REPORT 02-2016

Integrating Telemedicine Solutions with Electronic Health Records; Evaluation of Alternatives based on the Proposed Reference Architecture for Norway

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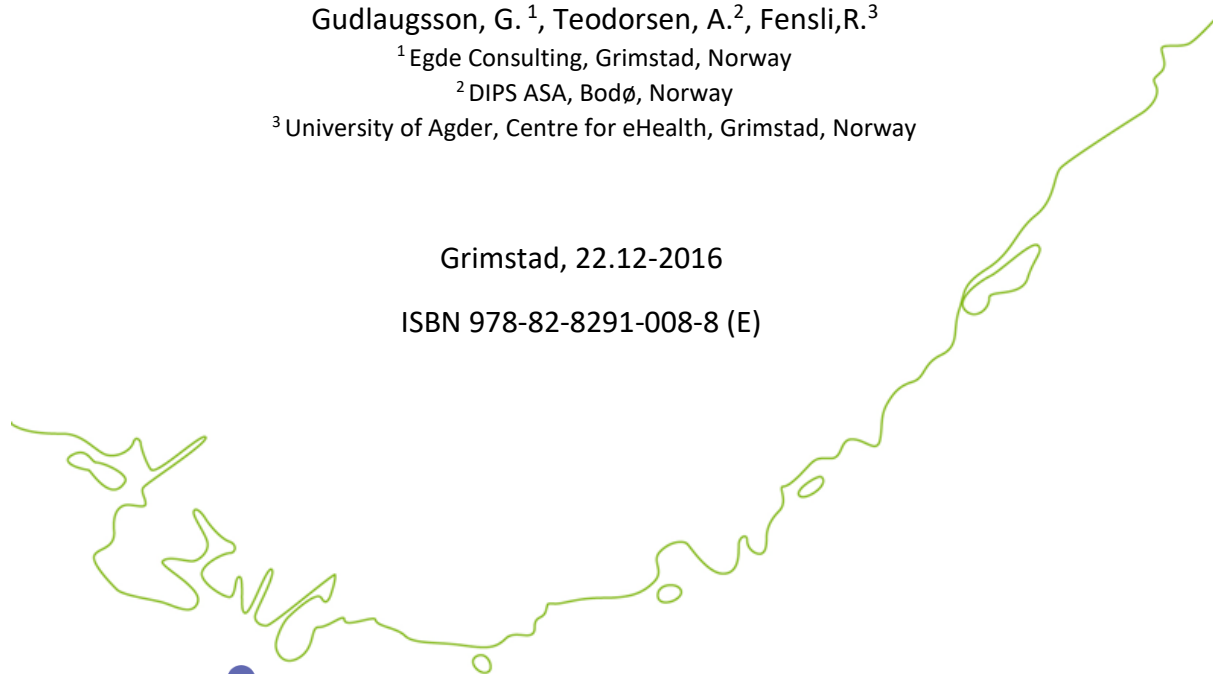Gudlaugsson, G. [1], Teodorsen, A.[2], Fensli,R.[3]

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Summary

This report studies the way forward for how a telemedicine solution can be integrated for exchange of data with an existing Electronic Health Record (EHR) system. The solution used an example for this report is based on a telemedicine solution for COPD patients (Chronic Obstructive Pulmonary Disease) developed in the project "Collaborative Point-of-Care Services Agder: Follow-up of COPD patients as part of the United4Health EU Project», with financial support from the Research Council of Norway. In addition, the EHR solution from DIPS ASA is used as an example of an existing system for integration.

Important parameters for choosing way forward on how to are:

- urgency with regards to timeline
- level of structuring of the data.
- compliance with the reference architecture[1]proposed by the Norwegian Directorate of eHealth (NDE)

Three alternative ways forward are discussed in this report, based on four different scenarios with their respectively defined use-cases.

Possibilities of integration exists already today which may support one of the use cases in the simplest way, but may not be a futureproof solution regarding functionality and recommended standards. Such a solution is supported by DIPS Classic as well as DIPS Arena by using HL7 V3 interface in DIPS. The journal data may be stored in an unstructured way as a PDF document in a patients EHR.

To send structured data from a Telemedicine System to an EHR will be the preferred way for the future, and will support several use cases in a more efficient way. This will require more work in total and is dependent on other parties (external storage, DIPS etc) for building infrastructure and new interfaces. Such solutions will still be of high interest in the future. This report describes two different scenarios for how such solutions can be implemented in the future using either external storage and XDS.b or using FHIR/OpenEHR. Which of these alternatives that will be the leading standard or best practice is hard to predict, since it will highly depend on how the user requirements from the health care market will request such solutions, and how the standardization requirements from National authorities evolves in the next years. In addition, it depends on how the developers/vendors of both telemedicine solutions and EHR-systems will responds to these requirements.

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[1] IS-2402: Arkitektur for Velferdsteknologi – anbefalinger for utprøving og faser for realisering (12/2015)

Contents

1. Background and Scope

This report is developed as an important activity under the project "Collaborative Point-of-Care Services Agder: Follow-up of COPD patients as part of the United4Health EU Project», with financial support from the Research Council of Norway, project number 227131/O70 (2013-2016). This project has been closely connected to the EU-project United4Health: "UNIversal solutions in TElemedicine Deployment for European HEALTH care, 2013-2015, ICT PSP call identifier: CIP-ICT PSP-2012-3. In this project, Sørlandet Hospital HF has been the project leader, with Centre for eHealth at University of Agder and Egde Consulting as partners.

Through the project, a solution for monitoring chronic COPD patients at home was developed. As it is important to obtain integration of data from such telemedicine solutions, normally trialled as stand-alone products, into existing electronic health record solutions used in Norwegian hospital today, it has been considered how the actual COPD solution developed in the United4Health project in Agder could be integrated with DIPS (both for Arena and Classic versions).

The reference architecture[2]proposed by the Norwegian Directorate of E-health (NDE) is basis for the evaluation of the solutions. The proposed architecture is based upon Continua Design Guidelines[3] with some adjustments.

An integrated solution where the COPD journal data can be accessible from external use opens for new ways of interaction between health personnel. The first step forward for interaction could be that the COPD solution uploads the patient's reported measurements of Vital Signs data (and eventually symptom specific questionnaire data) on a regular basis, or by request form COPD healthcare personnel, to DIPS or other external storage. These data may be useful for the health personnel at the hospital to make better decisions on patient treatment. In the long term, it is preferred that the health personnel can search and get such data by request. The next step will then require a solution where both sides (COPD Response Centre personnel and health personnel at hospital) will be able to initiate the storage and retrieval of EHR data. In the future the data collected by patients will be aggregated and analysed and be the base for both a more individual adapted and pro-active health treatment for individuals. In addition, it should be used as datasets to be base for research and health studies.

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[2] IS-2402: Arkitektur for Velferdsteknologi – anbefalinger for utprøving og faser for realisering (12/2015)
[3] H.810-H.813: Continua Design Guidelines (Personal Connected Health Alliance, 2008-2016)

2. U4H COPD Solution

The product developed is an application made to monitor the COPD patient at home when the patient is discharged from the hospital. The patients are closely monitored by healthcare personnel.

The patients get a Tablet, measuring equipment and user instructions after being dismissed from the hospital.

The patients answer to a questionnaire and perform their own measurements which are sent to the healthcare telemedicine centre. The centre will then analyse the medical records and take necessary measures/actions if needed.

This allows the healthcare personnel to react quickly to changes regarding the patient health. It also reinforces the patient to better managing their own health condition.

In the current solution, all data is stored in the U4H COPD Solution databases without possibility for other systems to access the data.

For the actual implementation in the clinical trial, a secured mobile data APN connection was established through the Norwegian Health Network, terminated at the secured network by Sykehuspartner HF. In total three different Telemedicine Centrals was implemented and in total more than 120 patients used the actual solution. Patients was included when discharged from the hospital after an acute exacerbation of COPD. The daily follow-up was organized from the Telemedicine Central operated by then municipality health care services, based on a data processing agreement with Sørlandet Sykehus HF.
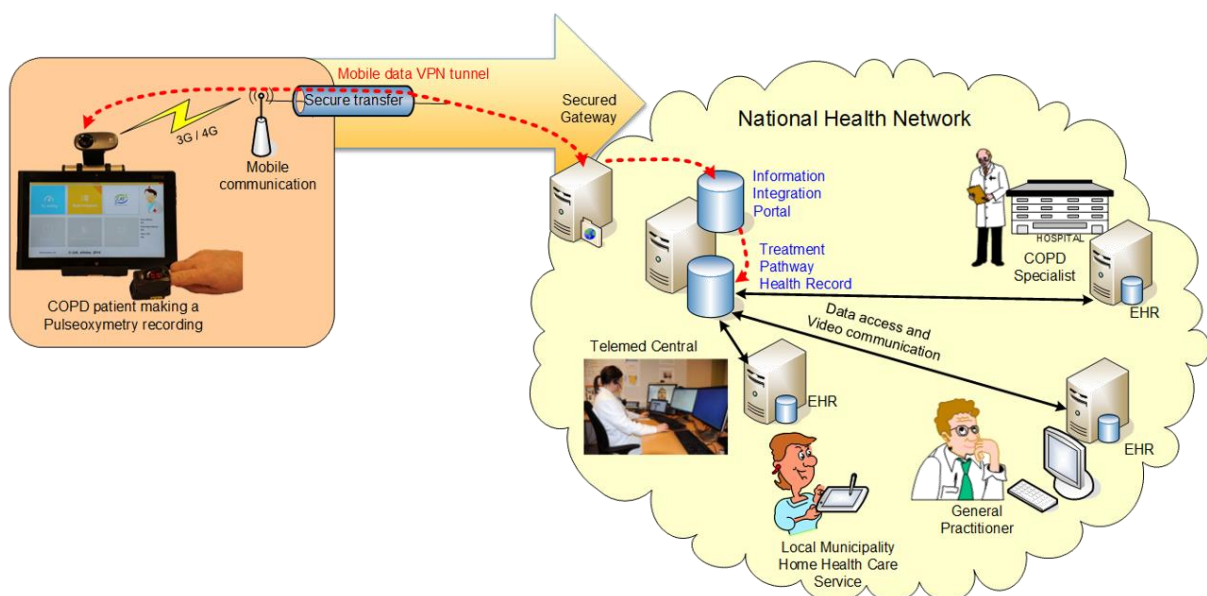

Figure 1: Principal overview of the implemented solution

2.1. Solution components

The solution has five components

- Pulse Oximeter with Bluetooth.
- Patient Tablet with COPD application
- IBM Integration Bus (IIB)
- COPD EHR Solution (Forløpsjournal) with
  - Data reception service (FHIR interface)
  - COPD EHR database
  - COPD web portal, with a GUI used by healthcare personnel.
- Healthcare Personnel workstation with connection to web portal
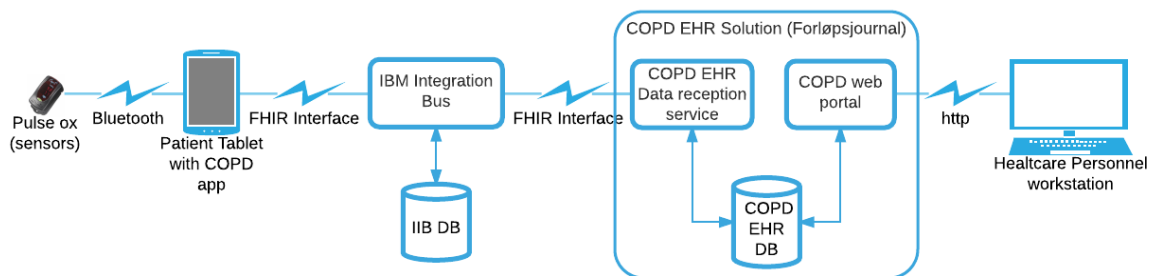
Figure 2: Overview of the COPD solution components.

2.1.1.   Pulse Oximeter sensor

To measure SpO2 and pulse a pulsoxymeter sensor from Nonin is used. It connects to the patient tablet PC over classic serial Bluetooth or by the Continua Bluetooth profile.

2.1.2.   Patient COPD application on Tablet PC

This is the component where the patients give input on their health condition. This is given through a Questionnaire and measurements (SpO2 and pulse) from the connected pulse oximeter sensor. The application communicates with the IBM Integration Bus using a FHIR interface. The application can also send the information over a proprietary interface.

Figure 3 The APP-solution implemented in the U4H project on a Windows 8.1 Tablet, with the pulsoxymeter on the finger.

2.1.3.   IBM Integration Bus (IIB)

All communication from the patient app to the COPD EHR Solution goes via this integration bus. This was included in the solution to be able to route the data from the Patient COPD application to several services if that would be applicable in the future. Also, the integration bus can be used to "translate" data from one interface standard to another. In the current solution, it only forwards the data using the same format as it is receiving in.

The IIB receives data from the patient's tablet based on a FHIR interface.

2.1.4.   COPD EHR Solution (Forløpsjournal)

This is the data gathering, storage and analysis part of the solution. The actual system connects to the IIB with a FIHR interface. The component gather data from the patients, analyses it and make decisions upon it. It stores data and provides a Web-portal for showing the patients status to healthcare personnel. The Data available in the COPD Solution is:

1. Measurements, SpO2 and pulse.
2. Questionnaire
3. Notes
4. Documents
5. To Do lists
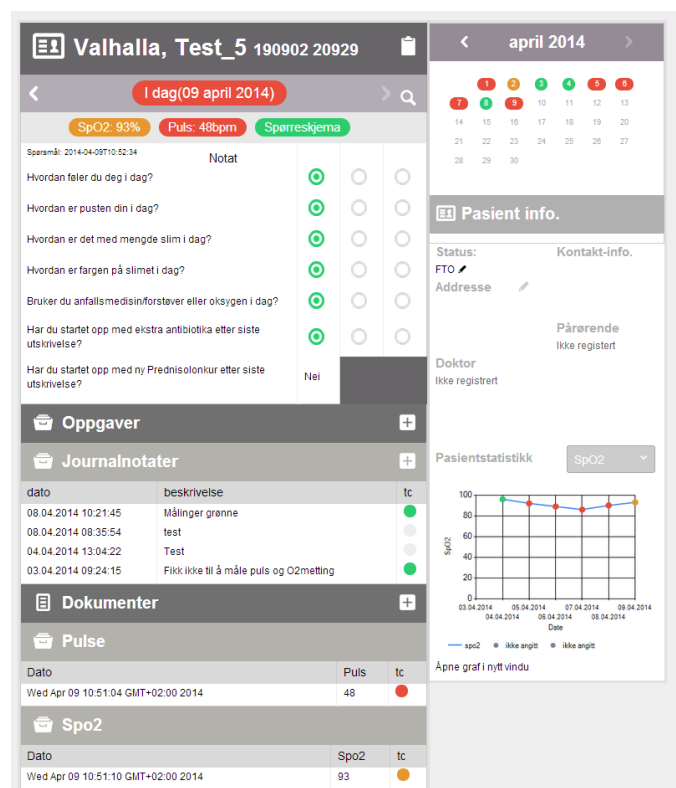6. Triage
7. Metadata, patient information

Figure 4: Screenshot from the "Forløpsjournal"

2.2. Interface

The solution has a HL7 FHIR[4] compatible REST interface towards the server (COPD EHR Solution (Forløpsjournal)) offering the Patient COPD application to use that interface instead of a proprietary one.

- REST interface between the Patient COPD Application and the IIB built on FHIR
- REST interface between IIB and COPD EHR Solution (Forløpsjournal) built on FHIR

FHIR is a specification of a REST API that represents resources from HL7. To implement FHIR one needs to implement a set of REST resources with a given behaviour.
To support the implementation, there are several libraries available.
Since the COPD EHR Solution (Forløpsjournal) was written using Microsoft .NET, we chose to use Furore's Spark library[5]. This is an open source project that provides a reference implementation of FHIR in Microsoft .NET. This enabled us to quickly build a skeleton of a FHIR server and then connect so that the data would be stored in our EHR database instead of the Spark demo database.
The standard code chosen for SpO2 and pulse used in this solution is LOINC. The current implementation is limited in functionality. It only implements the following FHIR resources:

- Observation, to be able to store pulse and oximeter observations
- Questionnaire/Response, to be able to receive answers to the COPD daily questionnaire
- Bundle, to be able to receive Observation and Questionnaire/Response bundled together in one message. Our Bundle implementation will only accept Bundles consisting of Observation and Questionnaire/Response items

In the future, it should be considered to implement the following functionality to be able to integrate towards DIPS:

- Expand the FHIR implementation to support more resources.
- The application should be upgraded to use Archetypes (ref Appendix B: Archetypes) as standard codes.

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[4] HL7 FHIR Norwegian Profile: http://www.hl7.no/index.php/standarder/hl7-fhir-norsk
[5] https://github.com/furore-fhir/spark

3. Norwegian reference architecture and Continua Design Guidelines

The reference architecture[6]proposed by the Norwegian Directorate of eHealth (NDE) is based on the Continua Design Guidelines[7] (CDG), but with some additions in recommendations.
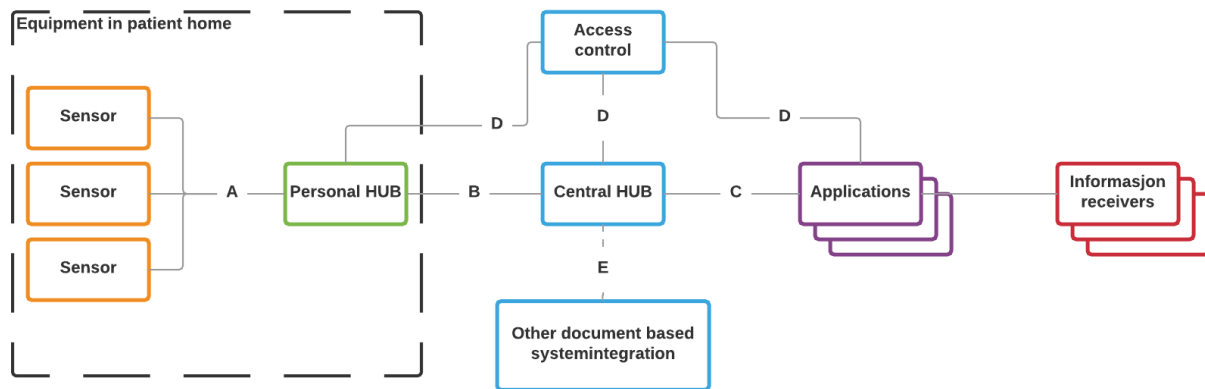
Figure 5: Reference architecture interfaces

This latest recommendation focuses on the interface between a personal HUB and a central HUB where Continua and HL7 FHIR[8] is recommended to be used for exchange of medical measurement data and SCAIP is to be used for social care alarms and related systems. For exchange of data between services (as the COPD solution) and EHR systems (such as DIPS), the reference architecture is based on Continua.

CDG for this interface, which is called the HIS (Health Information System) interface guides to the use of:

- HL7 CDA R2[9] for the document format standard.

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[6] IS-2402: Arkitektur for Velferdsteknologi – anbefalinger for utprøving og faser for realisering (12/2015)
[7] H.810-H.813: Continua Design Guidelines (Personal Connected Health Alliance, 2008-2016)
[8] HL7 FHIR: http://hl7.org/fhir/
[9] HL7 Implementation Guide for Clinical Document Architecture, Release 2: Consent Directives, Release 1, HL7 Draft Standard for Trial Use.

- For patient identity, the Integrating the Healthcare Enterprise (IHE) Patient Identifier Cross-reference[10] (PIX) profile is selected.
- The standard to use for messaging this information is IHE Cross-Enterprise Document Sharing (IHE XDS)
- To accomplish secure direct communication between care-givers, Continua points at the IHE XDR[11] (Cross-Enterprise Document Reliable interchange) standard.

NDE has not stated that HL7 FHIR will be the recommended standard to use for this interface in the Norwegian reference architecture, but if the trials with FHIR on the interface from personal HUB to a central HUB is successful this might change. FHIR is a standard that can be used even from sensors and all the way to the healthcare information systems such as DIPS.

4. DIPS

DIPS (Distribuert Informasjons og Pasientdatasystem i Sykehus) is a fully integrated patient record system including closed loop medication, charting, booking and planning, electronic document workflow, CPOE (Computer Patient Order Entry), multimedia and reporting.

DIPS is now implemented in all hospitals in Helse Sør-Øst. The standard legacy version DIPS Classic is currently getting replaced by a newer version, DIPS Arena, which is planned to be released in all regional hospitals by 2020.

DIPS Arena is a more dynamic tool than the current records system. Arena is based on good overview images, structured content and process and decision support. The new user interface will make it easier to get an overview of the content of the patient record.

DIPS Arena goes from a text-based journal for the benefit of searchable data that can be reused - a significant improvement on how information can be used in a clinical situation.

DIPS Arena is going to support FHIR but has not yet implemented all resources. The resources which are interesting for the COPD solution towards DIPS in a structured way are e.g. Observation, Questionnaire and Bundle. Ref. Appendix A for a description of all needed resources in FHIR.

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[10] IHE PIX: http://www.ihe.net/Technical_Framework/upload/IHE_ITI_Suppl_PIX_PDQ_HL7v3_Rev2-1_TI_2010-08-10.pdf
[11]IHE XDR:
http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Supplement_Cross_Enterprise_Document_Reliable_Interchange_XDR_TI_2009-08-10.pdf

4.1. DIPS Service Broker

Both DIPS Classic and DIPS Arena supports DIPS Service Broker which is an integration solution which offers synchronous Web Services over REST and SOAP. This service provides an immediate response to a query. This is an easy and well proven integration solution from external applications which exists today.

The DIPS Service Broker contains a set of integration components which utilizes services in DIPS.
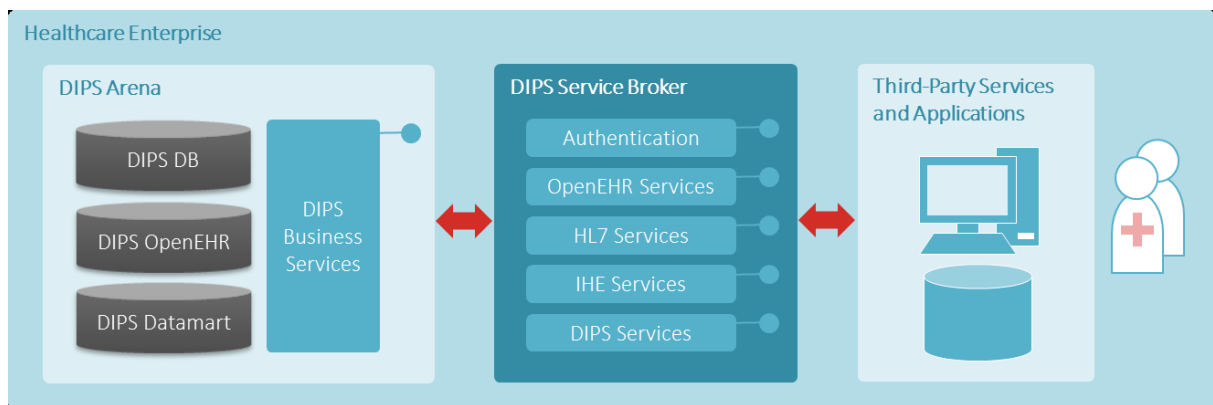
Figure 6: DIPS Service Broker integration components

4.1.1. DIPS Identity server

DIPS Identity Server is a component that allows implementing single sign-on and access control external web applications and APIs using protocols like OpenID Connect and OAuth2 for authentication and identity federation for external remote DIPS services.

4.1.2. DIPS HL7 V3 Services

As a stand-alone product in the Service Broker family's DIPS HL7 Connector which is a set of message-based web service interfaces to DIPS DB utilizing the international HL7 standard in its XML-bound version 3[12].

Integration interfaces currently offers services related to, inter alia, patient demographics, bulletin of patient contacts and related diagnoses.

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[12] HL7 v3 norsk implementasjonsguide: http://hl7.ihelse.net/Nedlasting.asp

4.1.3.   CDA

As part of the Service Broker architecture the Document manager and CDA is important components. CDA is used for defining document formats in a universal method to compile structured and unstructured information with connected metadata. Today DIPS support import of CDA documents through Service Broker Document manager.

Service Broker Document Manager is compatible with DIPS Classic version 7.3.9 or later. DIPS Classic only supports unstructured data in form of PDF, text or HTML to visualize data from an external system. DIPS Arena will support structured data in CDA XML Body

4.1.4.   DIPS IHE XDS.B

DIPS Arena also support IHE XDS.b which is an interoperability profile that facilitates the registration, distribution and access across health enterprises of patient electronic health records. This interface has some limitation regarding usage. DIPS Arena support ITI-18 and ITI-43, these are the interfaces between **Document Consumer** and **Document Registry** (ITI-18) and **Document Consumer** and **Document Repository** (ITI-43).

The **Document Consumer** Actor queries for documents that meet certain criteria, and may retrieve selected documents.

The **Document Registry** Actor maintains metadata about each registered document in a document entry. This includes a link to the Document in the Repository where it is stored. The Document Registry responds to queries from Document Consumer actors about documents that meet specific criteria. It also enforces some healthcare specific technical policies at the time of document registration.

The **Document Repository** is responsible for both the persistent storage of these documents as well as for their registration with the appropriate Document Registry.

XDS.b allows document content to be unstructured or structured. Initially HL7 CDA R2[13] is used for structured content, while PDF is used for unstructured content. In the medium term, it should also be possible to extract structured archetypes (openEHR archetypes, ref. Appendix B: Archetypes).

The XDS.b interface can also be used for external access (Tilgang på Tvers TpT) for lookup in a secondary document storage in other parties/companies (or regions). This requires that a new national security infrastructure is established for this kind of scenarios.

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[13] HL7 CDA implementasjonsguide: http://hl7.ihelse.net/Nedlasting.asp

4.1.5. DIPS FHIR implementation

DIPS have only implemented support for FHIR on a few cases. This does not include support for integration of journals. The FHIR resources already implemented in parts of DIPS is:

- **Patient**: A general Norwegian specific profile to describe how to generically exchange patient data. To define a patient, the **Condition** resource is used. A patient ID can be a F-number, H-number, D-Number or an FH-number.
- **Performer**: A general Norwegian specific profile to describe how to generically exchange performer data. To define a performer, the **Practitioner** resource is used. The performer must have an HPR-number.
- **Diagnosis Reporting**: A general Norwegian specific profile to describe how to generically exchange secondary care diagnosis. To define a diagnosis, the **Condition** resource is used. The code of the diagnosis must be defined using a ICD-10 NO code. The category of the condition is fixed to "diagnosis". The status is fixed to "confirmed".
- **Encounter**: A general Norwegian specific profile to describe how to generically exchange secondary care diagnosis. To define a diagnosis, the **Condition** resource is used. The **Encounter** resource is currently always contained inside a procedure or diagnosis resource. The encounter's status is fixed to "finished". A DIPS Encounter ID is required.
- **Condition:** Used to record detailed information pertinent to a clinician's assessment and assertion of an aspect of a person's state of health. Examples of condition include problems, diagnoses, concerns, issues.
- **Practitioner:** Practitioner covers all individuals who are engaged in the healthcare process and healthcare-related services as part of their formal responsibilities and this Resource is used for attribution of activities and responsibilities to these individuals.

DIPS have not decided exactly how they will approach FHIR regarding integration of information in the journal. But DIPS will need to support openEHR together with FHIR, which requires mappings between FHIR resources and the openEHR datamodels;

- FHIR Observation →openEHR observation
- FHIR Questinaire eller Composition → openEHR Composition
- FHIR DocumentReference → link in DIPS Arena Journal to external source (as IHE XDS.b)

The resources used by our COPD solution, Observation, QuestionaireResponse and Bundle is not implemented in DIPS yet, but a roadmap exists for this implementation. The support of FHIR document integration is a bit into the future in the DIPS roadmap.

5. Prerequisites and use cases

Since DIPS Arena has not yet implemented FHIR completely, timing is a vital parameter on choosing the best alternative for integration towards DIPS.

Another parameter is how structured the data needs to be when it is stored in DIPS or external storage (like helsenorge.no) for serving the purposes of the use cases. Almost all documentation in DIPS Arena should and will be structured in the future. Data collection must consider requirements for the storage of such structured data. In DIPS the chosen structure is openEHR Archetypes (ref Appendix B: Archetypes).

Parameters to consider is:

- What is important data to store? (triage rules to decide when and what to store)
- Efficiency of storage, search and retrieval of data
- Capacity
- Amount of effort needed to be able to store data in a structured way in DIPS or external storage.
- Futureproof solution and compliance to reference architecture

5.1. Typical scenarios

Depending on the parameters of timing and structuring of data we can foresee the following scenarios:

a) Exchange of EHR document (unstructured): COPD decides which data to be put in an unstructured document which should also be stored in DIPS.
b) Structured input towards DIPS: COPD decides to send structured data to be stored in a structured way in DIPS
c) Referencing of documents: Referencing and viewing documents located on a second document storage (secondary storage) used both against Helsenorge.no or other external register. External registers can be synchronized with metadata about available documents using asynchronous messages for HL7 Document Manager. E.g: COPD sends data to HelseNorge.no. DIPS initiates collection of data from Helsenorge.no
d) Form Builder in DIPS Arena: This way, other applications can serve as being working surface for completing forms that are saved to DIPS Arena. Using openEHR, FHIR and archetypes.

5.2. Use cases needed for storing COPD patient information in EHR

The following Use cases needs to be implemented seen from COPD solution:

1. Periodical storage of EHR data in DIPS/external storage
2. Issue triggered external storage:
    a. Triggered by a triage rule in COPD solution (red alert)
    b. Triggered by advanced reasoning analysis
    c. Triggered by the patient
    d. COPD Patient hospitalized
    e. Triggered by the healthcare telemedicine centre

6. Alternative solutions for integration

In this project some alternative solutions have been investigated in order to give recommendations on how actual solutions can be implemented.

6.1. Alternative 1 Using HL7 V3

DIPS offer an easy integration solution from external applications today:

- DIPS Service Broker with Document Manager
- SOA architecture to support import of documents and data
- Over SOAP interface
- Can be customized with use of message broker
- Requires HL7 CDA generic/universal message
- The service runs under IIS

In this alternative, the COPD will need to be the initiator of the process of storing data in DIPS in the format of a PDF-document. DIPS will act as recipient. Sykehuspartner will configure the integration towards DIPS through the existing regional platform.

To be able to use HL7 CDA a version of DIPS 7.3.9 or newer is needed. At present SSHF is using DIPS 7.3.9.5. The Document manager/CDA supports storage of journal data as PDF content in an attachment.
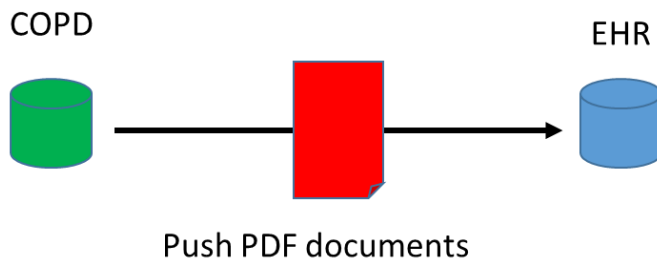
Figure 7 Alternative 1 Principles

Pros:

- This solution exists today in DIPS classic and DIPS Arena.
- Minor integration effort to make it possible.
- Minor effort to support simple use cases in the COPD to generate documents and initiate storage in DIPS.
- Not flooding DIPS with unnecessary data (measurements).
- Supports scenario a.

Cons:

- Not able to initiate the dialogue from DIPS.
- Not built for structured data input and storage (Not supporting scenario b, c and d).
- Not efficient for searching in the data.
- Not recommended in the Norwegian reference architecture or Continua Design Guidelines.
- This is not yet supported by all hospitals.

6.2. Alternative 2 Using accessible or national storage (Helsenorge.no) and XDS.b

This solution supports storing data in an external document repository and registry where DIPS can collect the data on request. Such a solution has been tested by several providers in a IHE connectathon during the Norwegian eHealth conference (EHIN) 2016 where a registry in Helsenorge.no was used. Alternatively, local or regional registries can be implemented in a similar way in order to make the actual documents available across organisations.

DIPS support XDS.b to enable referencing and search towards an external register. Using XDS.b is supported in DIPS Classic and Arena today. This type of integration opens for use of structured data when storing at a second document storage and is more aligned to future needs than HL7 V3. IHE XDS.b ITI-18 can be used to list metadata and IHE XDS.b ITI-43 to get journal data.

Storing info about a journal document in a secondary document storage can be done by implementing IHE XDS.b ITI-41/42. Thus, make a request to register metadata which points to a repository, or storing metadata and journal data in a central repository and registry.

External registers can be synchronized with metadata about available documents using asynchronous messages for HL7 Document Manager, where you can configure the types of journal documents to be sent information and at what level - it is possible pr. standard sending metadata creation, modification, deletion, approval etc.

XDS.b allows structured data contents to be stored in a HL7 CDA R2 document, which is also recommended as data structure in the CDG[14]. CDG also uses XDS, but they recommend XDR instead of XDS.b. The difference is that XDR sends the XDS message from a sender directly to a receiver instead of using registry and repository like XDS.b.

For structuring the data, the integration requires a higher effort than with alternative 1.

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[14] H.813: Continua Design Guidelines - Healthcare Information System Interface
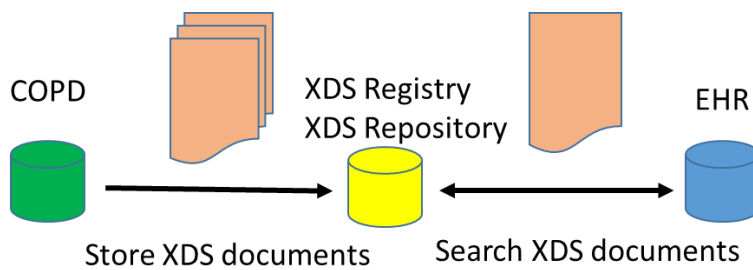
Figure 8 Alternative 2 Principles

Pros:

- This solution exists today in DIPS classic and DIPS Arena.
- Supports scenario c.
- Can implement structured data storage.
- This solution is the one that is closest to what is recommended by Continua in the CDG H.813[15]

Cons:

- Major integration effort in COPD to make structured data storage possible and efficient.

- The infrastructure for scenario c is not yet set. E.g.: This requires that a new national security infrastructure is established for this kind of scenarios.

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[15] H.813: Continua Design Guidelines - Healthcare Information System Interface

6.3. Alternative 3 Using FHIR/openEHR

DIPS Arena is going to be compliant to FHIR. The roadmap for a fully implementation of FHIR in DIPS depends on the market needs, thus not yet detailed planned in 2017/2018. This includes the resources used by the COPD solution. In this scenario, DIPS will be the master and initiator of the process of getting data from an external system. (May be manually initiated). The infrastructure and architecture for the integration will be managed by regions in the forthcoming years, and is intended to be a national service later (in 10-15 years).
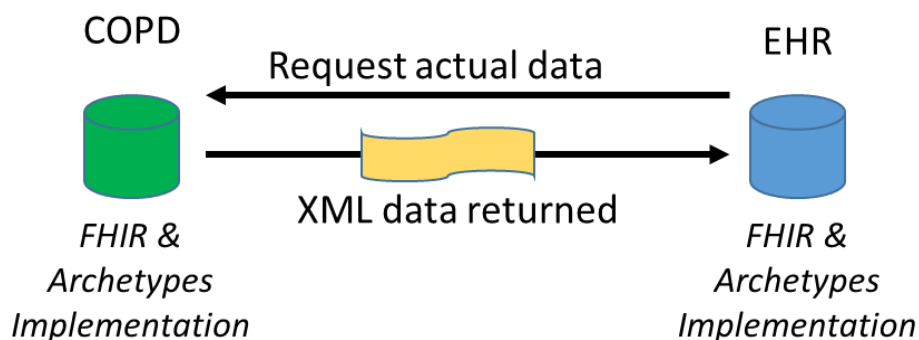

Figure 9 Alternative 3 Principles

Pros:

- Supports scenario b, c and d.
- Implements structured data storage.
- Might be compliant to a future reference architecture from the Norwegian Directorate of eHealth (NDE).

Cons:

- The implementation of DIPS FHIR is currently not fulfilling the needs of integrating COPD with DIPS.
    - Not supporting the resources Observations, Questionnaire and Bundle.
- Major integration effort in COPD to make structured storage possible and efficient.
    - FHIR not fully implemented yet.
    - Archetypes not implemented in COPD solution yet. (LOINC is used as codes).

7. Conclusion

Of the three alternatives outlined in the previous section, alternative 1 is the only one that is currently possible to implement without further development by other parties. This only allow us to send unstructured data to DIPS, but it is possible to do now.

To send structured data to DIPS will be the preferred way for DIPS in the future. This requires more work in total and is dependent on other parties. This will still be of high interest in the future. Which of the two latter alternatives (using external storage(Helsenorge.no) and XDS.b or using FHIR/openEHR) to go for in terms of being able to get structured data in DIPS will depend on the timing of deliveries of FHIR support in DIPS or a new national security infrastructure for alternative 3.

Neither of the alternatives is fully compliant to the reference architecture. The alternative that is closest to what is recommended by Continua is alternative 2. It might be that both Continua and NDE will recommend using FHIR also for this purpose in the near future, then alternative 3 will also be a good and futureproof solution.

Which of these two alternatives that will be possible and more relevant will depend on trends. If customers of DIPS require more FHIR support, that will drive DIPS or other vendors into implementing support for FHIR earlier. If several suppliers and customers (health providers) requests a security infrastructure supporting alternative 2, that might be delivered earlier.

8. Appendix A: FHIR

FHIR (*Fast Health Interoperability Resources*) is designed to enable information exchange to support the provision of healthcare in a wide variety of settings. The specification builds on and adapts modern, widely used RESTful practices to enable the provision of integrated healthcare across a wide range of teams and organizations.

The intended scope of FHIR is broad, covering human and veterinary, clinical care, public health, clinical trials, administration and financial aspects. The standard is intended for global use and in a wide variety of architectures and scenarios.

FHIR defines the "Resources" (object types) that the client and server may use in their communications and makes this communication using REST, which is a popular design pattern in modern applications. The "Resources" are the common building block for all exchanges. All together there are approximately 150 resources. In this report, a few are listed.

The advantages of using FHIR are:

- Based on REST, which is a common and widely supported communication method
- FHIR defines the object model to use, creating a known interface/contract between the client and the server
- HL7-FHIR is based on experience from earlier HL7 versions and is designed to be easy to implement in contrast to especially HL7 V3.

8.1. Observation

Observations are a central element in healthcare, used to support diagnosis, monitor progress, determine baselines and patterns and even capture demographic characteristics. Most observations are simple name/value pair assertions with some metadata, but some observations group other observations together logically, or even are multi-component observations

8.2. Questionnaire

A Questionnaire is an organized collection of questions intended to solicit information from patients, providers or other individuals involved in the healthcare domain. They may be simple flat lists of questions or can be hierarchically organized in groups and sub-groups, each containing questions. The Questionnaire defines the questions to be asked, how they are ordered and grouped and what the constraints are on the allowed answers. The results of a Questionnaire can be communicated using the QuestionnaireResponse resource.

Questionnaires cover the need to communicate data originating from forms used in medical history examinations, research questionnaires and sometimes full clinical specialty records. In many systems, this data is collected using user-defined screens and forms. Questionnaires define specifics about data capture - exactly what questions were asked, in what order, what choices for answers were, etc. Each of these questions is part of the Questionnaire, and as such the Questionnaire is a separately identifiable Resource, whereas the individual questions are not.

8.3. QuestionnaireResponse

QuestionnaireResponse provides a complete or partial list of answers to a set of questions filled when responding to a questionnaire. The questions may be included directly or by reference to a Questionnaire resource that defines the questions as well as the constraints on the allowed answers.

Each time a questionnaire is completed for a different subject or at a different time, a distinct QuestionnaireResponse is generated, though it may be possible for a previously entered set of answers to be edited or updated.

QuestionnaireResponse resources can be validated against their corresponding Questionnaire to verify that required groups and questions are answered and that answers fit constraints in terms of cardinality, data type, etc.

8.4. CommunicationRequest

This resource is a record of a request for a communication to be performed. A communication is a conveyance of information from one entity, a sender, to another entity, a receiver. The sender and receivers may be patients, practitioners, related persons, organizations, and devices.

8.5. Communication

This resource is a record of a communication. A communication is a conveyance of information from one entity, a sender, to another entity, a receiver. The sender and receivers may be patients, practitioners, related persons, organizations, or devices. The communication may be patient related or non-patient related.

8.6. What can prevent a FHIR compliant client and server from being compatible?

Although the FHIR standard standardizes many things in the contract between a client and a server, there is no guarantee that a FHIR compatible client and a FHIR compatible server will work together out of the box. This is a description of some of the things that FHIR doesn't solve.

8.6.1. Security (authentication)

FHIR doesn't specify what authentication mechanism to use. Since there are several possible methods for implementing authentication in a REST interface, this means that the client and the server may not agree on the method. Common scenarios include:

- Basic security: Simple security protocol using username and password. The implementation is straight forward and the protocol is clear, but since the username and password are not encrypted, the communication channel needs to be encrypted for sufficient security.
- OAuth2: A very common framework in mobile and web applications today, allowing for many authentication scenarios. Has good support for external authentication authorities, both governmental (e.g. IDPorten in Norway) or commercial (Google, Facebook, Microsoft etc.)

8.6.2. Partial implementation

The FHIR standard specifies a lot of resources (object types) that a service may implement, but in most cases a service will not implement all the resources. In our solution, we have only implemented support for Observation and QuestionnaireResponse. A client may require some resources that any given service is missing, so there is no guarantee that any given FHIR compatible service contains the resources needed by the client.

There is a partial solution for this in the FHIR standard, as a client may query the FHIR service for information about what resources the service has implemented, allowing the client to give a user-friendly message if the service is missing some resources.

8.6.3. FHIR Maturity (or lack thereof)

FHIR has not yet been carved in stone, it is still evolving. The same goes for the FHIR .Net libraries. There are currently multiple versions available in NuGet and there are some (subtle) differences.

8.6.4.   Some freedom in the FHIR standard

The FHIR standard doesn't specify everything needed in detail and leaves something to be agreed upon between the client and the service. This may result in an unexpected behaviour.

9.   Appendix B: Archetypes

As defined by the openEHR Foundation, "*an **archetype** is the model (or pattern) for the capture of clinical information - a machine readable specification of how to store patient data using the openEHR Reference Model.*"

The **openEHR** is here a computable definition or a specification that describes the management and storage, retrieval and exchange of health data in electronic health records (EHRs). In openEHR, all health data for a person is stored in a "one lifetime", vendor-independent, person-centered EHR.

The specification is structured according to this architecture which is based on the openEHR Reference Models[16] used by openEHR archetypes:

- information models (aka 'Reference Model' - RM)
- the archetype formalism (AM)
- the portable archetype query language;
- service models / APIs (SM)

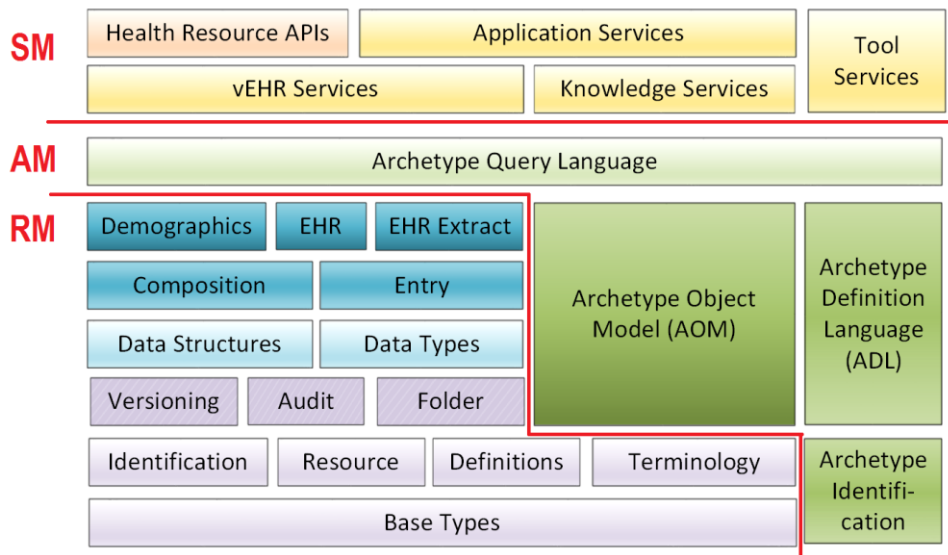[16] http://www.openehr.org/releases/RM/latest/docs/index

Figure 10: Block diagram of openEHR specification components.

With regards to this document, the **openEHR archetypes** provides a place to formally define re-usable data point and data group definitions, i.e. content items that will be re-used in numerous contexts. Many such data points occur in logical groups, e.g. the group of data items to document an allergic reaction, or the analytes in a liver function test result. Some archetypes contain numerous data points, e.g. 50, although a more common number is 10-20. A collection of archetypes can be understood as a "library" of re-usable domain content definitions, with each archetype functioning as a "governance unit", whose contents are co-designed, reviewed and published.

These archetypes have been designed to accommodate the concepts of the shared care plan. They provide a powerful way to define the meaning of clinical and related data, and to connect, or "bind", data to recognized terminologies such as LOINC codes. This latter code has been chosen for SpO2 and pulse in the COPD solution.

To comply with the openEHR archetypes, the FHIR compliant COPD solution (Forløpsjournalen) will need to be updated.

NB: DIPS uses Archetypes and Capgeminis codes, hence an update needs to be done.
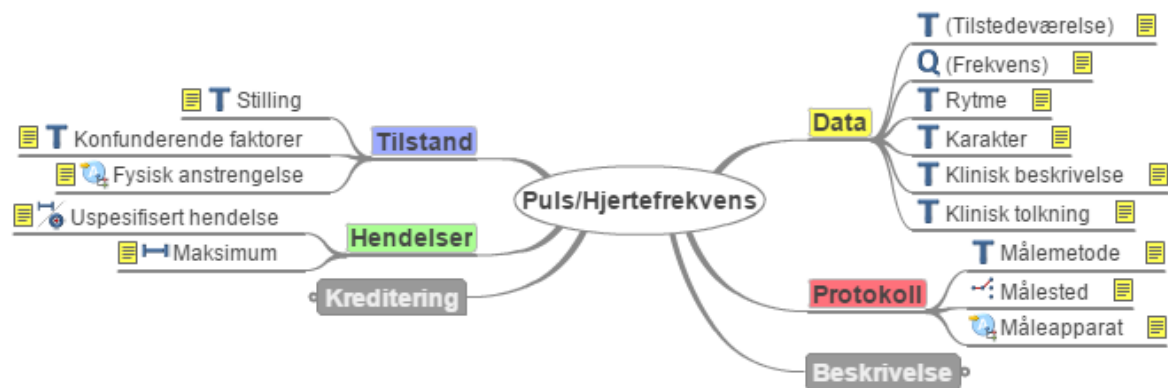
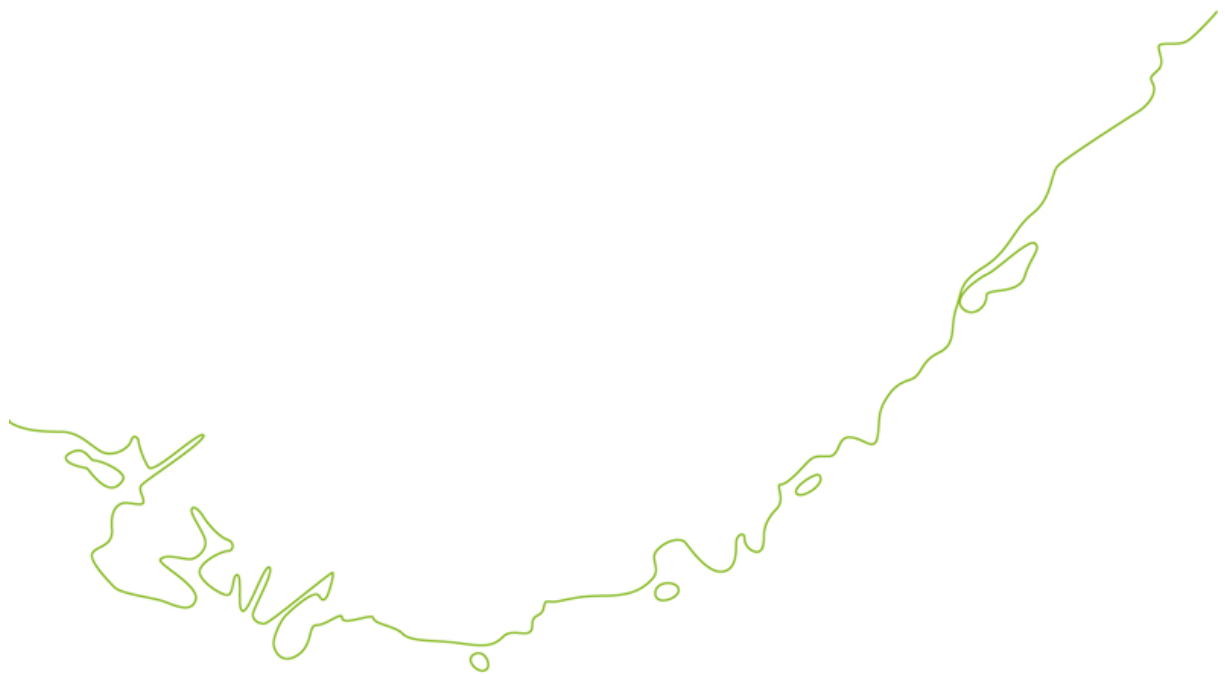*Figure 11: Example of Archetype for pulse measurements*

Use of archetypes when telemedicine solutions are recording vital signs data will easily facilitate transfer of data into an EHR system which supports archetypes. In addition, there are options for describing under which circumstances the measurements are made, as there can be a distinct difference from measurements made by the patient in a home-living situation compared to similar measurements made in a healthcare setting. The physical conditions can be of importance, and there can be important episode details than should be added. Also details of the actual devices used can be included. Thus recommendation of implementing archetypes in telemedicine solutions should be followed by the actual developers and vendors.

10. References

1. IS-2402: Arkitektur for Velferdsteknologi – anbefalinger for utprøving og faser for realisering (12/2015)
2. HL7 FHIR Norwegian Profile: http://www.hl7.no/index.php/standarder/hl7-fhir-norsk
3. H.810-H.813: Continua Design Guidelines (Personal Connected Health Alliance, 2008-2016)
4. H.813: Continua Design Guidelines - Healthcare Information System Interface
5. HL7 FHIR: http://hl7.org/fhir/
6. HL7 v3 norsk implementasjonsguide: http://hl7.ihelse.net/Nedlasting.asp
7. IHE XDS: http://wiki.ihe.net/index.php
8. IHE PIX: http://www.ihe.net/Technical_Framework/upload/IHE_ITI_Suppl_PIX_PDQ_HL7v3_Rev2-1_TI_2010-08-10.pdf
9. IHE XDR: http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_Supplement_Cross_Enterprise_Document_Reliable_Interchange_XDR_TI_2009-08-10.pdf
10. HL7 Implementation Guide for Clinical Document Architecture, Release 2: Consent Directives, Release 1, HL7 Draft Standard for Trial Use.
11. HL7 CDA implementasjonsguide: http://hl7.ihelse.net/Nedlasting.asp
12. Open EHR Reference Models: http://www.openehr.org/releases/RM/latest/docs/index
13. https://github.com/furore-fhir/spark