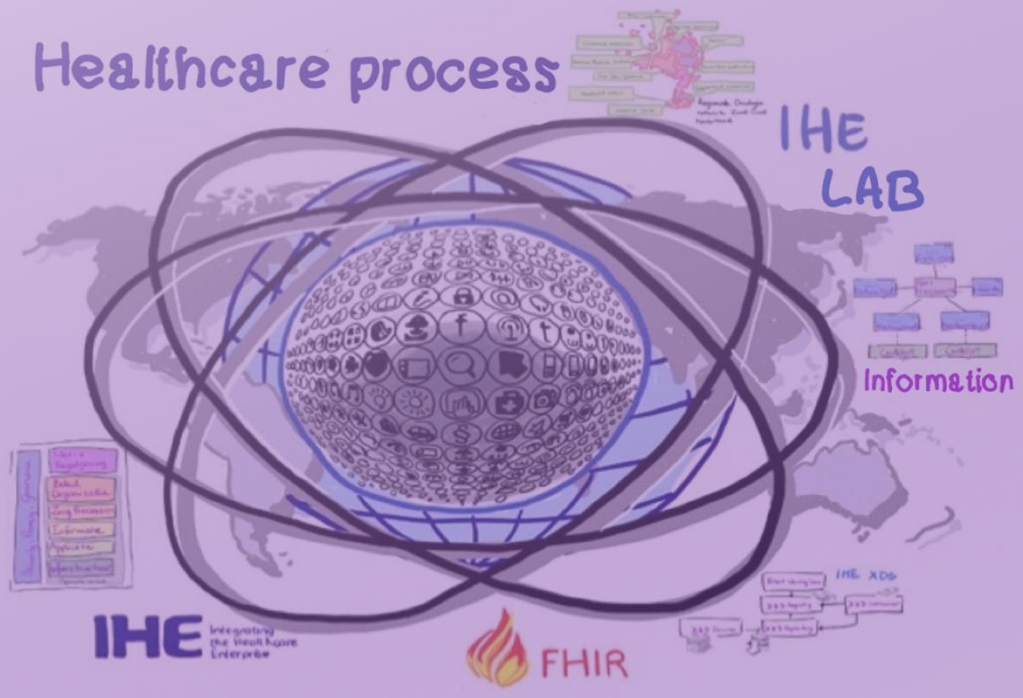
IHE THE NETHERLANDS
Integrating the Healthcare Enterprise

IHE Guidelines

Digital Exchange Laboratory data

based on national and international standards



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The members of the Healthcare processes working group and the reviewers of this document have taken the greatest possible care in terms of the content of this guide. Nevertheless, they accept no liability for any inaccuracies in this document for any damage or for any other consequences arising out of or in connection with the use of this guide. The document has been translated to American English, because all mentioned IHE profiles on which it is based, is written in American English. This has been done to avoid inconsistency.

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FOREWORD

Optimal Healthcare in networks, personal healthcare, joint decision-making, electronic exchange of data, reducing registration burden and the financial pressure on the healthcare system require cooperation and interoperability. Despite the urgency, virtually every healthcare network or cooperation struggles with the lack of interoperability: The ability of organizations – and their processes and systems – to share information effectively and efficiently with their environment. For example, electronic exchange of data becomes difficult, processes do not connect, system do not link.

This situation also applies to the transmural laboratory process. The electronic exchange of data between applicants and laboratory operators is difficult while the urgency to realize is high. The tariffs for laboratory research are thus also under considerable pressure. In various places in the Netherlands, people are therefore looking for efficiency and expansion of scale. After all, lower revenues demand more efficient processes and higher volumes.

This document was created at the request of the IHE Netherlands. The authors have been asked to draw up a guide that provides concrete guidelines for cooperation and interoperability in the transmural of laboratory process. Not only at the level of technical standards but at all levels of the interoperability model of Nictiz (NICTIZ, 2020).

The document is intended for a broad public of healthcare givers, directors, policymakers, information managers and ICT suppliers. The objective is to provide both insight into aspects and role of achieving interoperability in the laboratory process and provide a solution direction based on current technological standards. This should be done in a way that leaves room for innovation in regional, national and international laboratory networks without supplier lock-in.

The authors also hope to be able to contribute to the development of the knowledge on electronic data exchange. By sharing knowledge about a structured approach with a set of current standards, independent for suppliers, we are pragmatically seeking to accelerate the necessary interoperability in the transmural laboratory process. The aim is to speed up the digital connection from all parties involved, regardless of which digital networks, by applying current available standards.

We would like to thank everyone who has contributed to this guide.

June 2022

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THE SUMMARY

Cause and context
in the healthcare sector, more and more collaboration is taking place in networks to provide optimal care for patients and clients. The electronic exchange of data is a necessary precondition for the efficient and (cost)effective delivery of care. The government facilitates this development by means of various national programs aimed at the electronic exchange of data between healthcare providers and the patient/citizen. In addition, electronic exchange will be required by law within the foreseeable future by means of the Dutch Electronic Data Exchange (Wegiz) Act.

Laboratory data will also need to be exchanged electronically. Besides laboratories being part of a healthcare network, patients and healthcare givers have also requested for this and want to get rid of the paper transfers, overtyping and vulnerabilities associated with it. Through the merger of laboratories and diagnostic centers, organizations are created that provide their services across multiple regions to general practitioners, hospitals, other healthcare institutions and citizens. In this context, more and more laboratories are beginning to outsource logistic services – such as sample collection and transportation – to external parties.
All these developments require extensive digitization of laboratory process.

Cooperation and interoperability
These preciously named developments lead to more cooperation between parties in the transmural laboratory process. To ensure successful cooperation, organizations, including their processes and systems, need to be able to share information effectively and efficiently with their environment. This is called interoperability. Nictiz has created a model for interoperability. The model describes which arrangements should be made between organizations and at what level, to achieve interoperability. The model distinguishes between the following levels: Organization(policy), healthcare processes, information, application and ICT infrastructure. The use of (information) standards is part of the agreements made at the information and application level.

Interoperability agreements
For each layer of the interoperability model, this guide describes what arrangements should be made for cooperation and data exchange for the transmural laboratory process.
The *policy and organization* layer describes the policy frameworks (quality standards, use of standards and legislation), the architecture principles and the parties involved in the exchange of information and their role.

The *process* layer describes the process steps and the key points. This guide describes the following use cases as examples for digital data exchange in the transmural laboratory process:

1. Hospital practitioner files an application to a Diagnostic Center (DC).
2. General practitioner files an application to a DC and the patient makes an appointment at a DC location.
3. The general practitioner files an application to a DC and the DC uses an external supplier for the specimen extraction.
4. Patient applying for an examination themselves.
5. Outsource processing application by another laboratory.

Standardized data exchange is essential for requesting the process steps, request processing, sample take-off, transport, laboratory examination and reporting. IHE profiles offer a solution for this. Each process step describes which IHE profiles can be used for standardized exchange.

The next level, the *information* layer, describes which message standard and which coding system is used (NHG, LOINC, SNOMED-CT, NL-Lab code-set), per type of exchange.

The *application* layer describes the different applications that can support the laboratory process. However, many processes and applications are currently set up for the laboratory as one organization. The developments outlined show that the concept of a laboratory as a single organization is no longer self-explanatory. Multiple organizations working together in the laboratory process also mean that there are different applications that support specific parts of the process. In this guide, the applications are therefore described as separate applications (modules) with a specific functionality such as (entering) application, sample collection, transport, application processing, patient registration, etc. That does not mean that each of these applications needs to exist as a separate application: They can be part of an (commercially available) application that incorporates several of these functions. The interfaces between these applications as well as the exchange systems (e.g. XDS and LSP) that can be used in the laboratory process are described.

The guide also gives attention to the (re)design of the work process. How does the information become available: By requesting (pull) or receiving (push) the data? Is the exchange of information one-off or several-off? Does the exchange occur through separate messages or is an entire document exchanged?

The *infrastructure* layer in the definition as used by IHE is the 'bottom layer' of the interoperability model. This layer relates to the technical infrastructure in which the information systems of the parties concerned are located, such as the network, servers, database engine. It concerns the non-care specific ICT components.

Finally, for all layers of the interoperability model, for the electronic exchange of data, the organization and systems used must meet the requirements for information security and the applicable laws and regulations. These were briefly mentioned in the guide.

Advice

the current IHE profiles for exchanging information are mostly based on HL7 v2 standards and originate in supporting data exchange from the laboratory as a single organization. In practice however, it appears that suppliers have not incorporated in all transactions described in the IHE profiles, which means full interoperability is not fully implemented according to standards.

The developments do not stand still. The broad usage of the Internet has led to a new variant of the HL7 standard called HL7-FHIR. FHIR uses Internet standards to use application programming interfaces (APIs) to exchange healthcare information between systems. More and more innovative applications are emerging that communicates solely based on of FHIR. The current IHE integration profiles still do not include FHIR protocols for the laboratory, while the needed transactions is ideally suited for this. It is therefore necessary that new version of the current IHE profiles are made available in the foreseeable future in where protocols based on the FHIR standard are included.
However, it is already possible to set up a basic application landscape in which functional applications can transparently exchange information with each other, regardless of whether they support the IHE-XDS or FHIR protocols: An XDS-FHIR eco-system for exchange within the laboratory process. This eco-system is described in the section on the application layer.

1. INTRODUCTION

In healthcare there is on increasing collaboration between networks to provide optimal healthcare to patients and clients. The ability to exchange data electronically is a necessary precondition for the efficient and cost-effective provision of healthcare. Laboratory data will also have to be exchanged electronically. Not only because laboratories are part of a healthcare network: patients and healthcare providers demand this and want to get rid of the paper transfers, retyping and vulnerabilities that go with it.

This document is a guideline for the use of (information) standards that can be used for the implementation of electronic data exchange in the transmural laboratory process in the context of cooperation with healthcare providers and other laboratories. From laboratory application to delivery of the laboratory report (results) to the applicant.

Collaboration and interoperability

In order for the collaboration to run successfully, organizations including their processes and IT systems, must be able to share information effectively and efficiently with their environment. This is called interoperability. Nictiz has created a model for interoperability. The interoperability model (NICTIZ, 2020) describes which agreements must be made between organizations in order to exchange information efficiently and effectively. It concerns agreements that have to be made at different levels ('layers') in an organization. The model distinguishes between the following levels: organization (policy), care processes, information, application and ICT infrastructure.

Arrangements for interoperability

This guide describes the agreements made in regard to each of the five layers for the collaboration surrounding laboratory examinations.

Firstly, agreements will have to be made at organizational level between the collaborating parties. Several organizations are involved in the transmural laboratory process as well as the patient/citizen: healthcare institutions, general practitioners, other applicants for diagnostics, and laboratories that carry out the research and report results. In some cases, organizations that carry out the sample collection and/or the transport of the sample, are also involved.
Each organization is therefore involved in one or more sub-processes
(see figure 1).

Collaborative agreements must then be made to ensure that the (sub)processes are aligned. This includes agreements on which information is exchanged and between which application(s) that support the (sub)processes. Nowadays an organization uses different applications for different sub-processes to safeguard the entire chain of laboratory diagnostics. Information is exchanged between the applications based on information standards. Finally, agreements are made on the infrastructure on which the applications exchange information.

Current practice has its obstacles in the transmural laboratory process that are partly caused by

insufficient agreements created about the data exchange between the applications in order to ensure that the processes and sub-processes of the various organizations are optimally aligned.

IHE-integration profiles for data exchange
For standardized data exchange, IHE has IHE -integration profiles for specific use cases with the standards that are relevant for the respective situation.

This guide describes which IHE-integration profile can be used for standardized data exchange based on use cases for each subprocess of the transmural laboratory. When the ICT suppliers involved build their applications according to these IHE integration profiles and/or other relevant standards, interoperability is achieved within the laboratory process based on unity of language and technology. For the (healthcare) organizations involved, this also has the advantage that there is no longer a 'vendor lock in' because the exchange between applications takes place based on agreed IHE integration profiles and/or standards.

This document focuses particularly on the technical support of the transmural laboratory process based on the IHE integration profiles and available standards. The legal framework and matters surrounding information security have been kept out of scope, as well as the means for identification and authentication of healthcare providers and citizens/patients. Only a brief description of the legal framework is included in Appendix 6.

Reading Guide
After this preface, Chapter 2 provides an introduction to interoperability, how IHE integration profiles are created and other standards and guidelines for data exchange within the laboratory domain are created. Chapter 3 describes the transmural laboratory process. Chapter 4 describes the agreements that must be made at the various layers of the interoperability model. Chapter 5 contains the references and citations. Chapter 6, the members of the IHE-working group Healthcare processes that have drawn up this guide and the persons who have this document reviewed.

Finally, the following appendix is included:

Appendix 1:	Examples of IHE integration profiles
Appendix 2:	Description of the use cases
Appendix 3:	IHE integration profiles in the transmural laboratory process
Appendix 4:	The IHE integration profiles for each use case
Appendix 5:	Description of the IHE ICT Infrastructure domain
Appendix 6:	Brief description of the legal framework
Appendix 7:	Obstacles per interoperability layer
Appendix 8:	Terms, abbreviations and list of figures

2. BACKGROUND INFORMATION

To be able to collaborate successfully, organizations must make agreements with each other about interoperability and the use of (information) standards. This chapter explains the concept of interoperability and outlines the activities from IHE, Nictiz and HL7 regarding standardization of data exchange. In additionally, a description of a European project (X-eHealth) for electronic data exchange including that of the laboratory process.

2.1. INTEROPERABILITY

Interoperability is the ability of organizations (and their processes and systems) to effectively and efficiently share information with their environment. In the transmural laboratory work process, this means supporting the healthcare provider when requesting the examination until and including the delivery of the results with applications and equipment without additional manual intervention. This not only applies to the 'happy flow' but also to the exceptions in the work process. This is necessary for collaboration between organizations to run efficiently, safely and reliably. To achieve this, a well-designed architecture within an organization is required. A well-designed architecture is created by making agreements at all levels in the organization with all those involved. For example, from the infrastructure to the policy, and to structure the information provision and ICT within an organization. This creates operational solutions that are applicable within independently operating organizations.

Nictiz has developed the interoperability model for this, in which agreements have to be made at various levels ("layers") in an organization in which the data exchange is based on. Each layer has its own actors, concepts and standards.

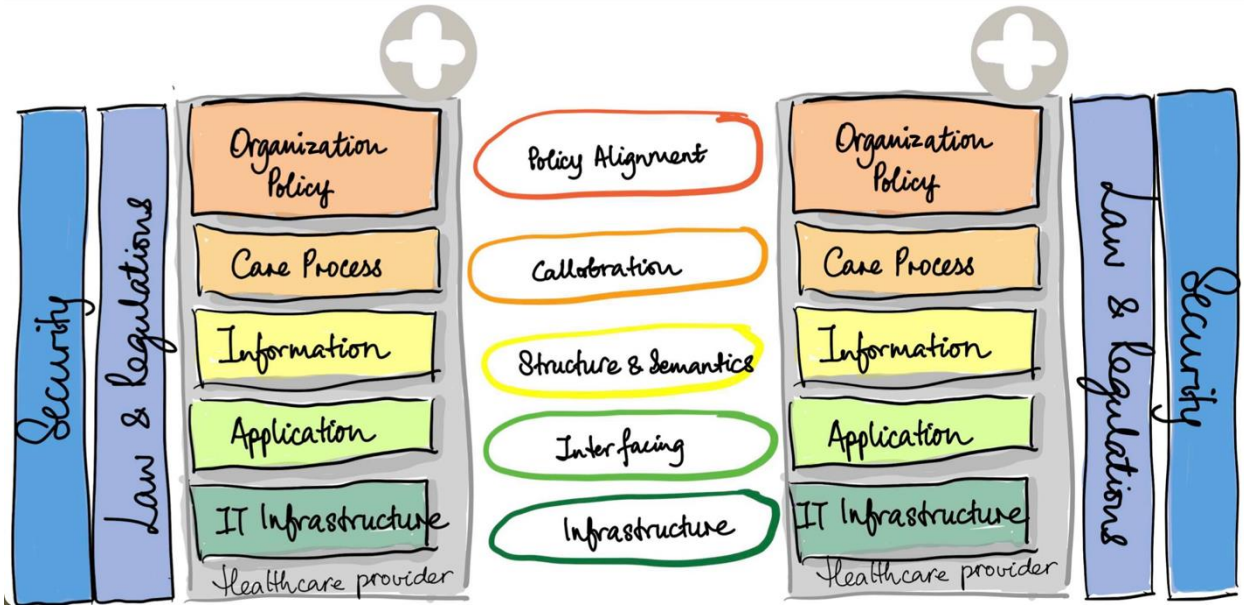


Figure 1 Nictiz Interoperability model

The model has the following five layers (see figure 2):

1. Policy and organization
   This level relates to the organizational side of the collaboration between the care organizations involved: who is involved in the collaboration and how are responsibilities and powers defined? These agreements are made at administrative level.

2. Healthcare processes
   In this case, this level relates to the cooperation between the involved care and laboratory organizations in the transmural laboratory process: among other things, which interfaces and transfer moments exist between the organizations involved. These agreements are made with healthcare professionals and managers.

3. Information
   This level relates to the information aspects. What information must be recorded and shared in the context of the collaboration during the transfer moments in the care processes: how is this structured or coded, and what is the coherence. These agreements are made with professionals from healthcare and information provision.

4. Applications
   This level relates to the information systems. Which information systems at the involved parties are relevant for the necessary process information and how is the required information shared between these systems? These agreements are made by healthcare professionals, application managers and sometimes suppliers. Examples of standards at this level are the IHE integration profiles and syntactic exchange structures such as HL7v2, HL7-FHIR, Edifact.

5. ICT Infrastructure
   The ICT infrastructure describes the basic functionalities that are required in the healthcare landscape, such as a solution to share medical data with each other and the way to determine the authentication and authorization of users. Setting up a safe and trusted IT environment with the necessary time synchronization is also described here. These are solutions that are based on open standards and are therefore supplier independent. What is not described here is what kind of servers are used, which firewalls, what a DMZ environment looks like or which database is used. These components are not based on open standards and we leave these solutions to the healthcare institution itself.

In addition, two preconditions apply to all layers, namely security requirements for electronic data exchange and the applicable laws and regulations. These preconditions are only briefly mentioned in this guide. For more information, an overview is included in appendix 6 of the legislation and regulations that are relevant to the laboratory process.

In this guide the five-layer model is used as a steppingstone for shaping the digital support of the transmural laboratory process between collaborating organizations based on the available and proven standards. It is indicated for each layer how interoperability can be achieved. IHE integration profiles are used for the Information and Application layers. In an IHE integration profile, the use and combination

of proven standards are described per defined part (per sub-process step) of the relevant healthcare process. This is further explained in the next section.

2.2. STANDARDIZATION

This section outlines the activities and initiatives of (international) organizations involved in data exchange standards in the Netherlands, namely IHE, Nictiz and HL7. It also includes a description of the activities within a European project on the exchange of laboratory data.

2.2.1. INTEGRATING THE HEALTCARE ENTERPRISE (IHE)

GENERAL

Integrating the Healthcare Enterprise (IHE) is an international and worldwide partnership between users and suppliers of ICT in the healthcare sector. IHE is a community. It's not a business. IHE is neutral and promotes the coordinated use of established healthcare and ICT standards such as DICOM, HL7, Syslog, SAML, ebXML, GS1, SNOMED CT, Rosetta, which specifically address clinical needs for optimal patient care. This mainly concerns the care processes, in which information exchange is indispensable, without any problems. More information can be found at https://ihe-nl.org/.

IHE PROCES

IHE brings involved shareholders, users and developers within a healthcare domain (eg cardiology, radiology, etc.) together in an annually recurring process to arrive at IHE Integration Profiles. The IHE process is an ISO-certified method[1] for identifying and solving identified problems in the healthcare information exchange. The IHE process consists of four steps:

1. Healthcare professionals define healthcare processes (use cases) in which the exchange of information is a critical success factor. The use case in which there is an actual experienced information problem is therefore caused by the healthcare field.
2. Technical experts create detailed specifications (IHE integration profiles) for the communication between the systems to fulfill these use cases. Existing standards are selected and optimized. An IHE integration profile contains a complete description of the actors (functional building blocks), transactions and required standards (such as e.g. HL7) that enable interoperability between the different systems in the relevant care process (the use case).
   An example of an IHE integration profile is included in Appendix 1. More information about IHE integration profiles can be found at https://the-nl.org/knowledge base/the-integration profile/.

3. The ICT suppliers implement the prescribed specifications, or IHE integration profiles, in their ICT systems/applications.

4. IHE tests the suppliers' systems in carefully planned and supervised events called Connectathons.

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

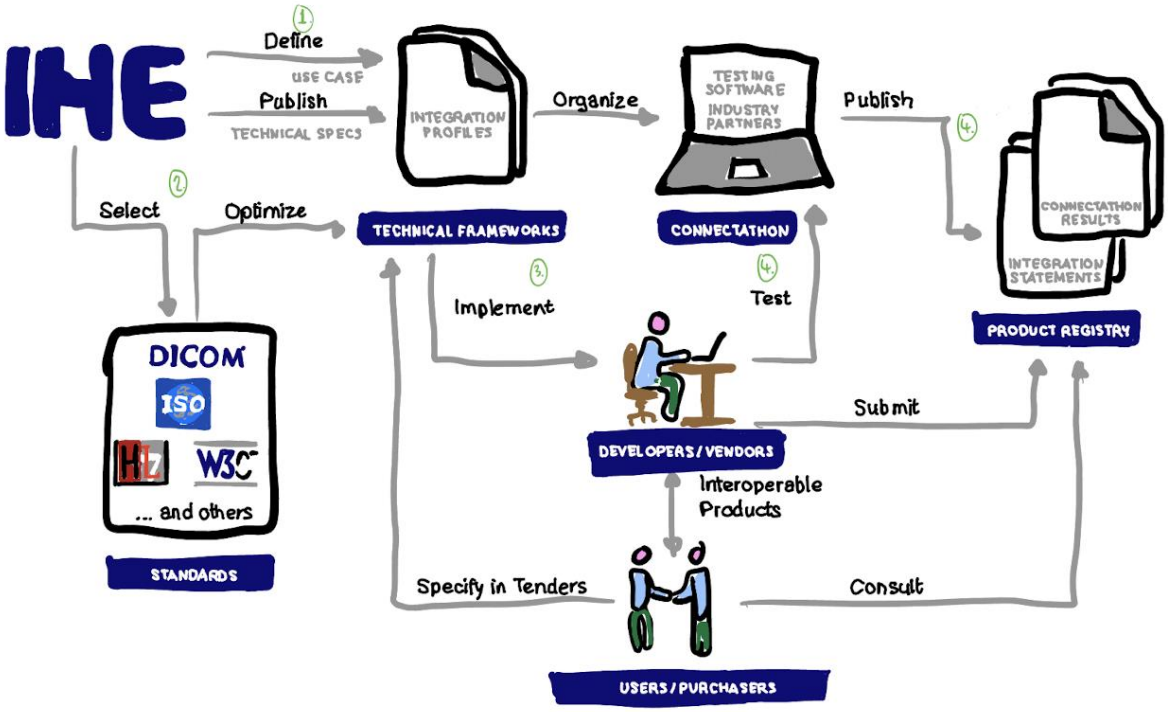


Figure 2: The IHE process

The outcomes of this process are interoperable products based on tested IHE integration profiles. When these IHE integration profiles are positively tested by the supplier on the Connectathons, the supplier may draw up an "Integration Statement" about this. This Statement about a specific IHE integration profile can be checked on the IHE website[2]. Healthcare institutions can contact (European) tenders to test these statements at IHE or against the requirements of the include tender specifications.

If suppliers use the tested IHE integration profiles in their applications, the exchange of information between the various applications should run smoothly.

IHE integration profiles have been developed for various domains:

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

[2] https://connectathon-results.he.nl

2.2.2. NICTIZ

GENERAL

The Netherlands ICT Institute in Healthcare (Nictiz) is the national, independent knowledge organization that is committed to digital information exchange in healthcare. It ensures that healthcare information can be unambiguously recorded and exchanged. To this end, it develops and manages standards that enable digital information exchange. Furthermore, Nictiz, as a knowledge center, ensures the collection and sharing of knowledge about digital information exchange in healthcare. This does not only involve the Netherlands, but also international developments. More information can be found at https://www.nictiz.nl/.

LABORATORY DATA EXCHANGE GUIDELINE

Nictiz published the Laboratory Data Exchange Directive in 2021 on the exchange of laboratory data [3].

The guideline describes the message and data set required for (automatic) electronic exchange of laboratory data between various parties in the healthcare sector:

- Lab2zorg: for submitting applications by the healthcare provider to a laboratory and the receiving of results; and for exchanging laboratory results between healthcare providers themselves;
- Lab2lab: for outsourcing laboratory research to another laboratory and feedback of the results after outsourcing;
- Lab2patient: for making laboratory results available to the patient;
- Lab2Publichealth: for exchanging public health results with the RIVM to prevent the spreading of diseases.

This guideline forms the basis for the information standard that describes the messages and data at a technical level. In the information standard, the parties involved lay down agreements that are important to enable the actual sharing and exchange of information. This guideline is complementary to this IHE guide. The advice is to consult both documents when implementing standardized data exchange in the transmural laboratory process. Where the guideline refers to 'patient journeys', this guideline uses the term use case.

The guideline was drawn up by Nictiz together with the Dutch Association for Clinical Chemistry and Laboratory Medicine (NVKC), the Dutch Association for Medical Microbiology (NVMM), the Dutch Association of General Practitioners (NHG), the Royal Dutch Society for the Promotion of Pharmacy (KNMP), the Dutch Association of Hospital Pharmacists (NVZA), the Dutch Patient Federation, the Federation of Dutch Thrombosis Services, the College of Medical Immunologists (CMI) and the Federation of Medical Specialists (FMS).

[3] https://www.nictiz.nl/wp-content/uploads/Richtlijn-uitwisseling-Labgegevens-v2.0.pdf

2.2.3. HL7

GENERAL

HL7 stands for Health Level Seven, the worldwide standard for secure, electronic information exchange in healthcare. The HL7 standard defines all types of data in all healthcare domains and sectors. The standard is developed and managed by the international HL7 organization, which is active in more than 30 countries.
In the Netherlands, the HL7 Netherlands Foundation develops, manages and coordinates the standards. The members of HL7 Netherlands put their employees available as volunteers to do the work within the foundation: developing and managing the models and standards, including implementation manuals and reusable building blocks for the Netherlands. More information can be found at www.hl7.nl

HL7 STANDARDS

The HL7 standards ensure information exchange and multiple use of information in healthcare for healthcare providers and patients. HL7 focuses on protocols in the application layer of the interoperability model

There are several variants of the HL7 standards: HL7 v2, HL7v3 CDA and HL7 FHIR.

HL7 v2	The HL7 v2 messages have traditionally been the core of HL7 and are becoming the most used. They support the most common transactions between HL7 v2 computer systems in healthcare institutions, including registration and recording of patients, placing orders and receiving results, writing prescriptions, agenda management and financial settlement.
HL7 v3 en CDA	HL7 version 3 is a group of standards based entirely on information models. The same models are used for HL7 v3 messages as well as HL7 CDA documents. The messages are intended for use between computer systems, while HL7 v3 and CDA documents are also readable for human. The standard defines communication produced and received by computer systems, with full preservation of semantics. As a result, HL7 v3 messages are useful when information has to be further processed and edited by the receiving healthcare organization in its own computer systems.
HL7 FHIR	HL7 FHIR (Fast Healthcare Interoperability Resource) is the latest variant and has been developed as an easy-to-use format for the exchange of healthcare information based on internet standards. 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 consists of reusable building blocks, the so-called resources, which can build fast-acting solutions for the exchange of both administrative and healthcare-related data. FHIR is currently named as the next major development in healthcare because of the possibilities for unlocking EMR-systems for mobile applications. Many suppliers have already adjusted to this standard. The expectations for FHIR are high in the Field.

2.2.4. EUROPEAN CONTEXT X-EHEALTH

The European X-eHealth project (www.x-ehealth eu) is working on a European framework for exchanging medical data, both within and between European countries, with the aim of a workable, interoperable, secure and cross-border electronic health record exchange format. One of the sub-goals of this project is the international exchange of laboratory data. With a working group containing members from different countries, this project proposes a specification for the exchange of laboratory data. Aspects addressed herein are:

-Functional Specifications
-Technical requirements
-Application requirements
-Logical information models
-Terminology systems

These are all considered within the framework of legislation and regulations. The project will run until September 2022, until then nothing in the project is final.

In order to achieve the goal, the project is based on the following principles:

- Using existing specifications and standards
- Specifications must be suitable for the major laboratory services
- Technology independent specifications
- Functional specifications must also be usable within a country and locally
- Establish a stable foundation for state-of-the-art and secure exchange of laboratory data

In the project, general matters concerning the exchange of laboratory results are first elaborated. This concerns matters such as legislation, regulations and policy, but also general semantics and, for example, the necessary licenses for the exchange of laboratory data. In addition, a number of use cases are elaborated. These use cases serve as a basis for the further development of specifications. These are prioritized and are picked up in order. A number of use cases have also been placed outside the scope of the project.

The use cases that will be developed are:

- Laboratory results reporting (priority 1)
- Lab order from a healthcare provider (priority 1)
- Searching laboratory results (priority 2)
- Searching laboratory orders (priority 2)
- Lab Services Search (Priority 2)
- Patient Lab Order (Priority 3)
- Lab suborder to another lab (priority 3)
- Patient tracking (priority 3)

The project builds an overview per chapter of all relevant matters for that use case, paying attention to the following matters:

- General information about the use case, such as the purpose and relevance of the use case, but also, for example, the general and possible deviations in process flow and the actors
- Laws and regulations that apply specifically to this use case
- Policy Information, such as organizational needs and, for example contracts

- Semantic choices, the project looks at LOINC, SNOMED CT and UCUM as semantic models. For each use case, it is elaborated how to use them, but also how conversions between code systems and units should work, for example.
- Engineering
- Information models are fully developed including data structures, data elements, semantic filling of these data elements and examples of how they should be filled
- Application requirements such as rules regarding the user interface are elaborated on the based-on examples
- Infrastructure
- Implementation; tips and examples are given here on how to deal with the implementation of the above points

Work is being done within the project to develop these matters. When Dutch suppliers / laboratories are involved in the implementation of one of the above-mentioned use cases, it is wise to take this into account and contact the X-ehealth organization. This can be done via IHE Netherlands.

3. THE TRANSMURAL LABORATORY PROCESS

This chapter describes the transmural laboratory process, the parties that play a role in it and what the obstacles are. In paragraph 4.2.2. use cases are described based on the obstacles.

3.1. PROCESS DESCRIPTION

For an applicant, the transmural laboratory process consists of applying for a laboratory research, possibly sending a sample and receiving the result. In current practice, it is a regular occurrence that the laboratory that initially receives the application outsources the application to another laboratory that carries out the research. In those cases, the applicant can receive the result of the application in parts.

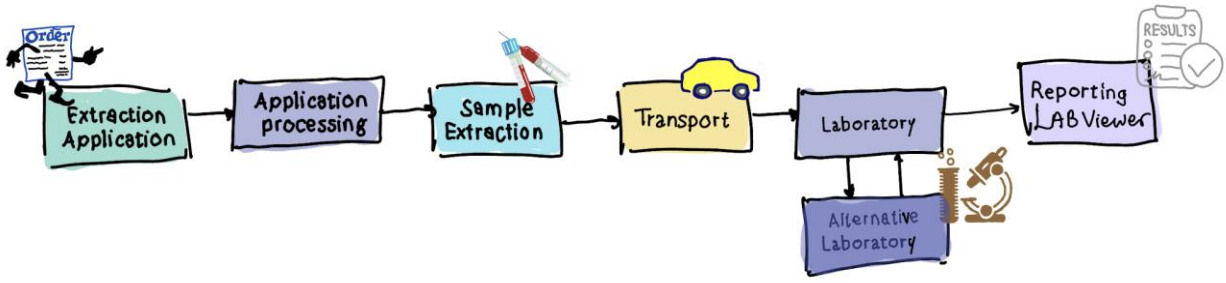


Figure 3: Transmural laboratory process

The process basically consists of the following steps:

- Extraction Application
  The process starts with the party that submits an application to a laboratory (healthcare provider). This guideline only focuses on the following types of applications:
  - Clinical chemistry
  - Medical microbiology
  - Pharmacy (medicine levels)
  - Thrombosis (anticoagulation)

  The Applicant can be a healthcare professional or the patient/client.
  The following applications fall outside the scope of this guideline: quality analysis (of e.g. drugs), function tests, pathology and imaging research.

- Application processing
  This application processor receives the application in this sub-process. Sometimes on paper, but ultimately preferably digitally. This application contains all the data necessary for the follow-up process. This includes the personal details of the patient, details of the applicant, any information about who should receive the results (report) and of course the research question in the form of the tests to be performed. The task of this sub-process is to check the data from the application and to supplement it if necessary. Think about:

incomplete information about the patient, an unknown applicant, the investigations to be performed is not being clear. In addition, the validity of the studies set to be performed must checked for the patient and applicant.

- Sample Extraction
  The sample is then taken, usually by a laboratory employee. This is done at the laboratory itself, a laboratory injection station, a ward or at the patient's home. During the sample collection process, the actual sample is collected from the patient and linked to the request. This process is responsible for labeling the sample (one or more), correctly linking the sample to the request, and establishing with certainty that the sample comes from the patient. To be able to do this, this process needs information about the sample to be collected and identification information from the patient. During this process, data about the sample and the collection is recorded. For example, think of time, location and person who took the sample.

- Transport
  Along with the relevant information, the sample is then transported to the laboratory. The transport is provided by the laboratory itself (for example by the employee who collected the sample) or by a party that collects the samples and delivers them to the laboratory.

- Execute application
  The result of the previous processes is a controlled application with the corresponding samples. During this step, the application may be split and individual or group tests will be performed. These groups can be performed in one or more laboratories. This process is responsible for correctly performing the tests mentioned in the application. In addition, this process will authorize the results. The determination is performed by the laboratory where the application is placed. In the event that the relevant laboratory is unable to perform the determination, the implementation will be outsourced to another laboratory. In practice it appears that only a small part of the applications is outsourced.

- Report
  The application contains the applicant's details and any copy of the applications. The system with the role of 'Order Result tracker'[4] ensures the correct reporting with the parties as specified in the agreements, included in the application.

- Receiving report
  This step is performed by various parties, almost always the party that has made the request. In practice, however, copies of (parts of) the results are often sent to third parties, such as pharmacists. Some parties have a legal obligation to provide this data. For others, local agreements have been made. More frequently reports are directly sent to the patient (legal law) which requires more explanation. Multiple reports can be sent from one set of data. It will be clear that privacy legislation applies in this context (appendix 6).

[4] See use cases in appendix 2 (with Reporting)

The number of organizations involved in the transmural laboratory process differs per situation. The options range from:

- (minimum) a healthcare provider (such as an institution, GP practice or GGD) where the healthcare provider or patient submits the application, and a laboratory organization act as executor,
- (maximum) a healthcare provider of the applicant, separate organization for respectively. sample collection and transport and a laboratory organization as executor in the role of "main contractor and one or more laboratory organizations to whom the execution has been outsourced.

Due to the digitization of the entire laboratory chain, the increasing need for digital exchange of laboratory data, as well as the increasing scale of laboratory organizations and expansion of the working area, it is expected that several parties will be involved in the laboratory process more often, as outlined in the maximum scenario. It should be clear that in this network of collaborating parties, data exchange plays a major role in achieving this efficiency, especially in these laboratory application processes.

In the transmural laboratory process, we mainly focus on data exchange between healthcare providers and laboratories (Lab2Zorg), between laboratories themselves (Lab2Lab) and between laboratory and patient (Lab2Patient).

3.2. PROCESS BOUNDARIES

A number of obstacles can be identified when setting up and executing the laboratory process. The bottlenecks have been inventoried in consultation with the participants in the IHE working group on care processes - laboratory. In specific situations there may be other obstacles that have not been addressed in this guideline. The list is not intended to be complete.

The figure below shows the broad outlines of the current obstacles in the Transmural system laboratory process.

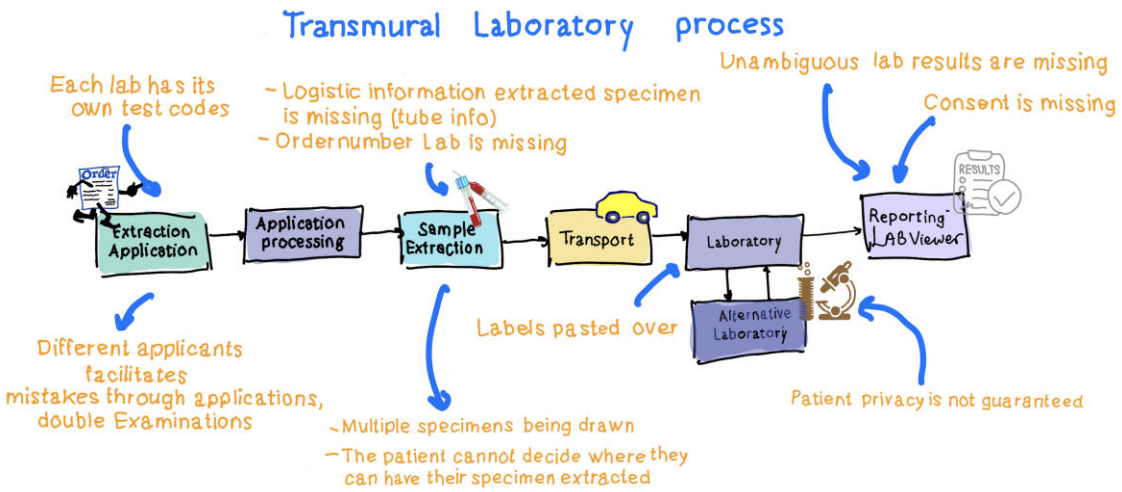


Figure 4: Obstacles in the Transmural laboratory process

Extraction Application

- Each lab has its own test codes
  Doctors in institutions without their own laboratory often have to send applications to different laboratories. For example, in a mental health institution where doctors can send clinical and outpatient patients to different laboratories. And in the evenings, nights and weekends to the hospital's laboratory.

  The problem is that each laboratory uses its own code sets for the lab tests. These are often their own codes linked to NHG codes and/or LOINC codes. This means managing multiple code tables (depending on the laboratory) in your own lab system and/or (in the link with) the applicant's system. In addition to the extra workload, this also creates problems in keeping the different code pages synchronized.

- Application errors
  When laboratories use their own test codes, errors may arise when applying because the applicant does not use the correct test code for the laboratory in question. Especially if applications are made to several laboratories and the same codes have a different meaning per laboratory.

- Coherence
  An extraction application can be a separate application, but it can also be part of a clinical path. There is a model that links requests together using unique keys. This model comes from IHE but has not yet been elaborated in this document. It is a general model to keep medical data together within a clinical path, not just for the laboratory.

Application processing

- Various extraction applications
  A laboratory receives extraction applications from various sources:
  - various healthcare providers such as general practitioners, doctors from the same hospital, doctors from nursing homes (without own laboratory)
  - other laboratory that outsource certain criterion, such as microbiology and medicines
  - the citizen/patient, for example Covid and STD tests

The challenge is to organize the flow of digital and paper applications from the various sources into an efficient work process, up to the reporting of results back to the applicant.

Extraction

- Logistical information (order number, purchase number, etc.) is missing
  When taking the order, the order number or the tube number is not recorded, which lead to the sample not being processed correctly. During extraction, several methods can be used to identify the pipes and containers. If an extraction is made using an order number or tube number, this must be recorded correctly.

  At the end of 2021, GS1, a standard organization for samples among other things standardized barcode, has launched a working group Identification and labeling of biological samples. GS1 wants to pay attention to the following:

- The worldwide inconsistency in identification and labeling of laboratory samples
- Increase of efficiency and decrease of error rate in work processes
- Improving patient safety and clinical outcomes
- Providing much greater understanding of the need for traceability
- Reducing the restrictions in hospital and laboratory systems that are the result of different solutions (analyzers, etc.) which, because of their own identifiers that are not interoperable

- *The patient wants to decide where the samples are taken*
  The patient increasingly wants to decide for themselves where they want to have their sample taken. Currently that's only possible at a location specified by the healthcare provider. For example the patient might consider whether the sample extraction location should be is close to home or close to work.

Report

- *Consent is missing*
  The results of certain applications are sometimes relevant for care providers other than the requesting physician. For example, the kidney function: this information is important for the pharmacist who is monitoring the medication. In addition to kidney function, there are some other factors that are relevant for monitoring medication and must therefore also be known to the pharmacist. In the current situation laboratories do not ask the patient for permission for sharing the lab results with care providers other than the applicant. As a result, the pharmacy can only obtain these lab results via the general practitioner.

- *Different formats of the reports*
  In the current situation, a doctor who files extraction applications at several laboratories often receives the results in different ways: electronically (in Edifact or HL7 format), on paper/email (PDF reports) or via a viewer directly in the LIS. This makes it impossible to obtain an integral overview of the results of all lab tests performed on the patient in question.

- *Application Report*
  When a research question is tackled by a laboratory other than the one where the application has been submitted, it is not always clear which laboratory reports the results to the applicant. The laboratory where the application had been filed? Or the lab that conducted the research?

- Presentation of lab results
  In the white paper "Exchanging laboratory results in healthcare (Laboratory Medicine, 2021) the laboratory specialists of the NVKC describe that the results of laboratory conclusions are increasingly regarded as independent bits of information. The number is supposed to belong to everyone. But blocks of information that are misplaced out of context may pose a risk to physician and patient. This certainly applies to the invisible use of laboratory results, for example in the increasingly broader use of results as input in decision-making algorithms.

4. INTEROPERABILITY IN THE TRANSMURAL LABORATORY PROCESS

This chapter describes which agreements must be made using the five layers of the Nictiz interoperability model to achieve interoperability between organizations that collaborate in the transmural laboratory process. Agreements are needed where both healthcare providers (such as institutions and GP practices) and suppliers of ICT systems must conform to achieve interoperability.

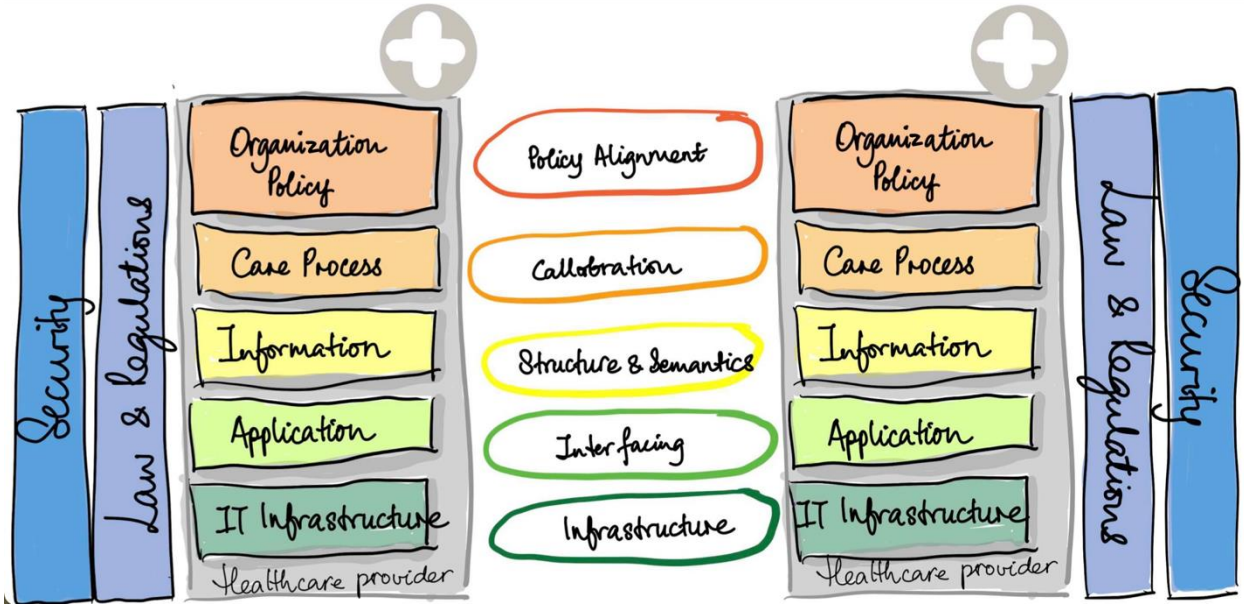


Figure 5: Nictiz Interoperability model

It concerns agreements on the following five levels of the interoperability model (see also chapter 2):

1. *Policy and organization*
   This level relates to the organizational side of the collaboration between the organizations involved: which parties are collaborating and how are responsibilities and powers defined? These agreements are made on management/administrative level.
2. *(Healthcare) process*
   This level relates to the process side of the cooperation between the organizations involved. For example, in which concrete sub-processes of the transmural laboratory process is collaboration needed, which interfaces and transfer moments exist between the organizations involved. These agreements are made with healthcare professionals and managers.
3. *Information*
   This level relates to the information aspects. What information should be recorded and shared at the transfer moments in laboratory processes between collaborating parties. How is it structured or coded and what is the coherence? These agreements are made with professionals from healthcare/laboratory and information provision.
4. *Application*
   This level relates to the information systems. Which information systems are relevant to the parties involved for the necessary process information and how is the necessary information

shared between these systems. These agreements are made by the healthcare professionals, the application managers and sometimes the suppliers.

5. *ICT Infrastructure*
   This level relates to the technical infrastructure in which the information systems of the parties involved are located, such as the network, servers, database engine. This concerns the non-healthcare-specific ICT components. On a technical level, how is it possible that information can be exchanged between the parties involved? Which communication infrastructure is needed for this? What mechanisms of information exchange should be chosen? These agreements are made by IT professionals.

In addition to the agreements made on these five levels, organizations must also adhere to the applicable laws, regulations and the standards for the secure exchange of medical data as expressed in the NEN standards. These subjects are broadly described in paragraph 4.6 of this document.

4.1. APPROACH 'POLICY AND ORGANIZATION LAYER ‘

In order to arrive at a well-implemented transmural laboratory process, it must be clear on an organizational level, what the frameworks are for the electronic exchange of data within this process. This concerns both policy frameworks and architectural principles. It is then important to get an idea of which different parties are collaborating and how the collaboration is structured.

4.1.1. POLICY FRAMEWORKS

On a national level, the frameworks are established for the agreements (guidelines) and the standards that are used for exchange at the other layers. The organization’s policy frameworks are the starting point for making agreements (contracts) about the electronic exchange of data between applicants and service providers.

Examples of policy frameworks:

- *Quality standards*
  One of the most important quality standards in this regard is ISO-15189, which sets the requirements for the quality and competence of medical laboratories. The software used will also have to take this into account. Furthermore, the 'Exchange laboratory data' guideline indicates which data must be exchanged in the laboratory process. The professional guideline 'Transfer of medication data in the chain' describes which laboratory data must be exchanged in relation to medication safety.
- *Use of standards*
  The guidelines may also include requirements for the application of standards to the information layer for exchanging data. The standards ensure unity of language and technology during the exchange
- *Laws and regulations*
  The Dealing of legislation and regulations falls outside the scope of this guide. For additional information, an overview of the laws and guidelines that are most relevant to the digital exchange of data in healthcare (see appendix 6) has been included. In addition, the Medical Device Regulation (MDR)[5] is also important for software suppliers. This only applies to systems that are also decisively supportive (e.g. giving advice).

[5] Medical Device Regulation: European regulation with rules concerning the placing on the market, making available on the market and putting into service of medical devices for human use and their accessories in the EU.

4.1.2. ARCHITECTURE PRINCIPES

For the design of the application layer it is important to have a number of architectures at the policy level principles as a starting point. The principles are intended to guide the design. The architectural principles fare listed from important to less important.

1. Only send data that is necessary for the process. Data that is not needed can pose a privacy problem. Especially if the data crosses an organizational boundary. If possible, data should only be viewed or made available via a reference. This is preferred over sending data. Data is stored at source. Reason: when data is retrieved from source system and saved as a copy in your own system, the risk is that the data is not up to date.

2. Conform to national and international standards. Reason: By using standards, fewer different interfaces will be needed and connections can be realized more easily because there is unity in language and technology. This applies to both the protocol and the encryption in the message. Reason: Using standards will reduce the need for different interfaces and links can be realized more easily because there is unity in language and technology. This applies to both the protocol and the encryption in the message.

3. Limit the number of interfaces. Reason: Fewer interfaces require less maintenance and simplifies configuration (fewer dependencies) and results in less downtime.

4. Security by Design. Reason: Security is not something that can be added. In addition, this is important when meeting the requirements with regard to information security (NEN7510, NEN7512 and NEN7513). Unfortunately, a lot of use is made in the field of poorly secured protocols such as HL7. It is preferable to solve security at several layers, but either way, definitely on the application layer.

4.1.3. PARTIES AND ROLES

Three parties can be distinguished at the highest level in the laboratory process: the patient, the care giver and the care provider. The complexity arises when care providers in the role of applicant can send different types of requests to different care providers. Healthcare providers can make use of other healthcare providers ('subcontractor') who carry out the research. Within the scope of this guideline we focus on four types of applications: Clinical Chemistry (KC), Medical Microbiology (MMB), Pharmacy (medicine levels) and Thrombosis Service. See figure below.

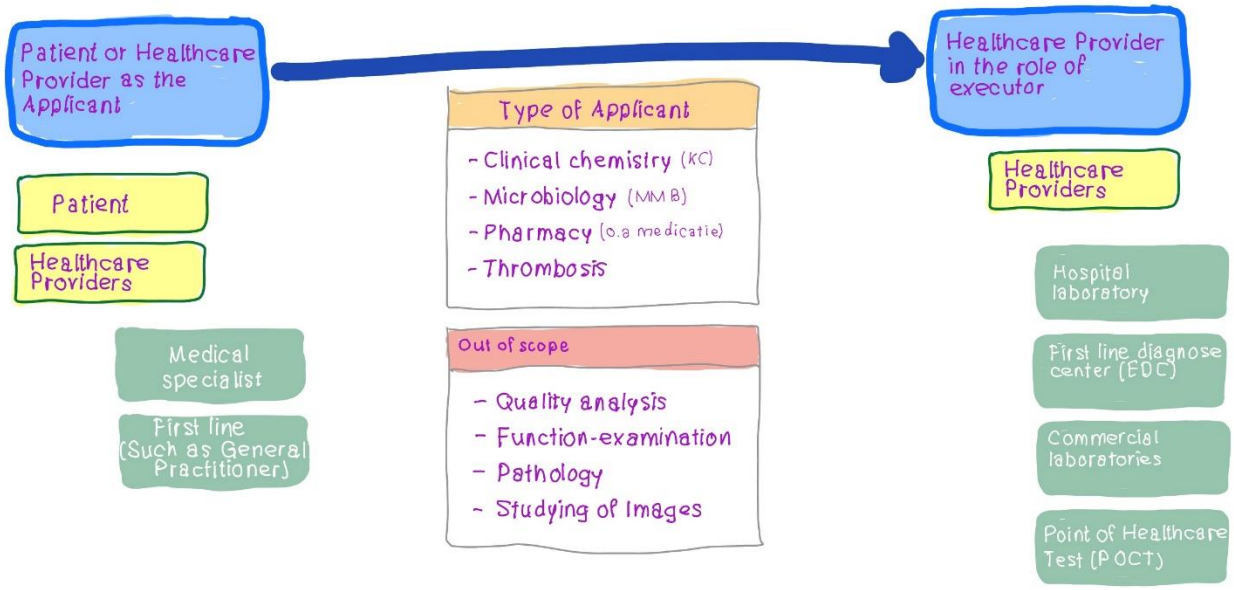


Figure 6: Parties involved in the laboratory process and their roles.

Applicants place orders with contractors. They do this based on of contracts in which agreements have been made about submitting applications and reporting the results. Listed are examples of agreements regarding:

- the type of applications
- status feedback of the request
- when and where the sample collection will take place
- how the results are reported back and what the lead times are
- how the deviation values are communicated
- how the urgent requests are placed
- how to deal with home injections
- the financial compensation and invoicing

It is also possible that the contractors forward an application to another laboratory. In this case the agreements are also needed here for comparison to the agreements between the applicant and the contractor. As the number of different applications increase, as well as the number of types of applications, so does the complexity.

Generally speaking, the following collaborations are possible:

- (Lab2zorg) between the healthcare provider as applicant and the laboratory as executor
- (Lab2patient) between the patient as applicant and the laboratory as executor
- (Lab2lab) between laboratories when outsourcing research
- When the logistics services related to purchase and transport are outsourced to a external party:
    - Between the laboratory as contractor and the collection service provider
    - (if applicable) Between the purchase service provider and the transport service provider
    - Between the laboratory as contractor and the transport service provider.

4.1.4. HIGHLIGHTS 'POLICY AND ORGANIZATIONAL LAYER'

In order to achieve a well-implemented digital transmural laboratory process, it must be clear at the level of the organization:

- what the policy frameworks are, such as the applicable quality standards and the use of standards,
- which party's electronic data exchange will take place and what type of applications are involved.

- Subsequently, cooperation agreements must be made between at least the requesting party (care provider, patient) and the executing laboratory about how the services (type of research, cost times, etc.) and the associated electronic data exchange will be performed. If the laboratory uses yet other service provider for the implementation -such as another laboratory, acceptance service provider and/or a transport service provider, agreements must also be made between these parties.

- The policy frameworks of the organization are the starting point for the cooperation agreement.

4.2. APPROACH 'PROCESS LAYER'

The transmural laboratory process, the people and organizations involved, and the obstacles are described in chapter 3. Based on the identified obstacles, this section describes a number of use cases that serve as examples of intended collaboration between the parties involved and their organizations, whereby electronic data exchange via standards leads to the desired Interoperability. These use cases form the mean theme for the elaboration in the following layers of the interoperability model.

4.2.1. USE CASES

The transmural laboratory application process focuses on placing laboratory applications from the applicant (healthcare provider or patient) to a contractor (one or more laboratories). Always with the feedback of the result (report). To give more explanation to this process of submitting applications and receiving results, we assume the following use cases:

1. *The practitioner in the hospital submits an application to a Diagnostic Center (DC)*. The patient stays in the hospital, the laboratory is not part of the hospital. The collection is performed in the hospital and the materials are sent to the laboratory under controlled conditions. The results are communicated to the applicant and are available to other healthcare providers based on the consents granted by the patient.

2. *The GP places an application to a DC and the patient makes an appointment at a location from the DC.* The patient reports to the general practitioner with complaints. The GP requests an examination from a laboratory and the patient is invited by the laboratory to make an appointment. The patient reports to the DC. The material is transferred to the laboratory. The results are communicated to the GP who uses them to determine follow-up actions.

3. *The GP places an application to a DC and the DC uses an external supplier for the extraction*. The GP requests an examination at a laboratory and the extraction is carried out by an extraction organization at the patient's home. The extraction organization sends the extracted material to the laboratory. The results are communicated to the GP who uses them to determine follow-up actions.

4. *The patient themselves who requests an examination*.
   The patient requests a laboratory test via a web portal.
   The patient receives the extraction kit at home and sends the sample to the laboratory by post.
   As soon as the result is available, the patient will receive a message and the result can be viewed in a secure environment.

5. *Outsource the processing of the request by another laboratory.*
   In this special use case, conclusions are drawn at a different laboratory. The outsourcing laboratory receives the purchased materials and prepares the outsourcing and shipment to the performing (outsourcing) laboratory. The results are communicated to the outsourcing laboratory and from there to the applicant and/or patient.

These use cases are detailed step by step in Appendix 2. Each use case goes through the lab process. In addition, the relevant IHE integration profile and Actor are mentioned for each step, providing insight into the coherence of applicable IHE profiles. Appendix 4 shows a schematic diagram of the IHE integration profiles used for each process step.

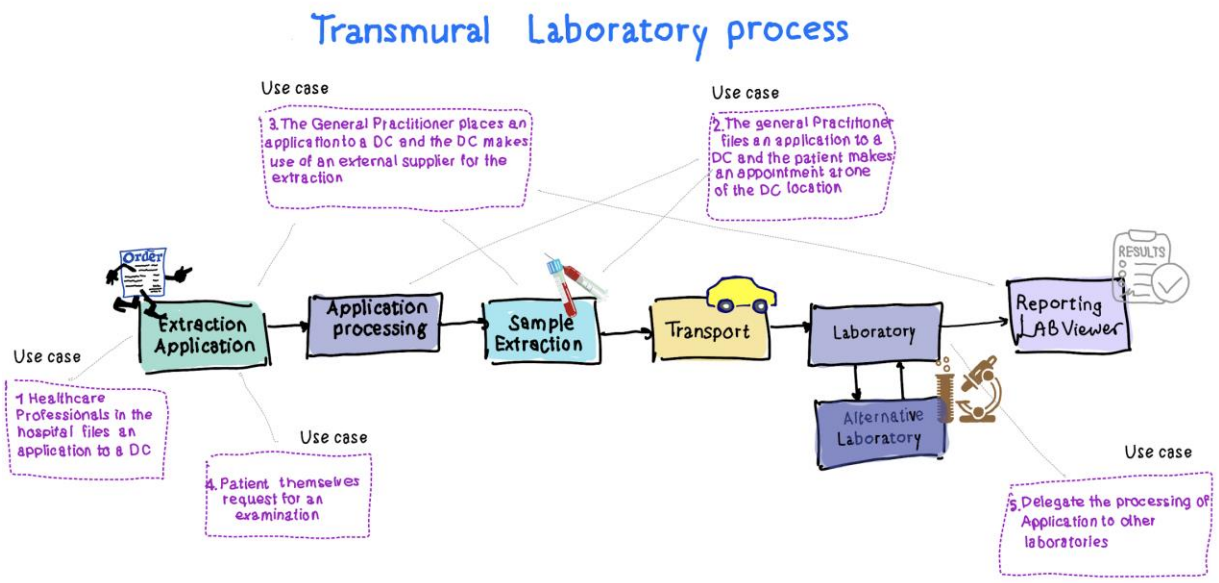


Figure 7: Use cases

Remark
The process diagram contains the step 'application processing. This step determines the workflow for the next process steps, such as an employee having to collect the sample, the trigger for the transport of the samples to the laboratory. An extra process step - which has occurred during the Corona pandemic, for example - is that a date/time is agreed with the patient. Before the pandemic, this was done without an appointment and was called a 'walk-in'. The planning could be a separate building block but could also be part of the application processing.

4.2.2. APPLYING IHE PROFILES TO THE PROCESS

IHE describes the way to integrate applications into IHE integration profiles for specific work processes. These IHE integration profiles show how the applications involved in a use case should communicate with each other through specified messages based on open standards. The figure below gives an overview of the relevant available IHE integration profiles per part process of the transmural laboratory process. In Appendix 3, this figure is more readable (digital zoom-in also possible).

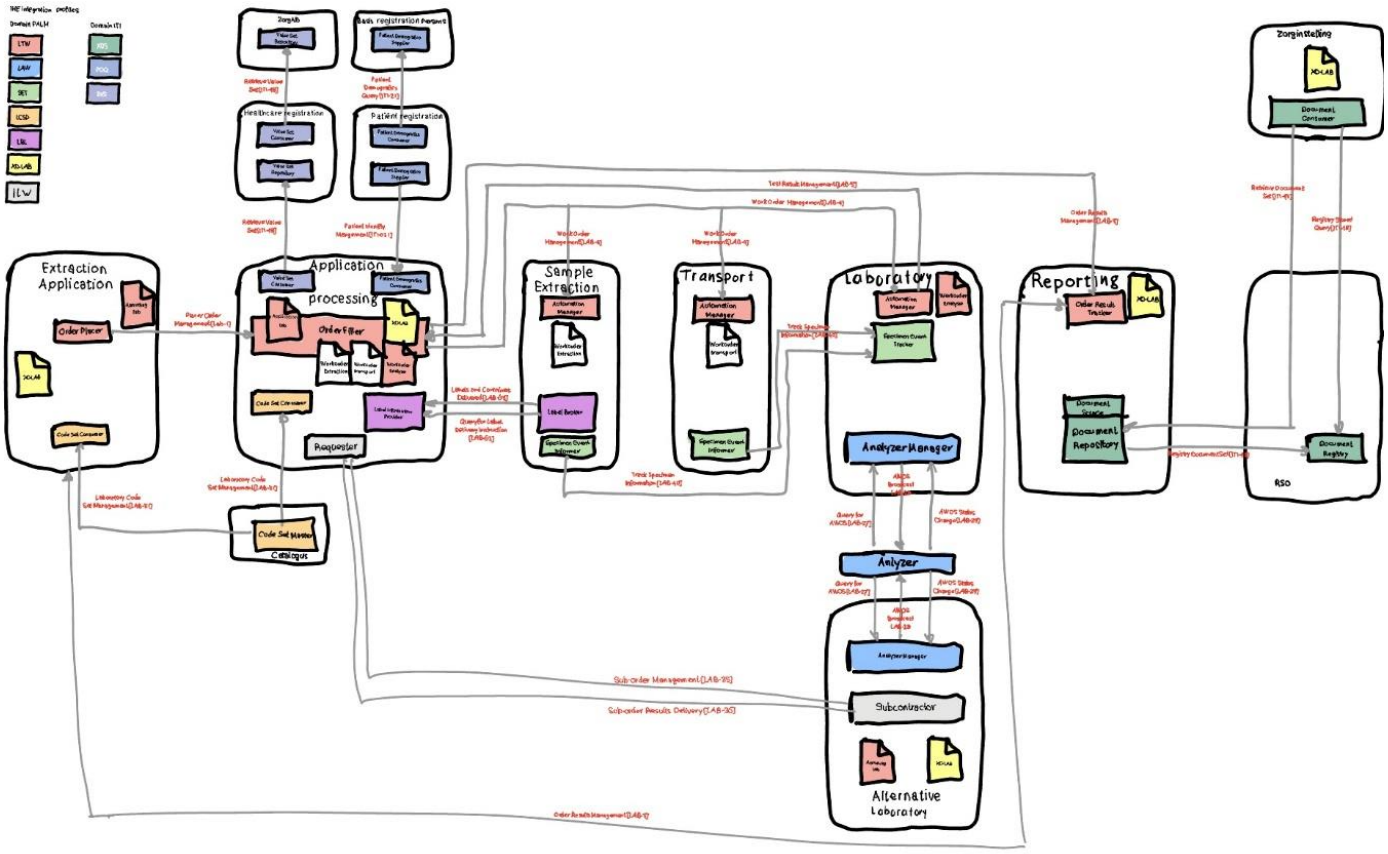


Figure 8: IHE integration profiles in the process (for a more readable figure see Appendix 3)

For each use cases of the transmural laboratory process, the specific use cases - associated with each process step - can be linked to the IHE integration profiles per process step. Some IHE integration profiles relate to the main process. In addition, IHE integration profiles are also available for the necessary support use cases. For example, use cases to monitor patient data.

When the systems involved in the exchange has implemented the mentioned IHE integration profiles for the role (actor/person) they have fulfilled, then the specific use case can be executed.

It is striking that the processes for applying and processing in the laboratory, as well as reporting are well described in various IHE integration profiles (LTW, XD-LAB, XDS). The process surrounding external

requests for purchase and transport is less well described. However, an IHE integration profile (SET) is available for keeping track of events with the collected material.

Outsourcing and insourcing between laboratories is described in the ILW integration profile. This is implemented in the Netherlands as Lab2Lab messages.

4.2.3. LABORATORY TESTING WORKFLOW (LTW)

The IHE integration profile LTW realizes the continuity and integrity of testing and result data within a healthcare institution. It is important to realize that the IHE integration profile is built around the processes and systems that are positioned within one institution. However, the LTW IHE integration profile is also useful when applications from outside the organization are processed and results need to be communicated directly to the applicant.

With regard to the use cases discussed in this guideline, the LTW IHE integration profile is recognizably present in use case 1, 2 and 3. In each use case there is a request submitting system that places the laboratory request via a message to a request fulfilling system. For example, a hospital EHR (Use case 1) that sends a request to the laboratory system. A system can fill in several roles/actors from the IHE integration profile. A supplier will indicate per system which Actors of a particular IHE Integration Profile have been implemented. The application is processed in the laboratory and it is determined which material must be collected. Once the received request has been processed, it is converted into work orders for the lab that are processed by a system with the Automation Manager role to the various machines in the lab. The automation manager can be part of the LIS but can also be a separate system for work order management. The laboratory keeps the applicant informed of the progress of the application and the results by sending result messages. These messages are processed by the applicant in a system with the role of 'Order Result Tracker', which is often part of the EHR system.

For a good understanding of the cooperation and processing order of transactions within a use case, a so-called sequence diagram is used. Such a diagram shows from top to bottom which transactions take place between the actors involved in chronological order. The actors are listed at the top of the diagram from left to right and each has its own vertical timeline.

Below is an example of a sequence diagram for the process where a request is made to the laboratory and is being processed and executed at the laboratory. The involved actors and transactions according to the LTW IHE integration profile are shown in the sequence diagram. What is not in the scope of LTW is the actual taking of the sample.

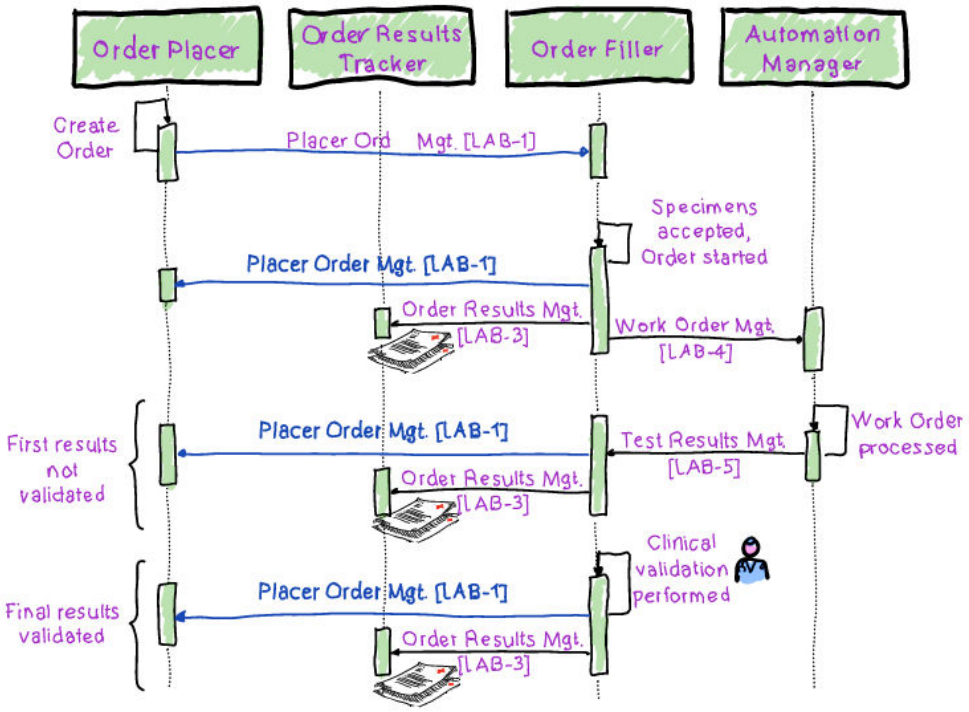


Figure 9 LTW IHE-integration profile

4.2.4. HIGHLIGHT 'PROCESS LAYER'

- Based on 5 examples of use cases, important aspects of the transmural process are discussed run through. By linking these process steps and required actors to existing IHE integration profiles, a guideline is created for setting up the relevant process step. Over there is not (yet) possible, the development of improved profiles with the relevant Where stakeholders to be addressed.
- In this paragraph specific attention is paid to the transmural process between laboratories and external parties that take over specific tasks in the process. By dividing the total process over several implementing organizations, bottlenecks arise which are often filled in per situation. This creates interoperability issues and unnecessary risks of loss of quality throughout the entire process.
- In the transmural process the expansion of the role of the patient is new. The patient, who is increasingly interested in the report of the results, can increasingly initiate processes on their own initiative.
- The entire laboratory process is already well described in the existing IHE integration profiles. Innovation in the external application process (purchase/transport) requires extra attention in order to adapt this, as well as more standards.

4.3. APPROACH 'INFORMATION LAYER'

Information that is exchanged describes established facts, these data only become Information if they are meaningful to the recipient. Information is what is ultimately used by the recipient in the healthcare process. It is important that all parties know what the data entail. That is why making agreements with regard to information is extremely important. To make these agreements concrete, Nictiz has drawn up guidelines and information standards. These have also been drawn up for the exchange of laboratory data.

In addition to the information standard, a healthcare information building block (Zorg informatie bouwsteen, ZIB) laboratory-results has also been published from the “Registration at the Source/ Registratie aan de bron” program. It is used in several exchanges to share lab results. The ZIB describes the concept, which contains the data with an agreed content, structure and mutual relationships.
The (healthcare for the) patient is the most important subject in this concept. The ZIB that describes laboratory results can be used in a lot of healthcare use cases. After all, the ZIB describes the patient's laboratory results, which do not change and do not depend on the specialty or setting in which this patient is currently receiving care. This ZIB is used in various exchanges and is also part of the BGZ (Dutch patient Summary). So, when the laboratory results are known and included in a patient file, they are exchanged as a ZIB. The information is encoded according to agreed standards (HL7 CDA, LOINC, SNOMED CT, FHIR, HL7v2) so that the receiving party can understand and can process it in their own system.

The ZIBs and the information standards are managed by Nictiz. On the Nictiz website you will find more information about the management of the ZIBs and the information standard.
See: https://www.nictiz.nl/standardization/zib-centrum.

4.3.1. INFORMATION STANDARD EXCHANGE LABORATORY

In the information standard exchange laboratory data as prepared by Nictiz in collaboration with, among others, the NVMM, NVKC and the RIVM, are 4 different domains appointed.
These domains are:

Lab2zorg	For all exchange of research requests and laboratory results between the laboratory and healthcare providers, but also exchange of laboratory results between healthcare providers. More information: https://informatiestandaarden.nictiz.nl/wiki/Lab.V1.10_ontwerp_lab2zorg
Lab2lab	For outsourcing laboratory research to another laboratory with the required specialization and the feedback of the results of this outsourcing. More information: https://informatiestandaarden.nictiz.nl/wiki/Lab:V1.0.0_ontwerp_Lab2lab
Lab2public Health	For the exchange of results related to public health with RIVM. This message is currently being used for the monitoring of resistant micro-organisms.

	More information: https://informatiestandaarden.nictiz.nl/wiki/Lab:V1.0.0_Ontwerp_Lab2publichealth
Lab2patiënt	For making laboratory results available in the patient domain. More information: https://informatiestandaarden.nictiz.nl/wiki/MedMii-V2020.01/OntwerpLab

The image below shows what the domains focus on within the transmural laboratory process.

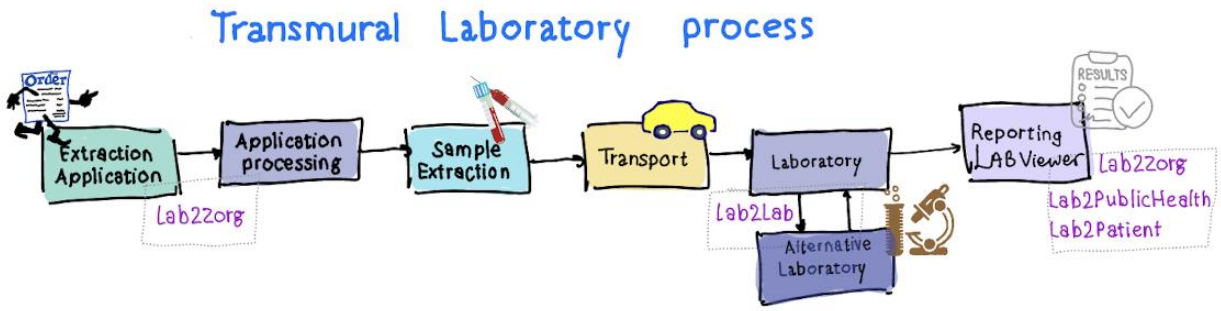


Figure 10: Domains and the Transmural laboratory process

In the context of this guideline, Lab2zorg and Lab2lab are especially important. After the amendments of the guideline in 2021, the domain Lab2zorg is still under development. The publications on these information standards can be found on the website of Nictiz:
https://www.nictiz.nl/standaardisatie/informatiestandaarden/laboratoria/en
https://informatiestandaarden.nictiz-pl/wik/Lab-MV2.0.1_Ontwero_laboverdacht.

The messages within this information standard are based on the IHE integration profile XD-Lab. This IHE integration profile has been adapted to suit the needs of Dutch healthcare and is tailored to different use cases.

4.3.2. TERMINOLOGY SYSTEMS

When exchanging data, it is important that agreements are made using terminology (unit of language). The agreements are included in the several terminology systems to achieve the unity of language. The most well-known are LOINC, SNOMED CT, NHG diagnostic provisions and the Dutch Lab code-set. The existence of several terminology systems has already been identified as an obstacle in paragraph 3.2. It is therefore important that the terminology system in which situations are chosen be determined in advance.

4.3.2.1. LOINC

LOINC is a standard for documenting and coding applications and results of medical laboratory determinations. LOINC was initially developed to meet the increasing demand for the exchange of encrypted laboratory data. LOINC is therefore specialized in the field of laboratory data from the various code systems.

The scope of LOINC includes laboratory observation and other clinical observations. The laboratory part of LOINC consists of the following areas: Chemistry, hematology, serology, microbiology, toxicology, parasitology and virology.

4.3.2.2. SNOMED CT

SNOMED CT is an international terminology system. It contains a large collection of medical terms including their synonyms. SNOMED CT contains English terms, in which the terms relevant in the Netherlands are translated into Dutch. In addition, the Nictiz terminology center is working on patient-friendly terms. The terms are used in direct patient care to record diagnosis, complaints, symptoms, conditions, disease processes, interventions, results and decision-making. SNOMED CT is managed by SNOMED International.

4.3.2.3. NHG-TABLE DIAGNOSTIC PROVISIONS

The NHG table diagnostic provisions is compiled by the NHG and contains codes for laboratory provisions, other diagnostic provisions and procedural provisions relevant to general practitioners. The table is intended for the reporting of laboratory examinations, physical examinations, medical examinations and auxiliary examinations as imaging diagnostics and function examinations. Within general medical systems, this is a common method of encoding.

4.3.2.4. DUTCH LAB CODESET

the Dutch lab code-set is a terminology set primarily intended for the exchange of laboratory information within the care system in the Netherlands. The lab code-set has resulted from the project Unit of Language. The basis of the Dutch lab code-set are provisions encoded with LOINC concepts which are enriched with:

- English and Dutch display names
- Links with materials as encoded in SNOMED CT
- Quantitative provisions that have been enriched with a UCUM unit; the agreement is that specific provisions should only be exchanged in that specific UCUM unit
- Ordinal provisions are linked to a value list with SNOMED CT codes
- Nominal provisions are linked to a SNOMED CT reference sets

The Dutch lab code-set has been developed and managed by the Dutch Association of Clinical Chemists (NVKC) and the Dutch Association for Medical Microbiologists (NVMM) in collaboration with Nictiz and the RIVM. More information about the lab code-set can be found at https://www.nictiz.nl/standaardisatie/terminologiecentrum/nederlandse-lab codeset/

All messages from the information standard use the Dutch Lab code-set.
The Lab2zorg message from the information standard also supports exchange on the basis of the NHG coding. The encryption standard used is included in the messages.

4.3.3. USE CASES TRANSMURAL LABORATORY PROCESS

Based on the use cases as described in section 4.2.1. It can be checked per exchange whether a description of the desired messages is available. The table below lists the necessary data exchanges. For each data exchange, it is indicated in which use cases this exchange occurs.

In the 3rd column indicates which IHE transactions describe the data exchanges. Column 4 lists the standard exchanges used by the IHE transactions. Furthermore, column 5 lists the code systems used by each transaction.

Exchange	Use case	Transaction	Message Standard	Code-systems	Remarks
Application laboratories	1, 2, 3, 4	IHE [LAB-1]	HL7 v2 OML EDIFACT	NHG-tabel NL-Lab code-set; SNOMED-CT LOINC	Nictiz Lab2zorg has not yet standardized any application form; There are 3 message structures for HL7 OML supported depends on whether the application focuses on specimen or prescription
Status application Laboratories	1, 2, 3, 4	IHE [LAB-1]	HL7 v2 ORL		Depending of type OML message
Work order Specimen Extraction	1, 2, 3	IHE [LAB-4]	HL7 v2 OML		
Work order transport	1, 2, 3	IHE [LAB-4]	HL7 v2 OML		
Work order analyze	1, 2, 3	IHE [LAB-4]	HL7 v2 OML		
Specimen tracking	1, 2, 3	IHE [LAB-40]	HL7 v2 SET		
Extraction (label) Information	1, 2, 3, 4	IHE [LAB-61]	HL7 v2 OML		
Care provider information	1, 2, 3	IHE [ITI-48] en [ITI-60]	HL7 v3 SVS	ZorgAB	'Zorg AdresBoek' from VZVZ. Information about possible applicant.
Patient information	1, 2, 3	IHE [ITI-031]	HL7 v2 ADT		
Laboratory report	1, 2, 3, 4	NICTIZ LAB2ZORG IHE [LAB-3] IHE [ITI-43] EDIFACT MEDLAB	HL7 v2 OUL; HL7 CDA v3; FHIR EDIFACT MEDLAB	NHG-tabel; NL-Lab code-set; SNOMED-CT LOINC UCUM	EDIFACT is used by General Practitioner's and other first line applicants, but Edifact is not compatible with the NICTIZ Information standard.
Outsourcing laboratory analyzing	5	NICTIZ Lab2Lab IHE [LAB-35] [LAB36]	HL7 v2 OML HL7 v2 OUL	NHG-tabel NL-Lab code-set SNOMED-CT LOINC UCUM	NICTIZ Lab2lab is in line with IHE-ILW profile but specified to the Dutch situation: See: https://decor.nictiz.nl/pub/labuitwisseling/lu-html-20191213T103632/sc-2.16.840.1.113883.2.4.3.11.60.25.3.2-2014-11-28T100607_HL7V2-IG.html
Retrieve result reports	1, 3, 4	NICTIZ Lab2Zorg; NCTIZ Lab2patient; IHE [ITI-43] icm [ITI-18] en [ITI-42]	HL7 CDA v3 FHIR	NHG-tabel; NL-Lab code-set; SNOMED-CT LOINC UCUM	Available data to be retrieves from the healthcare (PULL)
Available reports	1, 2, 3, 4		HL7 v2 MFN	NHG; SNOMED-CT;	

Table 1: Exchange and IHE integration profiles / Information

Each use case contains process steps in which data is exchanged. A certain process step can occur in multiple use cases. To properly define the information layer, we use the structure of the process steps and use cases. All relevant process steps related to the information layer are explained in more detail.

4.3.3.1. APPLICATIONS FOR LABORATORY

Applications through healthcare provider
For the applications of laboratory diagnosis through a healthcare provider there are a few critical factors to consider. The applications must contain the following information:

- Patient data
- Data from the applicant
- Requested study(s)/examinations
- At the time of request relevant information about the request. For example: Additional information about the patient that is relevant to the study
- if already collected: Sample data; it is important that the sample can be linked to the electronic application.

For the application filed by the general practitioner, Edifact is mainly used by means of the MEDEREQ message, the specification of this is available on the website of Nictiz.
For request messages in HL7, IHE provides the IHE Integration Profile Laboratory Testing Workflow (LTW).

Application by a patient
If the application is made directly by the patient, information is exchanged from Lab2Patient. The big difference with the previous use case is that the patient is not a healthcare provider applicant and therefore has no specific medical knowledge as a general practitioner or specialist does.

The Nictiz information standard does not currently contain definitions for patient request messages. Many laboratories that offer on-demand tests resolve this by presenting patients with the retrievable studies through their own application portal. The application is then sent directly to the laboratory. Patient identification is done by means of digital identification such as DigiD. As an applicant, a doctor affiliated with the DC is often linked to the application. The patient first goes through a questionnaire that is intended to collect the necessary meta-information on the basis of which the application can be processed.

4.3.3.2. MATERIAL COLLECTION

When engaging an external party to take the sample, it is important to make proper agreements about how this will be linked to the application. These are often actions within the LIS. However, if there are two separate registration systems, the request from the sampling system (including sample data) must be forwarded to the LIS.

When the sample extraction take place, it is critical that the patient is correctly identified and that the materials are uniquely tagged and matched to the correct application. Sufficient information must be made available to the consumer.

It is often necessary that specific information about the sample extraction is collected and added to the application. This can be information about the progress of the extraction or about the extraction conditions. It may also include information about the patient. For example, a questionnaire with additional information for the research may be required at the time of extraction.

It is clear which materials are to be extracted and how they are to be processed in the laboratory.

The LBL IHE Integration-Profile describes use cases and messages for issuing labels for the extracted materials.

4.3.3.3. RESULT RAPPORTING

When the laboratory examination is completed, the result report shall be returned to the applicant. This should include the following information:

- For each research the result including the test method
- The status of the research
- Overall interpretation done by the medical laboratory specialist
- Application data (to link it in the applicant's system)
    - Order details; order number, requesting party, patient data and urgency
    - Order question and reason
    - Clinical Patient Information
    - Material data; sample number, type of material, date/time of collection, volume, etc.
- Data from the performing laboratory and laboratory specialist

The main use of the Edifact standard is also currently being used for this message. For the specification see: https://www.nictiz.nl/standaardisatie/edifact/. The Edifact standard is no longer developed. As a result, no changes will be made to both the result and the request message.

For the further development of the laboratory standard, Nictiz recruits a new message in the information standard for the Lab2care domain based on the ZIB laboratory result. This is currently (still) not available. However, an IHE integration profile is available: LTW where laboratory results and status information can be exchanged via HL7 messages (OUL/ORU).

The report can also be used to submit the status of the research. This allows the delays and problems to be linked and the feedbacks to the applicant.

In the event that the request is made directly by the patient, there is a Lab2Patient information exchange. A major difference with the previous use case is that the patient is not an applicant-healthcare provider and therefore does not have specific medical knowledge that a GP or specialist does possess.

An email or text message is often sent to inform the patient that the result of the examination is available. This message does not contain any further information about the examination. The patient can then view the results in the web environment of the laboratory. The patient must identify himself and the laboratory is required to adequately protect access to the data.

It is also possible that laboratory results are shared in a Personal Health Environment (PGO) where the different patient data are archived. For the exchange of laboratory results the use of the zib - laboratory results is often used. This ZIB describes the concept of laboratory results using the data elements that make up this concept.

For more information: https://medmij.nl/informatiestandaarden.

Such an environment can use a number of shared concepts to ensure secure handling and access to data. This is to check who has the access to certain data who doesn't.

4.3.3.4. OUTSOURCING OF APPLICATION TO OTHER LABORATORY

Where a laboratory cannot (fully) carry out a requested extraction application, it is outsourced. For this process, the Lab 2lab messages from information standard exchange laboratory data can be used. These are 3 substantive messages and 3 technical receipts. These are HL7 v2 messages. The messages that would be sent are:

- The application message (OML^021) containing all the information relevant to the request such as:
  - Order data; Order number, ordering party, patient data and urgency
  - Order question and reason for application
  - Clinical information about the patient
  - Material data; Sample number, type of material, date/time collection, volume, etc.

- The application confirmation message (ORL^022), in which the laboratory indicates to accept or refuse the application.

- Result message (OUL^R22), the complete result report from the laboratory, contains the results of all the examination carried out by the laboratory. The interpretation done by the laboratory is also attached. The message will be linked back to the original request in the outsourcing laboratory upon receipt by the order number.

For example, the sample is sent separately to the laboratory by courier. In the meantime, the order number and sample number are linked to the application in the performing Laboratory.

4.3.4. 'INFORMATION LAYER' OBSTACLES

There are a number of obstacles in making of agreements on the information layer:

- There are many different possibilities for exchanging terms from the laboratory domain. This makes it difficult and unambiguous to adopt an approach. The lab code-set developed by the RIVM, the NVMM, NVKC and Nictiz is intended to bring in more uniformity. It has not yet been implemented in many places and is being expanded.

- NHG table 45 is still, being used frequently. This table differs from the lab code-set, so it is not easy to use the lab code-set and NHG table 45 alongside each other. This causes problems because the general practitioners see the NHG table 45 as the main business code set and it is already included in the EMR's. Other parties in the process prefer the lab code-set however this is not yet widely adopted.
- There are many initiatives to facilitate standardization. However, these initiatives are often still in development and no products are available that can be used directly yet.
- Edifact messages containing laboratory results do not have unique keys (ID's) that prevent a copy of the result from being seen. This ensures that no track and trace of whatever the source

is can be given. Fortunately, in HL7v3 CDA or FHIR this is the case. However the way to standardize these ID's, so that source data can be distinguished from the ID, has not been nationally organized.

- There is a difference in how complete the information (research results) from the laboratory examination is recorded in the file. Also, the knowledge of the healthcare provider who needs to interpret the lab result can differ. This difference in level of detail at which the information is recorded and knowledge/experience of the healthcare provider may lead to misinformation. This problem also occurs with the patient in a patient portal where the data is shared in this format. However, the practice is that most of the patients, certainly with the chronic patients, have positive laboratory data experiences.

4.3.5. MAIN POINTS 'INFORMATION LAYER'

- Mainly through the existing HL7 profiles, many messages have been recorded which are also useful in the transmural use cases which describes this document.
- For the standardized content and encoding of the information in the messages, ZIB's can be used for description and for the encoding of the Dutch lab code-set based on LOINC and SNOMED CT.
- On the parts where information exchange is needed, but where there is not yet an elaborated standard, it is advisable to stay close to the existing IHE structures and to make agreements with the specific persons concerned as broad as possible.

4.4. APPROACH 'APPLICATION LAYER'

In the layout according to the five-layer model, the development of the application and the infrastructure layer comes after the process layer. Within IHE, the following IHE ICT infrastructure domain exists: The infrastructure for the sharing of medical information. However, IHE ICT infrastructure domain is not equivalent to the infrastructure layer from the five-layer model. The infrastructure as ICT has meant for it to be consists of interoperability components. These are software applications, which provide common ICT functions that can be used as building blocks for multiple use cases. These components from the ICT infrastructure domain can be embedded in a functional application, such as the transmural laboratory process. The IHE ICT infrastructure domain is central in relation to other IHE domains. Appendix 5 contains a description of the ICT infrastructure domain and its components.

This section further explains the process and information layer. This is done by identifying the different applications in the transmural laboratory process and determining how the exchange of data (transactions) takes place between the applications. The applications are described as seperate applications with specific functionality. This doesn't mean that each of these applications have to exist as a separate application: They can be part of an application where several of these functions are integrated. However, it is wise to make the various interfaces so that it is possible to break down functionality (in the future) and/or replace it with other applications. The developments around the standardized exchange of data are constantly evolving. There are new versions of standards. And data exchange is no longer just done via point-to-point connections (such as VPN) or 'Zorgmail'.

There are also other data exchange infrastructures where healthcare providers can exchange laboratory data among themselves and with the patient. Therefore, the existing-IHE integration profiles must also be able to perform transactions based on the new exchange standards and infrastructures. This creates an eco-system in which both the new and existing standards and exchange infrastructures are operational.

4.4.1. FUNCTIONAL DISCRIPTION LABORATORY APPLICATIONS

The application architecture is based on a division into logical applications. This does not mean that each application needs to consist of multiple applications. But it does mean that if a certain functionality needs to be distributed across multiple organizations, that it needs to be partitioned into these applications.

The figure below shows the different logical applications and their transactions. The transactions and related protocols are described in paragraph 4.4.3.

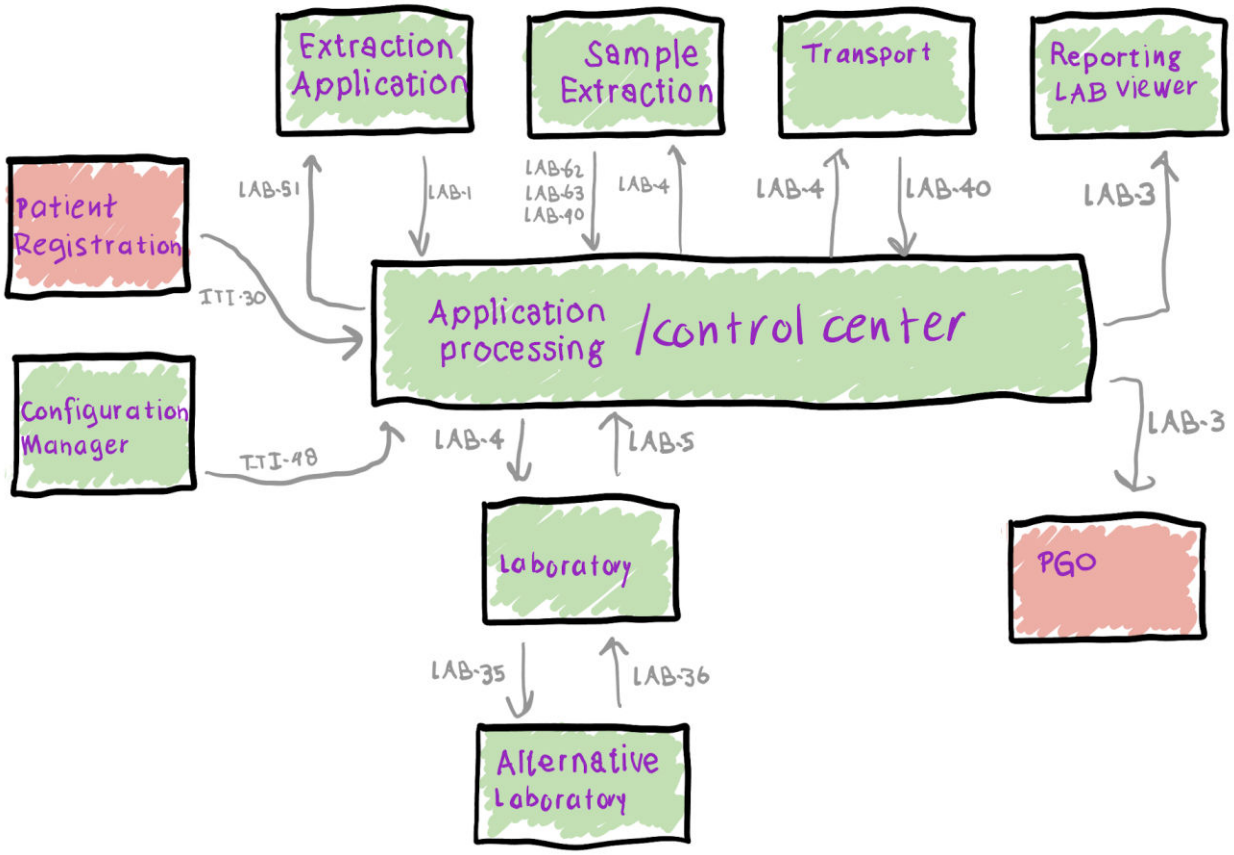


Figure 11: Applications and transactions

Description of the logical applications.

- *Application*
  Responsible for the entry of a correct application based on the tests in the catalog and for sending to the processing center.

- *Sample collection*
  Responsible for collecting and labeling a sample. This is done based on the data provided by the control center. The control center is notified by this application on the status of the sample collection. There may be other factors to include, for example, patient was not sober, failed collection, or difficult to extract samples.

- *Transport*
  Responsible for the transportation of the sample. This is controlled by the control center and also provides the status updates of the application.

- *LAB viewer / reporting*
  Responsible for viewing the results of the requestor. This application receives the results which has been checked by the control center.

- *Application processing / Control center*
  Responsible for the coordination of the laboratory application process. This means receiving and checking the order. Being in charge of the sample collection and transportation. In this particular application the labels to be used and the instruction for the collection must be provided. This application can optionally split the part orders and send it to one or more laboratories. When the results are available, the application will collect them. In the event of status updates, such as the receipt, material and results of the application. For example, this application will inform the applicant and other parties.
  This application is also responsible for providing information for the financial handling of the research which is being carried out. In this application, the results should be authorized with the help of clinical rules or an Artificial Intelligence (AI) system.
  In the current solutions, this application is part of the LIS, but this is certainly not necessary. This application could be a separate application or part of another larger application (for example, the EHR).

- Patient Registration
  Registration and Patient Data Verification. This application is responsible for providing the correct patient related data.

- Configuration Manager
  Responsible for providing basic tables with data such as an overview of all possible applicants to the control center, for example.

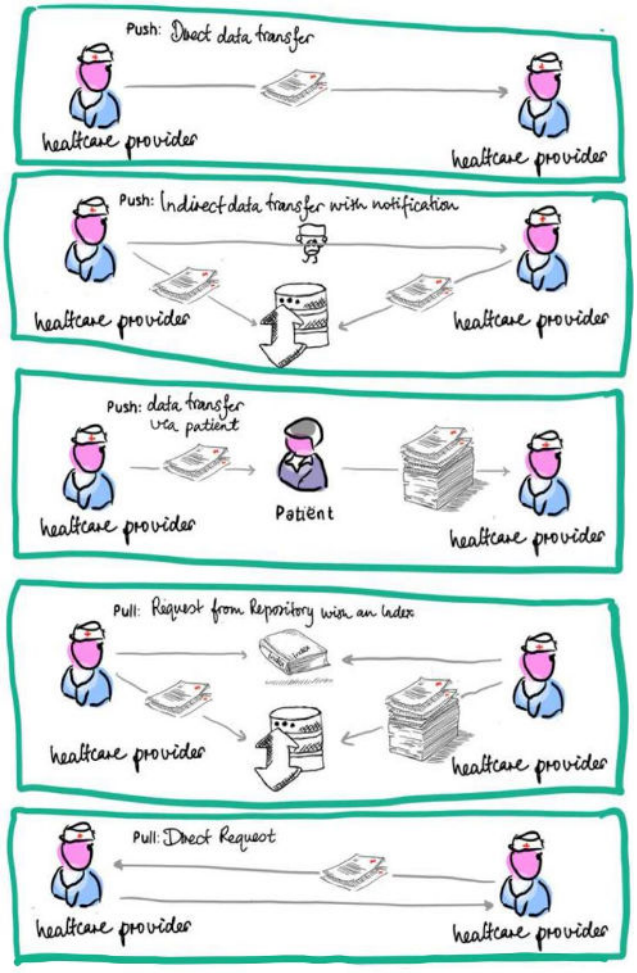
- Laboratory
  Responsible for carrying out one or more examinations commissioned by the control center and delivering the technically correct results.

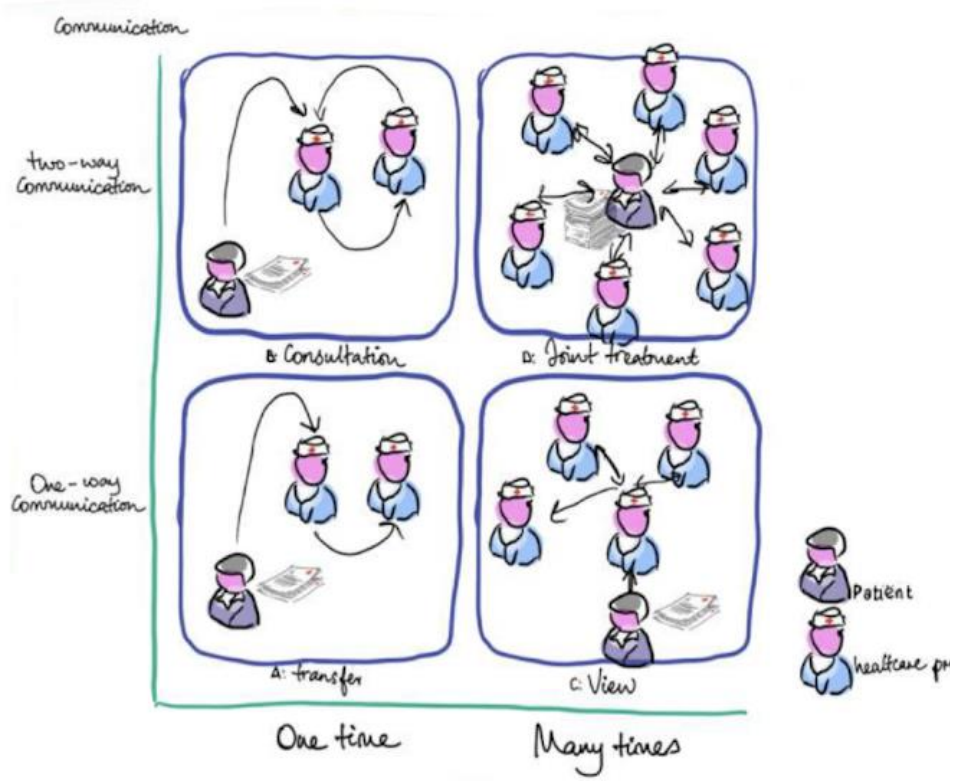
- External laboratory
  Same as the laboratory.

- PGO
  The Personal Health Environment (PGO) is an app (website) where a patient/client/citizen can keep a lifetime of information about their health and where the patient/client/citizen work on their health. It is therefore also necessary that the laboratory results can be exchanged with the patient/client/citizen PGO.

4.4.2. DATA EXCHANGE AND THE WORK PROCESS

Data exchange is intended to provide the healthcare provider/user with information necessary to perform a particular task in the work process. During the creation of the work process a few aspects of data exchange must be taken in consideration, namely:
1. Pull versus push;
2. Communication pattern (between therapist and patient);
3. Document vs. Message/confidential Data.

Push versus pull	This aspect relates to the transfer mechanism itself: • Push: when the data from a healthcare provider is sent directly to the other healthcare provider, • Pull: when a healthcare provider retrieves or access the data that may be shared from the source system. Based on both transfer mechanisms there are also some variations whereby, for example, notification is sent (push) with limited patient information and the receiver then retrieves the medical data (pull). There are also variations with a system 'in the middle' that receives and prepares data via a push message. The recipient then decides when the data should be collected. Think of a PGO or XDS environment. The figure below shows the different variations of push and pull data.  The selection of the transfer mechanism also has legal implications. For both ways of transferring money, the healthcare provider who receives the data (push) or retrieve (pull) must be treating the patient. This is in accordance with the Law on the Medical Treatment Agreement (WGBO).

	For the collection of data, it is also necessary to comply with the Additional provisions of the Act concerning the processing of personal data in the care (Wabvpz), which states that: • the patient must have explicitly (opt in) given permission for this, • there must be a guideline in which states which healthcare givers/roles are authorized to retrieve/access data from the source file. More information can be found in the EGiZ Code of Conduct 2019 report (https://www.knmg.nl/pdf/egiz/) and in Appendix 6 (legal framework).
Communication pattern	It is also important to determine for the relevant (partial) process whether data is exchanged once or more. Does the exchange take place between two healthcare providers/healthcare institution or involves multiple institutions. Soulve Innovations[6] [7] has created a model for the following situations (see figure): A. Data transfer (one-way communication; one-off), B. Healthcare providers who consult each other about the patient (two-way communication; one-off), C. Data access from the source file (one-way communication; Multiple), D. Joint treatment of a patient by multiple healthcare providers (two-directional communication; multiple-time). 

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

Document versus message	Last but not least it is important to recognize what kind of information is exchanged. XDS environments are infrastructure designed to store large amounts of information as documents, provide meta-data, easy to locate and accessible. The exchange with HL7-FHIR is more suitable for sending one-time messages or for retrieving discreet data.

The figure below shows the type of data transfer (push or pull) that can be used in situations ('transfer' and 'inspection') which are appropriate and which protocol can be used. The figure below shows the technical implementations using the communication pattern and the available transfer mechanisms.

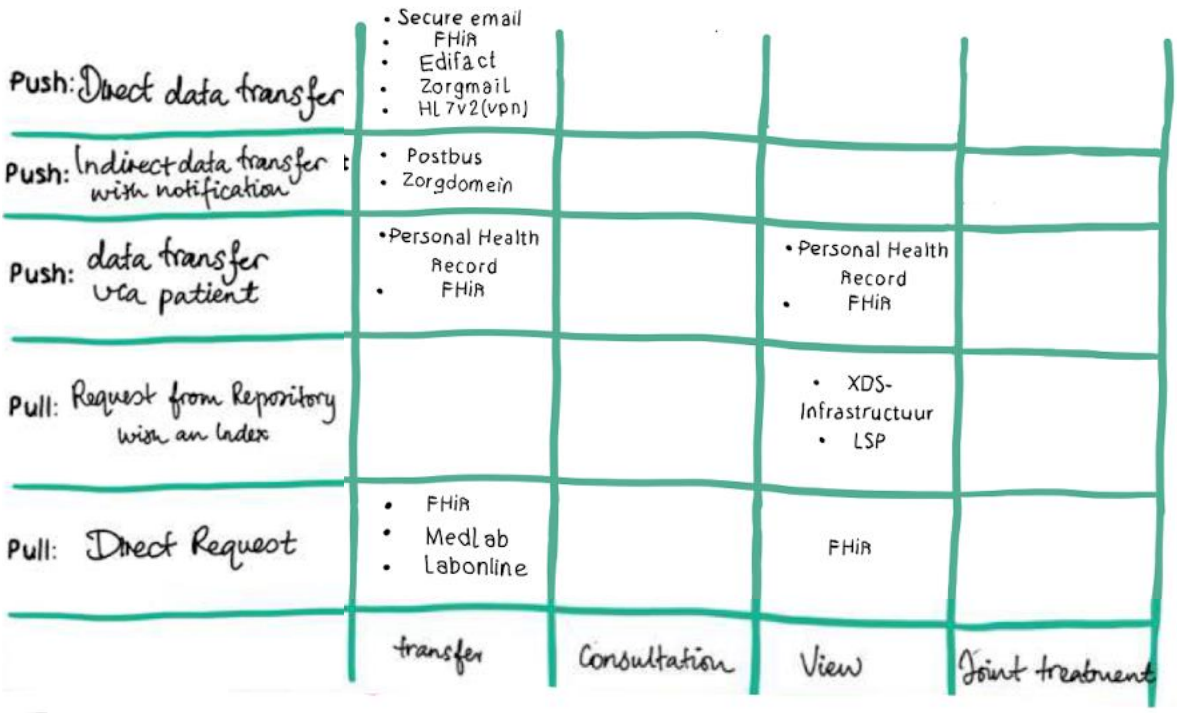


Figure 12: Overview of data transfer and protocols used

4.4.3. APPLICATIONS INTERFACES

4.4.3.1. TRANSACTIONS AND PROTOCOLS

The table below describes the protocol used in transactions between the applications described in section 4.4.1.

IHE-integration profiles	Transactions	Transaction name	Protocols
LTW	LAB-1	Place Order Management	HL7v2
LTW	LAB-51	Laboratory Code Set Management	HL7 v2.5.1 (OBX)
ITI	ITI-48	Retrieve Value	HL7 v3 Data Type XML ITS;
ITI	ITI-30	Patient Identity Management	HL7v2 (ADT)
ITI	ITI-21	Patient Demographics Query	HL7v2.5 (QBP)
LBL	LAB-63	Labels and Containers Delivered	HL7v2 (OML/ORL)
LBL	LAB-62	Query for Label Delivery Instruction	HL7v2.5 (QBP);
LTW	LAB-4	Work Order Management	HL7v2.5 (OML)
SET	LAB-40	Track Specimen Information	HL7V2.9 (SET)
LTW	LAB-5	Test Result Management	HL7v2.5 OML
LTW	LAB-3	Order Results Management	Hl7v2.5 (OUL/ORU)
ITI	ITI-42	Registry Document Set	OASIS ebXML
ITI	ITI-43	Retrieve Document Set	OASIS ebXML
ITI	ITI-18	Registry Stored Query	OASIS ebXML
ILW	LAB-35	Sub-order Management	HL7v2 (ADT/OML/ORL)
ILW	LAB-36	Sub-order Result Delivery	HL7v2 (ORU)

Table 2: IHE-integration profiles and protocols with transactions between applications

The IHE integration profiles have existed since 2015. At that time the laboratories were often located within healthcare institutions and there were only a limited number of protocols for transferring the data. These are all based on HL7 v2 standard. In practice, it appears that the suppliers have not incorporate all transactions. In addition, when exchanging laboratory data with general practitioners, the 'MedLab' message based on the Edifact standard is often used. This exchange is done via Zorgmail.

The broad use of the Internet has led to the development of new variations of the HL7 standard, namely HL7-FHIR (see also section 4.4.4.3). FHIR uses Internet standards to use APIs to switch healthcare information between systems. Internet standards are also used for authentication and authorization. This eliminates the need for a separate feature such as the HL7v2-based protocols. In general, FHIR is based on more efficient protocols than the older HL7 protocols that are now frequently used in the IHE profiles. Currently, the IHE integration profiles contain virtually no FHIR protocols. However, there is a dilemma. On one hand, the current HL7v2 protocols are indispensable to achieve interoperability between organizations and the systems 'today', but on the other hand, more and more innovative applications are emerging that only communicate based on FHIR. In order to keep up with new developments, the IHE community, together with the HL7 community, needs to make efforts to include the FHIR protocols in the IHE integration profiles.

4.4.3.2. SECURITY AND REDUNDANCY IN HL7 VERSIONS

For application-to-application communication, protocols are used. In turn, these protocols are based on underlying protocols. For example, HL7v2.x is built on MLLP (minimal Lower Layer on TCP/IP. Where as FHIR relies on HTTP/REST and then Protocol) which in itself builds on TCP/IP. These choices have a major impact on a number of aspects of the connection. MLLP is often seen as a permanent connection. If it is disconnected, a large number of implementations would be required for it to be started manually. This connection is stateful. The impact of this is that a failover solution cannot be activated by itself. At FHIR, the messages are stateless, which means that failover can be achieved using common techniques. In addition, it is unusual for HL7v2.x to add encryption to the connection. This can technically be done with Transport Layer Security (TLS). As a result, the origin and privacy of the messages is not guaranteed. This can be resolved by adding encryption to the IP layer using IPSec. Not only this important, if messages cross organizational borders, but also within organizations connections. FHIR builds on industry-standard protocols war security is an integral part. For FHIR it is possible to use SMART to control authentication, in addition SSL/TLS are used to achieve encryption

4.4.4. APPLICATION LANDSCAPE

From the above overview it becomes clear that both an 'infrastructure' for IHE-XDS and HL7- FHIR within the transmural laboratory setting are necessary. The choice for HL7-FHIR or IHE-XDS is therefore mainly determined by the specific care process supported by electronic data exchange. When it comes to the direct exchange of information between systems within the same care process, there is a preference for HL7-FHIR. For most transmural laboratory process transfers, this is sufficient. When it comes to giving others access to results and reports ('documents'), IHE-XDS is the most obvious choice[8]. In the laboratory we have to deal with both types of data exchange, the difference between a message and a document is described by HL7 as follows: "A document is designed to be persistent for long periods of time, whereas messages are more often expected to be transient. There is a place for both of these constructs in healthcare."[9]

For data exchange within the transmural laboratory process, not only do the multiple standards (HL7V2, HL7-FHIR and Edifact) apply, but they also play a role in multiple exchange infrastructures (such as XDS and LSP).

In the selection of protocols and the infrastructure for the transmission of laboratory data, it must be taken into account that not all suppliers have the three methods of data exchange - via point-to-point connections (with Edifact), via XDS or via LSP - implemented. For example, connecting to an XDS infrastructure is not affordable for a general practitioner, however a solution must be found if Edifact is not longer possible.

After all, the general practitioner is an important part of requesting laboratory examinations and receiving the results. The general practitioner generally has a connection to the LSP for the transfer of the general medical record and medication data. Moreover, the availability of laboratory data is

[8] Replace HL7-FHIR IHE-XDS? https://www.hl7.nl/overhl7/item/gaat-hl7-fhir-ihe-xds-vervangen.html
[9] 9 for more information: See John Moehrke's blog: "When is a document not a Document but still a document" https://healthcaresecprivacy.blogspot.com/2021/02/when-is-document-not-document-but-still.html?m=1

becoming increasingly important in the medication process. This is why we are also working on exchanging laboratory data via the LSP.

The following paragraphs explain the use of IHE-XDS LSP and HL7-FHIR. The co-existing solutions lead to the application layer being an eco-system for exchange based on IHE-XDS and HL7-FHIR. A description of this eco-system is part of this section.

4.4.4.1. IHE-XDS

XDS stands for Cross-enterprise Document sharing. XDS is widely used in the Netherlands within regional healthcare networks and ensures that laboratory-provided results can be collected or displayed safely and electronically when requested by a healthcare provider other than the requestor. For example, by a pharmacist who needs the kidney function value for the purpose of medication monitoring. All this subject to a treatment relationship and patient consent.

Although it may seem like XDS is an application, it is actually a framework of different applications that each have a specific function within this framework, but which meet the IHE integration profiles, as IHE has set up. Different suppliers can support different applications (in IHE terms of an application consisting of 1 or more IHE actors). The main application is the XDS registry. This is the heart of the XDS framework. The XDS registry acts as a telephone 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).

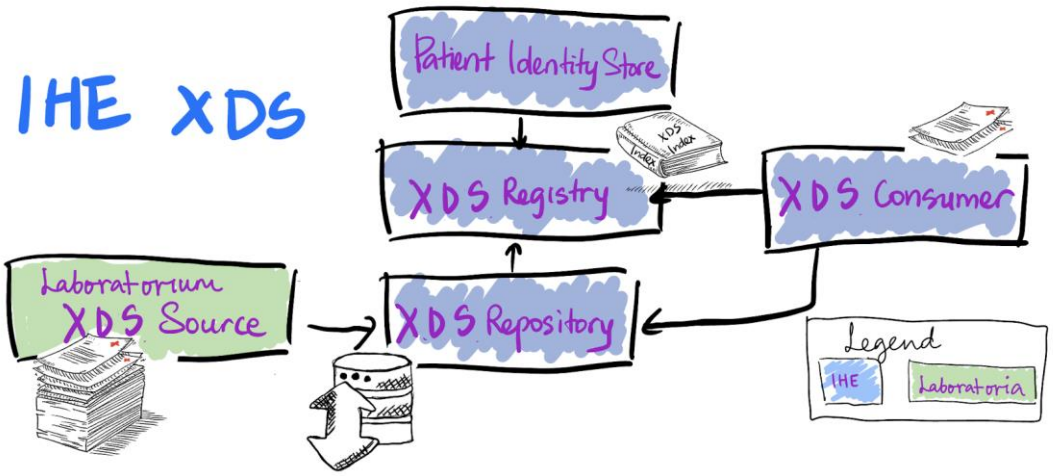


Figure 13: XDS Framework

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, even from different vendors. Just as now multiple XDS repositories and XDS Sources can exist in an XDS network. An XDS repository is responsible for registering the documents within the XDS network with the XDS registry. The document is created on the XDS source. An XDS source can be an EMR but this could also be a laboratory system such as ‘Labosys’, ‘Glims’ or ‘Molis’.

More and more hospitals have set up an XDS environment, especially for image sharing. However, setting up an XDS environment is not simple. The costs are relatively high if only a limited number of use cases are used. An XDS environment will only be truly effective if there are enough use cases running on it, and most XDS implementation projects face this challenge. Implementing use cases are organizational changes, while they are often implemented as solid an ICT change. Processes need to be adapted to work smarter and more effectively, and standards on the information layer need to be defined, which is difficult. There are now information standards that are excellent for placing documents in an XDS environment, such as the BGZ, E-medication, BabyConnect, E-lab, TBR mamma carcinoma, etc.
Finally, we would like to refer to the RSO-NL guideline program[10].

4.4.4.2. LANDELIJK SCHAKELPUNT (LSP)

Although the LSP is not based on IHE or FHIR [11] standards, the principle is the same. The LSP is a healthcare infrastructure: A network that healthcare providers can connect to. Through this network, they can access medical data about their patients in each other's systems - 24 hours a day, seven days a week. The LSP is specially developed and protected for this purpose.
The LSP is not a database: No medical data is stored. This data is simply kept in the source files with the general practitioner and pharmacy. Like an XDS Registry, the LSP is an Index of patient information references. This index allows a healthcare provider to request the information if all the conditions for access are met. The LSP exchanges messages are based on HL7 v3.

There are now links between the LSP and XDS infrastructure[12]. In addition, the LSP has the opportunity to obtain the information provided via the LSP for a PGO based on the Medmij agreements. This so-called 'provider of healthcare' (DVZA) is called LSP+.

From XDS, the LSP can be requested with On-Demand documents and the documents that go into XDS from the LSP can be returned as FHIR resources via the IHE-MHD, mXDE and QEDm profile.

[10] *Guideline RSO-NL: https://www.nictiz.nl/wp-content/uploads/Handreiking-interoperabiliteit-tussen-zorgverleners-2019.pdf*
[11] *The LSP will be made suitable for exchange bases on FHIR in 2022. see: https://www.hl7.nl/component/zoo/item/lsp-on-fhir.html*
[12] *https://www.nvkc.nl/sites/default/files/20171214%20Projectplan%20pilot%20eLab%20Helmond%202018%20-concept-%20vr0_1.pdf*

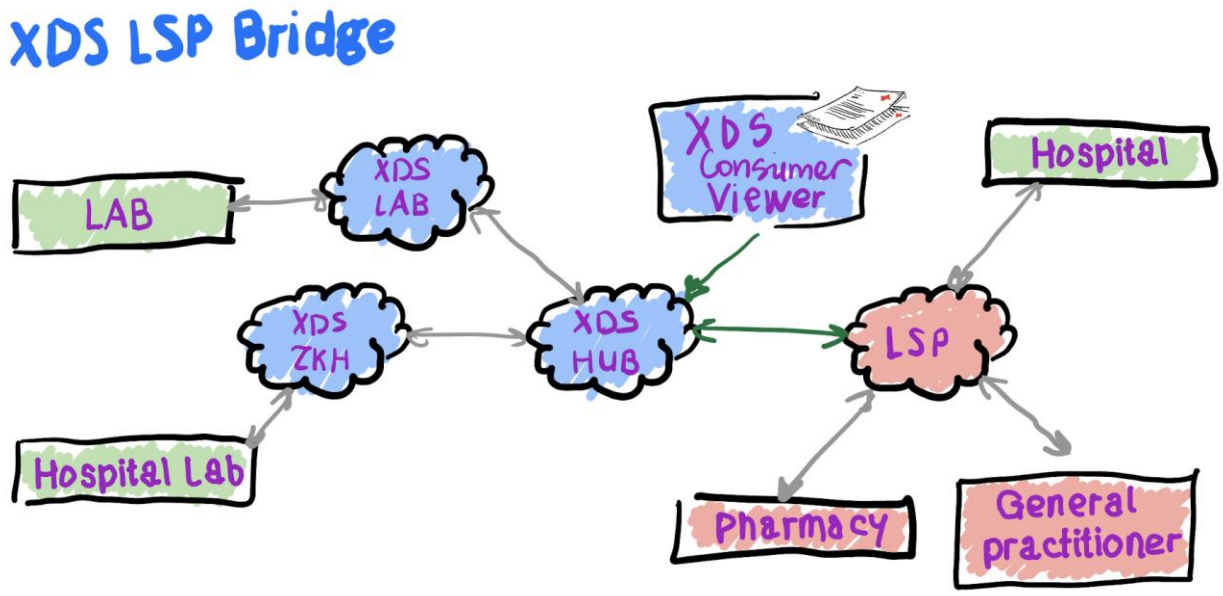


Figure 14 XDS LSP Bridge

4.4.4.3. FHIR

It is increasingly being argued that FHIR interoperability eliminates all problems. That it is the standard of the future. It is certain that FHIR is based on more efficient protocols than the older HL7 protocols that IHE frequently uses in its profiles. FHIR uses RESTful services. In addition to the fact that the FHIR protocols are faster and 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 real-time, that is demand driven, the processes in healthcare can be reshaped and this enables the desired healthcare innovation.

FHIR Resources, 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 regarding the difference between applications with
a) XDS, b) XDS with FHIR documents or c) FHIR API. Nowadays it is often stated: "We can do FHIR anyway with XDS?". 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 being duplicated, with adverse effects on current events, management, and AVG (GDPR) compliance. By definition, duplicated data is out of date within a certain period of time. The standards HL7v2, HL7v3, CDA, XDS, FHIR documents and XDS/XDW/FHIR documents combination are largely based on this duplication mechanism.

The purpose of the FHIR API is not to duplicate data: The data is retrieved in real time when it is needed and then the data is discarded. It is important to distinguish between FHIR documents and the FHIR REST API here. One of the following paragraphs uses FHIR REST API to create HL7 CDA documents published in XDS via On-Demand Documents. This is different from FHIR documents. Where a FHIR API retrieves a document (e.g. a PDF). Using FHIR, a hybrid environment is created.

The current version of FHIR (release 4) supports approximately 80% of the processes and data. Even though developments are fast, FHIR is not yet integrated into all EMRs.
An incentive for the use of FHIR is that the VIPP programs (which stimulate the VWS electronic data exchange) requiring data exchange between the EMRs from the healthcare providers and between the EMRs and the patient/citizen via a PGO in accordance with the MedMij framework. MedMij uses information standards based on FHIR[13].
In addition, not all medical data is swift. Letters and reports have a persistent character and are therefore classified as documents. It is expected that the adoption of FHIR by suppliers will support both documents and resources in the near future by EMRs.

The suppliers make little use of FHIR for the transmural laboratory process. This document is therefore a call to HL7, IHE and as well as the suppliers to update the existing IHE integration profiles and implement them in the applications. In view of the national developments concerning the electronic exchange of data and the upcoming legal obligation[14] to exchange data electronically between healthcare providers and with the patient, there is no way out.

4.4.5. IHE XDS FHIR LAB ECO SYSTEM

In recent years IHE has worked closely with the FHIR community to incorporate FHIR protocols into the various IHE integration profiles. Especially in the infrastructure domain of IHE. These new IHE infrastructure domain profiles allow the creation of a basic application landscape where functional applications can exchange information transparently, whether this application supports the IHE- XDS protocols or whether it supports the FHIR protocol[15]. This creates an IHE XDS-FHIR-LAB ecosystem as shown in figure 16. Each of the protocols are thus has its pros and cons[16].

[13] More information: https://medmij.nl/informatiestandaarden/
[14] Act on Electronic Data Exchange in Health Care (Wegiz): See Annex 5.
[15] https://hl7.nl/component/zoo/item/gaat-hl7-fhir-ihe-xds-vervangen.html
[16] https://www.hl7.nl/component/zoo/item/het-combineren-van-fhir-en-ihe-xds.html?Itemid=270

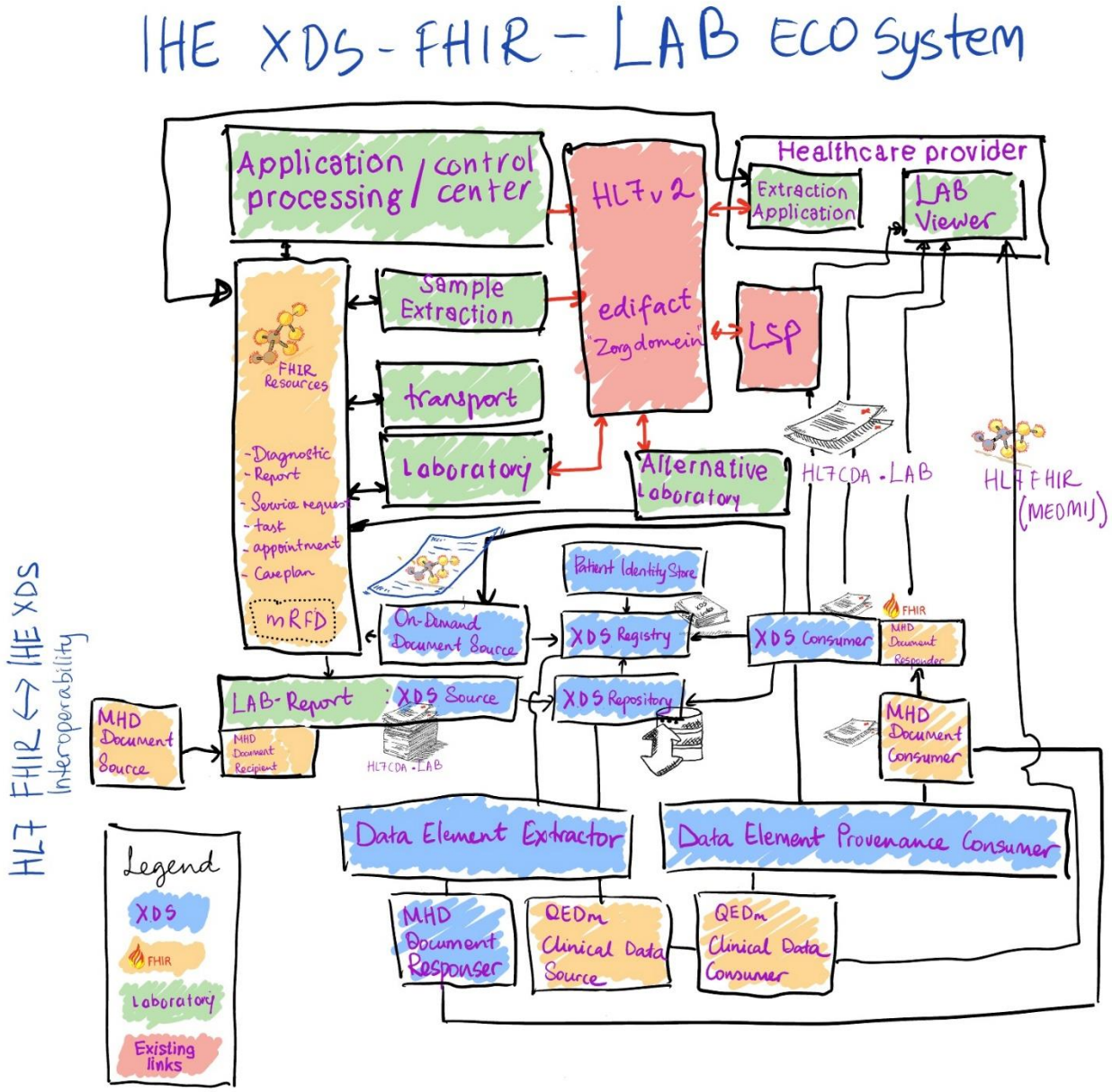


Figure 15: IHE XDS-FHIR-LAB Eco system

4.4.5.1. IHE ON-DEMAND DOCUMENTS

By using the On-Demand Documents profile it becomes possible to generate documents dynamically when an On-Demand Document is requested via XDS. On-Demand Documents are used when content is expected to change more frequently over time, while the requestor always wants to receive the most up-to-date content.

The use of On-Demand documents is intended for the application-architecture where there are systems containing patient data that are the most up-to-date content available via an application interface (API). This On-Demand Documents profile is not specifically written for FHIR, but for a Bundle of FHIR Resources and can be offered as a restful API.

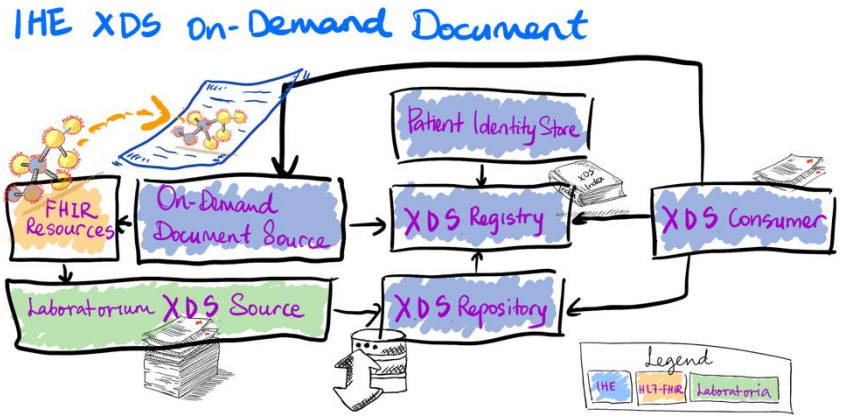


Figure 16: IHE XDS On Demand Documents

This IHE integration profile makes it possible to offer FHIR resources as an XDS document in the XDS network. XDS Consumers can retrieve the document as it is a 'normal' XDS document. MedMij FHIR Resources can be connected to an On-Demand-Document and can be presented as a 'normal' HL7 CDA document conformed the BGZ guidelines by Nictiz. This HL7 CDA document is described in the template section of Art-Decor.[17]

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

On-Demand Documents allows FHIR resources to create a document. With the IHE- MHD profile [18] it is possible to retrieve a document stored in the XDS infrastructure by means of a FHIR resource. If this IHE-MHD profile is used, the document can be retrieved through the RESTful service, but it still remains a

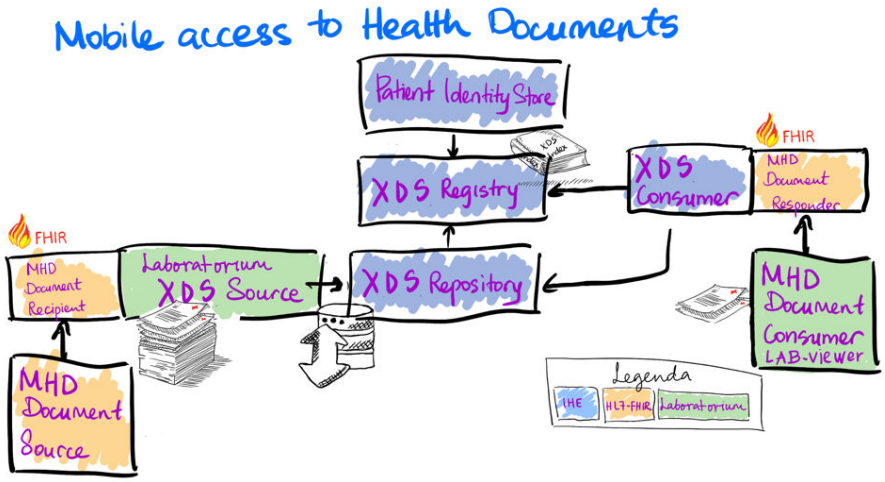


Figure 17: IHE Mobile Access to Health Documents

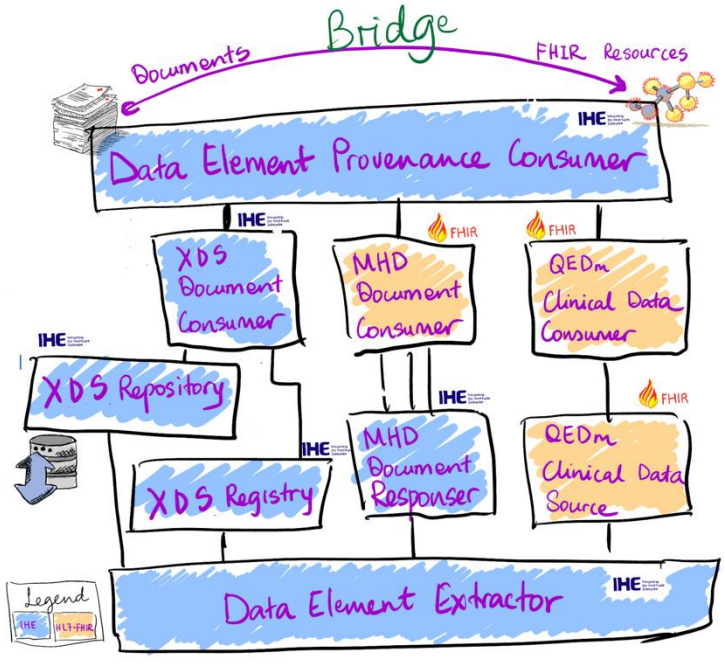
[17] http://decor.nictiz.nl/pub/bgz2017/bgz2017-html-20190313T152910/rules.html
[18] https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_MHD.pdf

document. The information objects in this document have not been translated into FHIR resources. Example: A laboratory system from laboratory A (is then the XDS source) reports a laboratory report as a HL7 CDA document to handle resources on the XDS repository. With the IHE-MHD profile a FHIR-user can retrieve this HL7 CDA document. Under the surface, the FHIR resources 'FHIR documents' are used. This will allow the user to retrieve this unedited HL7 CDA document.

4.4.5.3. IHE-MXDE AND IHE-QEDM

The Mobile Cross-Enterprise Document Data Element Extraction (mXDE) profile allows specific data elements to filter specific data elements form structured documents. The profile allows you to exchange discrete health data.

The IHE-mXDE profile makes it possible to request the laboratory results, written in several HL7 CDA documents in XDS and to filter out only the Cholesterol value. By filtering by LOINC it is better to compare different values since these include both meeting and measurement methodology/technique. The IHE-QEDm profile allows this filtered data to be provided as the FHIR Resources. The profile is designed in such a way that, when it is retrieved, not all the underlying documents need to be retrieved, but only those that are necessary for the FHIR command. This monitors the performance of the entire system. This makes it possible to easily filter the Cholesterol value from all stored documents and display a graph of it.



Figuur 18: IHE mXDE en IHE QEDm

Example: If a FHIR application wants to graph the Cholesterol value of a patient from a laboratory system, the system knows by using these IHE integration profiles in which documents the Cholesterol value is and which documents to retrieve. The laboratory documents that do not include Cholesterol value shall be left in the system. This allows you to move from documents to FHIR resources. By creating

a basic infrastructure with the different IHE integration profiles, complete bi-directional interoperability between FHIR resources and XDS documents has now been established.

4.4.5.4. IHE MRFD

A laboratory is in continuous motion. New more efficient equipment is purchased and new tests are introduced. This means that if a new device is purchased, applicants must be kept informed of the changes. However, this process must not take too much effort for the user.

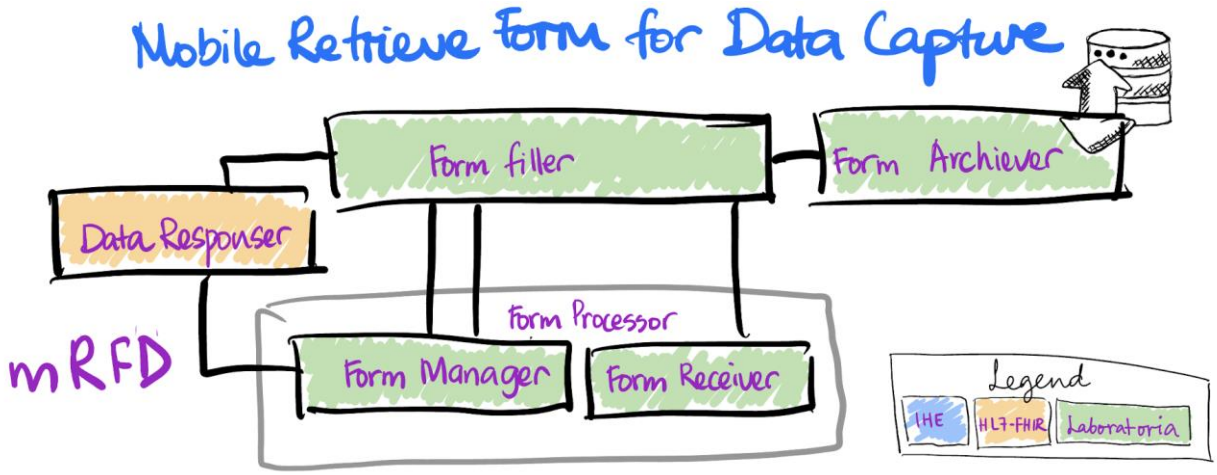


Figure 19: IHE Mobile Retrieve Form for Data Capture

At this time, a new update often sends a new survey form to all applicants. This is not efficient, and time consuming. The mRFD profile allows the administration of the application form to be left with the laboratory. Each application form at the laboratory will be checked for a new version of the form whenever an applicant wishes to make an application. If so, the new form will be downloaded automatically. As a result, the applicant always has the current tests available and the applications have the right test codes. IHE described this together with FHIR in an IHE integration profile: The Mobile Retrieve Form for Data Capture (IHE mRFD). This IHE integration profile is fully based on HL7 FHIR. This goes to show that IHE is constantly looking for the right existing standards and for a particular use case.

4.4.6. KEY POINTS 'APPLICATION LAYER'

- There are different functional applications in the application layer. Many transactions have been developed and included in the IHE integration profile over the years for the exchange of data between applications. These transactions use standards based on HL7 v2. This standard has a lot of disadvantages.

- Today there is more modern architecture to solve the interoperability issues. IHE and HL7 are requested to use these new architectures and in particular, include FHIR specifications in all laboratory profiles. SMART on FHIR is easier to deploy and safer. FHIR also offers the possibility that in the event of a failure of connections, failover mechanisms can be easily controlled. FHIR makes interoperability within the transmural laboratory setting cheaper and more efficient.

- Caregivers, patients/citizens, as well as suppliers will benefit from this.

- This creates an ecosystem of IHE XDS-FHIR for the transmural laboratory setting

- The work process must be considered when designing the architecture. For each step in the work process where data exchange is needed, it must be determined whether:
    - The information must be requested ('pull') or sent ('push')
    - it is about the exchange of discrete data or of complete documents

4.5. APPROACH 'INFRASTRUCTURE LAYER'

The infrastructure layer is the bottom layer of all layers of the (five) layer model. This layer relates to the technical infrastructure in which the information systems of the concerning parties are located, such as the network, servers, database engine. It concerns the non-healthcare specific ICT components. At the beginning of the network technology, this was still difficult due to the lack and/or the many different network standards. With modern internet technology, infrastructure is 'common business'. More and more facilities can be fully provisioned by cloud vendors. Physical servers have been replaced for virtual servers running in the cloud, physical firewalls have been replaced by virtual firewalls. It is also possible to create virtual networks yourself. Because of this far-reaching virtualization, the location where applications and data are stored are by definition no longer important. However, privacy and security legislation and requirements remain fully applicable. The standardization in the infrastructure has led to an increasing number of applications being offered from the cloud.

In Nictiz's five-layer model, agreements are made on the infrastructure layer on how information can be exchanged at a technical level between the parties involved. What communications infrastructure is required for this? What mechanisms of information exchange are chosen? At this level, as IHE XDS and LSP are referred to as standards. This guideline has been used to describe these standards at the application level (paragraph 4.4.). The reason for this is that it creates a more logical story that fits better within the context of the use of IHE integration profiles. In addition to IHE XDS and LSP, new exchange platforms such as NUTS [19] and the "Zorgplatform" from ChipSoft[20].

4.5.1. VPN/SSL

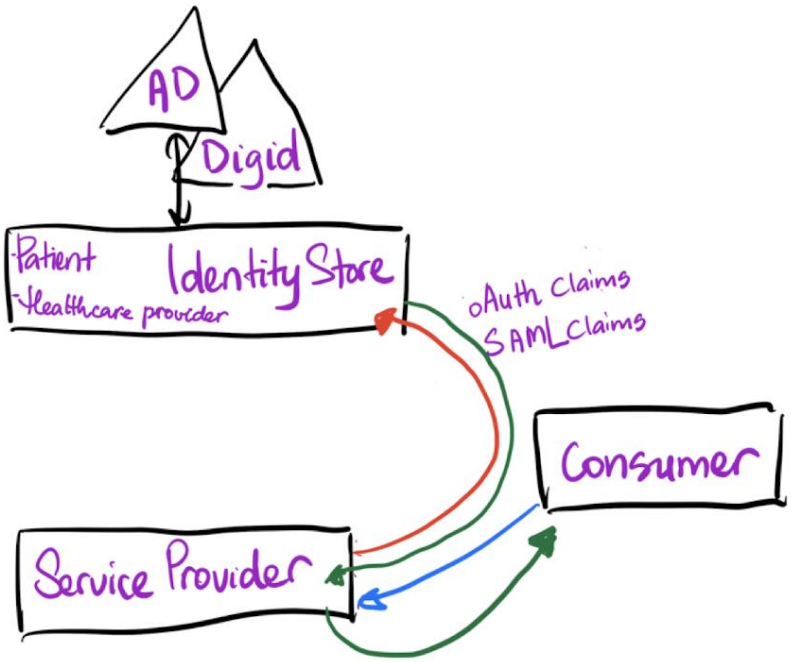
VPN/SSL most IHE integration profiles for the laboratory are described in HL7v2. HL7v2 is a standard message but does not describe how to secure messages during transport. At the moment, security is often done by setting up fixed VPN connections between sender and recipient. These VPN connections are heavy and cost a lot of maintenance.
Switching to the HL7-FHIR standard allows you to say goodbye to the VPN connections and to work toward SSL (Secure Socket Layer) connections. An encrypted connection, which is set up automatically per transfer, without any user noticing. This is explained in paragraph 4.4.3.2.

4.5.2. IDENTIFICATION, AUTHENTICATION AND AUTORIZATION

A point of concern in regards to the infrastructure layer is the control of the identification, authentication and authorization of users throughout the infrastructure. For the identification, authentication and authorization not only in the healthcare - the Security Assertion Markup Language (SAML) and Open Authorization (OAuth) standards are being used. Both standards are described by Organization for the Advancement of Structured Information Standards (OASIS).

[19] https://nuts.nl/
[20] https://www.chipsoft.nl/oplossingen/148/Zorgplatform

IHE has adopted these standards and described it in the ICT infrastructure (ITI) domain with the IHE integration profile Cross-Enterprise User assertion Profile (HE- XUA).



Figuur 20: Oauth en SAML

The IHE Integration Profile XUA works based on claims. When a user wants to access an application, they are prompted to enter their credentials. However, this task has outsourced the application to an independent trusted third party. This can be a user authentication store within a healthcare facility (usually a Microsoft AD server). But this could also be A DIGID code well-known to every citizen. Even more familiar identity systems are those of Facebook and Microsoft. These identifying and authenticating systems are called in the standard identity stores. If the user entered his credentials at the Identity store - with or without a 2- or 3-factor authentication mechanism, the user will receive a claim back.

A claim is an encrypted proof that the Identity store has positively identified the user. However, this evidence may also include other cases. This encrypted message can also include the organization for which the user is working or the role the user is logging in to. These added claims are necessary for the application (the service provider) as they allow the user to be authorized within the application.

For healthcare the role code table of the UZI register is used in the Netherlands for healthcare provider roles [21] (Pelt & Breas, 2015). The role codes are included in the UZI-Healthcare pass. The UZI-healthcare provider pass allows the healthcare provider to identify and authenticate itself, and the application can use an authorization table to verify that the concerning healthcare provider has access to the medical data. Unfortunately, these UZI role codes are not sufficiently fine-grained because only BIG- registered healthcare provider and UZI healthcare provider pas can request. Healthcare providers who do not have

[21] (Pelt & Breas, 2015)

the BIG-registered but do play a role in the healthcare process (for example, healthcare or medical secretaries) can access the patient's records only after being mandated by the BIG-registered healthcare provider. They need therefore the UZI employee pass-on name [22].

Note that many of the classic protocols in the healthcare, such as HL7v2, create unencrypted connections by default. This makes it impossible to guarantee authenticity and confidentiality without the need for additional network configuration. More modern protocols such as HL7-FHIR, for example, do have this capability.

4.5.3. GENERIC PROVISIONS

The government operates on a national network of infrastructures. This does not mean a single central ICT infrastructure for healthcare but a coherent national system of (agreements on) infrastructures to which the ICT systems of individual healthcare institutions are connected. This network enables the technical level to provide "..de right information at the right place at the right time to ensure that patients and clients receive the right healthcare." [23]. In order to link ICT systems together so that information can be exchanged reliably several generic functions are required. For example healthcare facilities must ensure that unauthorized persons do not have access to health information. A healthcare provider cannot share data until the healthcare provider can rely on themselves to exchange with the person with whom he or she intends to exchange information.

The government (the Information Council) has appointed a number of generic functions for the short term:

Function	What it does
Identification	identify healthcare provider and Client/Patient
Authentication	determine if the healthcare provider is actually who they claim to grant
Authorization	to healthcare providers to see data
Consent	consent from the patient/client to share or retrieve data
Localization	identify where the patient/client's data are located
Addressing	request from digital address of healthcare institution and healthcare provider

Table 3: Generic functions in the infrastructure layer

[22] More information about the UZI-pass: https://www.uziregister.nl/uzi-pas/vraag-een-uzi-pas-aan/kies-de-juiste-uzi-pas
[23] See letter of Dutch ministry: https://www.gegevensuitwisselingindezorg.nl/publicaties/brieven/2021/12/20/kamerbrief-over-generieke-functies-voor-elektronische-gegevensuitwisseling-in-de-zorg

Relevant to the infrastructures such as IHE-XDS and LSP are the generic features that have recently been developed:

- *MITZ*
  Where every Dutch citizen consent choices for all care sectors can be recorded [24].
- *ZORG-AB* (Address Book Healthcare Care)
  and common address information that all healthcare service providers can use to send standardized messages such as research requests, recipes, references to the right recipient. In addition to the necessary contact information, ZORG-AB also contains a variety of technical information to connect computers and applications.[25]

This guide is based on the use of a consent register and a care book is part of the application itself. The use of these new generic provisions has not yet been considered.

4.5.4. KEY POINTS 'INFRASTRUCTURE LAYER'

- The IHE infrastructure layer is not the same as the NICTIZ interoperability model's layer 5 infrastructures
- The transactions described within IHE are based mainly on HL7v2. These transactions require additional VPN complexity on the infrastructure layer
- The government is in process of normalizing for generic functions, which will further standardize infrastructures

[24] Mitz: https://www.vzvz.nl/diensten/gemeenschappelijke-diensten/mitz
[25] Zorg-AB: https://www.vzvz.nl/diensten/gemeenschappelijke-diensten/zorg-ab

4.6. INFORMATION SECURITY AND LEGISLATION

For all layers of the interoperability model, the organization and systems used must comply with the requirements for information protection in accordance with the applicable laws and regulations for the electronic exchange of data. VZVZ has developed a trust model for data exchange.
See: www.vzvz.nl/het-uitwisselingskompas.

4.6.1. INFORMATION SECURITY

Every caregiver themselves has to deal with all the layers and pillars in the model in order to ensure interoperability between two caregivers. The starting point is that both parties 'in-house' the internal information security have correctly in place. This means, among other things, organization and processes, the recording of information, access to the information and management of used systems and the infrastructure must have arranged. This is a necessary condition for interoperability between care providers and/or healthcare institutions. The requirements for this are described in the NEN 7510 for information security in care and the additional standards:

- NEN 7512: Trust basis for data exchange
- NEN 7513: logging of actions on the electronic patient record so that the patient can see who has consulted his/her file and what data has been duplicated and/or shared with which caregivers. This logging I according to the NEN 7513 in an ATNA (Audit Trail and Node Authentication) format must be saved.

4.6.2. LAW AND LEGISTRATION

The Following laws are particularly important for the ELECTRONIC exchange of information in the care sector. More information is included in Appendix 6.

- The General Data Protection Regulation (AVG), which lays down rules for carefully handling privacy-sensitive information from citizens.
- Specific to the electronic exchange of medical personal data, the Additional provisions of the Act concerning the processing of personal data in the care (Wabvpz) applies.
- The Law on the Medical Treatment Agreement (WGBO); it regulates the filing obligation and sets rules on the confidentiality of the file.
- The Social Security Number Act (WBSn-z), which governs the use of the social security number (BBS) between health care providers.

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6. IHE NL WORKING GROUP HEALTHCARE PROCESSES

The working group on healthcare processes consists of volunteers from the healthcare field with intrinsic interest in interoperability and the healthcare process.

Core team

- Sasja Beers (Nictiz)
- Rob den Bieman (Sint Maartenskliniek)
- Wim Hoeijenbos (MedicalPhit)
- Yoe Kwa (D&A Medical Group)
- Brian Sanderse (Star-SHL)
- Igor Schoonbrood (ITCAdvies en Maastricht Universitair Medisch Centrum+)
- Charles van Swieten (D&A Medical Group)
- Frans van Tilburg (M&I Partners, voorzitter)
- Tie Tjee (Grapevine World en Vendor-chair IHE Nederland)
- René de Vries (CGI)

Reviewers

- Rob den Bieman (Sint Maartenskliniek- Informatieanalist)
- Jan Dols (NVKC, commissie AICT en lid IHE-NL Bestuur)
- Jan Feenstra (MedicalPhit - Senior Consultant)
- Alma Mingels (MUMC+ - Klinisch Chemicus)
- Benno Naaijkens (Diagnost-IQ – CIO)
- Fokke Rispens (Visma Connect - Principal Consultant)
- Ruben Smeets (NVKC – RadboudUMC)

Graphic Design & Translation

- Karin Woo-Peters (ITCAdvies and CherryBlossom Vertaal Diensten)
- Dhana Peters (CherryBlossom Vertaal Diensten)

APPENDIX 1: EXAMPLE IHE-INTEGRATION PROFILE

For visual purpose, here is an example of IHE integration profiles from the Domain 'Patient Care devices'. The IHE 'Patient Care devices' domain describes the data transfer between one or more systems that are very closely connected to the patient and one or more other medical systems. As an example, in the Point of Care Infusion Verification Profile (PIV), the coupling between a syringe pump, which is used to administer medication to the patient in the hospital, and the hospital's EHR is described. This domain works with and supports other domains, such as 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).

IHE integration profiles of the Patient Care Device Domain.

IHE-integration profile	Abbreviation	Description
Device Enterprise Communication	DEC	sends information from medical devices from the measurement point to business applications.
Point of Care Infusion Verification	PIV	communicates medication order to and infusion pump or implantable device pump management system.
Implantable Device Cardiac Observation	IDCO	specifies the creation, transmission, and processing of individual data elements and report attachments associated with cardiac device observation.
Rosetta Terminology Mapping	RTM	harmonizes the use of existing terminology defined by the ISO/ IEEE 11073-10101- terminology standard, which must be used in all PCD transactions (Note: RTM is a set of limited values).
Alarm Communication Management	ACM	communicates alarms so that the correct alarm with the correct priority is delivered to the appropriate people with the correct content
Retrospective Data Query	RDQ	enables searching in 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 a Infusion pump to the information system for admission, activity or presentation to the user.
Waveform Content Module	WCM	provides guidelines for recording waveform data in applicable IHE PCD profiles such as DEC and ACM.
Pulse Oximetry Integration	POI	provides guidelines for the implementation of pulse oximetry devices using IHE PCD profiles.

Table 4: Patient Care Device Domain IHE-Integration profiles

In the associated Technical frameworks, described in IHE_PCD_TF_Vol1.pdf [26], further details are given on what should be done at the integration level, at the transaction level and at the level of semantic content for each IHE integration profile. The frequently used standard within the IHE Domain 'Patient Care devices' profile is mostly HL7 v2.

[26] *https://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_TF_Vol1.pdf en https://wiki.ihe.net/index.php/PCD_Technical_Framework*

APPENDIX 2: USE CASES

1. HOSPITAL PRACTITIONER PLACES AN APPLICATION TO A DIAGNOSTIC CENTER (DC)

1. Practitioner in hospital places an application to a Diagnostic Center (DC) See Appendix 4 for schematic overview		IHE-integration profile - Actor
1. Applications	• the Practitioner Franssen files an application for the patient van Rijn. The application is for the laboratory with the disease heart failure and chooses the panel 'Control: Sodium, potassium and creatinine'. • Patient van Rijn is admitted to the De Mark hospital in Breda. The application is digitally sent to the Diagnostic Center LabNB with the patient's data being admitted, given that the hospital is the temporary address.	LTW - Order Placer
2. Processing the application	The application is processed by the LabNB: • the Patient van Rijn is checked and is not known to the LabNB. • the Patient van Rijn is searched in the BRP of the Netherlands with the BSN and automatically registered in the patient registration of the Lab NB. The Patient is given an internal LabNB Identifier. • The healthcare provider's and the institution's AGB code are also checked. These are known list of AGB codes within the LabNB as the last requested product is checked with the existing product portfolio. No problems found. • The application is provided with the LabNB patient identifier and the internal application numbers. • As the second step, the application goes to the Laboratory system to the schedule and to log the application on the worklist of the nurse who do the extraction.	LTW – Order Filler PDQ* – Patient Demographics Consumer PDQ* – Patient Demographics Supplier SVS search in a central list for AGB codes LTW – Order Filler (Intern process) LTW - Automation Manager *In NL SVBZ-interfaces are used instead of PDQ

1. Practitioner in hospital places an application to a Diagnostic Center (DC) See Appendix 4 for schematic overview		IHE-integration profile - Actor
3. Extraction Body material	• Patient van Rijn is in the hospital the Mark department a/chamber 1/ bed 2 • The collection of samples is placed on the sample extraction work order of employee Monique • Monique identifies patient van Rijn (wristband with barcode). So she is sure that this is patient van Rijn. • Monique sees in her system what she needs to extract and in which tubes and under what conditions this should be done. • Monique prints the labels and sticks them on the tubes. The material is placed in a parcel box with its own barcode: • The extraction and sample collection of patient van Rijn is completed. • At the end of the extraction round, the parcel box filled by Monique during her rounds will be placed at a dispatch location. • The parcel box is notified to the logistic department.	LTW – Order Filler (workorder) LBL – Label Broker LBL – Label Broker SET – Specimen Event Informer SET – Specimen Event Informer LTW – Automation Manager (status) LTW - Order Filler (workorder)
4. Transport	• the box is picked up by the transport service and the status changed to 'Transport'. • The box will be delivered to the LabNB for processing and the status changed to 'delivered to Lab'	LTW – Automation Manager (status)
5. Lab	• The received parcel box is recorded. • the parcel box is checked for content and Temperature and the material is placed on the track of the LabNB. • the lab performs the assessment base on the sample.	SET – Specimen Event Informer LTW – Automation Manager (Workorder) LAW

1. Practitioner in hospital places an application to a Diagnostic Center (DC) See Appendix 4 for schematic overview		IHE-integration profile - Actor
6. Reporting	• after the processing of the LabNB, the authorized report returns to the applicant. a structured report and in the dossier linked to the application number and the patient van Rijn. • The results appear on Dr. Franssen's worklist. • The results are also automatically placed in the XDS registry for sharing medical data based on the Patient consent van Rijn.	LTW – Automation Manager (status) LTW – Order Result tracker XD-LAB - Document XDS - Source XDS - Repository XDS - Registry

2. GENERAL PRACTITIONER PLACES AN APPLICATION TO A DC AND THE PATIENT MAKES AN APPOINTMENT AT A DC LOCATION

2. General Practitioner places an application to a DC and the patient makes an appointment at a DC See Appendix 4 for schematic overview		IHE-integration profile Actor
1. Application	• General Practitioner van Veen files an application for Appelman. The application is for the disease image Thyroid and check Control: 'Therapy TSH, fT4' • The application digitally transported to LabBreda. • Patient Appelman needs to make an appointment for himself.	LTW - Order Placer
2. Processing Application	• LabBreda checks the application for correctness and completeness of the required data • The request is converted to an internal patient ID for patient Appelman. The internal application number will be assigned. • The application goes to the LabBreda system and to the planning. • Patient Appelman receives a notification via email to make an appointment for the collection of the material. • Patient Appelman logs in with his DigiD and see the application in the patient portal of LabBreda and then he makes an appointment. He also gets an eTicket in his Wallet and a calendar entry.	LTW - Order Filler LTW – Order Filler (Internal process) LTW – Automation Manager LTW – Order Filler (status)

2. General Practitioner places an application to a DC and the patient makes an appointment at a DC See Appendix 4 for schematic overview		IHE-integration profile Actor
3. Sample extraction	• when patient Appelman arrives at the location, he reports at the counter and sits in the waiting room. • Patient appears on the worklist of employee Karen. After 5 minutes, patient is being called. • Employee Karen confirms patient Appelman identity, extracts the material and link the material to the application. • Employee Karen checks the activity as "completed" and the activity disappears from her worklist. • The material is stored in the Parcel box. If the parcel box is full, it is signed up for transport.	LTW – Automation Manager (status) LTW – Order Filler (Workorder) LBL – Label Broker SET – Specimen Event Informer LTW – Automation Manager (Status) LTW – Order Filler (workorder) SET – Specimen Event Informer
4. Transport	• The box is picked up by the transport service and the status changed to 'Transport'. • The box will be delivered to LabBreda for processing and the status will change to 'delivered to Lab'.	LTW – Automation Manager (status)
5. Laboratory	• The parcel box is checked for contents and temperature and the material is placed on the LabBreda's Informer track. • The laboratory performs the study on the sample.	SET – Specimen Event Informer LTW – Order Filler (Workorder) LAW
6. Reporting	• The final result is digitally sent to the GP as a structured report.	LTW – Automation Manager (Status) LTW – Order Result Tracker XD-LAB – Content creator

3. GENERAL PRACTITIONER PLACES AN APPLICATION TO A DC AND THE DC USES AN EXTERNAL SUPPLIER FOR THE COLLECTION

3. General Practitioner places an application to a DC and DC uses a third-party supplier for extraction. See Appendix 4 for schematic overview		IHE-integration profile Actor
1. Application	• General Practitioner Albertsen places an application for Patient De Rooi. The application is for disease image MDL and selects Hepatitis E screening paired with an extraction date for the day after and the home address of patient De Rooi. • The application goes to LabZeeland.	LTW – Order Placer
2. Processing Application	• LabZeeland checks the application: • the requesting AGB code for the healthcare provider is not entered. Since this is an automatic process, a status returns to General Practitioner Albertsen with the message that the AGB code is not entered. • The application software of LabZeeland has this notification too. The general practitioner Albertsen immediately adjusts the AGB code and the application comes in again. The check is done and the application is further corrected. The notification in the software request is set to accepted. • The request is converted to an internal ID of Patient de Rooi. The internal request number is also assigned. The application goes to the LabZeeland system and to the planning of an external extraction supplier “Alles4enPrikkie”. • The application will of course include the patient's BSN from de Rooi with his email, mobile number and the date of the appointment. The extraction of the material will be on the worklist of employee Diana.	LTW – Order Filler LTW – Order Filler (status) LTW – Order Placer (update) LTW – Order Filler LTW – Order Filler (workorder)
3. Sample-Extraction	• Diana goes to the patient De Rooi’s home. • After identifying the patient De Rooi accordingly to the protocol (e.g. positive patient-identification), Diana can access the extraction work order via her tablet. • Diana extracts the requested sample. • The material is linked to the application and placed in the parcel box and the extraction activity is ready.	LBL – Label Broker

3. General Practitioner places an application to a DC and DC uses a third-party supplier for extraction. See Appendix 4 for schematic overview		IHE-integration profile Actor
4. Transport	• Diana goes to LabZeeland and gives the parcel box and the status changes to 'delivered to Lab'.	LTW – Automation Manager (status)
5. Laboratory	• LabZeeland checks the contents and the temperature. The material goes on track. • The laboratory performs the study on the sample.	SET - Specimen Event Informer LTW – Order Filler (Workorder)
6. Reporting	• The result is approved and delivered to the general practitioner Albertsen as an EDIFACT MEDLAB document and in the application linked to the Rooi's patient file.	LTW – Automation Manager (Status) LTW – Order Result Tracker

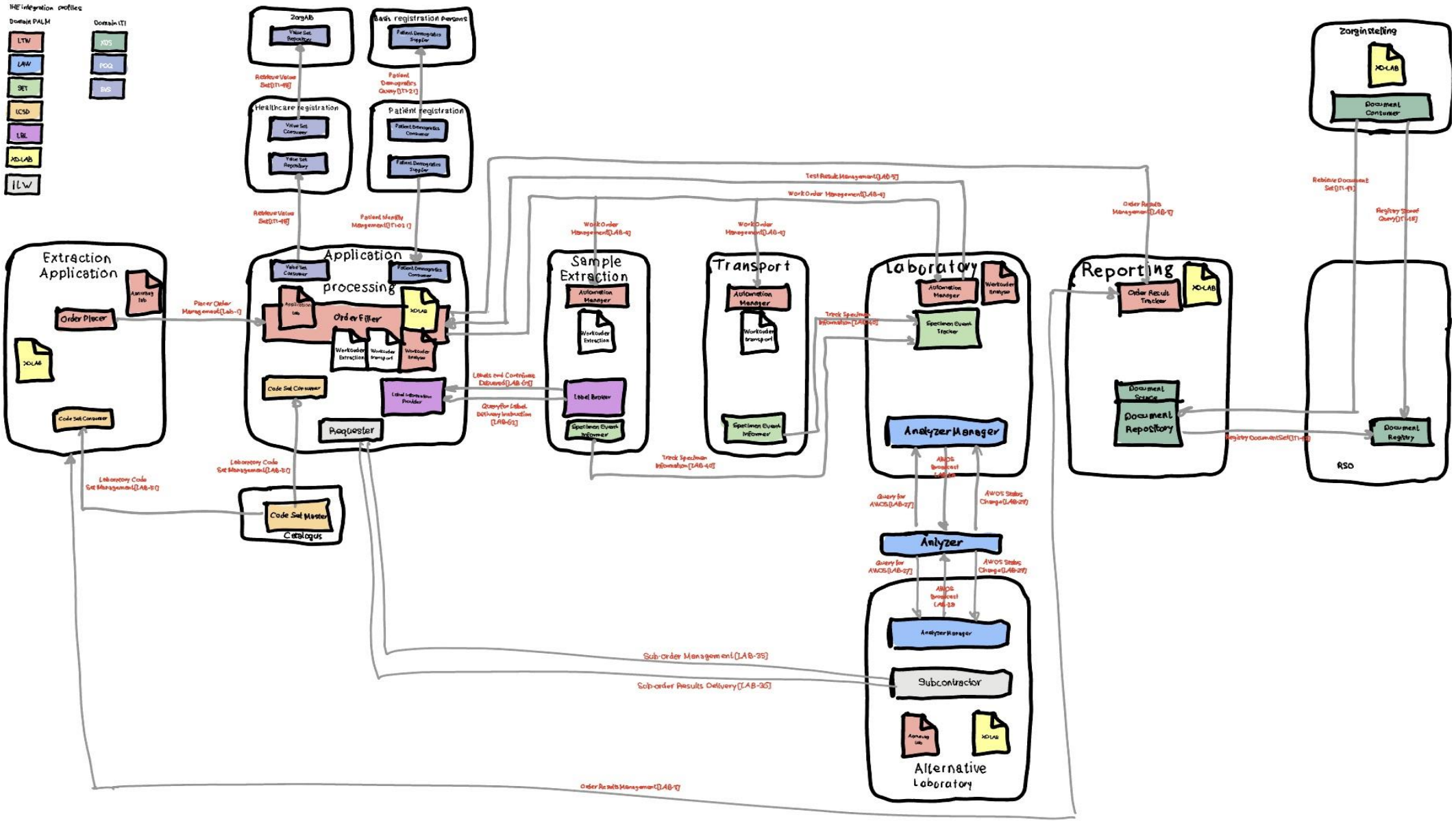
4. PATIËNT HIMSELF REQUESTS FOR AN EXAMINATION

4. patient Himself request for an Examination See Appendix 4 for schematic overview		IHE-integration profile Actor
1. Application	• A client who wants to find out if they have a SOA, without a doctor as a middleman, can do so directly through laboratory. • To do this, the consumer goes to the website to order this test. During the ordering process, the test is checked online.	LTW – Order Placer
2. Processing Application	• The application from the online environment is processed as an application on the laboratory. • After the order, an instruction together with the material for collection (or self-collection by the patient) of the samples follows. The labels are attached to the material.	LTW-Order Filler LBL – Label Broker LTW – Automation Manager (status) SET - Specimen Event Informer
3. Sample-Extraction	• After the order, an instruction with the material for extraction for the patient to be extracted (or patient self-extraction) for the samples will be sent. • The consumer himself extracts the material. This material is sent to the laboratory where the relevant tests are carried out.	LTW – Order Filler (workorder)
4. Transport	• Post • Material received and checked.	LTW – Automation Manager (Status)
5. Laboratory	• The laboratory performs the study of the sample.	SET - Specimen Event Informer LTW – Order Filler (workorder)
6. Reporting	• Through a message the client is informed of the result. The client goes to the website and finds the results and the explanation.	
Points of Attention	The results are not sent to the General Practitioner.	

5. SUBCONTRACT PROCESSING APPLICATION BY ANOTHER LABORATORY

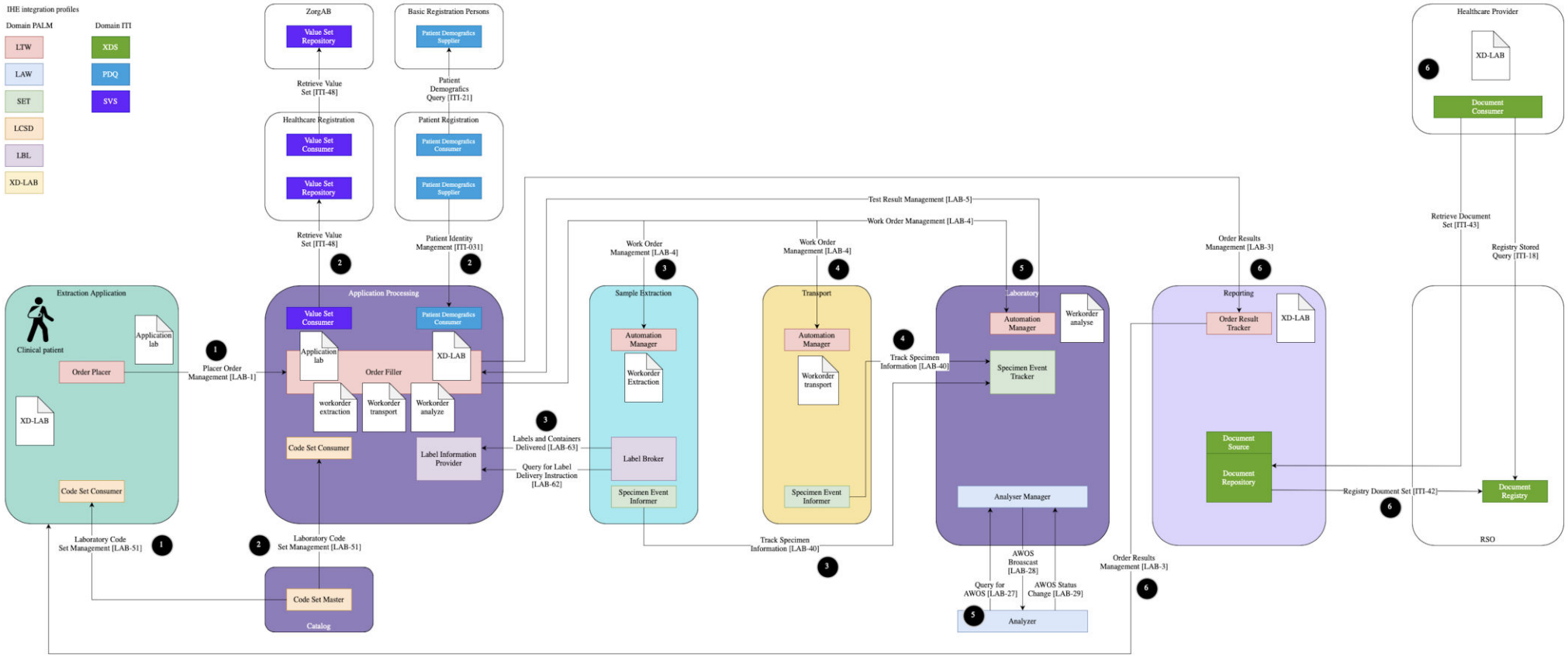
5. Subcontract processing application by another laboratory See Appendix 4 for schematic overview		IHE-integration profile Actor
1. Processing Application	• Receiving and processing the application (regular work process).	
2. Subcontract/ Outsourcing laboratory tests **3. Reporting**	• A laboratory from a hospital has a variety of analytical equipment to make the proper diagnosis. However, some lab tests are requested so little that it is just not profitable for a hospital laboratory to purchase self-analysis equipment. • Director Labirox has therefore decided to outsource the lab tests that are not profitable to another laboratory. While director Laborix of an UMC outsources only some of the expensive tests, director Micronix from a small General Hospital decides to outsource all tests of microbiology and pathology.	ILW – Requester ILW - Subcontractor
Points of Attention	• Privacy (which information may or may not be sent to external lab). • Sample extraction (multiple tests are determined from 1 tube. If a part is outsourced, 2 tubes should be taken. • Financing (who declares the tests). • Joint diagnosis and reports. (Tests are requested in conjunction. Who determines the consistency in diagnosis)? • Transport.	

APPENDIX 3: IHE INTEGRATION PROFILES IN THE TRANSMURAL LABORATORY PROCESS



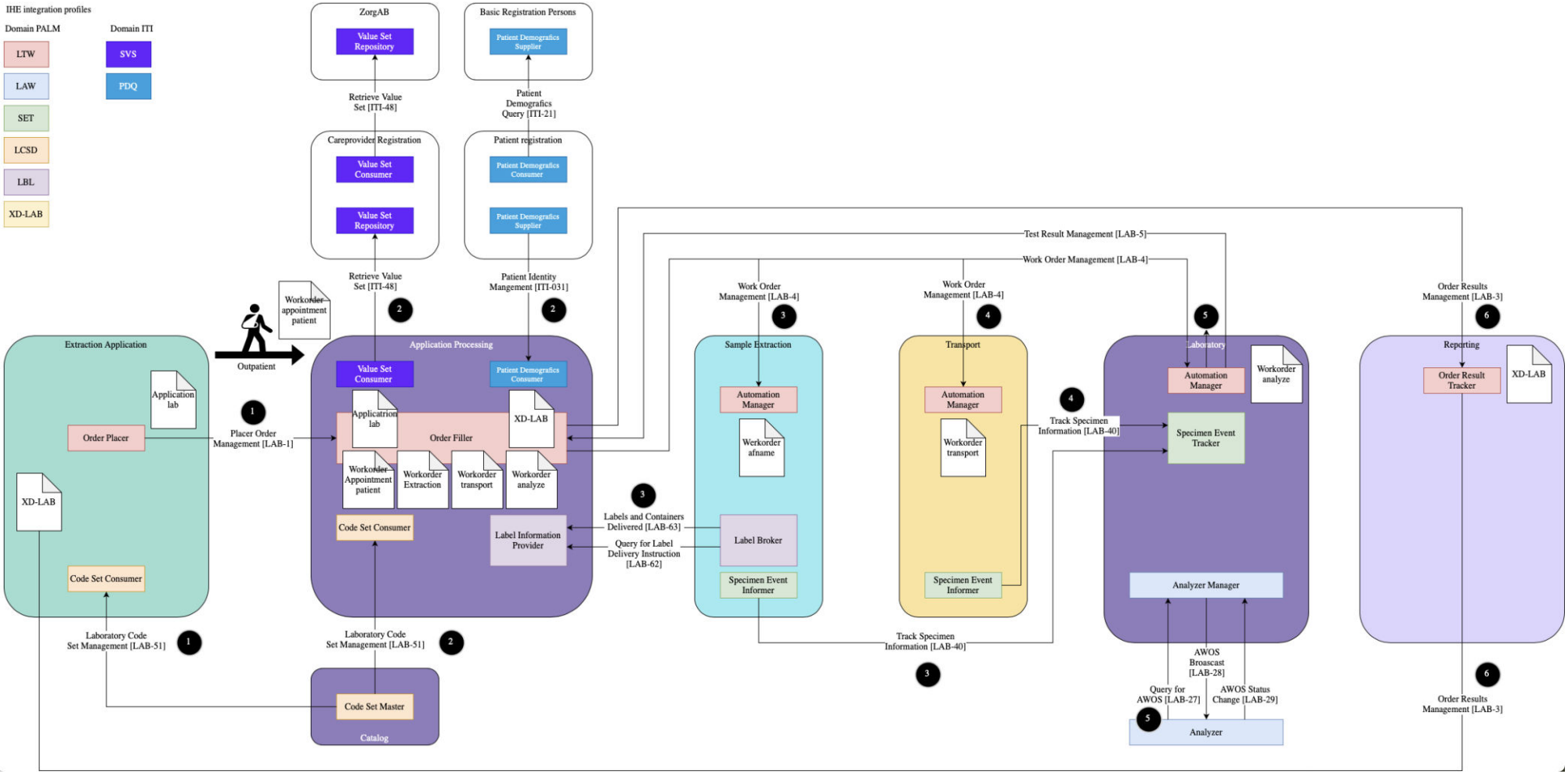
APPENDIX 4: IHE-PROFILES AND USE CASES

Use case-1: See Appendix 2. The numbers refer to the relevant process step
Practitioner in a hospital places an application to a Diagnostic Center (DC)



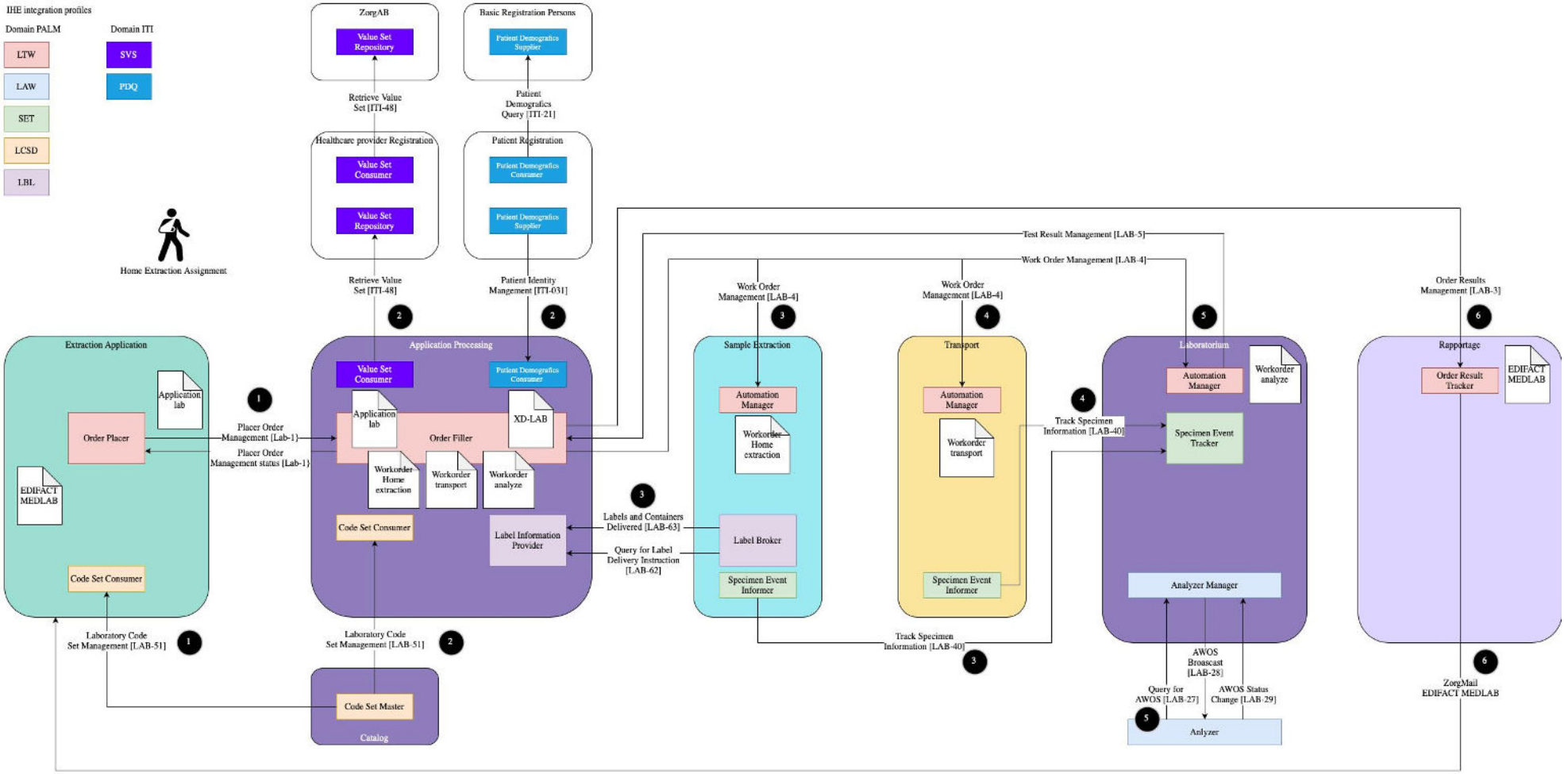
Use case 2: See Appendix 2. The numbers refer to the relevant process step

2. The General Practitioner places an application to a DC and the patient makes an appointment at a DC site



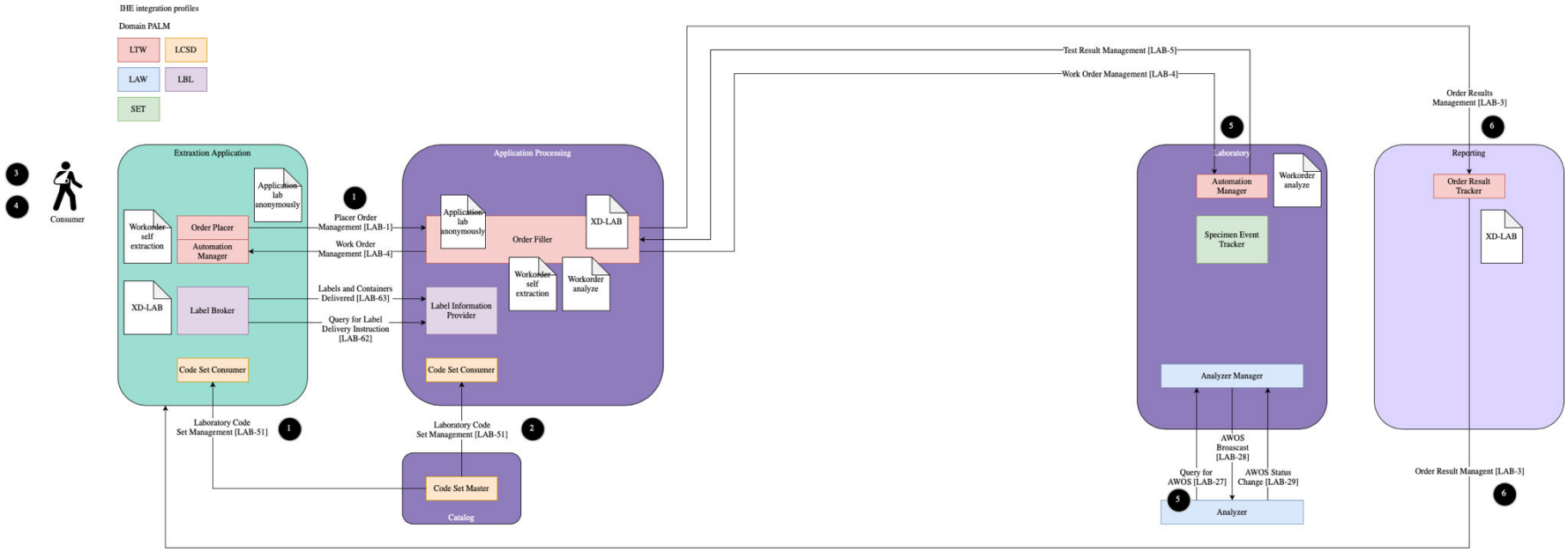
Use case 3: See Appendix 2. The numbers refer to the relevant process step

3. General Practitioner places an application to a DC and DC uses third party process step for extraction.



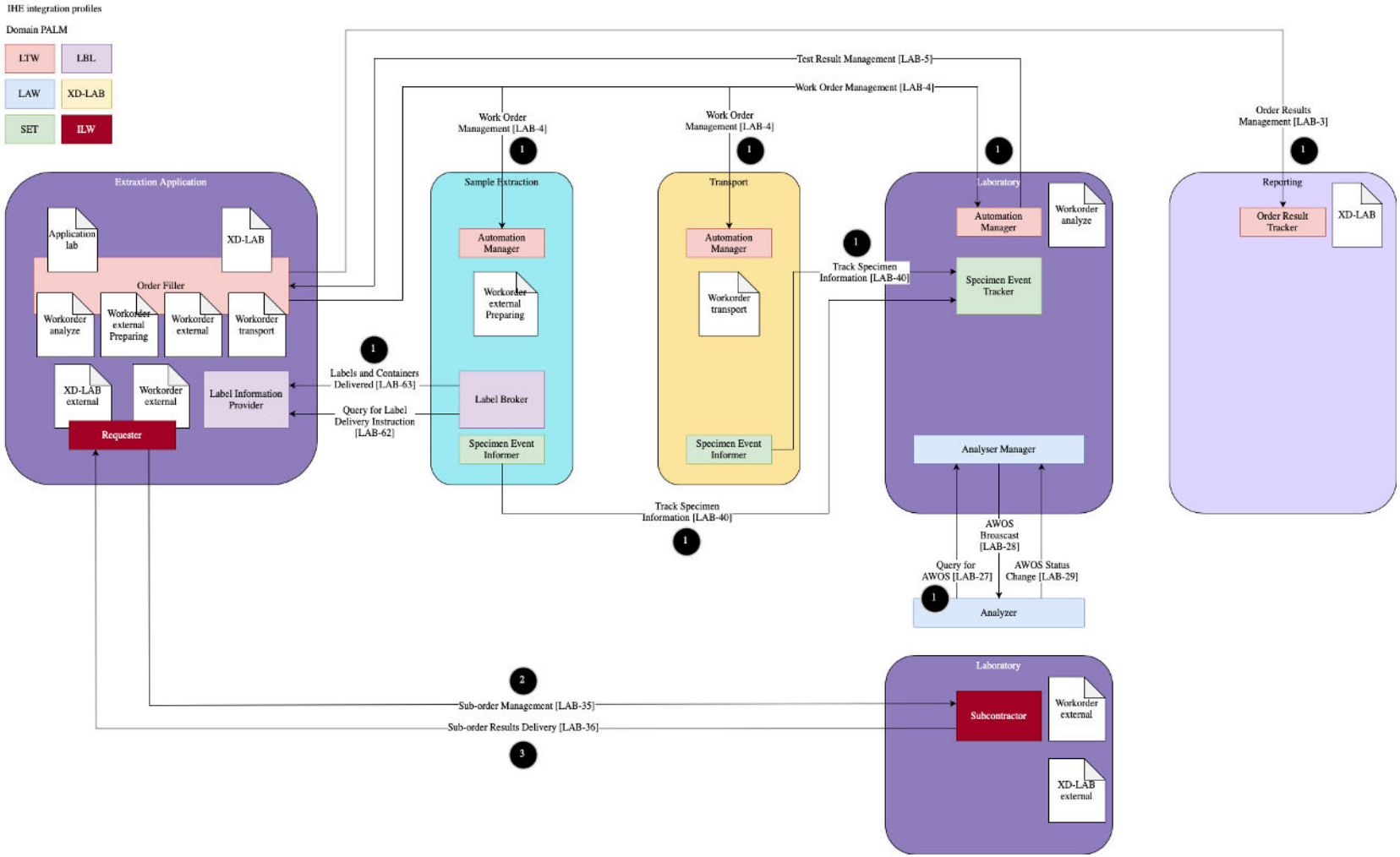
Use case 4: See Appendix 2. The numbers refer to the relevant process step

4. Patient himself requests an examination



Use case 5: See Appendix 2. The numbers refer to the relevant process step

5. Outsource processing application by another laboratory



APPENDIX 5: THE IHE ICT-INFRASTRUCTURE DOMAIN

The IHE ICT-infrastructure domain provides the infrastructure for the sharing of medical information. Often the IHE ICT infrastructure domain is placed at the same level as all the infrastructure layers in the (five) layer model. However, this is incorrect. An infrastructure as IHE means for it to be consists of interoperability components. Software applications, which provide common ICT functions can be used as building blocks for many user cases. These components are very popular in the Netherlands, can be embedded in a functional application, such as the transmural laboratory process. More often, they are used as a shared application within and collaboration network. Especially collaborations where images and reports are shared among organizations, the IHE infrastructure domain is widely used. The IHE ICT-infrastructure domain is central to many other IHE domains. The components can also be deployed independently of other domains to achieve exchange and interoperability. There are about 25 ICT-infrastructure IHE integration profiles.
Here below you will find the most important[27].

IHE-integration profile	abbreviation	Description
Audit Trail and Node Authentication	ATNA	Basic Security by (a) Functional Access Controls, (b) defined security audit logging and (c) security network communication.
Basic Patient Privacy Consent	BPPC	Method for recording patient consent for viewing and exchanging privacy-sensitive data
Consistent Time	CT	Method to synchronize system clocks and timestamps of computers on a network (mean error less than 1 second)
Cross-Community Access	XCA	allows you to query and retrieve patient data in other clinical affinity domains.
Cross-enterprise Document Media Interchange	XDM	Document Exchange and Interchange metadata using CDs, USB memory, or email attachments.
Cross-enterprise Document Reliable Interchange	XDR	Documents exchange between healthcare facilities using an online service based on point-to-point push network communication.
Cross Enterprise Document Sharing	XDS (XDS-B, XDS-I)	Sharing and discovery between all healthcare institutions of medical records and documents (XDS-B) and XDS-1 (for imaging) adds images to it.
Cross-enterprise Sharing of Scanned Documents	XDS-SD	Creates electronic records of legacy paper, film, and other unstructured documents.
Cross-Enterprise User Assertion	XUA	Communicates claims about the identity of an authenticated entity (user, application, system ...) across the boundaries of a clinical affinity domain Federated Identity. (SAML

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

IHE-integration profile	abbreviation	Description
		and OAuth)
Patient Administration Management	PAM	establishes the continuity and integrity of patient data across various care institutions.
Patient Demographics Query	PDQ	Allows applications to ask a question about patient identity from a central patient information server via patient demographics.
Patient Identifier Cross Referencing	PIX	Allows applications to verify patient identity through cross-references between hospitals, HIE networks, etc.
Cross-Community Patient Discovery	XCPD	Support for identifying patient identifiers between clinical affinity domains
Cross Enterprise Workflow	XDW	Coordinate different workflows across multiple organizations.
Document Metadata Subscription	DSUB	Describes the use of a subscriber and notification mechanism for use within an XDS clinical affinity domain or between clinical affinity domains
Notification of Document Availability	NAV	Supports out-of-band notification of documents between systems or users.

Table 5: IHE-integration profile in the IHE ICT Infrastructure Domain

APPENDIX 6: LEGAL FRAMEWORK

The following legal frameworks apply to the digital exchange of data.

Law/Legistration	Description
[AVG] Algemene verordening Gegevensbescherming "General Privacy Regulation"	The AVG sets rules for the processing of personal data. Data protection processing for personal data must meet a number of requirements. Processing must be carried out in a proper and careful manner and must have a precise and clearly defined purpose. The AVG also states that the processing register indicates what happens to the data being requested. In addition to the objective, there must also be a fundament for processing. The AVG provides the fundament for processing of personal data
[Wabvpz] Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg "Wet Complementary Law specifically provisions Processing personal data."	The law focuses specifically on the electronic exchange of medical personal data. The law applies to a system of exchange that allows data to be made available and accessed between different providers of care (so-called pull systems). Healthcare providers may only make the data available in electronic exchange systems under this law if the patient has explicitly given permission to do so. In addition, the system must be able to identify which healthcare provider wants access to this system and be certain that the healthcare provider is actually who he says he is (authentication). The system must also be able to grant (authorization) specific rights to access patient data to healthcare providers and must be able to verify who has (had) access to this data (log-in).
[Wbsn-z] Wet gebruik Burgerservicenummer in de zorg "The Law for the social security numbers in the Healthcare"	de WBSn-z regulates that in all reports between healthcare providers, the social security number is present to prevent personal change and thereby prevent (possible) medical errors. The use of the Social Security Number (BSN) in the healthcare sector is mandatory. The BSN replaces the different personal numbers that were first used in the healthcare: Policy number patient number, customer number, number on the punch card etc, on the punch card etc. This means that all healthcare providers, indicator bodies and health insurers (includes healthcare offices) are obliged to register the BSN in their records and to use the BSN in the communication between patients (data exchange). The BSN may only be used by the health care provider after the patient has legalized himself with a legal identification document.
[WGBO] Wet op de geneeskundige behandelingsovereenkomst "The Law on Medical Treatment Agreement"	The WGBO controls the private law relationship between the healthcare provider and the patient. The responder has a duty to file. Access to the file for healthcare workers other than those involved in the treatment may only be authorized by the patient. Inspection without permission may be required by law or regulation. The patient himself shall have the right to inspect his file and to have a copy of it.
[WKKGZ] Wet kwaliteit en klachten zorg "Law Quality and complaints healthcare"	the government has legally established what good healthcare means. The WKKGZ regulates what should be done if people have a complaint about healthcare. The law regulates a better and rapid approach to complaints, healthcare workers can report incidents safely, a stronger position for the client and an extension of the reporting obligation for healthcare providers. The WKKGZ applies to all healthcare providers.

Law/Legistration	Description
[EGIZ] Gedragscode Elektronische Gegevens-uitwisseling in de Zorg[28]	The domes of healthcare providers and various regional (ICT) partnerships between healthcare providers have brought together and made practical use of the legal rules on privacy and professional confidentiality when exchanging patient data. The EGIZ code of conduct does not contain new rules but promotes safe handling of these sensitive personal data. It helps healthcare providers and partnerships, among other things, to give proper interpretation of patient rights in terms of information and consent and clarifies responsibilities.
[WEGIZ] Wet Elektronische Gegevensuitwisseling in de Zorg	The Ministry of Health, Welfare and Sport is working on a law that requires data exchange healthcare providers to be electronically exchanged. The Electronic health care Data Exchange Act is a framework law. This means that additional rules will be laid down about which data exchanges should take place electronically from the time of electronic exchange. These rules are called general administrative measures (AMvB). In such an AMvB, for example, it is about prescriptions that the General Practitioner sends digital to the pharmacy. The minister does not determine which data health care professionals need to exchange for good healthcare. That information is stated in the agreement they have made together: The quality standards. It contains exactly what is good health care for a particular condition or condition. The AMvB also includes agreements on language and technique for exchange. The Wegiz is now another legislative proposal. The law is expected to be adopted in 2022. For more information visit: https://www.gegevensuitwisselingindezorg.nl/gegevensuitwisseling/wetgevingstraject
[MDR] Medical Device Regulation	European regulations on marketing, marketing and commissioning of medical devices for human use and accessories for such devices in the EU.

Table 5: Legal Framework

[28] https://www.knmg.nl/web/file?uuid=fd2e8f1b-b0ac-4b78-85d3-a09d2ce00e06&owner=5c945405-d6ca-4deb-aa16-7af2088aa173&contentid=78264

APPENDIX 7: OBSTACLES PER INTEROPERABILITY LAYER

Interoperability layer	Obstacles
Process Layer	Each laboratory has test codes. *Doctors in the institutions without their own laboratory often have to send their own applications to different laboratories*.
Process Layer	Application errors. When laboratories use their own test codes, errors can occur when applying, because the applicant does not use the correct test code for the appropriate laboratory.
Process Layer	Consistency. A request can be a separate application but can also be part of a clinical trial.
Process Layer	Various requests. A laboratory receives requests from different sources:
Process Layer	Logistical information (order number, extraction number, etc.) is missing. At the extraction, the order number or tube number is not recorded, and the sample cannot be processed correctly. In case of extraction, several methods are possible to identify the tubes and containers. If an order number or tube number is used for extraction, this must be recorded correctly
Process layer	Absence of consent. The current situation is that the laboratory does not seek consent from the patient to share the laboratory results with other healthcare providers other than the applicant.
Process layer	Different formats of reporting. A doctor whose applications are placed at multiple laboratories often receives the results in different ways in the current situation: Electronic (in Edifact or HL7 format), paper/email (PDF reports) or via a viewer directly in the LIS.
Process Layer	Examination Report. When an examination is carried out by a laboratory other than where the application was made, it is not always clear which laboratory reports the results to the applicant.
Process layer	Presentation laboratory results. In the white paper 'exchanging laboratory results in healthcare' (Laboratory Medicine, 2021), NVKC's laboratory specialists describe that the results of laboratory definitions are increasingly seen as independent pieces of information. The number is, so to speak, 'from everyone'. But pieces of information that are placed indiscriminately outside their context can pose a risk to the General practitioners and the patient. This is certainly true for the invisible use of laboratory results, for example in the ever-wide usage of results as input in the decision of algorithms.
Information layer	There are many different possibilities in exchanging terms in the laboratory domain. This makes it difficult to adopt a unified approach. The laboratory code set developed by the RIVM, the NVMM, NVKC and Nictiz intended to bring in more uniformity. It has not yet been implemented in many places and is being expanded.
Information layer	NHG Table 45 is still frequently in use. This table differs from the laboratory code set, so it is not easy to use the laboratory code set and NHG Table 45 side by side. This causes problems because general practitioners see NHG Table 45 as the main business code set as it is already included in the EMR's. Other parties in the process prefer the laboratory code set however this is not widely adopted yet.
Information layer	There are many initiatives to facilitate standardization. However, these are often still in development and no products on the shelf that can be developed yet.
Information layer	Edifact messages with laboratory results have no unique keys that prevent a copy of a result from being seen. This ensures that no track and trace of where the source is from can also be given. Fortunately, in HL7v3 CDA or FHIR, this is the case, but it is not yet nationally organized how to standardize these IDS so that source data can be distinguished from the ID.
Information layer	There is a difference on how fully the information (examination results) from the laboratory examination is recorded in the files. But the knowledge of the healthcare provider who needs to interpret the laboratory result can also differ. This difference in level of detail at which the information is recorded and the knowledge or experience of the healthcare provider may lead to the information being used in error and out of context. This problem also occurs in a patient portal where the data is shared with the patient in this format. However, in practice is that most of the patients, certainly chronic patients, have positive experiences with regard to their own laboratory data

Table 6: Obstacles per interoperability layer

APPENDIX 8: TERMS, ABBREVIATIONS AND A LIST OF USED FIGURES

TERMS

Terms	
Actor (IHE)	in the context of the IHE integration profile, an actor is responsible for producing, managing and acting on the information. An actor can be either a person or an application or part of an application.
IHE-integration profile	IHE Integration profiles describe specific solutions for interoperability problems. IHE integration profiles specify how 'actors' use standards to address a specific use case in healthcare. Each domain defines and publishes IHE integration profiles to address clinical and operational scope of interoperability issues. For convenience, each IHE integration profile gets a full name and a short acronym. Referencing IHE integration profiles provides performers and users with a common language for solutions supported by detailed specifications to ensure interoperability.
Interoperability	Interoperability is the ability of organizations (and their processes and systems) to effectively and efficiently share information with their environment. In the transmural laboratory work process, this means supporting the healthcare provider when requesting the examination and including the result of the examination with applications and equipment without extra manual intervention. See also section 2.1.
Interoperability model (5 layer model)	Nictiz has created a model that distinguishes it in the five layers of interoperability. Each layer has its own actors, concepts and standards. In addition, there are two prerequisite subject that apply to all layers, namely the legislation and Information Security. See also section 2.1.
IHE-Infrastructure	Required infrastructure for the sharing of medical information and consists of interoperability components (see Annex 4) differs from the infrastructure layer in the 5-layer model
NEN norm	Standards drawn up by the Royal Netherlands Standardization Institute. One of the standards that are relevant in the context of this guide are the standards for information security (NEN 7510, NEN 7512 and NEN 7513). The standard NEN 7510 is the standard for Information Security for the healthcare sector in the Netherlands. The NEN 7510 is supplemented by: • NEN 7512: Basis of trust for data exchange • NEN 7513: Logging, specifically recording actions on the electronic patient record, so that it can be found who has had access to the file
XDS-infrastructure	Affinity Domain file made up of it a registry and repository
XDS-Registry	Index module
XDS-Repository	Document storage module
XDS-Source	Document source

Table 7: Terms

ABBREVIATIONS

Abbreviation	
AGB	General Data Management; Unique code for Dutch healthcare providers or healthcare providers organizations. Since 2016 mandatory on the basis of the Health Care Organization (WMG)
API	Application Programming Interface: defines the access to the functionality it represents
BGZ	Patient Summary
CDA	Clinical Document Architecture
CMI	College of Medical Immunologists
DC	Diagnostic Center
Dicom	Digital Imaging and Communications in Medicine. Standard definition of the file format and the network protocol for communication
DigiD	Digital Identity issued by the government
DMZ	Demilitarized zone. A computer network that acts as a buffer zone between two networks: The Internet and an organization's internal network.
DVZA	Service Provider health care provider = interface between healthcare provider and PGO
ebXML	Electronic Business XML massaging Services (Oasis)
Edifact	standard based on exchanging messages via mailboxes. This standard is no longer developed in healthcare. HTTP/REST with the HTTP protocol, REST APIs can allow software on one device to talk to software on another device (or on the same device), even if they use different operating systems and architecture
EPD	Electronic Patients File
FHIR	Fast Healthcare Interoperability Resource, Internet-based standards with reusable building blocks to quickly create a working exchange
FMS	Federation Medical Specialists
GS1	Standard bar code organization
HL7	Health Level Seven: standard for safety/security, electronic information exchange in the Healthcare V2 is based on transactions between systems based on messages V3 Information Model oriented standards uses CDA documents
HTTP/REST	With the HTTP Protocol, REST API's are able to communicate between software on one device with software on another device even if the devices uses different operating systems or uses different architectures.
ID	Identity
IHE	Integrating the Healthcare Enterprise, a community of users and ICT-suppliers in the healthcare sectors that stimulates the coordinated use of established healthcare and ICT standards
IHE-MHD	IHE-Integration Profile; Mobile access to Health Documents
IHE-mRFD	IHE-Integration Profile; Mobile Retrieve Form for Data Capture, based on HL7 FHIR
IHE-mXDE	IHE-Integration Profile; Mobile Cross-Enterprise Document Data Element Extraction
IHE-QEDm	IHE-Integration Profile; Query for Existing Data for Mobile
ILW	IHE Integration Profile for outsourcing and contracting between laboratories (implemented as Lab2Lab in the Netherlands)
KC	Clinical Chemistry
KNMP	Royal Dutch Society for the Promotion of Pharmacy
LBL	IHE Integration Profile aimed at issuing labels for extracted materials
LIMS	Laboratory Information System
LIS	Laboratory Information System
LOINC	Logical Observation, Identifiers, Names and Codes. Standard for documenting and coding applications and results of medical laboratory determinations. Covers areas of chemistry, Hematology, Serology, Microbiology, Toxicology, Parasitology and Virology.

Abbreviation	
LSP	National switching point
LTW	IHE integration profile realizes the continuity and integrity of testing and the result data within and healthcare facility
MDL	Stomach - Gastrointestinal and Liver diseases
MDR	Medical Device Regulation
MEDLAB	Message within the Edifact domain, specific for the exchange of laboratory reports
MedMij	Foundation for Management of the appointment system to enable communication between Healthcare provider and citizen
MLLP	Minimal Lower Layer Protocol
MMB	Medical Microbiology
NHG	Dutch General Practitioner Society
NHG-codes	Code table for among others lab tests, specifically for the general medical domain
Nictiz	National Institute for ICT in the Healthcare
NVKC	Dutch Association for Clinical Chemistry and Laboratory Medicine
NVMM	Dutch Association for Medical Microbiology
NVZA	Dutch Association of Hospital Pharmacists
OASIS	Organization to promote open structured standards on the information layer; worldwide consortium that aims to promote the development, cooperation and application of e-business and web service.
Oauth	Open Authorization (Oasis)
OML	HL7 v2 message for requesting an exam
ORL	HL7 v2 message/report that the application has been accepted by laboratory
ORU	HL7 V2 message/report for results of examination
OUL	HL7 V2 message/report for requesting for an examination
PGO	Personal Health Environment: Provision for the citizen to bring together life-long health information from multiple health care providers
PULL	Care Manager can view or retrieve data from the source system of another health care provider on the basis of obtained consent
PUSH	Data from one Healthcare provider send directly to the other healthcare provider
RIVM	National Institute for Public Health and the Environment
Rosetta	Harmonizes the use of existing nomenclatures terms defined by the ISO / IEEE 11073-10101 nomenclatures standard
SAML	Security Assertion Markup Language (Oasis)
SET	IHE-Integration Profile for keeping tracking of (extracted material)
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms International Terminology System in the Netherlands already as the central standard for Unity of Language
SSL	Secure Socket Layer
Syslog	Standard Logging for Reports/messages
TCP-IP	Collective name for a series of network protocols used for the most part from the Network communication between computers (including Internet)
TLS	Transport Layer Security (encryption)
UCUM	Unified Code for Units of Measure
UZI-register	Unique Healthcare Providers Identification Register control at CIG (Ministry of Health, Welfare and Sport)
VIPP	Speed-up programs for the exchange between professionals and with patients/clients
VPN	Virtual Private Network
XD-LAB	IHE Integration Profile for exchange of laboratory reports Hospital Information System
XDS	Cross-enterprise Document Sharing; Technical Integration Profile for sharing of medical documents and images between collaborating healthcare institutions.
ZIB	Health Information building block: describes the concept that the data in itself contains with an agreed content, structure and its mutual relationships
ZIS	Hospital Information System

Tabel 8: Abbreviations

FIGURES

LIST OF TABLES