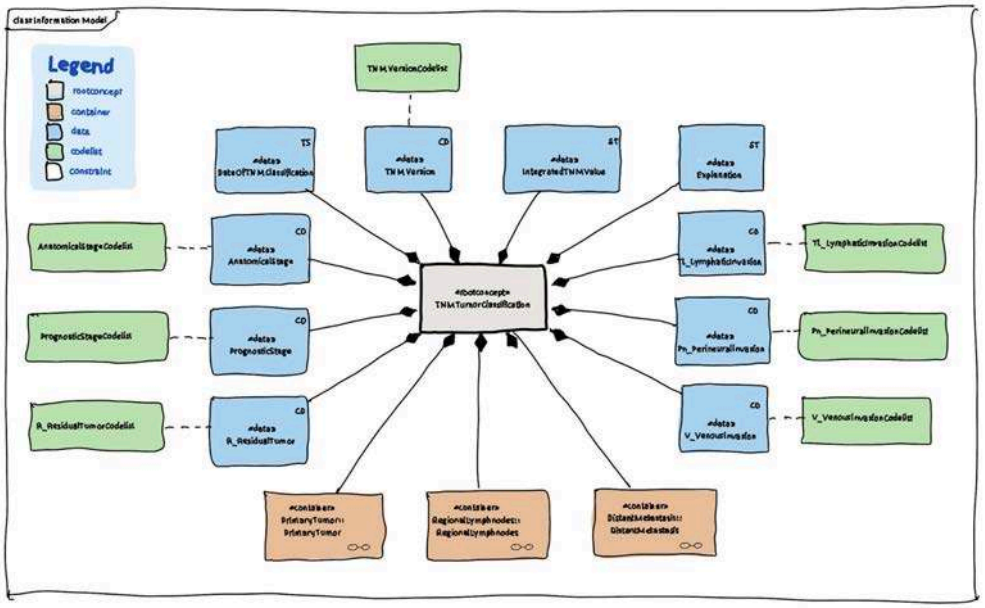

Figure 19: Candidate ZIB TNM Classification

These reports and questionnaires are expected to be fully Snomed CT encoded in Q3 2020, and modelled within Art-Decor by Nictiz

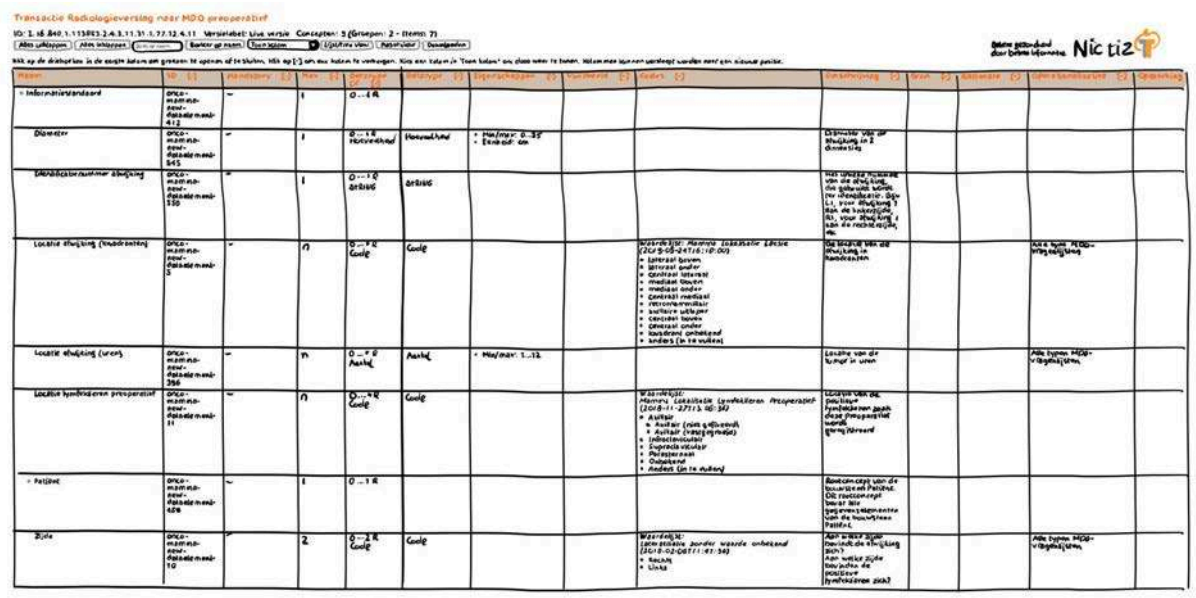

Figure 23: Information standard Breast Carcinoma Radiology Report

[29] *https://www.iknl.nl/getmedia/2456f8c3-6a37-456b-b6ee-311d6dc28261/informatiestandaarden-ter-invulling-van-zibs_rapport_iknl-mei2019_def.pdf*

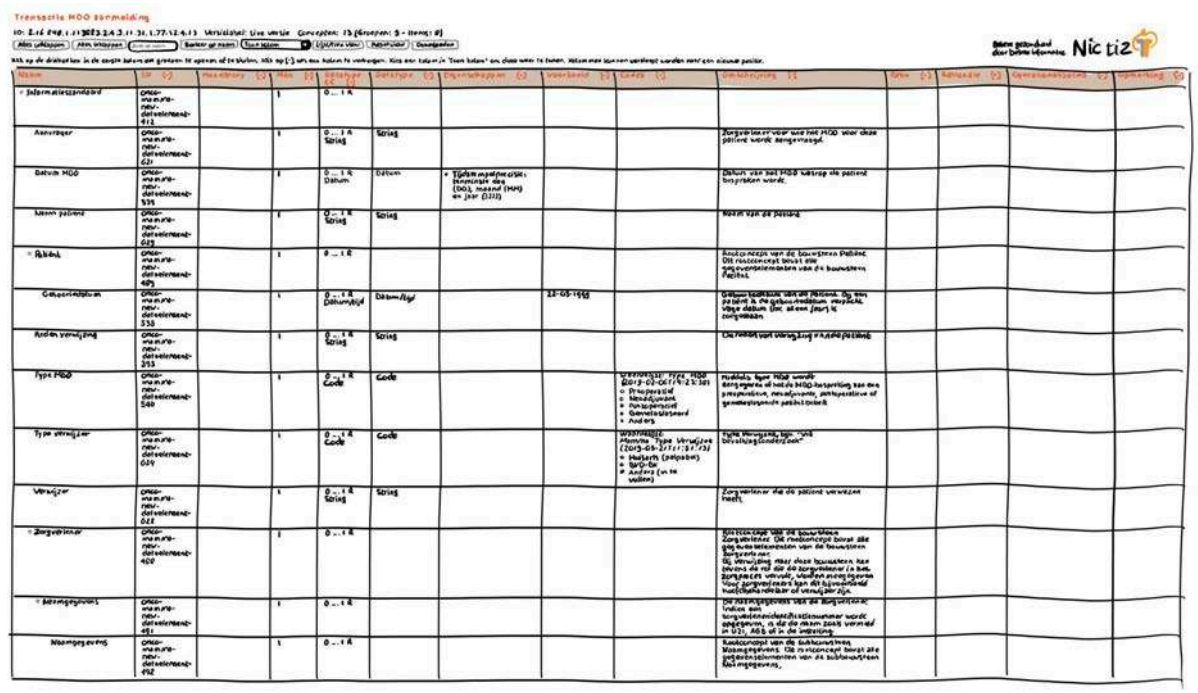

Figure 24: Information standard Breast Carcinoma Pathology Report

For Breast Carcinoma a lot of good work has been done in the field of information modeling. The NABON is the first to have a national information standard for all TBR, adapted by all professional associations. OncoZon is now far ahead with the information standard for Colorectal with liver metastases[30]. The information models are essential if you want to exchange information institutionally.

Similarly, the radiology and pathology report is concluded in the information standard. Not the whole pathology report is contained in the information standard, but only the relevant data for the TBR from the pathology report are included in the information standard. This was agreed with PALGA at the time. Publishing the entire pathology report dataset on Art-Decor is not ideal because of the management efforts to keep it up to date. The NABON is working with the NVvR (Dutch Community of Radiology) and the suppliers to establish structured capture of data in the radiology report. A national (Dutch) information standard for Breast Cancer patients is expected to be available in Q2 2020. Standardized and structured radiology reports can also be done through the IHE profile MRRT. MRRT bridges the gap between images and reports: making measurements in the image automatically part of the report, for example, with the associated coordinates. At the next inspection of a liver tumor for example, the radiologist will immediately be able to determine the deviation by synchronizing and by comparing the old and the latest tumor image. This synchronization is expected to become very important for all kinds of other measurements. Thus, it has to be done one-time, not only the texts, but also the measurements must be stored structured and standardized[31,32,33].

[30] *https://www.oncologienetwerken.nl/sites/default/files/2018-06/Rapportage_OncoZON_RegistratieAanDeBron.pdf*
[31] *https://wiki.ihe.net/index.php/How_RadLex,_radreport.org,_RTE,_MRRT,_CDA,_and_XDS_work_together_White_Paper*
[32] *https://www.rsna.org/practice-tools/data-tools-and-standards*
[33] *https://www.ihe.net/uploadedFiles/Documents/Radiology/IHE_RAD_Suppl_MRRT.pdf*

In the event that the data elements are recorded, but not in a structured way, Natural Language Processing (NLP) (Sander Puts & Martijn Nobel, 2020) can play an important role as stated earlier.

In this chapter we worked out the process step request TBR Breast Carcinoma (Request_TBR). The steps taken must also be performed for the other four steps in this profile. In this document, we will not elaborate this any further.

5.3.2. CONCLUSION 'INFORMATION LAYER'

Conclusion
- The information needs to be associated with certain type of TBR (tumor type) and the different participants make the TBR unique. Not the process and not the application / Infrastructure;
- Not all information standards have been worked out. For the TBR Breast Carcinoma, it has been worked out;
- Knowledge to create and encrypt these data sets is available nationwide, but they lack in the hospitals. This makes it difficult to establish national information standards for TBR. IKNL is working on this;
- National structured standard for the radiology reporting reports for the Breast Cancer case is in pilot and for the pathology, a national synoptic reporting is already widely used via the Palga module. For other disease images, semi-structured and/ or encoded reports are still frequently used, resulting in manual transfer of information;
- The finding and retrieving of the right data and placing it in the right structure gives a lot of registration burden which is undesirable.

5.4. 'APPLICATION LAYER' APPROACH

As described in the previous chapters, the necessary information and the different participants makes a TBR unique. The basic process does not change. What about the "application layer" does it change?

To answer this question, we take the IHE-WTB WD profile as the starting point.

To get the XTB-WD profile built into applications, the applications must meet the specifications of the XDW definitions. These are the five different steps in the XTB-WD profile:

Table 4: Application Actors XTB-WD

Application Actors	
Proces Stap	XDW Actoren
(1)TBR Requestor Actor	XDW CONTENT CREATOR XDW CONTENT CONSUMER XDW CONTENT UPDATER
(2)TBR Scheduler Actor	XDW CONTENT CONSUMER XDW CONTENT UPDATER
(3)TBR Preparator Actor	XDW CONTENT CONSUMER XDW CONTENT UPDATER
(4)TBR Report Writer Actor	XDW CONTENT CONSUMER XDW CONTENT UPDATER
(5)TBR Finalizer Actor	XDW CONTENT CONSUMER XDW CONTENT UPDATER

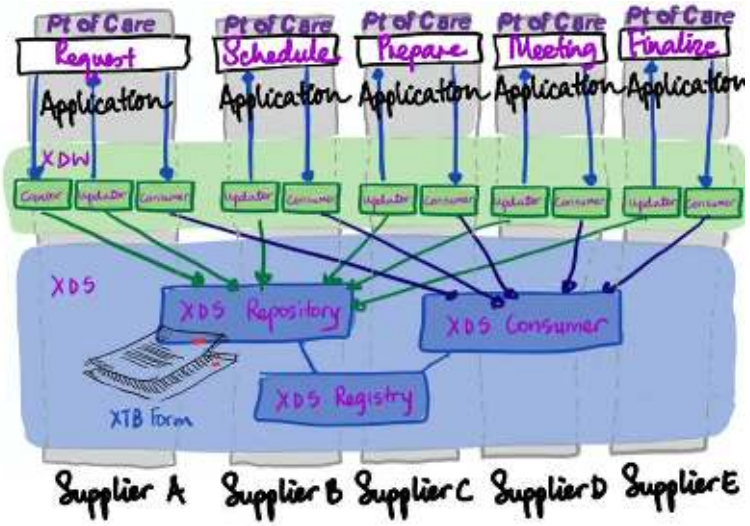

Figure 25: Applications in relation to the XTB-WD profile

There are TBR application suppliers which have integrated the five applications into one product with the five process steps. There are also suppliers who, for example, only incorporate the TBR request process and the report process as an application into its system. For example, an EHR supplier, who has built in the NABON form for the TBR carcinoma. However, it does not matter whether a supplier builds all five process steps into its system or focuses more on one of the five process steps, as long as this application is creating or updating the XDS based Workflow document (XTB-Form), in line with the XDS actors. In this way, all other applications can play a role in the process, without having to modify applications.

Additionally, all the medical documents used (the input and output documents) should be on XDS. This mainly concerns a fixed set of data so that everyone can view the same data. In some cases, such as images and reports in Radiology, this is often already the case as for all other documents, the application will have to put the documents on XDS (preferably not in an on demand Document (ODD) document).

It is therefore possible for supplier A to create the Request form, for supplier B to set up the planning and have the report be prepared by supplier E.

Thus, the XTB-WD profile enables the TBR process to be supported simultaneously and relatively independent of each other through the use of standards. But there is a catch. The XTB-WD profile depends on an XDS infrastructure, described in the IHE-IT Infrastructure Domain.

5.4.1. IHE IT-INFRASTRUCTURE DOMAIN

The IHE IT-Infrastructure domain provides the infrastructure for sharing medical information. Often times, the IHE IT-Infrastructure domain is placed at the same level as the infrastructure layer in the (five) layer model. However, this is incorrect.
An infrastructure as is meant by IHE means it consists of interoperability components. Software applications, which provides common IT functions that can be used as building blocks in themselves in many user situations (use cases). These components, very popular in the Netherlands, can be embedded in a functional application, such as the TBR. More often, they are deployed as a shared application within a collaboration where images and reports are shared among organizations, the IHE infrastructure domain is widely used. The IHE IT-Infrastructure domain is central to many other IHE domains. Its components can also be deployed independently from other domains to achieve exchange and interoperability. There are about 25 IT infrastructure profiles. Here you will find the most important profiles[34].

[34] *https://joinup.ec.europa.eu/collection/ict-standards-procurement/identified-ict-specifications-procurement*

Table 5: IHE Profiles in the IHE IT Infrastructure Domain

Profiel	Afkorting	Beschrijving
Audit Trail and Node Authentication	ATNA	Basic security through (a) functional access controls, (b) defined security audit logging and (c) secure network communications.
Basic Patient Privacy Consent	BPPC	Records a patient's privacy consent acknowledgement (for enforcing privacy appropriate to the use).
Consistent Time	CT	Synchronizes system clocks and time stamps of computers in a network (median error less than 1 second).
Cross-Community Access	XCA	Queries and retrieves patient electronic health records held by other communities.
Cross-enterprise Document Media Interchange	XDM	Transfers documents and metadata using CDs, USB memory, or email attachments.
Cross-enterprise Document Reliable Interchange	XDR	Changes health documents between health enterprises using a web-service based point-to-point push network communication.
Cross Enterprise Document Sharing	XDS (XDS-B, XDS-I)	Shares and discovers electronic health record documents between healthcare enterprises, physician offices, clinics, acute care in-patient facilities and personal health records
Cross-enterprise Sharing of Scanned Documents	XDS-SD	Shares unstructured electronic documents including scanned legacy paper and film
Cross-Enterprise User Assertion	XUA	Communicates claims about the identity of an authenticated principal (user, application, system...) across enterprise boundaries - Federated Identity.
Patient Administration Management	PAM	Establishes the continuity and integrity of patient data in and across acute care settings, as well as among ambulatory caregivers.
Patient Demographics Query	PDQ	Queries by patient demographics for patient identity from a central patient information server.
Patient Identifier Cross Referencing	PIX	Queries for patient identity cross-references between hospitals, sites, health information exchange networks, etc
Cross-Community Patient Discovery	XCPD	Locates communities with electronic health records for a patient and translates patient identifiers across communities.
Cross Enterprise Workflow	XDW	Coordinates human and applications mediated workflows across multiple organizations.
Document Metadata Subscription	DSUB	Subscribes for metadata-triggered notifications within an XDS Affinity Domain and across communities.
Notification of Document Availability	NAV	Supports out-of-band notifications of documents of interest between systems or users.

5.4.1.1. CROSS-ENTERPRISE DOCUMENT SHARING (XDS)

XDS stands for Cross-Enterprise Document Sharing. XDS is widely used in the Netherlands within regional healthcare networks and ensures that medical documents and/or images made available by a healthcare facility can be retrieved or displayed in a secure and electronic way when needed in another healthcare facility. All of this depends on a treatment relationship and patient consent. For example, the MRI from a cancer patient made in a general hospital can be used in the regional oncology discussion. The MRI can be retrieved when the patient has been referred to a university medical centre.

Although it seems like XDS is an application, it is actually the framework of different applications that each have a specific function within this framework, but all of which meet the integration profiles, as IHE has created them. Different suppliers can support different applications (IHE called these actors).

The main application is the XDS registry. This is the heart of the XDS framework. The XDS registry acts as a directory and keeps track of all references of documents shared on the network. Only one XDS registry can be present within an XDS Affinity Domain (network). However, multiple XDS networks can be linked together with the XCA profile. The XDS Consumer makes it possible to request the XDS registry and then retrieve the documents. There can be many different XDS consumers in an XDS network, as well as different suppliers. Just as multiple XDS repositories and XDS Sources can exist in a XDS network. An XDS repository is responsible for directing the documents within the XDS network to the XDS registry. The documents are created on the XDS source. An XDS source can be an EHR or, for example a PACS system.

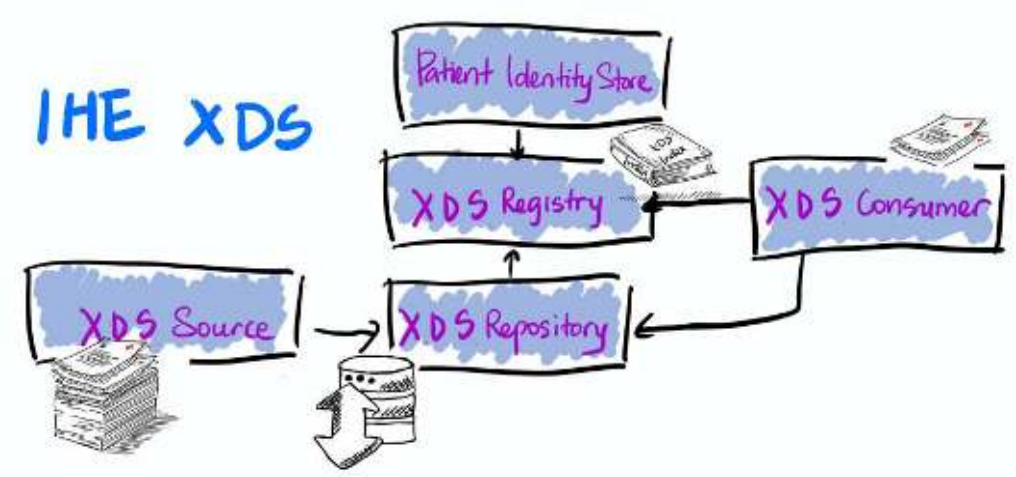

Figure 26: XDS Framework

More and more hospitals have set up an XDS environment, especially for image sharing. However, setting up an XDS environment is not easy. The costs can be relatively high if only a limited number of “use cases” use XDS. A XDS environment will only be truly effective if there are enough “use cases” running on it, and this is the biggest challenge in most XDS implementation. Implementing “use cases” are change management projects, but they are often being picked up as IT projects. Processes need to be adapted to work smarter and more effectively, and information standards need to be defined, which is difficult. There are now information standards that are excellent for placing documents in a XDS environment, such as the BGZ, E-medication, Baby Connect, E-lab, TBR Breast Carcinoma, etc..

5.4.1.2. FHIR

More often you hear that FHIR removes all interoperability problems. It is the standard of the future. It is certain that FHIR is based on more efficient protocols than the older HL7 protocols IHE uses frequently in its profile. FHIR uses RESTful services. In addition to the fact that the FHIR protocols are performing better and are more efficient than the current HL7 protocols, the use of these RESTful services makes it easier to develop new healthcare features. By providing information in demand-driven, real-time, the processes in healthcare can be reshaped and this enables the desired healthcare innovation.

FHIR Resource, also known as RESTful services or RESTful APIs, enable discrete data elements to be exchanged in real time between healthcare systems. There is a misunderstanding about the difference between applications with a) XDS, b) XDS with FHIR documents, or c) FHIR API. Nowadays it is often stated: “We can also do XDS with FHIR?”. However, there is a world of difference between FHIR documents and FHIR API. This difference has major implications for the functionality that can be provided with it. In healthcare, many patients’ data are currently duplicating, with adverse effects on current events, management, and AVG compliance. By definition, duplicated data is out of date within a certain period of time. The HL7v2, v3, CDA, XDS, FHIR document combination standards are largely based on this duplication mechanism. The purpose of the FHIR API is not to duplicate data: You request the data in real time if you need it and afterwards you throw it away.

It is important here to distinguish the difference between FHIR documents and the FHIR REST API. The following chapter uses FHIR REST API to create HL7-CDA documents published in XDS via on-Demand Documents. This is different from FHIR documents that use a FHIR API to retrieve a document (e.g., a PDF). With the help of FHIR we can create a hybrid environment.

FHIR started 8 years ago and has currently arrived at the normative Release 4. FHIR release 4 supports approximately 80% of processes and data. Even though development is fast, FHIR is not yet integrated into many EHRs. Additionally, not all medical data is volatile. Letters and reports have a persistent character and are therefore classified as documents, also the way we deal with images (Radiology) in the Netherlands makes them persistent. The authors are convinced that through the adoption of FHIR by the suppliers, EHRs will be able to support both documents and resources in the future.

For the TBR, FHIR defines different resources such as the FHIR resources Care Plan, Care Teams, and Care Tasks. If the regional TBR should make full use of these FHIR resources, then all EHR providers of all healthcare institutions participating in this TBR, must support these FHIR resources and the TBR process in their systems. However, this is not the case at this moment.

At the moment, there is an urgent need to support the transmural TBR process with both documents and discrete data elements. This enables us to use the existing environments in which investments have been made in the regions of the Netherlands over the past few years, supplemented by functionality that offers new standard to us.

5.4.2. FHIR AND XDS INCORPORATION

IHE has worked closely with the FHIR community over the last three years to incorporate FHIR protocols into the various IHE profiles. These new IHE profiles allow the creation of a basic application landscape where functional applications can exchange information transparently, whether or not the application supports the IHE-XDS protocols or the FHIR protocol[35]. Each of these protocols has its advantages and disadvantages[36]. In the following paragraphs, the necessary profiles are described. In the attached Addendum the IHE profile MHDS is described. MHDS is seen as the successor of IHE-XDS.

5.4.2.1. IHE ON-DEMAND DOCUMENTS (IHE ODD)

By using the On-Demand Documents profile, it is possible to generate documents dynamically when an On-Demand Document is requested via XDS. On-Demand Documents are used when the content is expected to change more frequently over time, while the document requester always wants to receive the most current content. The use of the On-Demand Documents is intended for an application architecture where the systems contains the patient data via the most up-to-date content available through an Application Interface (API). This On-Demand Documents profile is not specifically written for FHIR, but we can offer ODD's a collection of FHIR Resources as a RESTful API. This ODD profile allows FHIR Resources to be presented as a XDS document in the XDS network. XDS consumers can retrieve the document as if it was an "normal" XDS document. MedMij FHIR Resources can be linked to the On-Demand Document and presented as a "normal" HL7 CDA document in accordance with the Patient Summary/BGZ guidelines defined by Nictiz. This HL7 CDA document is described in the template section of Art-Decor.[37]

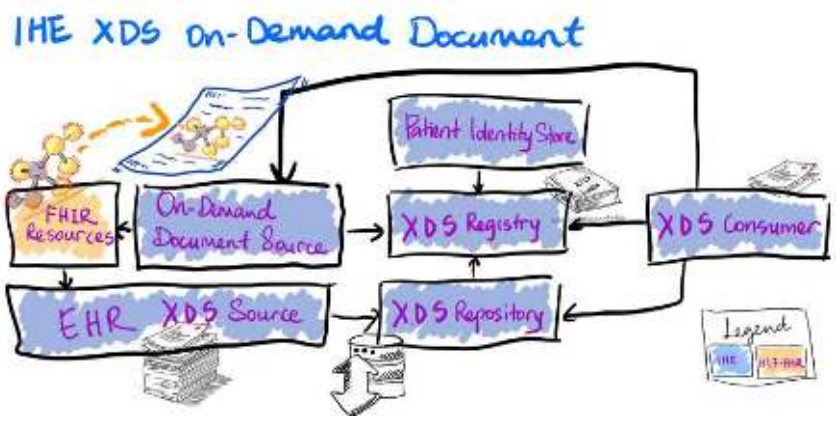

Figure 27: IHE XDS On Demand Documents

[35] *https://hl7.nl/component/zoo/item/gaat-hl7-fhir-ihe-xds-vervangen.html*
[36] *https://www.hl7.nl/component/zoo/item/het-combineren-van-fhir-en-ihe-xds.html?Itemid=270*
[37] *http://decor.nictiz.nl/pub/bgz2017/bgz2017-html-20190313T152910/rules.html*

5.4.2.2. IHE MOBILE ACCESS TO HEALTH DOCUMENTS (IHE-MHD)

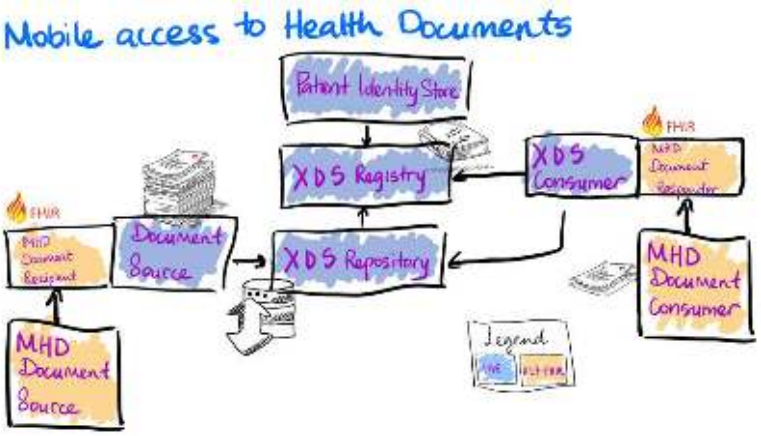

Figure 28: IHE Mobile Access to Health Documents

With On-Demand Documents, it is possible to create a document from FHIR resources. With the IHE-MHD profile [38] it is possible to retrieve a document stored in the XDS infrastructure by means of an FHIR resource. If this IHE-MHD profile is used, a RESTful service can retrieve the document, but the exchanged data still remains as a document. The information objects in this document have not been translated into FHIR resources. For example, EHR healthcare provider A provides the Patient Summary/BGZ as the MedMij FHIR resources. The IHE-ODD profile allows the MedMij FHIR resources[39] for the Patient Summary/BGZ to be packaged in the BGZ HL7 CDA format as determined[40] by the Registry at the Source. Now Healthcare provider B uses the IHE-MHD profile to retrieve the BGZ in HL7 CDA format. They do this with a RESTful call. This will allow them to retrieve the HL7 CDA document unchanged. At this point it is still one document. To turn the HL7 CDA document into the various FHIR Resources, 2 other IHE profiles are needed.

5.4.2.3. IHE MXDE AND IHE-QEDM

The Mobile Cross-Enterprise Document Data Element Extraction (mXDE) profile provides the ability to break a HL7 CDA document into specific data elements. This profile allows you to exchange discrete health data.

The IHE-mXDE profile allows you to request the Patient Summary/BGZ HL7 CDA document in XDS and, for example, filter out only the medication data. The IHE-QEDm profile allows this filtered data to be presented as FHIR Resources. The profile is designed in such a way that a retrieval does not require the underlying documents to be retrieved, but only those that are necessary for the FHIR call. This is to keep performance of the system on a high level.

[38] *https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_MHD.pdf*
[39] *https://informatiestandaarden.nictiz.nl/wiki/MedMij:V2019.01_FHIR_BGZ_2017*
[40] *http://decor.nictiz.nl/pub/bgz2017/bgz2017-html-20190313T152910/rules.html*

For example, if a FHIR application wants to graph out the zinc levels of a patient from a lab system, the system knows which document contains the needed zinc levels and which documents to be retrieved by using these profiles. The lab documents that do not contain the zinc levels would be left out in the system during the request. This allows you to move from document to FHIR resources. By creating a basic infrastructure with the different profiles, complete bi-directional interoperability has emerged between FHIR resources and XDS documents.

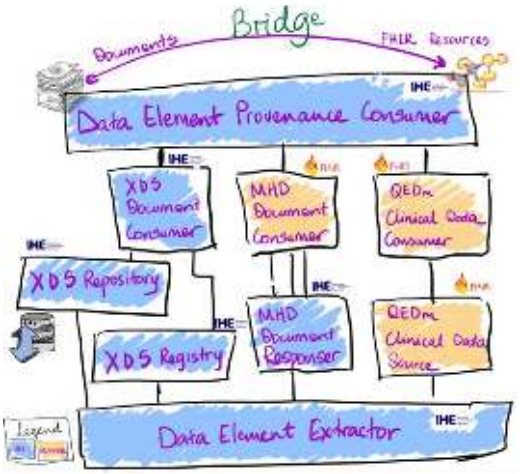

Figure 29: IHE mXDE and IHE QEDm

5.4.3. LSP

Although the Dutch National Patient Health Record Register (LSP) is not based on the IHE or FHIR standards, the same principles apply. The LSP can be called-up with On-Demand Documents and the documents that end up in the XDS from the LSP can be returned as FHIR resources via the IHE-MHD, mXDE and QEDm profile.

5.4.4. PUSH VERSUS PULL

For each “use case” it is important to research which technological standard is the best suited. This can be viewed from two different angles. The first angle is that of the type use case. When information is exchange once or more in a “use case”; the exchange take place between two healthcare providers, or more institutions are involved. A second angle is whether the information is requested (pull) or sent (push). In the Advisory Report on Infrastructure to Aczie written by Soulve[41] and in the final report nationwide referral[42] (Soulve Innovations, 2015), this has been discussed in more detail. The core of Both the reports are still valid, but the new technology FHIR-standard has not yet been taken into account (First FHIR implementation was in 2017). This explains why the statements of Soulve with FHIR are completed in the figure below.

From the overview below, it is clear that an “infrastructure” is required for both IHE-XDS and for FHIR. FHIR is sufficient for most “use cases”, but where more joint treatment in a transmural setting is needed, the XDS profile is currently the obvious standard.

We also have to take into account the fact that not all suppliers have both or one of the two standards built in the choice of technologies. There are also other standards such as Secure Mail, XDR and XDM. Like other proprietary solutions, such as “Zorg Mail”, “Zorg Domain” and for example, Evocs.

Finally, it is important to consider the Radiology and Cardiology images (DICOM). Increasingly, regions already have an environment based on the XDS profile in which healthcare organizations register all the images and related reports. If there is already such an environment, it is obvious that XDS us used for the Images, but also for other patient information. After all we want to duplicate as

[41] *http://www.landelijkdoorverwijzen.nl/wp-content/uploads/2014/03/2013-09-23_Advies-Infrastructuur-aan-AcZie-V1.1.pdf*
[42] *http://www.landelijkdoorverwijzen.nl/wp-content/uploads/2015/01/Eindrapport_v1.1.pdf*

minimal information as possible and reuse systems that are already available as much as possible. If the image and/or other patient information is already registered on XDS, we can refer with a reference link to XDS. If there is no XDS environment available, then IHE Cross-Enterprise Document reliable Interchange (IHE-XDR) profiles, for one-to-one transmission over the networks, and/or IHE Cross-Enterprise Document Media Interchange (IHE-XDM), for transfer by portable storage media, are suitable for the transfer of images and reports. DVDExit is based on IHE-XDM.

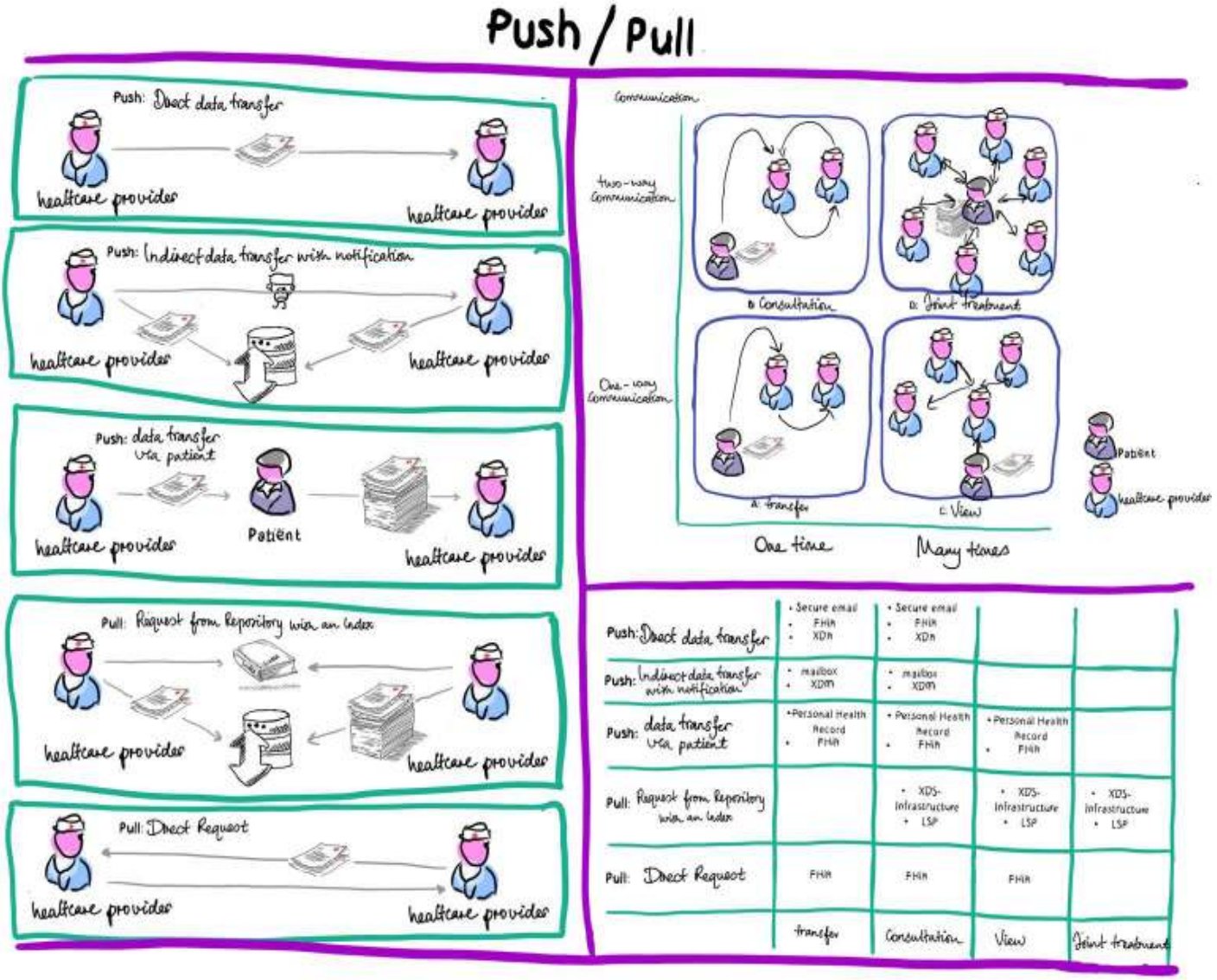

Figure 30: Push and Pull Scenarios

5.4.4.1. IHE PCC SUPPLEMENT DCP

THE IHE XTB-WD is a profile from the IHE Patient Care Coordination domain which tracks patients' workflow in the XDW workflow document.
The profiles described in the IHE "IT Infrastructure" domain are necessary to share the patient information between healthcare providers/healthcare institutions. The XDS profile from the "IT Infrastructure" domain supports the XDW workflow document. The actors who update the content of the workflow document are described technically with the condition that an XDS environment is available. However, many healthcare providers do not have access to an XDS environment. IHE together with HL7-FHIR has come up with a solution. The IHE Patient Care Coordination (IHE-PCC) Supplement Dynamic Care Planning (IHE-PCC-DCP) profile describe the link between the FHIR Resource Care Plan and XDW. This links the XDW Task with FHIR Task, as well as between FHIR Care Team and XTB participants. The document[43] (IHE Patient Care Coordination Domain, 2019) also describes all mapping on the meta-data level.

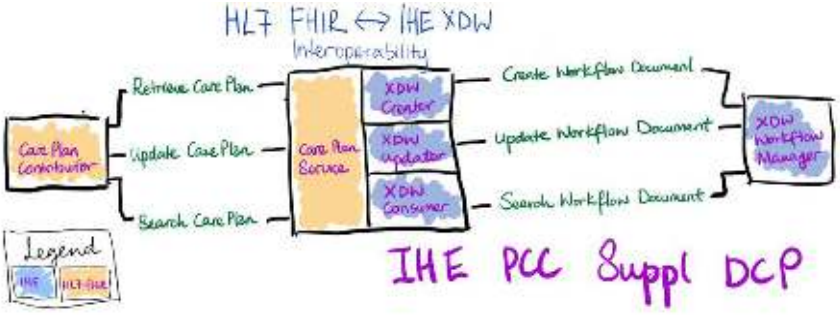

Figure 31: IHE PCC Suppl DCP

5.4.5. REGIONAL PLATFORM

If we want regional, national or international collaboration we have to work on independent data platforms. These can be set up regionally. KPMG also talks about the need for regional platforms in a whitepaper[44] "who does it with whom" (Poucke, 2019). In another whitepaper[45], KPMG writes that healthcare providers must prepare for these healthcare platforms. KPMG refers to a number of examples in China and the United Kingdom. KPMG believes that healthcare platform, as they describe as "healthcare control tower", cannot be stop. In order to achieve a standardized data platform, it is important that the above standards get an important position in the region. In this way, we can make rapid innovations possible and prevent suppliers and data lock-in's. Additionally to all the other benefits of reusing the data for scientific research and value for the patient and the healthcare provider, this can also lead to long-term cost reduction. The regional platform in the following example has an IHE XDS-FHIR-XDW Ecosystem under the bonnet. This is based on current implementation of the EHRs and the presence of an XDS environment. Open data platforms, partially present in the academic world, and open EHR functions by using FHIR API, require modifications to the current processes. Since we have assumed the current process and system design in this document, we have left a further development of a FHIR REST API based platform outside the scope of this document.

[43] *https://www.ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_DCP.pdf*
[44] *https://assets.kpmg/content/dam/kpmg/nl/pdf/2019/advisory/wie-doet-het-met-wie-2019.pdf*
[45] *https://www.icthealth.nl/nieuws/zorgaanbieders-moeten-zich-voorbereiden-op-platformzorg/*

THE REGIOPLATFORM IN IHE PROFILES

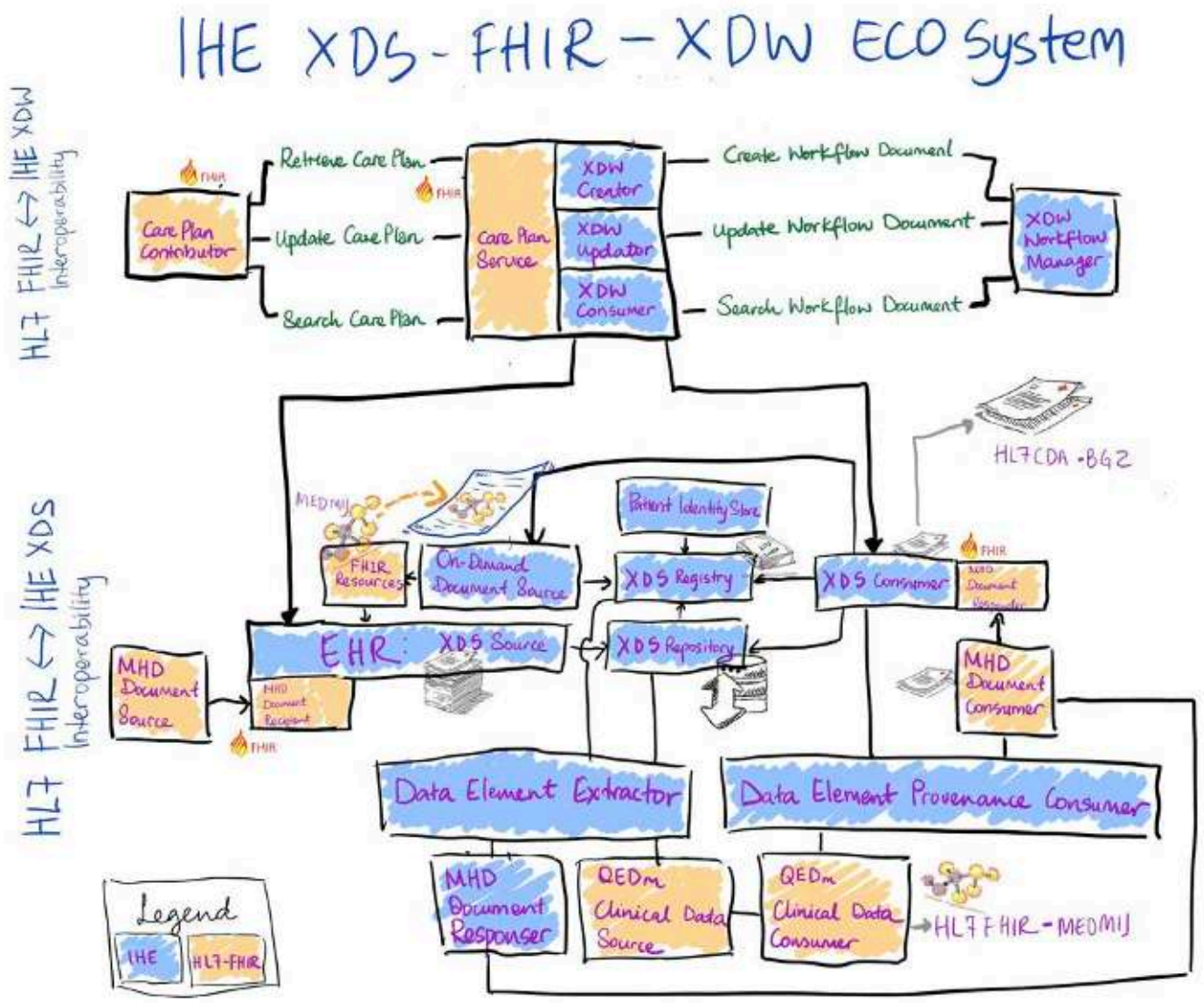

Figure 32: IHE XDS-FHIR-XDW Ecosystem

5.4.5.1. IHE MRFD

Many information standards also have pre-defined forms. These forms are managed by a national organization. Often these are professional associations, but this could also be Nictiz. NABON has, as described above, developed a number of forms that are managed by IKNL. It would be good if a healthcare institution who wants to use this form in a TBR, would ask IKNL if there is a newer version of this form every time it starts a TBR and if so, collect it. In this way, you are always sure you have the right version and that you are always in touch with the latest guidelines, which are part of this specific TBR. IHE described this, together with FHIR in an IHE profile. It is called; Mobile Retrieve Form for Data Capture (IHE-mRFD). This profile is entirely based on HL7 FHIR, which shows that IHE is constantly looking for the right existing standards for a particular “use case”. Together with OncoZon, IKNL is investigating whether this standard can be used in the TBR case.

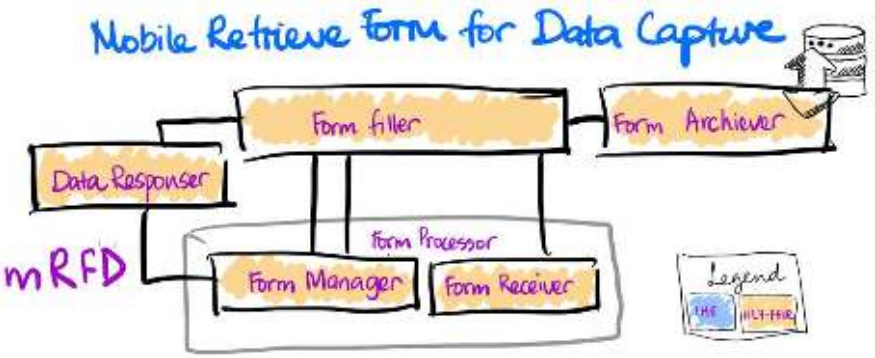

Figure 33: IHE Mobile Retrieve Form for Data Capture

5.4.5.2. DUTCH PATIENT SUMMARY (BGZ)

Although the Patient Summary/BGZ is not an application, it is useful to mention it here. The Patient Summary BGZ is generated from the applicant’s EHR upon request. If this maintained properly, it can be made available to the applicant to complete the form. This can made available in several ways:

- The application form is an integral part of the EHR and is filled on the background;
- The application form is not part of the EHR, but the EHR makes the Patient Summary/BGZ available for the data platform through FHIR resources;
- The application form is not part of the EHR, but the EHR makes the Patient Summary/BGZ available for the data platform by placing the Patient Summary/BGZ HL7CDA on the XDS environment as part of the data platform.

5.4.5.3. NATURAL LANGUAGE PROCESSING (NLP)

Much of the information that is necessary to be in structured form for a TBR is recorded in an unstructured way in the pathology and radiology reports. In the Maastricht UMC+ and Maastro Clinic, the radiology and radiotherapy [46] departments are working to extract the necessary structured data from the reports by natural language processing (NLP). The MEDSTRUCT-NLP application developed by S. Puts and M. Nobel is currently in a pilot environment. To date, this pilot seems to be very effective in filling the forms automatically. However with NLP it is not 100% accurate that the data is correct, but it can quickly be checked during the request process. After all, checking is less work than starting from the beginning. Machine learning is also intended to be used to allow the algorithms to achieve 100% accuracy.

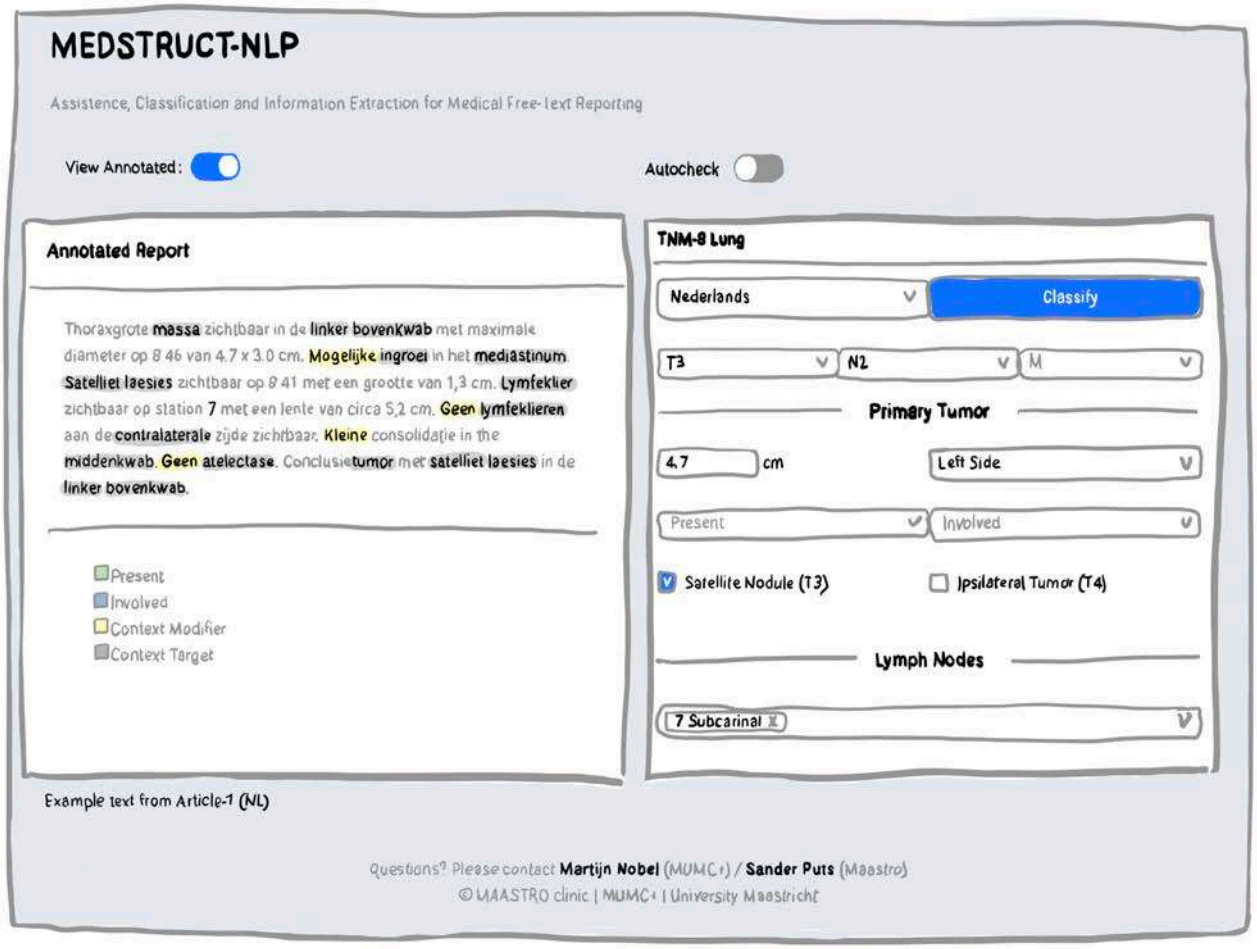

Figure 34: Medstruct-NLP developed by Maastro Clinic and Maastricht MUMC+

[46] *S. Puts, Maastro Clinic and J.M. Nobel (MSc), Maastricht UMC+*

5.4.5.4. ONCOGUIDE

An interesting development in the shared decision making is Oncoguide[47]. Oncoguide offers healthcare professionals the ability to navigate through oncology guidelines through a demand driven decision tree to reach the personalized treatment advice. Oncoguide is linked to the National Information Standards and the Dutch treatment guidelines of the professional groups. In Oncoguide, the decision tree is available based on the guidelines of Breasts Carcinoma. Additionally, Oncoguide can be linked to a Real-World dataset such as the Dutch Cancer Registration (NKR), thus using AI and Machine learning will make the predictive models increasingly better. By providing all the information in a structured form during the request, the decision tree can be automatically completed, and the treatment advice can be generated at the request, thus making the Oncology TBR quicker and more qualitative. However, healthcare professionals always stay in control and make the final decision. Thus, Oncoguide is a tool that can increase the efficiency of the TBR.

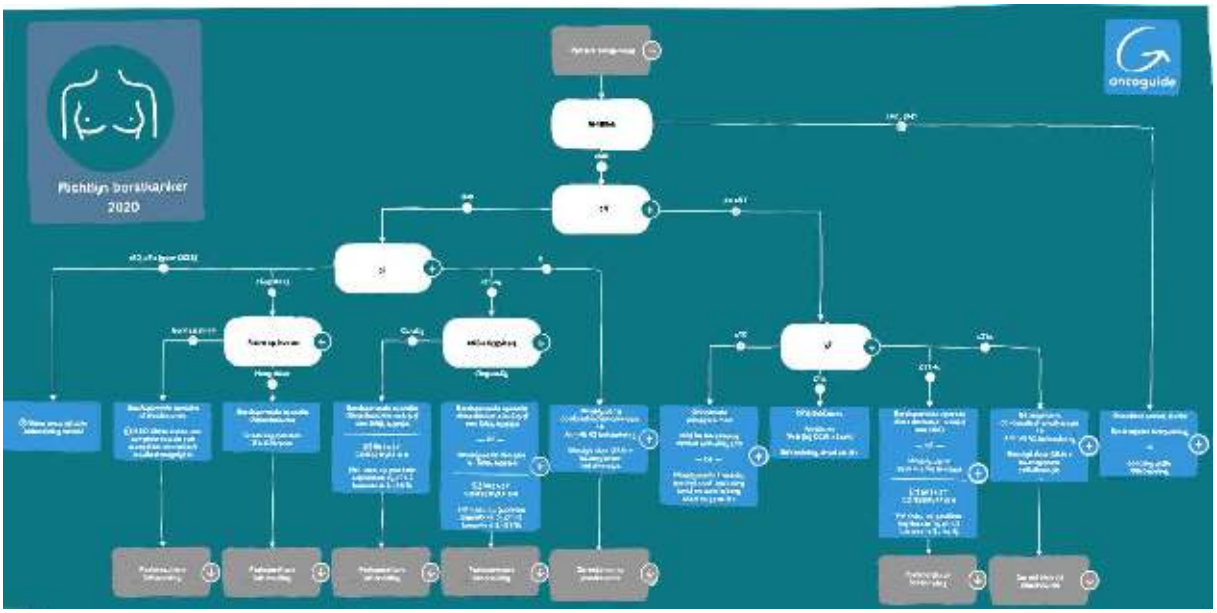

Figure 35: Oncoguide Decision Tree Breast Carcinoma

5.4.6. EXAMPLE TUMOR BOARD REVIEW BREAST CARCINOMA

To set up the application landscape for a TBR Breast Carcinoma, it will be necessary to look at each process step to determine which application best fits the healthcare provider's setting. Each healthcare institution or region has a different IT landscape and a "one-man-fits-all" approach is not possible. However, there are guidelines that gives guidance in making choices. The starting point here is that there is a regional platform that offers features as described in the Ecosystem. We do this using the following table.

[47] *https://oncoguide.nl/Oncoguide*

Table 6: Choise of data exchange model for MDO

Keuze Standaard MDO				
	Type of Communication	**Type of Data Exchange**	**PUSH/PULL**	**Choise Standard**
(1)Request	Data Exchange	Direct Data Exchange	PUSH	FHIR XDR, XDM (DICOM) XTB
(2)Schedule	Data Exchange	Indirect with notification	PUSH	MAIL XTB
(3)Prepare	View	Request from a repository with an Registry	PULL	XDS Omgeving XTB LSP
(4)Meeting	Joint treatment	Request from a repository with an Registry	PULL/PUSH	XDS Omgeving XTB LSP
(5)Finalize	Data Exchange	Direct Data Exchange	PUSH	FHIR XTB

In the first process step (request), a healthcare provider sends the request with all the necessary data to the TBR planner/coordinator. This request is characterized as a direct or indirect transfer of data that is being “pushed”.

Depending on the situation, different possible solutions can now be found that must comply with the standards used in the IHE-XDS - FHIR-XDW Ecosystem. These can be found in table 6. The application can be transferred to the Ecosystem via FHIR for medical data. IHE-XDR can be used to transfer images and reports. Mail can also be used for the transfer. These standards can be used if the request does not have a connected XDS environment. Some hospitals have already built the TBR form in the EHR. If this form is fully integrated with the rest of the EHR and in “Registration at the Source” format, the TBR form is already largely filled. This allows an applicant to work more efficiently by reducing the amount of information to be transferred. The completed forms can be sent to the platform through FHIR. The images can be sent via IHE-XDR. The platform is created in accordance with standards of a XDW document and the form will be registered in XDS, for those applications that do have a XDS environment.

Another possibility for the applicant is if the EHR builds all three IHE-XTB actors. The requestor must have a XDS environment on which the EHR can place the documents as we all as create the XTB workflow document. At the moment, there is no EHR supplier that supports this profile but theoretically that is possible.

Another variant is a TBR system as part of a platform. This TBR system has all the FHIR and IHE profiles necessary for a loosely coupled TBR system. The TBR application can then be called from the EHR. The context of the requestor and the patient is passed one on one. Single-Sign-On (SSO) should be arranged. From the participants point of view it does not matter functionally. This is the solution chosen in Utrecht (Raku) and OncoZon.

The difference between the form which is built by the EHR supplier and TBR application is that an EHR has all the data required to fill the forms. No additional Connection is required. The TBR application will need to retrieve this information from the EHR. This TBR application can retrieve the information via IHE XDS if the information is created by the EHR in a document form (HL7-CDA) or TBR application can retrieve the information using FHIR if the EHR offers the data as a FHIR Resource.

In this way, we can also set up all other applications. As long as the applications are connected to the platform, using the named standards, it will automatically synchronize all the underlying documents between XDS and FHIR without the user noticing it. We created independently and loosely coupled application landscape.

Based on NLP, unstructured text (e.g., Radiology reports) can be converted into structured fields according to the NABON information model. In this way, the applicant types less, and the request will be realized more quickly and easily. Machine learning also reduces the margin of error in the long run.

If the data of the request is entered, the structured data can be sent to Oncoguide. In thec Oncoguide the flow of decision tree is automatically completed, and a treatment advice is received by the requestor. This treatment advice is transferred with all the information (FHIR, Mail or XDS) to the planner (scheduler).

In the following paragraphs, we presume that a TBR coordinator is available. It would be desirable to describe another scenario for the hospitals where there is no TBR coordinator available; however, this scenario is not included in this document. A similar process can be followed with some other roles and casts.

The second step is that of the TBR coordinator (planner). The coordinator has received the data from the requestor. Based on the data, the TBR coordinator will choose the suitable TBR. At this moment, the selection of the suitable TBR (Echelons) is done by the coordinator. The coordinator does this based on the information he/she receives. Since the data is often incomplete or hidden in unstructured texts, it is a lot of work for the coordinator and mistakes are made, as a result an incorrect TBR is selected and the patient has to be discussed again later in another TBR. This takes time which is not good for the quality of the patients healthcare and it is also not cost effective. If we receive the data in accordance with the NABON information model, we can automate the planning using the decision-supporting tools.

After the TBR has been scheduled, the participants are notified (Push). This is an indirect transfer with notification. According to the model, it is best to use the e-mail for this. In the (secure) mail the appointment can be confirmed as well as the link to the necessary documents for the assessment. If the mail passes through the platform, the platform can modify the patient's XTB workflow document.

The third and the last step described in this document is that of Preparation. The Preparation is the Inspection and Transfer based on a XDS repository and a XDS registry. The type of information exchange is "Pull", because the planner determines when he wants to have access to the documents. It is not desirable to duplicate and to "give" the data to the participants in this case.

Therefore, the application necessary for the preparation is an XDS Consumer for viewing the documents and the application must provide the opportunity to take notes and place these notes on XDS to share them with other participants. The application also needs to modify the patient's XTB Workflow document.

5.4.7. CONCLUSION 'APPLICATION LAYER'

Conclusion

- The TBR application landscape can be configured independently of the type of TBR. The necessary information and the forms make the difference. Not the process and not the applications;
- Any process step could be implemented by and other application/supplier as long as it adheres to the FHIR or the standards in the IHE profiles;
- There should be a regional/national platform which links the IHE XDS environment to FHIR, the IHE- XDS – FHIR- XDW Ecosystem;
- Also, those healthcare providers who do not have access to a XDS environment can participate in a TBR process;
- Data is made available for reuse by using the standards independently of the source;
- The IHE IT-Infrastructure domain is located especially at the application level of the (five) layer model.

5.5. 'INFRASTRUCTURE LAYER' APPROACH

The infrastructure layer is the "simplest layer" of all layers of the (five) layer model. This layer contains all the servers running the applications described in the previous chapter. In addition, the servers are connected securely via networks. In the beginning of the network technology, this was difficult due to the lack of different network standards. Nowadays with the advent of internet technology, infrastructure is "common business". More and more facilities can be fully provisioned by cloud suppliers. Physical servers have been replaced by virtual servers, physical firewalls have been replaced by virtual firewalls and today we can create virtual networks ourselves. It is because of this far-reaching virtualization, that the location where applications and data stored is no longer important in principle, outside of the legislation and Privacy & Security. Amazon, Google and Microsoft are large cloud providers of this kind of infrastructure services. The fact that the infrastructure has already been so standardized, and that the cloud services are already so mature, also ensures that the applications are delivered from the cloud. For example, you see more and more companies reducing workforce systems as well as financial systems from the cloud. It is therefore expected that the healthcare applications will be offered from the cloud in a short matter of time. Patient portals, PGOs', questionnaires and also TBR "portals".

One of the focal points of the Infrastructure layer that we mention in this context is the regulation of the identification, authentication and authorization of users throughout the infrastructure. Of course, we can debate on whether this is an infrastructure service or an application. For identification, authentication and authorization the Security Assertion Markup Language (SAML) and open authorization (OAuth) standards are used. These standards are not only used in the healthcare sector. Both standards are described by "Organization for the Advancement of Structured Information" (OASIS). IHE has adopted these standards and described them in the IT Infrastructure (ITI) domain with the Cross-Enterprise User Assertion Profile (IHE-XUA).

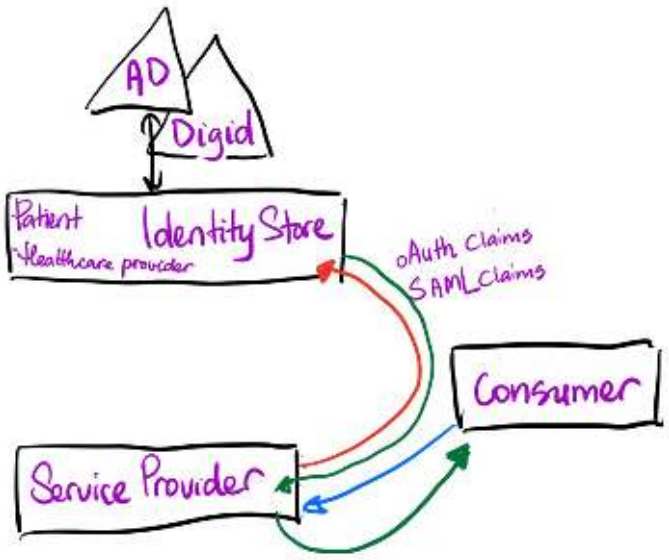

Figure 36: oAuth and SAML

The IHE profile XUA works with claims. When a user wants to access an application, they are asked to enter their credentials. However, this task has outsourced this functionality to an independent trusted third party. This can be a user authentication store within a healthcare institution (usually the Microsoft AD Server) but this could also be done by DIGID, known to every citizen. Even more familiar identity systems are those of Facebook and Microsoft. These identifying and authentication systems are called identity stores in the standard. If the user entered his credentials at the identity store (whether or not with 2 or 3 authentication factors), the user will receive a claim back. This claim is encrypted and proves that the Identity store has identified you. However, this proof may also include other items; "the claim". This encrypted message also includes the organization where the user works for or the role with which the user logs in to. These added claims are necessary for the application (the service provider), as they allow the user to be authorized within application.

Within the Netherlands, the role code table of the UZI-register[48] is used for the roles (Pelt & Breas, 2015). This is sufficient for the functionality in the applications. Unfortunately, these UZI roles codes are not sufficiently fine-grained which means that additional agreements are to be made at regional level, which do not always work at national level. It would be nice if a more extensive and finer set of role codes would be defined nationally. Especially for employees who are not registered in the UZI registration but who do have a role in the healthcare process. For example, think of the coordinator or the secretary of the TBR. They can only log in under the authorization (mandating arrangement) of a UZI registered employee.

5.5.1. EXAMPLE TUMOR BOARD REVIEW

For the Breast Carcinoma case, the EHR supplier has already developed a form. The EHR also contains the Patient Summary/BGZ and the Radiology reports. The EHR can use this to complete the forms automatically, possibly using NLP. The requestor then has little left to do to complete his/her request form. Once the form has been completed, the data can be sent via a FHIR message to a TBR-portal in the region. If the requestor does not have an XDS environment in this regional connected to a TBR portal, the requestor can load additional data such as images using IHE-XDR. If the requestor has a linked XDS environment, he/she can link the documents stored within the portal with a link to the request. Using the data obtained TBR portal can ask Oncoguide for a treatment advice. The TBR process is handled further in the TBR portal. At the end, the definitive report is sent back to the applicant using FHIR which can be processed automatically in the EHR.

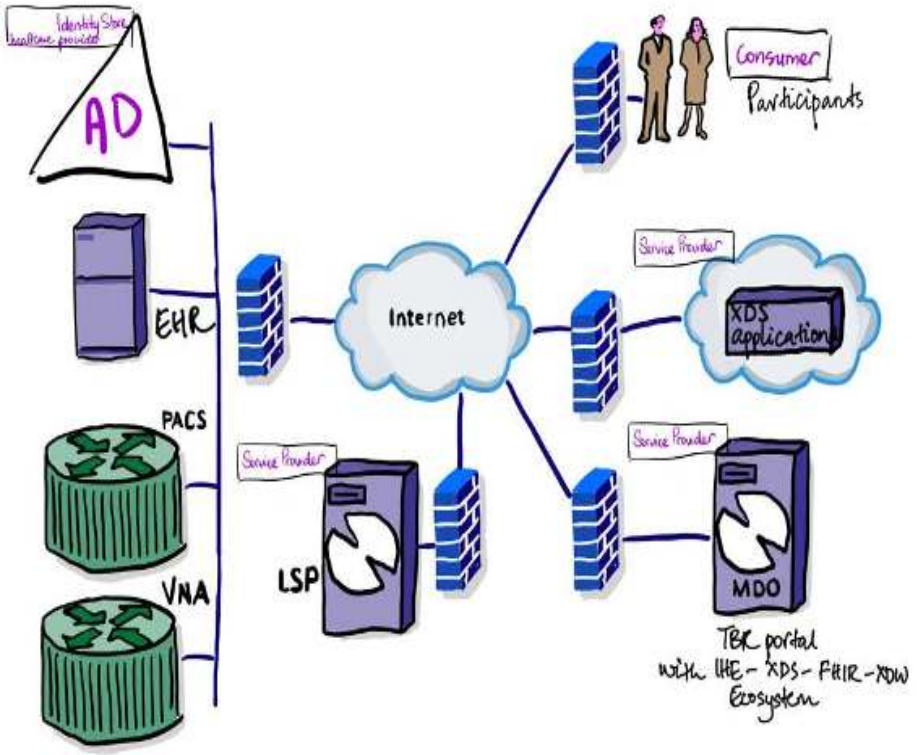

Figure 37: Simple Infrastructure Model for TBR

The “Infrastructure layer” / “application layer” under the regional TBR portal has an IHE- FHIR- XDW Ecosystem. An EHR is also used. The EHR can install the form itself or use the IHE profile to retrieve mRFD at IKNL. The Link with Oncoguide for retrieving the forms as well as for requesting a treatment advice is not mentioned in the drawing.

[48] *(Pelt & Breas, 2015)*

In the figure below is the traffic flow drawn. The connections will have to be secured over an SSL and/or via VPN connections.

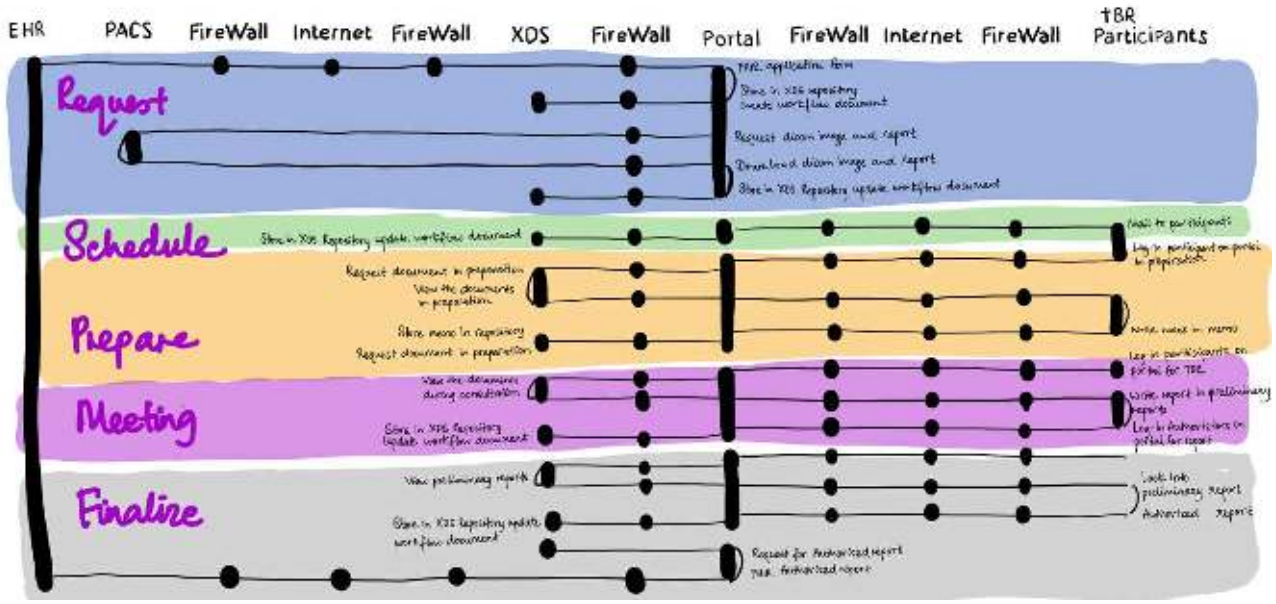

Figure 38: TBR Traffic Flow

5.5.2. CONCLUSION 'INFRASTRUCTURE LAYER'

Conclusie

- By using a regional IHE- XDS- FHIR- XDW Ecosystem, it doesn't technically matter for the applications if they use FHIR or IHE profiles;
- The infrastructure layer is completely disconnected from the application layer;
- More and more infrastructure services are already as "gas-water-electricity". The infrastructure are increasingly become Cloud services;
- It is expected that TBR solutions will be offered as Cloud services according to the standards.

6. FINAL CONCLUSION

Transmural TBRs are increasingly better and more efficient partly due to the use of echelons. However, collecting the required information for TBR still seems to cost a lot of effort and is often a (too) lengthy process. The number of transmural TBRs continues to increase and the need for efficient data collection is evident. We can see that transmural TBRs on the "Policy and Organization", "Process", "Application" and "Infrastructure" layers are not substantially different and can be arranged relatively uniformly. It is the "information" layer that makes the difference. The information models, the structure and the codes are necessary for interoperability and the deployment of decision-supporting systems.

The Program "Registration at the Source" is essential and in the example of the transmural TBR Breast Carcinoma, the information models have been largely elaborated. However, there is still a technical obstacle in collecting the required information for the participant in this TBR. This obstacle can be solved by using existing technical standards and profiles such as HL7-FHIR and IHE-XDS. It is because all data can easily be added to the request, a lot of time is saved. Without overtyping, structured in such a way that decision support systems can support the choice of echelons, with the preparation of treatment proposals in accordance with oncology guidelines, and that quality parameters and deviating treatment, proposals are easily linked back.

This guide therefore describes a pragmatic solution for setting up a transmural TBR based on the combination of FHIR and XDS and the existing IT environments. Both XDS and FHIR can be used in parallely and/or in sequentially, depending on the "use case". It is no longer the case that you are obliged to purchase all the applications from one supplier for the whole process or that the absence of XDS is an obstacle to a transmural TBR. The standards are integrated in such a way that it is possible to support and connect components of the transmural TBR process from different applications and systems. The relationship between XDS and FHIR enables data to be provided automatically for the transmural TBR, without anyone working in the same application.

The use of an IHE-XDS-FHIR-XDW Ecosystem makes data accessible independently of supplier's implementation. This Ecosystem can be used not only for TBRs but also for the support and innovation of other transmural healthcare processes and possibly reuse of data for Scientific Research and AI. The emerge of FHIR REST APIs enables process-innovation and the availability of real-time information.

The IHE process is based on the "use case" and the interoperability problem experienced by the healthcare professional. By defining the technical solution in an IHE profile, this can be tested by different suppliers at the IHE Connectathons. With this we kill two birds with one stone: the supplier has more scalable technical solution and the customer has a solution based on standards that is easier to connect and replace. IHE also has projectathons[49], where a use case with a whole set of profiles and multiple suppliers in different roles can be tested.

[49] *https://www.ihe-europe.net/testing-IHE/projectathons*

Figures

Tables

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IHE Guideline

Addendum

TBR within more Affinity Domains

& IHE MHDS

Foreword

In the IHE Guide “the transmural TBR Breast Carcinoma designed on the basic of National and International Standards” the use of multi-affinity domains has remained beyond scope. After this document was delivered, it was mainly from the suppliers that they needed, clarification and recommendation on how to deal with multi-affinity domains. It was also asked to explain a very recent IHE profile. This concerns the IHE-MHDS profile which is fully based on FHIR and has been made available to public comments.

The addendum is mainly technical in nature and particularly interesting for suppliers, architects, consultants and information managers. The following two questions are answered in sequence:

1) What to do if a TBR is held over multiple Affinity Domains (XDS) environments?

2) How to deal with the new IHE profile: Mobile Health Document Sharing (IHE-MHDS)?

November 2021, Marlene Gigase and Igor Schoonbrood

1. AFFINITY DOMAINS

More and more often, especially in the transmural TBR where several experts are involved, we see that there is more than one XDS affinity domain, which needs to be taken into account. This means that these different XDS environment will be linked together. For this link, the IHE profile “Cross Community Access Gateways” (IHE-XCA) is available.

1.2 MULTI AFFINITY DOMAINS

In 2015 Nictiz wrote in a guide on how to connect XDS affinity domain[50]. This document indicates that on a functional level within one affinity domain, a number of health institutions agree to cooperate under jointly agreed policies and share a common infrastructure. At a technical level, the document describes that an affinity domain consists of a number of well-defined document-repositories and document-consumers who have agreed to share clinical documents with each other. An XDS affinity domain has a number of properties:

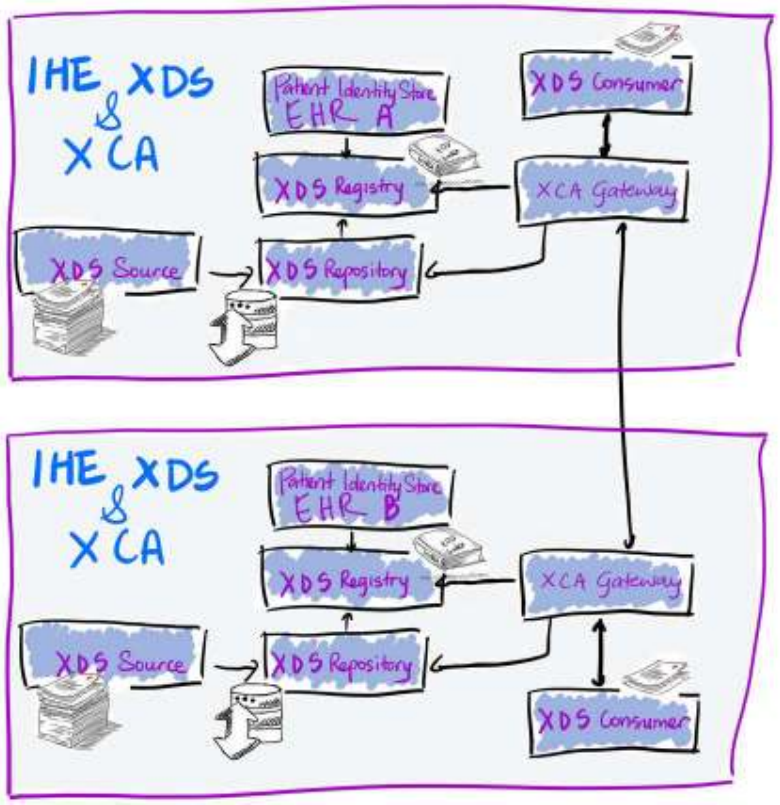

Figure 39: Addendum XDS and XCA

1. A XDS affinity domain has a single XDS Registry;
2. A XDS affinity domain may consist of one or more XDS repositories;
3. A XDS affinity domain may consist of one or more XDS consumers.

[50] *https://www.nictiz.nl/wp-content/uploads/2018/03/Handreiking_interoperabiliteit_tussen_XDS_Affinity_Domains_2015.pdf*

1.2.1 META DATA IN AN AFFINITY DOMAIN

When the information from patients within one affinity domain has to be disclosed to another affinity domain, the need arises to connect these affinity domains. This has led to the development of (Cross-Community Access) from IHE profile XCA, which allows affinity domains to be connected in a standardized and proven way. However, when linking several affinity domains, the problem arises, that these affinity domains can be arranged and organized in different ways. It is because though the IHE-XDS profile demands many things, there are parts that IHE does not make any statement over. This is partly due to the fact that the interpretation is different in different countries, for example due to legislation and regulations. Although IHE profiles are implementation guidelines, they still leave sufficient degree of freedom open allowing differences in the final implementations of XDS infrastructures. In a situation where multiple XDS affinity domains must be interoperable, these degrees of freedom must be restricted, and overarching agreements must be made. This is why Nictiz has made the “Interoperability between XDS Affinity Domains 2015” guide. In 2019, a new version of Metadata was published[51]. This version is internationally aligned with a dozen European countries and the U.S..

PATIENT REGISTRATION IN AN AFFINITY DOMAIN

An important point of attention within an XDS affinity domain is the patient registration. The patient must be known in the XDS environment before a document from this patient can be published in the XDS environment. IHE describes in its XDW profile[52] that there must be a patient registration system present. In the profile this is called the "Patient Identity Store" (see figure 2). Usually, this "Patient Identity Store" is the EHR. This fact has an influence on the choice when using an XDW profile in a multi-affinity domain.
This is further explained in section 1.3.1.2.

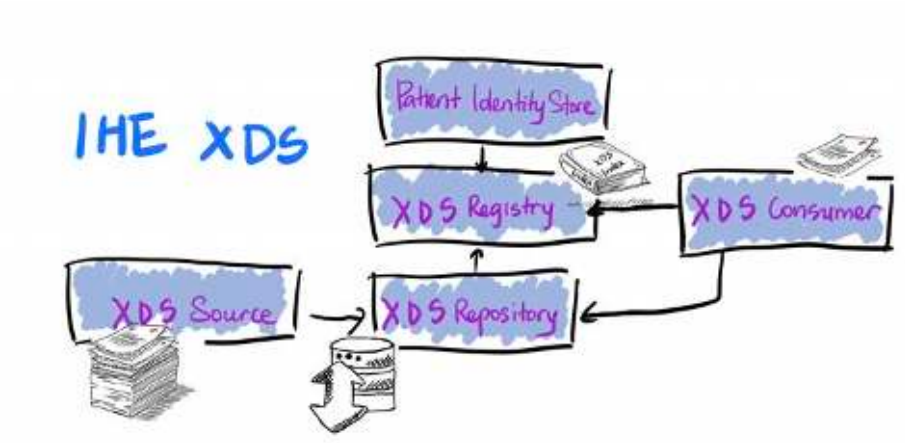

Figure 40: Addendum: XDS affinity domain with a Patient Identity Store

[51] *https://www.nictiz.nl/standaarden/xds-metadata/*
[52] *https://wiki.ihe.net/index.php/Cross-Enterprise_Document_Sharing*

1.3 MULTIPLE AFFINITY DOMAINS IN A TBR

As described in the guideline "The transmural TBR Breast Carcinoma designed based on national and international standards", the Cross Enterprise Document Workflow profile (IHE-XDW) is used for TBR, more specifically the Cross Enterprise Tumor Board Workflow Definition profile (IHE-XTB-WD). The basic IHE-XDW profile assumed that a workflow would only be within one XDS affinity domain. Later on, in 2015, a Supplement to this profile was called: "Cross-Enterprise Document Workflow Extension for Cross-Community Environment"[53]

This supplement describes in addition to a single XDS affinity domain, three possible scenarios for allowing XDW and thus also TBRs to work across multiple affinity domains.

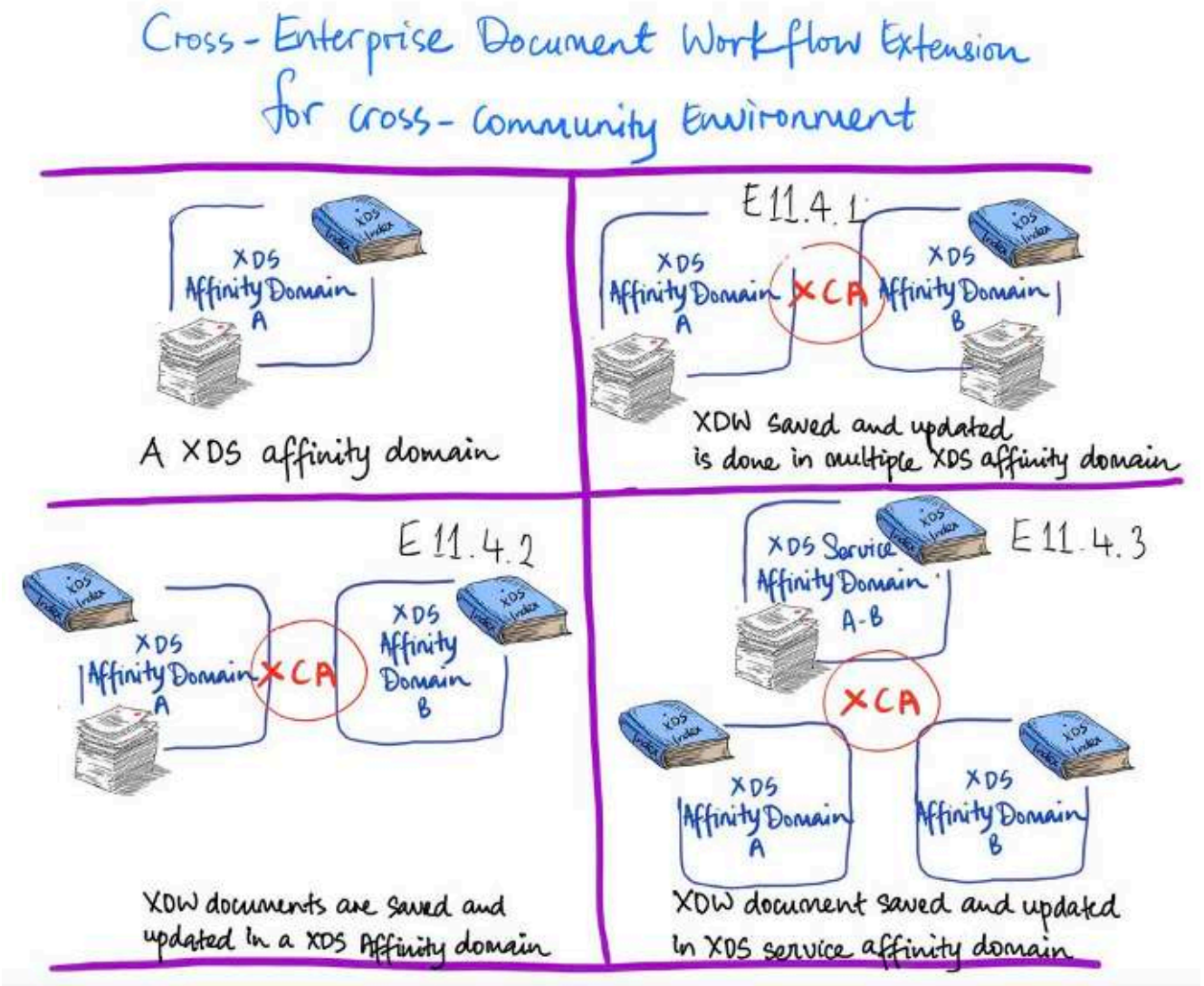

Figure 41: Addendum: Possibility of XDW Scenarios

[53] *https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_XDW_for_XCA_and_XCDR.pdf*

Basically, two scenarios are described in the profile.

1) All XDW documents are stored in the domain where the workflow starts.
2) All XDW documents are stored in one predefined domain.

The third scenario that is described, uses a "service" domain, in which the XDW documents are stored and updated. This is a combination of both basic scenarios.

There is a fourth variant that is not described in this IHE profile, but that can be implemented using the same standards. The assumption here is that wherever the XDW document is created or modified, the document is stored. The XDW document can therefore be stored in a different affinity domain each time, depending on where the last update was taken place. Since the authors consider this solution to be extremely opaque and complex,
we will not discuss it further in this addendum. We do not recommend this solution.

1.3.1 CHOICE OF SCENARIO

Each scenario has its advantages and disadvantages. It is therefore important to mention a number of points that are important to make the right choice.

1.3.1.1 RIGHTS TO WRITE DOCUMENTS

In the XTB-WD profile every participant has the possibility to change the status of an XDW document. For example, during the preparation of a TBR, each participant can add extra documents that the participant considers important for the TBR. In addition, in this preparation phase, one document is used in which each participant can write their comments in advance. This is a shared document in which each participant reads and writes.

This means that if one of the healthcare provider in affinity domain A, saves the XDW document, the other healthcare provider from affinity domain B can read and write in it. The healthcare provider from affinity domain B must be given the rights to actually make changes to the document. In addition, in one of the domains the shared preparation document must be made accessible to everyone and it must be possible to be able to modify it.

The question is therefore whether one of the healthcare institutions is prepared to open up its infrastructure to such an extent that these documents can be adapted by others.

1.3.1.2 PATIENT IDENTIFICATION

Within an XDS affinity domain it is necessary that the patient is known before a document about this patient can be created. The single source of truth of the known patient is, in accordance with the IHE XDW profile, a Patient Identity store. In general, this is an EHR or ECD from a healthcare institution. This EHR or ECD registers the patient data for the affinity domain.

In many cases, patients from different hospitals are discussed in one transmural TBR. The question is whether a Hospital A wants to register a patient in their EHR, while the patient is being treated by Hospital B, but delegates a Radiologist From Hospital A in the TBR. There should be a whole registration process for this, without the patient ever coming to this hospital. It is possible to register

a patient in the XDS environment without having to go through the EHR. However, this would mean that all kinds of identification guarantees that are present in an EHR and there would then be no single source of truth, which is not desirable. The Patient Information Reconciliation Profile (IHE-PIR)[54] describes the possibility of use a temporary patient number. This number can be merged with the new patient number at a later stage, after the patient has been included in the EHR. In this way the process in XDS can still go ahead and the temporary number can be "corrected" later. In other words, the IHE-PIR profile does not prevent the patient who is never treated in a certain hospital from being registered in this EHR.

1.3.1.3 UNAMBIGUOUS INFRASTRUCTURE/MANAGEMENT

From a management perspective, it is important that it is clear to everyone how the information flows open, what interfaces are needed, how the information is managed, where the documents are stored and when updates are made by whom. Even though the IHE profile "Cross-Enterprise Document Workflow Extension for Cross-Community Environment" gives the possibility to store (XDW) documents in affinity domains, it is not easy in term of management to solve malfunctions. Especially if different suppliers are used within the infrastructure that regularly look at each other when it's not working. From a management point of view, it is wise to store the XDW documents in one affinity domain.

1.3.1.4 RE-USE OF DATA

Information that is stored in XDW documents is very valuable to employees who are working process optimization. Additionally, on top of this data, process dashboards can be bought or developed. This data is also interesting for researchers (provided they have the proper consent). It is therefore important to keep the XDW documents in one place as much as possible. The medical data of the patient should remain at the source as much as possible.

1.3.1.5 TBR OF PATIENT FROM HEALTHCARE INSTITUTION WITHOUT AFFINITY DOMAIN

It may also happen that a patient needs to be discussed from a healthcare institution that is not (yet) connected to an XDS affinity domain. For example, a patient from an entirely different region or from abroad. Where do you store the patient data then? Where is the XDW document then?
In the guide "Transmural MDO Mammary Cancer designed on the basis of national and international based on national and International standards" refers to "THE XDS-FHIR-XDW Eco System". Here we can also ask the question where the documents are stored of the patients who are registered via FHIR. It is then useful to be clear in advance about which XDS affinity domain these patients are registered in and where their data is stored. Also, in this case, it is important that the documents are stored in one XDS affinity domain.

[54] *https://wiki.ihe.net/index.php/Patient_Information_Reconciliation*

1.3.1.6 DECISION PLAN

The above considerations in this addendum are in the following Decision Plan. Using this Decision Plan, an appropriate XDS/XDW affinity topology can be selected.

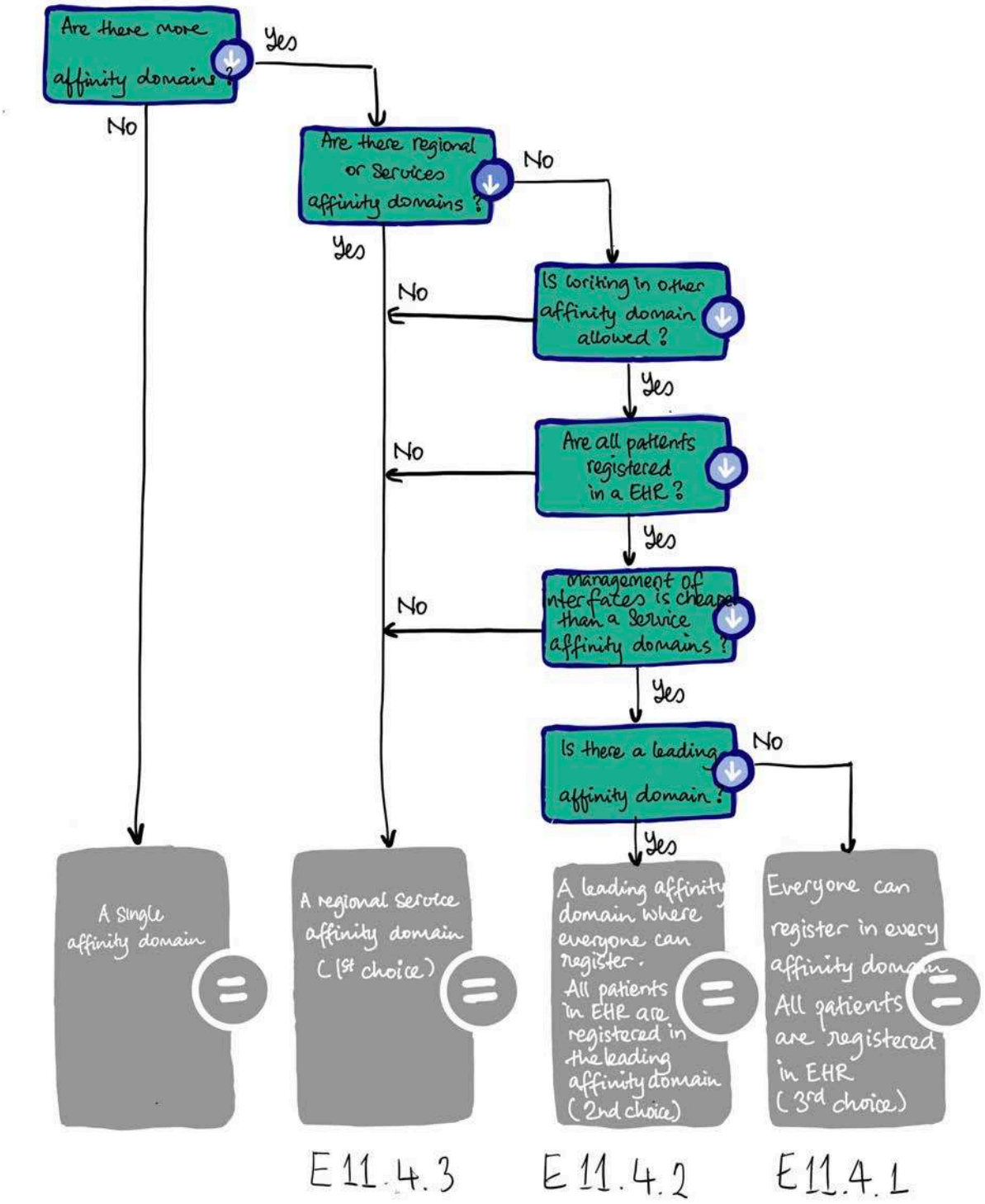

Figure 42: Addendum: Decision Plan XDS in multiple affinity domains

2. MOBILE HEALTH DOCUMENT SHARING (IHE-MHDS)

On 5 March 2020 , the Mobile Health Document Sharing (IHE-MHDS) profile for the 2nd review (Draft for public Comment) published.
A very promising profile that provides the possibilities of sharing documents entirely on the basis of HL7 FHIR. This raises the question whether the IHE XDS profile is now obsolete.

The IHE-MHDS profile proves that IHE and HL7 are increasingly working together. Profiles such as XDS, which were developed between 2004 and 2007, are based on SOAP (Simple Object Access Protocol) web services.

A web service is a software system that is designed to enable interoperable machine-to-machine interaction over a network. In general, the term refers to clients and servers that communicate using the HyperText Transfer Protocol (HTTP) protocol. Such services usually fall into one of two camps: SOAP Web Services (upon which is based on IHE-XDS) and RESTful Web Services.

SOAP Web services use Extensible Markup Language (XML) messages that follow the SOAP-standard are popular with traditional enterprises. In such systems, there is often a machine-readable description of the operations offered by the service that is written in the Web Services Description Language (WSDL).

More recently, REpresentational State Transfer (RESTful) web services have become popular again. RESTful negotiations Web Services makes greater use of the HTTP protocol, including: for media types, caching, authentication, and the HTTP methods such as the verbs: PUT (replace or update), GET (display or retrieve), POST (create) DELETE (delete). This makes RESTFul more efficient, simpler and cheaper to use. HL7 FHIR was developed in 2011 it uses RESTFul web services.

An update from IHE-XDS to IHE-MHDS was therefore in line with expectations. In the video[55] by John Moehrke, Co-Chair IHE IT Planning and Technical Committee, which also includes the IHE-MHDS profile, explains when you can and when you cannot opt for an MHDS profile.
In this video, it is also made clear that this profile is still in public review and that various topics have not yet been worked out. For example, the federative model has not yet been worked out. In addition, after reading the proposed profile, we can see that no account has been taken of the profile that DICOM messages have not been taken into account. Inquiries to John Moehrke that this item has been placed with the IHE Radiology Domain, where it has not yet been taken up. Furthermore no description or elaboration has not yet been made how XDS will co-operate with MHDS.

Given the developments in the market and the possibilities of RESTFul/FHIR, MHDS is a very interesting profile. However, it is not yet developed and there are still many questions to be able to say that IHE XDS is obsolete, as can be seen from the decision diagram (figure 5) presented in the video by John Moehrke. It will take a number of years before this profile is mature and proven. The authors consider this a very nice development and encourage us to contribute to it as much as possible. Certainly with regard to XDW, which is also not yet fully developed in this profile.

[55] *https://youtu.be/CX8q4hThmII*

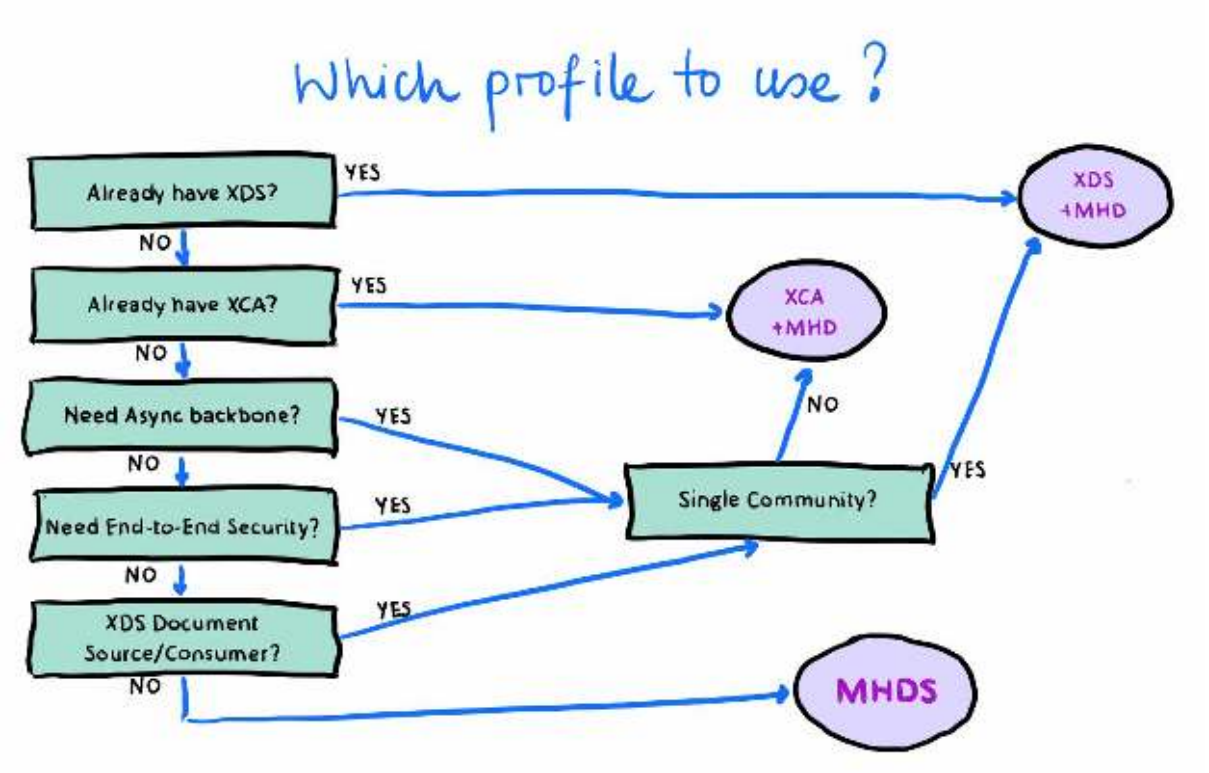

Figure 43: Addendum: decision diagram of MHDS