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Electronic antenatal health care records - potentials for structured representation with openEHR archetypes and templates.

A qualitative case study.

Master of Science in Health Informatics

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Master's thesis

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Abstract

The primary intention of this work is to provide a starting point for a realisation of an electronic antenatal health record in Norway. Furthermore, the ambition was to conduction an evaluation into the potential for using archetypes for representation of structured clinical information in antenatal health care in Norway. Focus of work has been to investigate former projects in electronic solutions for antenatal health records, to gain knowledge of earlier practical experiences regarding development of archetypes and finally how lessons learnt in both can be applicable and utilised in the development of an electronic antenatal health care record in Norway. To answer these questions a qualitative case study has been performed including a literature review and interviews with informants acting within antenatal health care.

As a proof-of-concept for direct reuse of formerly developed archetypes, candidate archetypes have been translated and a template has been designed. In addition all candidate archetypes have been evaluated as to clinical content coverage as regards Norwegian requirements, as well as thoroughly assessed utilising published Archetype Quality Requirements.

Through this qualitative case study I have learnt the importance of involving all stakeholders as early as possible in development projects in general as in archetype development specifically. It is also important to sustain stakeholder involvement throughout the development cycle to ensure that the interests of all stakeholders are met.
The in-depth validation of clinical content in candidate archetypes shows that Norwegian requirements for clinical content in antenatal health care records are met. Furthermore, the in depth validation of the quality of archetypes has resulted in significant findings for Norwegian stakeholders in antenatal health care; a thorough investigation and clarification process regarding intended use of an electronic antenatal health care record has to be initiated and concluded before development activities can commence. The need for stakeholder inclusion in a development project is also identified for antenatal health records. The identification of clinical content provided by the present project can be seen as a first step in the development of a Norwegian

antenatal health record. There has also been identified significant findings regarding how translation of archetypes can be facilitated; by establishing a demonstration archetype including most commonly utilised terms in archetypes, in order to secure consistent translations with good quality in all archetypes. Finally, the in-depth evaluation regarding the metadata quality in archetypes has provided significant results with proposals for additions, specifications and needed alterations of the Archetype Quality Requirements that are published by Kalra et al (2012). To my knowledge, no other project has utilised and thoroughly evaluated these quality requirements.

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1. Introduction

Our time may be described as a world where ICT systems run every day life, their use in all aspect of life has sky-rocketed and ICT literacy is general knowledge. Also in health care ICT systems are widely utilised, both smaller systems supporting one specialists´ need and larger comprehensive electronic health records that contain clinical information about patients. There are challenges in regard to structure of which the systems are built upon, what standards that are utilised as well as legal restrictions that have had an impact on the level of interoperability and communicative aspects within the electronic health care systems in use today. Present visions and political goals are to include the patients more actively in the management of their health; both in health management generally as well as in antenatal health care.

1.1 Background

Antenatal care is a part of the Norwegian preventive public health program, and routine examinations (check-ups) are provided to the pregnant women. General practitioners (GPs), midwifes in local health centres as well as specialists and midwifes in specialist care contribute in the preventive public health program for antenatal care. Information from the individual check-ups is documented on a nationally utilised paper based antenatal health record (Norwegian: Helsekort for gravide), in addition to documentation in local electronic health records (EHRs). The pregnant women act as information providers between different health professionals in each individual case, as she stores the health record in between each check-up.

Antenatal health care has often been looked upon as a "perfect area" for the establishment of electronic solutions where patients (i.e. the pregnant women) can have access to its content. There have been several attempts of establishing different electronic solutions, both nationally as well as internationally. Some have succeeded both for most part the proposed technical solutions have not prevailed.

In Norway previous attempts have identified factors that have challenged the realisations of persistent electronic solutions. These factors, although not all of them relevant in all previous projects, are:

- Lack of cooperation between the different stakeholders and other relevant organisations.
- There are no conclusion of what system is most fit-for-purpose
- Requirements for a regional or central database vs. message exchanges between many independent systems have not been fully investigated
- Legislation for a centralised solution (regional or national level) has not been available in Norway
- A solution and investigation for an integrated approach to the antenatal health record vis-à- vis other health record information has not been fully established.
- There is no common dataset with all clinical content definitions established

Based in openEHR Foundation, there are international initiatives, as well as national, working with developing electronic health records by using dual modelling. The idea of dual modelling is to separate knowledge and reference models and data storage concerns. By doing this, the aim is to facilitate health personnel in describing their identified and required clinical content in health records with archetypes and templates, while not having to concentrate around technical specifications of databases and how integration exchanges should be set up. When health personnel have identified and described their clinical needs in regards to clinical content and how this will be used, technical staff will have a clearer understanding of how to design the actual technical system.

1.2   Objective

Although not been practically incorporated in electronic health care support systems as of yet, movements within Norwegian legislation open up for the establishment of centralised solutions. In addition several of identified factors concentrate around challenges with choosing what technical solutions best fits the need for clinical use and information exchange. Cooperative efforts between the different stakeholders are also identified as a challenge. My perceived notion when starting this qualitative case study was that there is a wish for an establishment of an electronic solution to be used in antenatal health care. This perception is supported by the numerous national White Papers that reference the need for such a solution as well as the previous attempts of establishing technical solutions.

However, it is my view that the abovementioned challenges has not dug into the core of the subject. The core is, as I see it, what view do clinicians have of todays antenatal health record, what is it used for and what are the clinical routines when utilising this

record. In addition a big challenge is not having a common dataset with all clinical content definitions established.

With this background in mind, the main objective of this thesis is to further investigate the clinical routines when utilising antenatal health record and more importantly, the required clinical content for an electronic solution. Further, focus is to evaluate whether dual modelling with description of clinical content with archetypes and templates can be utilised for describing a proposed common dataset with clinical definitions.

The objectives are summarised in following scientific questions:

Scientific question 1:

What has caused the failure or success of solutions developed for antenatal health care nationally and internationally? What lessons can be learnt?

Scientific question 2:

What practical experiences regarding development of archetypes are there and how are these relevant?

Scientific question 3:

Can previously developed archetypes cover clinical content and work process requirements in Norwegian antenatal health care?

1.3   Outline

Introduction of thesis and chosen topics with theoretical approaches for information retrieval

Chapter 1	Gives a short introduction to content of this thesis. The information described in this chapter will be investigated and described in full in subsequent chapters.
Chapter 2	Introducing theoretical approaches for information retrieval in general, with focus on chosen methods used in this thesis in special.

Introduction of chosen area of study: antenatal health care

Chapter 3	Antenatal health care in Norway is described with national demands for reporting of information gained through antenatal heath care in national registries.

Chapter 4   The antenatal health record is introduced. Prior national and international experiences with developments of electronic solutions for antenatal care are summarised. The documentation process while utilising the antenatal health record is described

Technical background and its implications to development of electronic solutions for health care domain.

Chapter 5   Introduces standardisation within health care and its implications for development of electronic health records

Chapter 6   Structure and communication within health care with electronic health records is described.

What is dual-modelling and how should this methodology be utilised

Chapter 7   The dual-modelling initiative is introduced, with focus on archetypes and templates

Chapter 8   Theory of how to develop archetypes for the description of clinical content

Utilisation of dual-modelling for antenatal health care with focus on archetypes and templates

Chapter 9   Brings together the two domains antenatal health records and archetypes, while describing the utilisation of openEHR design process

Discussion and conclusion

Chapter 10   Discussion – the scientific questions are discussed based on information declared in previous chapters.

Chapter 11   Conclusion – what results have been found and implications for further work is described

2   Theoretical approach and information retrieval

In this thesis two different domains are discussed; antenatal health care records and archetypes and the interaction between the two. To obtain needed information about my chosen area of study, there are different approaches that could have been relevant as research methods. In chapter 2 potential data collection methods are presented and described with a focus on chosen methods for present thesis. Using these methods, data that has been gathered is utilised in subsequent parts of this thesis.

2.1   Study approach

The two domains that are analysed cover a broad range of topics and within these topics the actors vary greatly. Within archetype methodology the actors are few in Norway but also internationally the number of actors is relatively small. When it comes to antenatal health care the number of actors are numerous and spread across the health care sector and geographically in Norway.

These topics of interest vary from technical support systems implementation, both including dual modelling and other methods, to user experiences with antenatal health record systems. Consequently, different methods have been deemed necessary for information retrieval. The aim for the information retrieval has been to gain an overview and insight into following areas:

Experiences with:

Different electronic solutions for antenatal health records

What challenges have been identified in earlier projects – what has caused their failure or success?

Use of dual model methodology within health care informatics

What experiences are there with the use of dual modelling and what are the perceived benefits?

Paper based antenatal health record

What users experiences are there with the paper based antenatal health record? Are the experiences predominately positive or negative? What

5

level of needed documentation support is there?

Workflow processes within:

Antenatal health care delivery

What are the workflow processes in antenatal health care delivery and how should an antenatal health record support this

Utilisation of dual-model methodology

How is the workflow process when it comes to clinical input and design of archetypes? What is best practice?

Potential areas for improvement

Documentation support within antenatal health care

Design and quality assurance in dual-model methodology

2.2   Methods for research

Different research approaches and methods are distinguished as qualitative or quantitative research methods. Generally speaking the difference between the methods is that a qualitative method seeks insight and understanding in a particular domain whilst quantitative methods produce knowledge in terms of gaining overview and explanation. Still, the techniques can produce knowledge about the same phenomenon but the results may vary in terms of different aspects of the same phenomenon (Tjora, 2011).

Qualitative methods explore and create theories generated from the observation of the few. To create these theories, techniques such as literature studies, observational studies and interviews are used. By using these methods knowledge and insight about a domain is acquired without prior assumptions to describe gained knowledge based on specific phenomena's. If one wishes to explain a phenomenon, a quantitative method might be appropriate. In quantitative research data sets that have a good representation in the population of study should be utilised. For instance, with a questionnaire a high number of responses are needed to have high quality results from statistical techniques.

Results from quantitative studies will often be visualised with graphs and diagrams and other easy to understand models (Tjora, 2011).

There are similarities within the different research paradigms however. The researches will, regardless of what research paradigm they have used in their study, thoroughly describe presented data as well as provide arguments and speculations on how and why the research outcomes are as they are. Johnson and Onwuegbuzie (2004) have in their article conducted a comparison between qualitative and quantitative research methods. In addition, they propose a third method, mixed methods that extract and utilise elements from both qualitative and quantitive research methods. While they clearly distinguish and identify strengths and weaknesses within all three methodologies, they argue that "... research approaches should be mixed in ways that offer the best opportunities for answering important research questions"(2004:16). They further argue that researchers should be pragmatic in the way in which research is being performed when selecting research methods and they propose a mix between methods generally characterised as either qualitative or quantitative. Others, while not explicitly proposing a mixed methods approach, also identify pragmatism as key factor when designing and conduction research (Tjora, 2011).

Wisom et al (2012) conducted a study to describe the frequency of mixed methods as chosen methodological approach in published health services articles. Their results show that only 2,85% of a total of 1651 included articles had used mixed methods as research method. They also found that quantitative methods predominate in health research articles (90,98%). Tjora (2011) concur to the trends found by Wisdom et al where he declare that most people perceive diagrams and graphs as more credible than written dissemination, thus a higher number of research are quantitative based rather than qualitative. Tjora further remarks that it may be wise to include some sort of quantitative analysis or quantitative representation of qualitative data in order to reach out to specific types of readers.

In present thesis, quantitative representation of the qualitative data has been utilised.

2.3   Literature review

Most studies include literature reviews as either background or complementary data. Others use literature reviews as primary data, i.e. as the only source of information in a study. The documents and literature that are studied are often produced for other means than research. No matter for what reason the documents are produced in a specific setting, at a specific time and contain information that often is produced with a specific group of reader in mind (Tjora, 2011). In this thesis this challenge has specifically been clear in search for and the extraction of clinical content and user processes in antenatal health care. Sources found in this domain have mostly focused on technical solutions for electronic health records, not the specific use cases in the provision of antenatal health care.

For the present thesis, a large range of references appropriate for the domains and topics being studied has been gathered. On a large scale the included literature discuss either antenatal health records or archetypes. Main sources of reference have been PubMed and Google Scholar. Key words for the antenatal health record domain has been; antenatal, maternity, prenatal, svangrejournal, mødrevårdjournal, helsekort, helsekort for gravide, electronic health record, electronic medical record and combinations of these terms.

For the archetype domain key words have been: archetypes, openEHR, semantic interoperability, quality requirements, quality management, two-level modelling, dual modelling, domain knowledge governance, archetype development and combinations of these terms. Finally combinations of archetype and antenatal related key words have been applied.

During the search it became clear that only limited relevant literature could be found in published articles. In order to find unpublished literature, such as reports and eHealth policies, search was also performed on sites like national health authorities, standardisation organisations and other pages where I assumed relevant information were to be found. In addition some of the references with practical experience in the domains came to my attention through sources like ICT vendors, other key people with experience in the field of health ICT and from reference lists of literature found in PubMed and Google Scholar.

The search for literature has been performed in three iterations; May 2012, September – December 2012 and finally May- December 2013. Articles that discuss the usage of archetypes in more complex processes, for instance mapping to SNOMED or ontologies have been excluded. Only literature published after year 2000 has been included.

In this thesis the information from the literature review is regarded as primary information as regards dual modelling and archetype methodology. For the antenatal health care record the literature review serves as background and complementary data to the semi-structured interviews.

2.4 Interviews

The literature review indicated a need to further investigate certain areas within antenatal health records:

- User processes; how is the paper based antenatal health record used in daily routine
- Positive and negative experiences in using the paper based version
- Proposals for amendments of paper based version and needed new functionality

In qualitative research, the most used way of generating data is through various forms of interviewing. Interviews can be in-depth where the researcher meets the informant for a relatively speaking unstructured conversation about a topic decided by the researcher. Semi-structured interviews are a variant of the in-depth interviews, where the researcher has prepared an interview guide to be used during the interview. Semi-structured interviews with a shorter length may be sensible to use when topics are confined and not of a delicate nature (Tjora, 2011). This variant is called focused interviews. I evaluated personal experiences of antenatal health care records as not being of a delicate nature. Additionally, my assumption was that a maximum of 30-minute interview was feasible given that the interview would keep the health care professionals away from daily clinical work. Focused interviews were therefore regarded as the best strategy in gaining supplemental information to results found in literature as well as providing an opportunity to investigate further areas for clarification and enlightenment with regards to antenatal health records.

2.4.1 Interview recruitment

The ambition for clinical content retrieval in this thesis was not only to support information requirements in antenatal health care, but also to identify needed information structures used when reporting to National Birth Registry of Norway (see later chapter). The ambition was therefore to interview health personnel both in primary care (GPs and midwifes at local health centres) and in specialist care. The literature review had shown that there is difference in electronic support systems in antenatal health care as well as in maternity care in Norway. The ambition was to obtain a total of 12 interviews by health care personnel that as of the time of interviews had differentiated electronic solutions; one midwife in hospital, one specialist from hospital as well as one GP and midwife from primary care for each of the targeted areas. The targeted areas were Oslo with Oslo University Hospital, Ullevål as well as Haukeland University Hospital (Bergen) and St.Olavs Hospital (Trondheim University Hospital) including the hospitals´ collaborative partners in primary care. A request for participation letter was sent out via e-mail to 8 local health centres, 8 general practitioners offices and a total of 20 Heads of Departments and clinical leaders in Maternity wards. Reminders were resent after a week or telephone contact was initiated. After a three weeks of recruiting 4 agreed to be interviewed.

Profession	Area	Part of healthcare	Years of experience
GP	Oslo	Primary care	Approx. 36 years
Medical specialist	Trondheim	Specialist care	Approx. 30 years
Midwife	Oslo	Specialist care	Approx. 13 years
Midwife	Oslo	Specialist care	Approx. 11 years

Table 1 Responders in focused interviews

As the table shows, the interviewed health personnel represent both specialist and primary care. No midwifes from local health centres agreed to participate in the study. One of the midwives interviewed had however worked approximately two years in primary care with antenatal health care. I did not succeed in having informants from Bergen area, thus only Oslo and Trondheim area are represented. The interviews were conducted end of November/start of December 2014. The average length of interviews was 46 minutes.

2.4.2 Focused interviews

Each of the interviews started off with an introduction about myself, my clinical background as a nurse and the need for information retrieval that would complement findings from literature. My ambition of introducing myself including my clinical background was to openly inform about prior knowledge while giving them the understanding of having needed background knowledge to understand topics for discussion. After this brief introduction I referred to the Request for information letter and asked if there were any questions or hesitations to perceived content of interview. All agreed to proceed with the interviews.

Former responses to hearings and reports, as summarised by Svarlien (2008) gave me an assumption that the respondents might have highly differentiating opinions about the paper based antenatal health record in general, as well as abovementioned areas in particular. Open-ended questions were prepared, facilitating and allowing conversation and in-depth reflexion about the assumed differentiating opinions of topic. The questions were compiled in an interview guide, structured to ensure that all interviews concerned the same broad topics, while allowing the responders to reflect deeper in areas of their particular interest. Semi-structured and focused interviews allow flexibility in terms of the order of questions. This flexibility allowed me to structure the interviews as best suited each of the responders. Some started the interviews by asking in depth questions about archetypes and technical implications in a future system, others wished for me to structure the interview as I saw best. Using the interview guide allowed this flexibility while still ensuring that the same questions all were asked. I returned to the questions in the interview guide as best fit the conversation.

2.4.3 Telephone interviewing

For the focused interviews I wanted to interview health care professionals that had different experiences with antenatal health care records and electronic delivery records. From the literature review I knew that preferred respondent groups would be found in different parts of Norway (Oslo, Bergen and Trondheim). Due to cost, time and practical implications, I had no opportunity of travelling to the different cities to conduct the interviews. The decision of conducting the interviews by telephone was therefore made.

In qualitative research, the context and inter-subjective dynamics in an interview situation is to be given great focus. Generally speaking telephone interviews are often seen "…as a less attractive alternative to face-to-face interviewing" (Novick, 2008:e1) as one will not have visual cues and nonverbal data that is thought to compromise the data generated from the interviews. Still, there is little data that can prove that data generated from telephone interviews are of a lower quality (Novick, 2008; Shuy, 2003). The responders close to Oslo had the option to be interviewed face-to-face interview or by telephone. Of the three local responders, only one opted for the face-to-face interview. The remaining two chose telephone. The reasoning for this was that it was practical, they felt greater flexibility as to when the interviews could take place and they had their own offices where they comfortably could reside during the interview.

Novick (2008) proposes the need for further research to examine impact on data quality and further comparison between face-to-face and telephone interviews as this is a field that one has little knowledge of today. As for this thesis, data generated from the telephone interviews has not been found to be of neither higher nor lower quality than from the face-to-face interviews. The data generated from all the interviews has been analysed collectively.

2.4.4   Technical

All respondents permitted recording of the interviews. A dictaphone and telephone pick-up microphone (ear-plug) was used. Headphones with noise-reduction were connected to the telephone giving a crystal clear recording of the conversations. As for the face-to-face interview, the dictaphone was placed on a table in between us.

All interviews were completely transcribed in anonymous form, with identifier of the respondents being health profession/place in Norway/specialist vs. primary health care. Coding and further data analysis has been performed in Dedoose (www.dedoose.com).

3 Antenatal health care in Norway

The Norwegian health care system consists of three organisational layers; national, regional and municipality level. The Norwegian Directorate of Health is the national executive agency and authority subordinate to the Norwegian Ministry of Health and Care Services. The role is to determine national health policy, prepare legislative amendments and allocate funds for health care providers. The main responsibility for the provision of health care lies within the four regional health authorities for specialised health care and the municipalities for primary care (Johnsen, 2006). The Health Care Personnel Act (*Helsepersonelloven,* 2001) regulates what groups of health care personnel that are to document their health care actions in a health record, as well as how and when shall be done. The National Regulation Act for Health Records (Norw.: Journalforskriften) regulates minimum criteria's of information that should be included in a health record (*Forskrift Om Pasientjournal,* 2001).

3.1 Public health programme

Antenatal care is a part of the Norwegian preventive public health program, it is also one of the largest with about 720 000 antenatal check-ups for about 60 000 pregnant women every year (Svarlien, 2008). The check-ups are free-of-charge and the women themselves can choose whether they prefer check-ups by their general practitioner (GP), a midwife or both. There is a growing number of midwifes establishing private clinics but the majority of pregnant women, 70%, are receiving check-ups at the local health centres (Helse- og omsorgsdepartementet, 2011).

The White Paper *En gledelig begivenhet* (HOD, 2009) issued a request for a survey with an aim of gathering user experiences of pregnancy, birth and postnatal care. The national survey was recently published: *User experiences of pregnancy, birth and postnatal care. National results* (Sjetne et al., 2013)). The sample was established among women over 16 years who had given birth last quarter of 2011. Concerning who the women had received check-ups by, the results show that 63% received check-ups by both midwife and GP/others (for instance private practicing midwife), 16% only

attended check-ups by GP or other, whilst 21% received check-ups solely by midwifes at local health centres.

The antenatal public health program aims to offer the women continuity in their care during pregnancy by limiting the number of involved health care professionals. The national survey shows that a small group of the women (5%) had attended check-ups by four or more different health care professionals during their pregnancy. 76% of the responders clearly indicated that a reduction of involved health professionals was extremely or very important (Sjetne et al., 2013).

3.2 National Clinical Guideline for Antenatal Care

Guidelines establish statements and general rules with the aim of creating a common set of actions in different processes. In Norway the National Clinical Guideline for Antenatal Care was published in 2005 (Helsedirektoratet, 2005). Its content was established on the basis of professional advice and the best available knowledge. Compared to previous guidance documents in antenatal health care, the guideline has a shifted focus "...from control to information, advice and guidance" (Helsedir., 2005:3) and it includes recommendations of basic antenatal programme and what should be the focus at the different check-ups time points.

3.2.1 Basic antenatal programme

In the basic antenatal programme the guideline recommends 8 routine check-ups during the pregnancy, when there are no specific risk factors identified. One of the check-ups is a routine ultrasound diagnostic test that is offered to all pregnant women. The ultrasound is done at the local hospital. After week 41 of pregnancy, routines for post-term pregnancies should be followed, including additional check-ups (Helsedir., 2005). The guideline includes recommendations on what kind of information that should be given the women at what time, as well as when the different examinations should be carried out.

Week of pregnancy								
´8-12	18	24	28	32	36	38	40	41

Table 2 Routine check-ups recommended in basic programme

While the programme proposes a total of 8 check-ups, the national survey shows that 51% of pregnant women had 5-10 check-ups during the pregnancy, while 37% had 10-

16 check ups (Sjetne et al., 2013). The survey has not given any indication as to why one group had more check ups than the basic antenatal programme proposes.

3.2.2 Revision of the National Clinical Guideline for Antenatal Care

In 2014, a revision of the guideline will be started. The revision will include adjustments and additions covering violence and sexual abuse as well as gestational Diabetes. There are sections in the guideline however that already have been revised and published. The amended parts include revision of practices to detect asymptomatic bacteruri and treatment for it and guidelines for the treatment and check-ups for pregnancies > 294 days (i.e. 42 weeks of pregnancy) (Helsedir., 2013; Helsedir., 2012).

3.3 Medical Birth Registry of Norway

A health register is a collection of health information that is systematically collected and saved, so that information about individuals can be retrieved (FHI, 2009). The definition is quite broad: a health register can be (e.g.) a local medical health record (either on paper or electronic) or nationwide registries used for statistics and research. The paper based antenatal health record is an example of a local medical health record while the Medical Birth Registry of Norway is a nationwide register. Every birth of live and stillborn babies, as well as every abortion (provoked or spontaneous) after week 12 of pregnancy, has to be reported to the Medical Birth Registry of Norway. Data collection started in 1967 and the register now contains data about 2,6 million births with over 300 data elements per birth (Ebbing, 2014). This registry is therefore a unique source of knowledge and the data can be used for surveillance, quality of care, planning/administration and research in an international perspective (Ebbing, 2014; Stoltenberg, 2011). Main sources of information sent to the register are three ICT systems; Partus, Natus and Obstetrix. The recent national survey (Sjetne et al., 2013) used the registry for inclusion of women that had given birth last quarter of 2011.

There is a National Health Registry Project with a strategy and plan for modernising and harmonising central health registries and national medical quality registries. The project will evaluate the further development of a common health register for pregnancy, birth and infants (FHI, 2009:16,125). Still, key moves to realise the vision of continuously updated, reliable and secure health registries are an integrated model for technological solutions and structured data (Stoltenberg, 2011; FHI, 2009).

Legislation regarding health registries is found in The Personal Health Data Filing System Act (Helseregisterloven, 2001). There is currently a proposal for the revision of The Personal Health Data Filing System Act. It is under revision, still pending parliament adoption (Helse- og omsorgsdepartementet, 2013).

3.4 Secondary use of data

The Norwegian government has a national vision that information in health registries shall be automatically retrieved from the EHR systems. In order to realise this vision one has to plan for secondary use of data when starting to design health information systems (Helse- og omsorgsdepartementet, 2012).

4   Antenatal health records

The Norwegian National Clinical Guideline for Antenatal Care states that a structured health record for pregnancy should be used. A paper based structured health record is in use (in Norwegian; *Helsekort for gravide*) and even though the use of this specific record is not mandatory, the coverage of use is about 100% (Krossen and Roland, 2007). The idea of the antenatal health record is to monitor the health of both the mother and child in order to detect risk factors and potential harmful behaviours in order to secure the health of both. The main advantage of the paper based antenatal health record is that the pregnant women themselves are in charge of the document. With the shift of focus to information, advice and guidance in antenatal health care services, the aim is to make it easier for women to assume responsibility for their own health. Being responsible for the antenatal health record enhances the focus of information being available for the women. The interviewed specialist had a slightly differentiated view upon the paper based record:

> *I do not look upon the paper based record as a complete health record. It is documentation for the women that the provided care is in line with guideline proposal. The record is an instrument where some of the relevant information is transferred from one healthcare provider to another.*

The general notion, internationally but also one that is commented in responses to previous reports in Norway, is that antenatal care is suitable for developing cross-sectional and cross-organisational electronic health records. This notion is based on the fact that pregnancies have a pre-determined duration and the provided health care has an established workflow with actors clearly identified. In addition, the expecting women are seen as a suitable "patient" group as they find themselves in a positive situation, the outcome of the "patient" period is often highly awaited and the group is in a high degree of computer literacy age. In addition to the general notion of having a so-called "perfect domain" to establish a cross-sectional and cross-organisational electronic health record, there also is a growing urgency to do so, due to the fact that current solution cannot

meet the demands of security of sensitive data, efficiency in information retrieval for communication activities as well as effective electronic reporting (Helsedir., 2014; Fawdry et al., 2011; Vestad and Svarlien, 2009; Svarlien, 2008; Bansler et al., 2007; Krossen and Roland, 2007; Rønneberg and Fjeld, 2005; Bach et al., 2005).

4.1 Norwegian initiatives

Health care professionals have requested electronic antenatal health records for a long time. With the revision of the National Clinical Guideline for Antenatal Care (2005) activities started to establish an updated and adjusted antenatal health record. After the proposed revision, requests from the GPs came for an electronic version adjusted and integrated to their electronic health record (EHR) system. Discussions followed whether the revision of the paper based antenatal health record rather should be replaced with the development of an electronic version (Krossen and Roland, 2007).

The Norwegian initiatives consist of, generally speaking, groups of stakeholders that have summoned needed experience and requirements for an electronic antenatal health care record. The results are published in reports that outline what preparatory work that needs to be done, by who and possible solutions for the realisation of an electronic version (Bach et al., 2005). A preliminary report for an electronic antenatal health record lists up different possible solutions for an electronic version. These are:

   i.   Local solutions, registrations done in local EHR with the pregnant women accessing their data through print-outs from the systems

   ii.   An electronic collaborative solution for all actors:

        a.   Message-based solution implemented in each EHR system

        b.   One common module

   iii.   An electronic collaborative solution based on a "National Summary Care Record"[1] solution

        a.   One collaborative solution for all actors within antenatal health care

        b.   One collaborative solution for all actors within antenatal health care, including the pregnant women (the "patient").

(Svarlien, 2008).

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[1] http://helsedirektoratet.no/it-helse/kjernejournal/Sider/default.aspx

The proposed solution from the preliminary project was the establishment of an electronic collaborative solution (for all actors) based on one common module (alternative ii b).

The general demand is that an electronic counterpart should, as a minimum, contain the same information elements as the paperbased version. In addition, an electronic solution should include new information and facilitate new collaborative solutions, such as reuse of data for reporting. Another demand is to maintain the access expecting women have to their information today and additionally they should be given the opportunity to create their own documentation and communciate electronically with their health care providers (Helsedir., 2014; Bach et al., 2005). The preliminary report (Svarlien, 2008) proposed inclusion of the pregnant women as a phase two of development.

Given the fact that a lot of the information that is to be included is already in the local EHR systems, the conclusion has been that a silo-system without integration would not support the actual needs. Shared data-systems should be available both in local EHR systems in primary and specialist care (Krossen and Roland, 2007; Bach et al., 2005). An electronic solution, including opportunities for automatic information retrieval and information updates, demands a common dataset with definitions of content. The challenges in establishing one common dataset is that there has not been a decision as to who should collect and unify the definitions, there lacks an overview of definitions used in different EHR systems and that the definitions are not determined collectively (Svarlien, 2008). To summarise: work identifying what information elements that are to be included should be first priority.

Even though antenatal care is seen as "the perfect" area to develop bridging health records and attempts of establishing electronic solutions have been made, there is today no national electronic solution for antenatal health records in Norway. However, one solution is in use in central Norway. The system, Natus, is available in the Trondheim area, so it has been an aim of this thesis to obtain user experience of the use of this system.

In summary the establishment of a national system for antenatal electronic health record is complicated in that it comprise much more than just the definition of an electronic message as a counterpart to the paper record. Maybe it is an ideal case for testing new ways of electronic collaboration in health – but it is not an easy one. Some of the challenges are:

- Different organisations need to co-operate and conclude which solution is most fit-for-purpose
- Requirements for a regional or central database vs. message exchanges between many independent systems have not been fully investigated
- Legislation for a centralised solution (regional or national level) has not been available in Norway
- A solution and investigation for an integrated approach to the antenatal health record vis-à- vis other health record information has not been fully established.
- No common dataset with all definitions is established

And finally, is it a good idea to deploy a separate system for this type of specialised information (ideal for following a normal pregnancy) when so much effort goes into the development of general-purpose EHR systems? The local EHRs include additional information for the more complicated pregnancies. Is it meaningful to continue message-based development (for Norway only) or should a movement towards a methodology based on international standards such as the archetypes be advocated?

4.2   International experiences

The purpose of the antenatal health records may vary to some degree from country to country. Still, when searching in relevant literature, antenatal health records seem to be quite similar regardless of what country the literature originates from. The list below summarises the objectives found in literature:

Antenatal health records are:

i. Essential for individual care to support a continuous health care for the pregnant women and for the monitoring of worrisome trends by easily detecting problems and concerns (HOD, 2009; Phelan, 2008; Bansler et al., 2007; Helsedirektoratet, 2005).
ii. A complete documentation of a comprehensive prenatal care and risk assessment triage (HOD, 2009; Phelan, 2008; Svarlien, 2008)
iii. A communication tool in between the health care providers (Phelan, 2008; HOD, 2009; Helsedir., 2005)
iv. Supporting ancillary functions like patient education, billing, reimbursements and other necessary documentation for the health care workflow (Hasley, 2011; Phelan, 2008; Helsedir., 2005)

v.   A standardised record that is systematically updated (Phelan, 2008; Svarlien, 2008)

vi.   A documentation of quality indicators (HOD, 2009; Phelan, 2008)

vii.   A check-list to serve as reminder for key components of care (Hasley, 2011; Phelan, 2008)

Internationally the status of electronic antenatal health records seems much the same as in Norway. The exception is Sweden where Obstetrix, developed 20 years ago, is used for a great majority of the antenatal health records in both outpatient clinics and delivery units. The birth module in Obstetrix was also used at Oslo University Hospital until March 2014. Another EHR vendor in Sweden, Cambio has recently developed an alternative solution that is integrated with the EHR system used for other patients. This solution is a potential advantage for the women with a complicated health history which does not comply with an antenatal health record, and for the transfer of data from the foetal state to the paediatrics recording to continue the post-partum treatment (Cambio Healthcare Systems, 2012; Siemens, 2012). Other initiatives include attempts to establish one antenatal EHR in a national health platform whilst other projects have focused on making the information from local EHR systems available to other health personnel as well as the pregnant women by the use of USB sticks, smartcards etc. (Helse- og omsorgsdepartementet, 2012; Holmberg, 2012; House of Commons, 2011; Fawdry et al., 2011; Wäckerle et al., 2010; Bansler et al., 2007; Krossen and Roland, 2007).

Most projects and solutions that have been developed and tested have a common end result; they are not in use today. The reasons for termination are many, but the overall conclusion is that the "perfect area of health" often is underestimated in regards to its complexity. The Danish project failed because of inadequate equipment for electronic documentation in the specific facilities where the check-ups and ultrasound diagnostic test were performed. This resulted in extra workload for the health personnel due to the need for registration of data after the check-ups were performed (Bansler et al., 2007). Other projects have reported that the challenges lies within the numerous actors involved, most of which have their own solitary EHR system, and that the interoperability between these actors and their EHRs have been difficult to handle. The two systems in use in Sweden, Cambio and Obstetrix, has to my knowledge yet no functionality supporting electronic availability for expecting women. The ambition to

make the antenatal health record available to the expecting women makes the interoperability even harder to solve.

4.2.1 Northern Territory Shared Electronic Health Record

A current project in Northern Territory of Australia attempts to establish an electronic antenatal health record. The record consists of information elements found in two primary care systems and it is developed with archetypes to be shared in a shared atomised data repository. A third party developer carries out the development of an antenatal health record/ care plan. This electronic antenatal health record will provide health care professionals with reading, writing and decision support functionalities. The information is then sent back to the primary care system with a transformation from the archetype format. Further plans are to include the information in the My eHealth Record[2]. A national initiative in Australia is the establishment of a paper-based National Antenatal Shared Health Record. This project is in its final approval process (Leslie, 2013).

4.2.2 Flexibility of paper

Other reports comment that the flexibility of paper records has not been sufficiently acknowledged (Fawdry et al., 2011). With an experienced glance of an eye, health care professionals can quickly determine status of a pregnancy when the pregnant women has brought their antenatal health record with them to all their check-ups. All the evaluations are then collected in a structured way and all relevant information is gathered in one document. Still, the paper versions are not problem free in that they easily can be lost or damaged and provided space for documentation are often to small in size. Also, creating a record that encompasses all the information that ought to be there can make the records very large. Fawdry et al (2011) comments that St.Thomas´ Hospital has a 75-page antenatal record while the new Australian health record has 19 pages. With a paper based antenatal health record the women have gained some degree of empowerment in that they have access to all health information in relation to their pregnancy and they can choose to whom they want to share this information. This was also concurred by the interviewed medical specialist:

> *... the document is the woman's possession. It is not a complete health record, it is a document where she also can decide what should be documented or not. For*

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[2] http://www.myehealthrecord.com.au/Pages/default.aspx

instance, it the woman previously has been raped or that she is a battered wife, she
can decide if that information should be included on the paper based record. In a
complete health record on the other hand, this information should be documented.
So this in turn enhances the woman's feel of coping. This has also been documented
in previous studies.

4.2.3 Challenges with implementation

In previous chapters it has been shown that many earlier projects are not in use today. Indirectly it has been stated that the projects have not been a success. Berg (2001) argues that there are many ways a project or system implementation can be regarded as a success or not. One system can be regarded as a success economically, in that it did not exceed its budget or cost reductions have been met due to workforce downsizing, that systems are up and running or they were implemented on time according to implementation plan. Other factors of success could be seen as the number of users that use the system or in fact the high appreciation the system has by its users. In sum success has "…many dimensions: effectiveness, efficiency, organizational attitudes and commitment, worker satisfaction, patient satisfaction…"(Berg, 2001:145). As regards abovementioned projects they all were a success in regards patient satisfaction. The patient being the pregnant women; they had access to their information and several said they were satisfied with the systems (Holmberg, 2012; Wäckerle et al., 2010). However, in regards to worker satisfaction and efficiency the projects were not a success: there was an increase in health professionals workload, they had to re-enter already documented information and collectively this was negatively affected their satisfaction with the systems (Bansler et al., 2007).

Implementation of electronic support systems will fundamentally affect health care work processes and the organisational structures in health care. When introducing electronic health records the documentation practices will be altered and they also raise concerns about who will have access to the data and under what conditions this will happen. This will in turn set off user processes and discussions concerning "… who gets to fill in what parts of the record, who "owns" what information, and who gets to check on whose work" (Berg, 2001:147). Concerning intra-organisational cooperative health records used in antenatal health care, these processes should not be underestimated. In

former responses to reports, as summarised by Svarlien (2008) some comments did encapsulate those kinds of concerns. Also, when implementing electronic support systems one should have a clear view of the sociotechnical change this imposes on an organisation (Ellingsen et al., 2007; Hanseth et al., 2003; Berg, 2001). With this in focus, adequate end-user involvement is key.

Early involvement and thorough investigations through participant observation and in-depth interviews are seen as useful techniques for the in depth study of social organisation of work processes (Berg, 2001). However, system implementation should not entirely focus on adapting to current work practices. An introduction can have positive results in changing and shaping current work practices into newer and maybe more efficient ways of performing health care. There should be a clear vision in what way a system should be developed according to current work practices and in what ways a system can positively impact with new work practices in the organisation (Berg, 2001).

A case study regarding the implementation of electronic support systems in health care sums up with three essential factors that are important for a successful and positive enhancement of an implementation:

i.   *"It is useful to have a big focus on clinical work processes and workflow as early as possible in a project involving development- and implementation of a electronic support system"*

ii.   *"It is useful to involve end users well ahead prior to the implementation of a new system"*

iii. *"It is useful to identify core concepts and to ensure common perceptions of these for all actors"*

(Eltvik and Torsvik, 2013:148–149)

4.2.4   The impact of legislation

In Norway, many of the current challenges in the sharing of information between health care professionals in different health care sectors and between different health care organisations, stem from current legislation. In comparison with Sweden, a country that resembles Norway in many aspects, the structure of health care provision in the two countries is quite different. Norwegian health care sector is divided into three layers

with main responsibility for the provision of specialised health care within the four regional health authorities and primary care by the municipalities. In Sweden the county councils/regions are responsible for provision and funding of health care services to their population (Anell and Glenngård, 2012). The different organisational structures of health care in the two countries impact how collaboration between specialist health care and primary health care is performed. In Sweden the organisational structure supports collaboration between entities by shared use of health records also where the entities have different owners, while in Norway there are different owners and strict regulations as to how, to whom and for what reason information is shared between the different legislative entities. Hence, legislative regulations have challenged the collaboration between cooperating health care professionals in Norway.

In January 2012 an amendment in the Personal Health Data Filing Systems Act (Helseregisterloven, 2001) took effect allowing the establishment of inter-institutional personal health data filing systems, established for therapeutic purposes (§6a). To date no actual inter-institutional systems have been established, but the future will show if the amendment will allow for a greater collaboration in Norwegian health care in terms of interoperability between different EHR systems. The newly published National Plan of Action for eHealth describes a strategy for further investigations into collaborative and commonly utilised electronic health records (Helsedir., 2014).

4.3   Documentation process with paper based antenatal health record

When the paper based antenatal health record is used in every check-up and consultation, the record gives a thorough and complete picture of the current pregnancy, and a good basis for the evaluation of necessary actions to identify potential risk factors related to pregnancy and birth (Svarlien, 2008). It is routine by health care providers to document antenatal care in local EHR system in addition to the paper based antenatal health record. This double-documentation serves as a backup and as long as the woman has check-ups with the one health care provider, omissions of bringing the paper based antenatal health record to check-ups have little impact. The challenge arises when the women alternate between GPs and midwife (-s), as was the case for approximately 63% of pregnant women in 2011 (Sjetne et al., 2013).

If there are any risk factors that require special precautions or medical treatment, this is commented in the antenatal health record but detailed documentation has to be included in the local EHR system. *Antenatal health record contains only data from basic screening of apparently healthy women* (interviewed specialist). The specialist then summarised the process as *we use antenatal health record to document any deviations from basic antenatal care, but the deviation itself unleashes the need for a completely different documentation system*. The midwives that were interviewed concurred this to: *As you know there is little room for documentation on the paper based record. So if preeclampsia or gestational diabetes for instance occurs, then I have to document thoroughly in my local EHR system.*

The World Health Organisation (WHO) has estimated that 25% of total pregnant population have a condition or a risk factor that requires special care in addition to basic antenatal program (HOD, 2009; Helsedirektoratet, 2005). This means that for every fourth woman the antenatal health record will not serve as a complete documentation of the pregnancy. This also means that the local EHR system is not only serving as a back up, it contains highly relevant information about the pregnancy and health that is not documented elsewhere. The doctors interviewed further commented:

> *Everyone that provides antenatal health care will have to document in a local EHR independently of the paper based antenatal record. The purpose for documenting in local EHR is different from the intention of documenting in the paper based record. They* [local EHR systems] *are looked upon as our tool where we can document our actions and evaluations. Additionally the local EHR is used in complaints* [complaints about health care received]*, so it is a necessity to have full determination of its content and that it cannot get lost* [like the paper based record can]*.*

The risk of not having a complete documentation of a pregnancy is in addition heightened since 63% of the women alternate between check-ups with their GP and midwife.

The aim of chapter 3 and 4 was to give an overview of basic antenatal health programs and which health registries are in use within antenatal health care. The potentials of

structured data for reuse in medical registries have been introduced. Challenges with today´s registers for antenatal care in Norway have been identified and relate to:

– Having a complete documentation of pregnancy and health,

– Access to the documentation for all relevant parties,

– Restrictions and opportunities within legislation and work processes and

– Current demands of security and efficiency.

Previous Norwegian projects have tried to establish electronic solutions for antenatal health records, but the predominant result is negative and thus no sustainable national system is in use in Norway today. The National Clinical Guideline for Antenatal Care is described and with it the statement that a structured health record should be used.

The following chapters are concentrated around the idea of utilising dual-modelling and structured clinical content for the realisation of an electronic antenatal health record. When mowing into the realm of electronic health records, additional considerations have to be investigated thoroughly. In chapter 5 standardisation activities and implications for health care are investigated. The concepts of structuring of data and communication in general, and health care specifically are discussed in chapter 6. An introduction to dual modelling and structuring of clinical content is provided in chapters 7 and 8. In chapter 9 the final connection between antenatal health care and dual modelling is presented, with the utilisation and implementation of the openEHR design process.

5 Standardisation

In a well-functioning IT system in the health area, i.e. electronic health records (EHRs), there are many advantages:

- More reliable data collection and distribution of data,
- Faster electronically transmission of letters and reports,
- Potential access to data from anywhere,
- Reduced duplication of data and
- Potential for electronic translation.

Also, accessibility of electronic records plays a significant role in research and the reuse of data that have been collected. There are challenges in meeting all these potential advantages however, as to securing interoperability in between the systems and in establishing systems that all are developed using the same standards (Helsedir., 2014).

The general idea of standardising of ICT systems is not new, including standardisation in in the health care domain. Standards are available today with regards to programming languages, protocols, operating systems and file formats to mention a few. The reasons for requesting the use of standards vary by the different interest groups. Efforts to improve efficiency and sufficient quality of treatment and care in the health domain are key factors by the health authorities (Ellingsen et al., 2007). Digitalising and standardising enables aggregation and analysis of data at population level. By analysing at population level one is enabling the use of "…various indicators, benchmarks and trends of public health issues" (European Union et al., 2009:25). Standards that represent outcome specifications, like the Norwegian standard *EPJ standard Part 1-6* and the *ISO EN 13606 standard,* detail requirements to ensure compatibility, integration and support logistics in EHR systems. Other standards have been developed "… to ensure consistency of meaning across time and place" (Ellingsen et al., 2007:311). These terminological types of standards are heavily represented in health care and have existed for many years. Examples are ICD (International Classification of Diseases), SNOMED (Systematized Nomenclature of Medicine) and NANDA (North American Nursing Diagnosis Association) to mention some. The use of

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these standards enables opportunities as quality assurance work, ancillary functions as well as research at local, national and international level as they are internationally adopted. Movements and users call for the need to extend focus from standardisation of products and artefacts, to develop and include standards that support workflow within the EHR systems (Ellingsen et al., 2007; Nasjonal IKT, 2007). The National Clinical Guideline for Antenatal Care is one example of a standard that to some extent supports workflows, protocols and care plans.

Although trends are shifting, there has not been one specific (or one set of specific) standard in use in electronic solutions used within health care. The different vendors of health information systems have been able to choose (or develop their own) standards resulting in numerous standards and ways of using them (Kawamoto et al., 2010). Accordingly the different customers have had a great degree of freedom to choose the system they found best suited their needs. This again has resulted in numerous systems with many different designs and standards. There are demands however of the utilisation of national standards found in Volven[3] as well as utilising internationally recognised standards (Helsedir., 2014). The proposed requirement document for an electronic antenatal health record (Svarlien, 2008) have included requirements for the utilisation of terminologies and standards found in Volven.

5.1   The standardisation process

Internationally there are a number of organisations that establish standard that provide requirements and specifications as rules/ guidelines in their specific field. The process of developing a new standard is started when it is requested from the industry or other stakeholders. The process of developing design, performance and terminological standards is fulfilled with involvement of all stakeholders, through a transparent process and with a consensus on the final result (CEN, 2012; ISO, 2012). The standards development cycle with a voluntary, open participation and committee-based consensus decision-making allows interested parties to contribute and adjust the final standard. Note that interested parties (stakeholders) are normally experts from the relevant industry, but can also include academia, consumer organisations, non-governmental organisations and governments. However, many comment on the

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[3] http://www.volven.no/

standards development cycle being very time-consuming and therefore not keeping up the pace with technical development. Standardisation organisations should continually improve their timeliness and performance to ensure that the results meet the expectations of the interested parties. In 2009 the development cycle was reduced to an average of 32,8 months, a decrease of 30% since 2002 (Holmblad, 2011; Lehr, 1992).

Present work will not further investigate how time-usage in standards development cycles are compared to clinical content standardisation activities with archetypes. The history of openEHR and archetype development is short and only limited scientific investigations exists as yet. However it can be argued that development of information model standards and standardisation of clinical content is not comparable, as the outcomes and main stakeholders of these two activities are quite different.

Literature review has resulted in only one report on time usage in a dual-modelling project with archetypes and templates. The project, the Brazilian project of a Regional EHR System of Minas Gerais State, used about ten months to complete the whole archetype development process (Santos et al., 2012). It will be very interesting to follow how standardisation activities within dual modelling and archetypes compare over time and detailed description of work as described by Santos et al, should be encouraged. As the archetype and dual-modelling community grows and more developed archetypes are available for reuse, one could assume that ten months development time can be reduced. Still, there are activities that all development projects involving archetypes have to perform; defining data sets and clinical concepts and research for existing archetypes. The Brazilian project used 120 days and 45 days when performing these activities respectively.

5.1.1 Standardisation organisations

There is a close relationship between the standardisation bodies internationally, on the European level and finally on the national level. Within the area of health and ICT in Norway, the organisations with the greatest impact are the International Organization for Standardization (ISO), the European Committee for Standardization (CEN) and finally Standards Norway.

ISO is a network of national standards organisations. The network is independent and non-governmental, and is made up of the members of the different national standard bodies. These national standard bodies also represent ISO in their country. ISO develop voluntary international standards (ISO, 2012). Within the field of health informatics the main standard to notice is the ISO 13606 "Health informatics – Electronic health record communication".

CEN works with its national members to develop European standards (ENs). The national members consist of the European Union members plus Switzerland, Iceland and Norway. CEN is a major provider of standards and technical specifications in Europe (CEN, 2012). CEN has adopted ISO 13606; hence the most often cited reference to this standard is ISO EN 13606.

Standards Norway is Norway's representative in both ISO and CEN, and responsible for Norway's participation in both European and global standardisation work. The membership in CEN and The Agreement on the European Economic Area (EEA agreement) means that a European standard becomes a national standard in Norway, as for all the other member countries. An ISO standard may not be endorsed as a national standard (EFTA, 2013; Standard Norge, 2012).

In addition to European standards becoming Norwegian standards through the EEA agreement, there are regulations for inclusion of standards within ICT systems in the health domain when specified by the organisations that are to use the ICT system. In Norway examples of such organisations are the Norwegian Directorate of Health, the regional health authorities or health care agents in hospitals and in the primary care sector.

5.2 Standards adoption

Once a standard is finalised and approved, the industry to which the standard is relevant shall adapt to the standard. Challenges may arise when an international standard is approved and there is already an existing national standard within the same field. The EPJ-standard (part 1-6) was developed simultaneously with the ISO EN 13606. The two standards have slight different objectives; the basic EPJ- standard is more general than the ISO EN 13606. Investigations show however that information

registered in line with the requirements in ISO EN 13606 can be represented in an EPJ-standard compliant EHR system without loss of information (Nasjonal IKT, 2012).

There are agents that argue that traditional standardising efforts are top-down, with little focus on standardisation of work and routines (Ellingsen et al., 2007). There are many clinical guidelines and protocols; the challenge is often how to follow the different procedural standards, while using the terminological standards and documenting clinical information in electronic health records (EHRs). One can argue that the EHRs are packages of standards, built on technical (design and performance) standards while embedding terminological and procedural standards (Hanseth et al., 2003). One cannot however see beyond the fact that there is a socio-technical complexity in information systems and there has been argued that one should further proceed into a co-constructive perspective where standardisation and work practice mutually shape and constitute each other. Standards should incorporate current clinical practices and clinicians must be able to conform to the standards while communicating with relevant parties in daily clinical work practice (Pirnejad et al., 2008; Ellingsen et al., 2007; Nasjonal IKT, 2007; Stefanelli, 2004; Hanseth et al., 2003).

5.3   Standardisation of clinical work

Arguments have been made about the need for embracing the socio-technical complexity with a co-constructive perspective where standardisation and work practice mutually shape and constitute each other. In other words, standards should incorporate clinical work practices. Additionally in work continuing the national strategy for electronic health record in Norway, requirements for having EHR system that support clinical processes have been identified (Nasjonal IKT, 2007).

In chapter 3.2 the National Clinical Guideline for Antenatal Care was introduced. Guidelines are documents compiled for clinical ease of use and include recommendations for any topic, disease or as in this case pregnancy. Hovenga et al (2007) have compared the processes of guideline development with archetype development, and in their view the design processes have several similarities. Both should convey best available evidence and be the result of a multidisciplinary approach with focus on clinical practice, implementation and evaluation. They further

differentiate between guidelines and archetypes with that clinical practice guidelines "…require evidence about appropriate interventions to solve specific clinical problems [while archetypes] require evidence about the fundamental knowledge object, including the specifics detailing how each aspect of an intervention is undertaken and documented" (2007:9). Most clinical practice guidelines can only be found in paper-documents (although electronically available) as of today. Many projects however try to incorporate knowledge found in EHR systems and clinical guidelines into computer programs specifically aimed at helping health professionals make clinical decisions. These types of programs are called Clinical decision-support systems (CDSSs).

Marcos et al (2013) have performed a case study involving the utilisation of archetypes to achieve interoperability between CDSSs and EHRs. In their work they found that using archetypes offered advantages in medical and technical validity, semantic descriptions and also at the data model perspective. The creation of a standardised form of CDSSs are however not an easy task, as Garcia et al (2013) describe. Clinical guidelines also, in addition to clinical data, describe the relationship between the data needed for decision-making. Although the challenges in the area of clinical decision-support systems are continuously being worked on by many, it is interesting to see the additional potential archetype development and usage of them in electronic health records may contribute to overcoming present challenges. This thesis does not further investigate clinical decision-support systems or the use of clinical guidelines within such systems. It should be noted however that work with developing a Guideline Definition Language (GDL) is currently being undertaken [4].

5.4 The openEHR foundation – bridging the socio-technical divide?

The openEHR foundation is an international not-for-profit organisation formally established in 1999. Although the foundation is not a standardisation organisation as such, it participates in the development of international standards and develops open specifications and open-source software. While not directly aiming to incorporate clinical guidelines, protocols and care plans into EHR systems, the openEHR Foundations key focus is to establish two-level modelling by the use of archetypes and templates. Within the different archetypes and templates the connection to

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[4] http://openehr.org/news_events/releases.php?id=79

terminological standards is established. The formalisation of the archetypes and templates are based on the ISO EN 13606.

Different projects internationally have worked with archetypes and templates to validate if the dual model approach can represent clinical information as well as supporting procedural standards like guidelines and different regional and national standards (Marcos et al., 2013; Rosenälv and Lundell, 2012; Santos et al., 2012; Hovenga et al., 2007). Although future holds the truth about the outcome of many of these projects, the different projects argue that the dual modelling approach seems to support the need for unambiguous clinical data input and reuse while supporting the different standard requirements.

The dual model approach is further presented and discussed in chapter 8 and 9.

5.4.1   Design specifications

It is a great challenge to design and agree on the specifications for changeable concepts that are to be represented by archetypes. Several studies and articles stress the need for including health professionals in the design work. This is in line with the proposed development process; that domain experts should develop the knowledge level. Technical support staff facilitates the technical design process of archetypes, while the domain specialists focus more on the actual content (Nasjonal IKT, 2012; Kalra et al., 2012; Santos et al., 2012; Buck et al., 2009; Leslie et al., 2009; Hovenga et al., 2007; Michelsen et al., 2005).

The aim is nevertheless to reach international agreement on clinical knowledge. Thus, when agreements are met, the archetypes can be implemented and used throughout the health care sector both locally, nationally as well as internationally (Nasjonal IKT, 2011; Nasjonal IKT and KITH, 2009). This however is dependent on implementation of a common reference model.

5.5   Visions for semantic interoperability in the European Union

The SemanticHEALTH project has in the report *Semantic Interoperability for Better Health and Safer Healthcare* developed a roadmap for research and deployment strategies for the realisation of semantic interoperability. The vision is "... to identify key steps towards realising semantic interoperability across the whole health value system, thereby focusing on the needs of patient care, biomedical and clinical research

as well as of public health through the re-use of primary health data" (European Union et al., 2009:2). They have established short and long-term goals:

- Development of a network for terminologies and archetypes

- Establish links between tools in order to implement collaborative web-based workflows

- Creation of resource centres where users can get quick responses

- Create environments for a coordinated development of terminologies and EHR standards

- Create environments for the linking of terminologies to archetypes and CEN EN 13606 standard

- Greater involvement of end-users, create feelings of ownership

(2009:23–24).

The report summarises present challenges and the vision for a EU with nationwide collaboration in eHealth. When the visions depicted in *Semantic Interoperability for Better Health and Safer Healthcare* are realised, these will no doubt heavily influence eHealth also in Norway.

Chapter 5 gives a summarised overview of standardisation activities and implications for health care. Activities relating to standardisation of clinical content have been identified, and with this clinical modelling activities with archetypes and templates have been introduced. The visions regarding semantic interoperability within European Union has been presented giving a taste of international activities that may influence future development of clinical ICT systems also in Norway. This serves as background information giving an understanding of the complexities of standardisation activities, specifically within the health care domain. Use of time in standardisation activities has been discussed, with reference to what has been one of key selling points by the dual-modelling community: reduction of time used in standardising of clinical content. To what degree this notion actually is valid has not however been clearly identified, as surveys and reports discussing dual-modelling rarely include information about time-usage.

Chapter 6 will investigate further communication activities while subsequent chapters will introduce dual modelling and structuring of clinical content (Chapters 7 and 8).

6   Structuring and communication

Electronic health records supports various needs; they are used as a database containing all relevant information about the patients and are the basis of which many of the clinical actions and treatment choices are made upon. In addition to these important areas of use, is the fact that the EHR is a basis on which health professionals, health organisations and other stakeholders communicate.

Information within the system again shapes clinical actions, treatment choice and investigation. When information about patients is difficult to obtain, information exchanges may have a poor quality resulting in a poorer quality of clinical care. Clinicians create input to the system by communicating with other health professionals and patients, either in an active direct dialogue, or by evaluating the existing documentation within the system. In antenatal health care the paper based record is used for communication, with the pregnant women as information conveyers.
In order to support communication, either within an EHR system or between different systems, a fundamental prerequisite is some degree of standardisation and structuring. To what extent standardisation has to be fulfilled depend on what communication scenario that is to be fulfilled (Pirnejad et al., 2008; Stefanelli, 2004; Coiera, 2003).

6.1   Structuring in electronic health records

The need for communication, with an opportunity of gaining relevant information quickly, has resulted in electronic health information systems with a certain degree of structuring. The degree of structure for clinical content is limited however, as todays electronic health records primarily have been centred around production of clinical documents (Nasjonal IKT, 2007).

Information about patients is collated in different types of documents, stored in different folders. Most systems have one folder per health profession group (i.e. nursing, medical, dental etc.), so the number of folders may be multiple. The documents are structured with different headings depending of the health professional group utilises the document. In general one can simplify that headings within the documents are used

to structure information that belongs together. Examples are allergy information, nutrition status, medical and nursing diagnosis etc.

The ISO EN 13606 standard has communication of EHR extract as objective and has taken into account the hierarchical design of EHR systems. The EHR extract (reference model) is developed consisting of sub-divisions in order to be consistent with a hierarchical design (ISO, 2008). The standard recognises that archetypes may be used to support semantic interoperability, but the use of archetypes is not mandatory within the standard.

Health professionals interviewed in this work look upon the highly structured format of the antenatal record as a great feature as it quickly gives an overview of a pregnant woman's health status. When interviewed, the general concern was how an electronic solution may convey and visualise needed information in the same highly structured way as present paper-based record.

6.2   Communication

Activities of performing health care services rely heavily on communication between the different actors. If communication fails the results may not only affect the actual health care delivery, but it may also give the result of unnecessary referrals, repeated investigations or poorly informed clinical practice (Pirnejad et al., 2008; Coiera, 2003). In Norwegian antenatal health care, the tool for enabling communication between health care providers is the paper based antenatal health record (Phelan, 2008; HOD, 2009; Helsedir., 2005). The semi-structured 1-page A4-form gives a quick overview and is a good basis for the evaluation of current pregnancy. The challenge rises if the record does not contain information from every check-up, if the record is lost or if the woman have a condition or risk factor (-s) that requires specialised care in addition to the usual maternal care. According to World Health Organization the latter group represent 25% of total pregnant women population (HOD, 2009; Helsedir., 2005). If specialised care is needed, the antenatal health record will not give a complete overview of the pregnancy, as the documentation of care will be found in the local hospital / or specialists EHR system.

6.2.1 Challenges in communication

The challenge in communication is ensuring that the message sent contains same information as the message received. The structure of the message determines how well it is understood, and the actual knowledge base of the sending party and the recipient may wary (Coiera, 2003). Knowledge as a whole cannot be contained and gathered completely in an information system, i.e. the people working in health care also have explicit and implicit knowledge they use when performing health care evaluations and actions and the communication that occurs as a result of this (Stefanelli, 2004).

The knowledge shared by two communicating parties to enable communication, is known as common ground (Kuziemsky and Varpio, 2010). In antenatal health care, the providers of health care most likely share same knowledge, i.e. they share common ground. In an electronic health record there is an unambiguous criterion to establish a common knowledge base. A common knowledge base will, in addition to standardise and structure an EHR system, enhance the quality of communication between the different actors with the reduction of distorting channels.

6.2.2 Semantic interoperability with openEHR archetypes

Within healthcare, including antenatal, the different information systems used (EHRs) by the different health care provides, must be able to interoperate. Challenges in existing interoperability efforts are that the design existing systems are based on different types of standards. This gives the result of having different granularity leaving interoperability a major challenge since one-to-one mapping is not achievable (Kawamoto et al., 2010). In order to be a quality communication the systems should understand the context and meaning of the information provided by another system (Garde et al., 2007). Electronic communication that includes context and meaning is called semantic interoperability. Systems have semantic interoperability when information "… entered in one system can be used by another system and its users just as well as if the information originated from the same system" (Sundvall, 2013:10).

In order to support semantic interoperability the sender of a message should know what knowledge base the receiver of the message has, thus the different agents should share common ground between them. Without common ground, the communication

depends on what the sending agent think is the knowledge base of the recipient of the message.

Although archetypes aren´t a formalised standard, the use of archetypes formalise and separate knowledge- and reference models (database). Standards can be seen upon as a publicly agreed common ground, and with the use of archetypes the different agents in a message communication will have the same knowledge base. When archetypes are used the agents have a good change in understanding what the message means.

When comparing the communication with and without common ground, the nature of message communication will be altered:
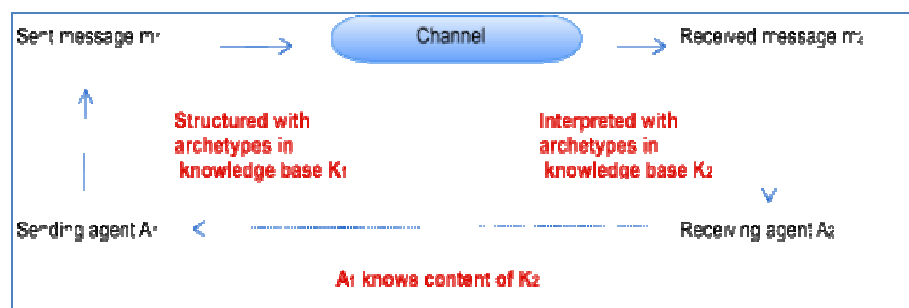
Figure 1 Messages and agents - with common ground (revised from Coiera, 2003)

One can therefore conclude that the proposed work of establishing a set of archetypes and templates with internal structures, rules and associated data model to be used within antenatal health care, is one way of establishing semantic interoperability. Still, work has to be done in order for the different health care agents to take into use an established common ground designed with archetypes. One shall not however underestimate that common ground contains both static as well as dynamic aspects, so a key factor is to keep the common ground up to speed with a rapidly evolving clinical knowledge (Kuziemsky and Varpio, 2010).

6.3   Reuse of information

The structure of paper based antenatal health records support communication between health professionals. When it is properly used one health professional can reuse previous documented information (on the card) in their clinical evaluation of the pregnant woman and her baby (-ies). The health professionals interviewed in this work collectively argue that the high level of structure is the foremost key value of the paper

based system. When discussing reporting however, the health professionals comment on challenges in reporting needed information as the information may not have been documented and time used for reporting comes in conflict to attending other women that also are under their care at the time of issuing reports.

Electronic solutions have an advantage in being able to support communication activities within EHR systems, as well as between systems and health care institutions. Challenges in the actual structuring of clinical data will be further discussed in following chapters. However, having structured data may provide other follow-on effects both in terms of reporting, for administrative purposes as well as for aggregation and analysis of data at population level (Helsedir., 2014; Rosenälv and Lundell, 2012; Wollersheim et al., 2009). The National Health Registry Project has identified key moves for the realisation of continuously updated, reliable and secure health registries. These are requirements of an integrated model for technological solutions and structured data. The responders in interviews commented on time-challenges in reporting activities, but more importantly they admitted that many reports to the National Birth Registry were incomplete and of less good quality. They collectively saw upon structuring of clinical content as giving great potential in heightening quality of data in the antenatal health record itself, but also having a health register with complete and reliable content. The interviewed midwives commented the perceived benefits regarding reporting activities as very positive. They saw this as positive features of an electronic antenatal health care record.

Archetypes are not designed for be used in reporting specifically, but their structure facilitate querying for specific needs (Wollersheim et al., 2009). On the other hand, other initiatives have identified challenges in direct reuse of clinical data captured in health registries like National Birth Registry. This initiative, a Swedish project called IFK2 (2010, in Nasjonal IKT, 2012) needed to develop new archetypes to support content extraction for registries as reuse of existing ones did not provide sufficient data collection. Work performed in this thesis does not include further investigations into potential challenges with archetypes and clinical content in direct reuse for reporting issues. On the other hand it should be noted that openEHR has developed Archetype

Query Language (AQL) that is aimed for direct reuse of clinical data represented with archetypes[5].

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[5]http://www.openehr.org/wiki/display/spec/Archetype+Query+Language+Description#ArchetypeQueryLanguageDescription-WhatisAQL?

7 openEHR

Semantic interoperability is reached when the electronic communication includes context and meaning of the information provided by one system to another. This means that there has to be a consistent way of representing every conceivable kind of health record structure, with the semantics intact (ISO, 2008; Garde et al., 2007). Reaching semantic interoperability is described as one of key challenges within ICT systems, also within the health care domain.

7.1 Dual modelling

There are several ways systems can be developed. Historically system development has been characterised as "single-level" development, i.e. that "… both informational and knowledge concepts are built into one level of object and data models" (Beale, 2002:1). The openEHR foundation proposes a change in how systems should be developed by separating the semantics of information and knowledge into two separated (but linked) models. By doing this the concerns of record keeping can be separated from the clinical data collection. Duplication of data can be minimised and future changes and extension in the knowledge model is supported without the need for changing the basic functions of a system (Garde et al., 2007; Michelsen et al., 2005; Coiera, 2003). Erlikh suggests that 85-90% of an organisations costs concerning software is evolution costs(2000 in Sommerville, 2011). Other surveys adjust this number to that evolution costs of software add up to 2/3 of total costs. Undoubtedly the numbers are high given the clinical domain is constantly encompassing new knowledge and include new and improved technology (Michelsen et al., 2005; Rector 2001 in Beale, 2002).

With the dual model approach of system development, domain specialists (for example clinicians) now have the possibility of preparing ICT systems and information within them that are future-proof. However great the benefits of a dual model methodology seems, the challenges in developing in line with this methodology should not be thought upon as trivial. This methodology is the most complex of information structures as the database and knowledge base is defined as separate entities. After the development, these models have to be cross-linked. Beale (2002) describes challenges in the

methodology as knowing how to perform the separation of concepts, how to structure each of the models at each level, to understand the relationship (cross-linkage) between the models, and finally to understand how to develop EHR systems on the first level, but which are aware of the second.

In the following chapters the main focus will be on the second level, i.e. the knowledge level with archetypes. This is due to the fact that the focus of this thesis is not so much on the technical aspects of an actual development of an EHR system, but more on the need for a knowledge model, based upon an established common ground, to be used within antenatal health care delivery.

7.2   First level of model – the reference model (RM)

The reference model (RM) is a key factor in order to secure semantic interoperability. The model ensures that clinicians always can "…send information to another provider and receive information which they can read" (Garde et al., 2007:333). The reference model comprises the bare minimum of what is needed to represent the characteristics of health record components, i.e. the RM depicts concepts that are stable over time and generic. In order to be comprehensible the model should be small of size (ISO, 2008; Garde et al., 2007; Michelsen et al., 2005). The challenge is to find the non-volatile classes that create the information model (the RM). In general, only reasonably abstract classes will be defined in the reference model and only those classes, relationships and attributes that are truly non-volatile over time should be included (Beale, 2002).

7.3   Second level of model – the knowledge level with archetypes

In the knowledge level, concepts that are changeable are included and described with archetypes. Generally speaking one can say that an archetype is a specification of the clinical contents in an EHR. The archetypes describe complex and rich information structures by indicating how clinical information is to be expressed, indicating rules as to what information that is optional and what is mandatory, proposing and allowing sensible values for the different data elements and finally including any other potential rules that need to be included and expressed. The purpose of archetypes is to ensure that only data elements with a certain structure can be added into an electronic health record (EHR) (Hovenga et al., 2007; Michelsen et al., 2005).

One archetype represents one clinical concept (or other specific concept in the health domain) by including constraints to the different instances in the information model. By constraining the information models valid structures, data types and values are expressed. The aim when designing archetypes is to standardise clinical content as much as possible, but still allow the flexibility needed for a proper usage of them (Garde et al., 2007; Hovenga et al., 2007). The flexibility of an archetype is also enhanced by the possibility of translating archetypes to any other language; terms entered in one language can automatically be displayed in another language. Additionally, terms within archetypes can be bound to (linked with) any number of different terminology standards; either internationally recognised standards, national standards or they can be specified within each archetype if they are highly specific to the archetyped concept (Sundvall, 2013; Hovenga et al., 2007). The numbers of clinical concepts are multiple, so the knowledge level represented with archetypes demands its own structure and formalism.

7.4 Types of archetypes

The openEHR reference model (RM) has distinct classes and provides the attributes and structures for these. While the archetypes correspond to the classes in the RM, they additionally have attributes that correspond to the different clinical processes (Heard, 2011). The ISO EN 13606-1 standard describes the components of the EHR Extract Reference Model (RM). Archetypes correspond to the EHR Extract RM.

Figure 2 EHR Extract Reference Model and openEHR archetypes

The four main types of archetypes that are useful to understand, especially from a clinicians view, are the following:

Compositions Correspond to commonly used clinical documents. Examples are care plan, admission notes or antenatal check-up

Sections Correspond to document headings, are mostly used to secure ease of reading and retrieving relevant information for the clinicians (for instance)

Entries Have data that comprise most of the clinical information. Examples are test results, observations, orders, symptoms etc. There are four main types of Entry classes within the openEHR structure:

    iv.   Observations

    v.   Evaluations

    vi.   Instructions

    vii.   Actions

Clusters Clusters can be thought of as reusable fragments of clinical

information. They do not contain information that can stand alone, but contain data that are reusable within many of the different Entry archetypes. Examples are anatomical location, dimensions etc.

7.4.1 Clinical process and archetypes

In order to clearly understand the different types of Entry archetypes, one should start by looking at the clinical process when providing health care to an individual.

Clinicians have their personal knowledge base, based on personal experience and published evidence. When meeting a patient (health care receiver) the clinical process is to:

	Clinical process	Entry class
1	Observe patient – talk to the individual and assess	Observations
2	Evaluate what type of health care the individual needs	Evaluation
3	Possibly order tests or plan health care actions	Instructions
4	Perform the tests and/or actions	Actions
5	Finally the outcome of the tests and/or actions will be evaluated and the whole process starts again	Observations

Table 3 - Clinical process and mapping to Entry classes

7.5 Templates

Templates are aggregations of several archetypes. When designing archetypes the aim is to cover the breadth and width of every potential clinical concept, allowing it to be used in various settings and for various purposes. When designing templates however, one can constrain the different archetypes that are aggregated into the template further, making the data selection fit-for-purpose at specific use-cases. By adding these constraints one can specify what clinical information that is required in any specific

context. None of the data elements from archetypes are deleted; they are merely hidden in the templates allowing structured clinical data input for those data elements relevant in the situation. The possibility of hiding elements is allowed when parts of the archetypes are set as non-mandatory in the archetype.

7.6 openEHR tools

There are different tools available for archetype and template editing. Some are provided through openEHR Foundation or can be downloaded at different vendors. The tools are used when designing and editing archetypes and templates (Archetype Editor and Template Designer) and when working in the technical realm of dual modelling (Archetype Definition Language – Workbench).

In this project the Archetype Editor and Template Designer provided by openEHR Foundation and Ocean informatics respectively have been used. In addition, an essential tool while working with and exploring archetypes is the Clinical Knowledge Manager (CKM).

7.6.1 Clinical Knowledge Manager (CKM)

Clinical Knowledge Managers (CKMs) are archetype repositories/applications where one can gather and store archetypes and templates that are developed. The CKMs represent the archetypes with all archetype information intact, including versioning history, authors and publication status. The repositories are used for storing, but more importantly they are used in the assessments of archetypes including revisions in the management process in an archetype development process.

There are several publically available CKMs in use internationally. The CKMs of openEHR[6] and The National E-Health Transition Authority in Australia (NEHTA)[7] have been used in this thesis when searching for existing archetypes. Furthermore, a Norwegian project initiated by Nasjonal IKT has established a first version of a

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[6] http://www.openehr.org/ckm/
[7] http://dcm.nehta.org.au/ckm/#

Norwegian CKM[8]. This repository has also been used during this project for the translation activities performed.

In addition to abovementioned CKMs, there are three more CKMs in existence: in the city of Moscow[9], UK clinical community[10] and Slovenian eHealth program CKM[11]. These additional repositories have not been included as sources for present thesis.
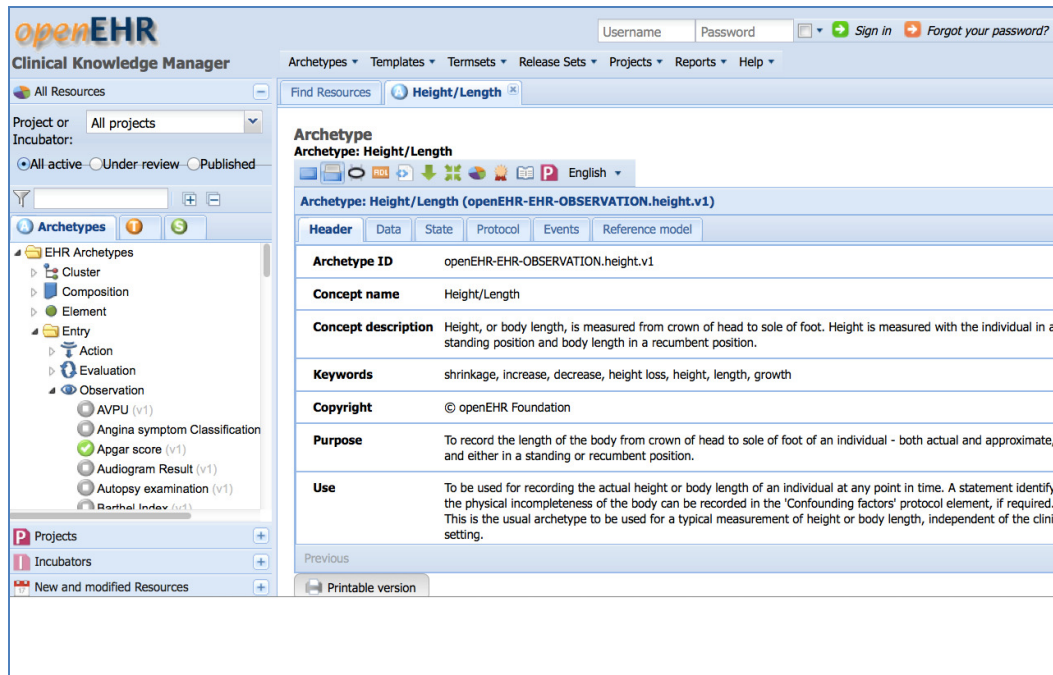
Figure 3 - openEHR Clinical Knowledge Manager (CKM)

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[8] http://78.47.196.39/ckm/
[9] http://simickm.ru/
[10] http://www.clinicalmodels.org.uk/ckm/
[11] http://ukz.ezdrav.si/ckm/OKM.html

8   openEHR design process

Even if the dual model approach makes ICT systems more dynamic and susceptible to future demand for changes, there is still a need for an agreement on the basic structure and structural elements of the EHR system. This basic structure is the first level of openEHR model – the reference model (RM). Secondly, there is the need for various groups of clinical experts to agree on the specific data sets that are to be used for different purposes. This is part of the process of developing and designing archetypes (Chen et al., 2009).

In the following the proposed structure of archetype development process will be described. The chapter will not include design process of first level of model, the reference model. The purpose of the dual-model approach is to divide the development of a system between ICT personnel and domain experts. Thus clinicians provide the needed content for a safe health care delivery whilst enabling software developers to develop the technical infrastructure needed (Wollersheim et al., 2009; Hovenga et al., 2007).

Present focus is how dual-modelling and archetype development supports domain experts in producing "…concept models and artefacts that will control how the information system they use will function" (Beale, 2002). The aim is processes that establish consistent granularity, avoids overlapping items and that revisions and alterations are performed within proposed quality governance model. Background information covering these aspects are presented in this chapter, while utilisation and evaluation of development and governance model is performed in Chapter 9.

8.1   Methodology of archetype development

The process of building and creating archetypes is based on the concept "re-use whenever possible". The sole idea of openEHR and archetypes is that the community as a whole (nationally and internationally) builds a common clinical knowledge model, thus ensuring semantic interoperability within national borders as well securing future possibilities for international sematic interoperability. This methodology supports a

way of sharing clinical information that evolves without loss of meaning at the new location (Hovenga et al., 2007).

Summarised the process of the development is to gather the content and clinical concepts relevant for the present project. Before development of new archetypes starts one should check if there are existing archetypes that can be reused. If needed archetypes have been developed earlier, evaluate if there are any modifications needed. Finally one should create new archetypes if there are none existing/applicable for present demands.

Core design steps

1. Identify concepts	2. Check existing archetypes	3. Possible to re-use?	4. Modification necessary?	5. Create new archetype
Brainstorm Consider clinical concepts from all angles Is it a simple concept? Is it made up of multiple concepts Source all possible content (datasets, internet, publications, other clinical experts) Produce mind map[1] - Organize[2]	Research existing archetypes Are there archetypes already designed?	Are the existing archetypes a maximal dataset for your purpose?	If the archetype (-s) is not a maximal dataset for purpose, create and add modifications/ additions Consider specialisation of archetype (s)	Choose archetype class Build archetype Combine multiple archetypes within larger composite archetypes or templates

[1] **Mind maps:** are a diagram used to visually outline information. It is often created around a single word or text, placed in the center, to which associated ideas, words and concepts are added (Wikipedia, 2013)

[2] **Organize** focusing on identification of data elements, protocol, state, allowable events, pathway steps, concepts needing coding/terminology

Design steps from Leslie and Beale (2008) and Hovenga et al (2007)

Figure 4 Core design steps - archetypes

This methodology identifies and analyses concepts in as many angles as possible while being developed. To support the building of individual care concept, Buck et al (2009) studied in total three different EHR systems (two electronic and one paperbased) and identified clinical concepts to be redesigned with the use of openEHR archetypes. In Brazil Santos et al (2012) wanted to ensure that all data elements that previously constituted their Patient´s Clinical Summary was represented with archetypes. While

Buck et al (2009) followed core design steps and checked existing archetypes prior to designing new, the Brazilian project modelled and validated archetypes to suit their needs prior to checking existing repositories. Their chosen method was to i) select data elements that already was represented in the clinical summary ii) identify clinical concepts iii) model and validate archetypes (by the use of spreadsheets), iv) identify terminologies, rules of permanence and domain tables, v) search for existing archetypes and finally vi) codify each archetype in ADL.

Two somewhat different approaches to archetype development methodology, end up with designing future-proof archetypes. Central repositories are checked to ensure no development of overlapping archetypes in both of the approaches, but the effort of work invested in creating new archetypes is possibly higher in the latter methodology. Not knowing the specific archetypes developed in the Brazillian project, it is hard to argue wether the extra work effort resulted in higher quality archetypes or not. However, this approach ensured that all data elements already present in their central repository of Clinical Patient Summary were mapped with existing constraints intact (Santos et al., 2012).

Work performed in current project has had an aim of covering clinical content needed for a Norwegian antenatal health record, but not to design new archetypes if the ones found cover needed information. The core design steps as depicted in figure 4 have been followed, i.e. thoroughly investigating archetype repositories prior to creating new ones.

8.2   Experiences with archetype development

The openEHR supports the knowledge model development by providing tools for the development of archetypes and templates. The process to be performed by domain experts is to create technical specifications of clinical content and the challenge therefore is how to support the clinicians so they are "…able to make some sense of a computable representation" (Leslie et al., 2009:126). By providing support material it is easier for domain experts to get engaged with designing clinical content models..

Experiences show however that it takes quite some time and that needed time should be planned for, to gain the needed understanding of how reference models influence the archetype development process (Nasjonal IKT, 2012; Santos et al., 2012; Hovenga et al., 2007). Santos et al decided to leave the actual archetype encoding over to technical staff, having the clinical team working in spreadsheets to facilitate the modelling process. This decision was made due to the experience that many of the health care professionals involved in the project "…had difficulties in using archetype editors directly because of the technical skills that were required" (Santos et al., 2012:264). Nasjonal IKT (2012) experienced the advantage of having health care professionals with thorough ICT knowledge when using technical tools for archetype development.

The major use of time in archetype development is related to defining data elements, identifying concepts and researching existing archetypes that may be applicable to use (Nasjonal IKT, 2012; Santos et al., 2012). How much time this work will take naturally depends on the maturity of archetype development by actors involved as well as prior knowledge as to what archetypes that already exist in different CKMs. Santos et al have included detailled effort summary to each modelling step, showing that a total of 300 days was used prior to the actual encoding of archetypes in ADL (Archetype Definition Language). Some of the work effort was overlapping in time, but nevertheless a vast amount of time is needed to ensure high quality archetypes that cover clinical need. For the techncial encoding in ADL 45 days were used. A total of approximately 345 days were used on step 1-5 in Core design steps as described in Figure 4. To my knowledge, other projects have not declared actual time usage in detail.

8.2.1 Consistent granularity

A common ground clinical knowledge model that supports semantic interoperability can only be achieved when archetypes are developed in a consistent manner, with the same level of granularity among the concepts (Kalra et al., 2012; Rosenälv and Lundell, 2012). Accordingly, the concepts should capture domain knowledge that can be used in multiple ways by many different stakeholders in all clinical domains (Hovenga et al., 2007). Efforts to ensure same level of granularity in concepts and archetypes is noted as challenging and taking large amount of time (Nasjonal IKT, 2012; Rosenälv and Lundell, 2012; Santos et al., 2012; Michelsen et al., 2005). Same level of granularity is needed to ensure consistency and reusability between different EHR projects and systems.

Different projects often end up using mind-maps[12] to facilitate this process, thus allowing "…visualization of the relationships between concepts and data elements and the existing overlaps" (Santos et al., 2012:266). Consistent granulrity is also a demand in relation to follow-on effects like guideline representation and querying (see Chapters 5.3 and 6.3).

8.3 Quality requirements

Kalra et al (2012) have, based on years of experience with archetype development and implementation of systems for them, defined a set of quality requirements for archetypes. The set of requirements defined comprises business, clinical and technical requirements:

Business requirements (archetypes shall) :	
QR1	have the sufficient detail and precision to specify the constraint pattern. By ensuring this different conforming clinical data instances from various EHR systems can be consistently represented
Clinical requirements (archetypes shall):	
QR2	specify the precise clinical scope of the entity (-ies) for which it defines a constraint pattern
QR3	specify for which clinical scenario or workflow it is inteded for
QR4	specify any particular speciality, discipline or professional groups
QR5	include or reference minimum one term from an internationally registered terminology system
QR6	be sufficiently precise so that EHR instances conforming to it may be meaningfully interpreted and analysed
QR7	include references to one or more kinds of published evidence, and include dates for which the published evidence is due to be reviewed
Technical requirements (archetypes shall):	
QR8	specify the EHR information model
QR9	specify the class within the EHR information model that it is the corresponding node for EHR instances
QR10	have an identifier that is globally unique and replicated consistently

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[12] Mind maps are diagrams used to visually outline information (Wikipedia, 2013)

	whenever it is communicated, both for the archetype and each of its nodes				
QR11	information in an archetype shall be capable of being represented using the information model specified in Section 7 of ISO EN 13606 part 2				

Table 4 - Quality requirements for archetypes (Kalra et al, 2012)

Rosenälv and Lundell (2012) concur to the need for unambiguous data attributes and have in addition proposed inclusion of attributes for free text and "…follow-up perspectives, such as quality registers" (2012:11). The powerful potential for secondary reuse of data has a major focus by Rosenälv and Lundell as these proposed attributes indicate (see chapter 6.3 for reuse of clinical information). Prior to Kalra et als article discussing quality requirements, Leslie proposed quality parameters (Leslie, 2011) with wider definitions as to what an archetype of good quality represents. She have gathered a candidate framework that should be considered in a table:

	Design requirements/ methodology	Business requirements	Stakeholder requirements	Technical requirements	Information governance requirements
Requirements gathering & analysis	√	√	√	√	X
Design & Build	√	√	√	√	X
Collaboration & Verification	√	√	√	√	√
Publication, Maintenance & Distribution	X	X	√	√	√

Figure 5 Candidate framework for quality development of archetypes (Leslie, 2011)

In the figure, quality criteria and indicators that should be used to measure or assessment are indicated by a tick (√).

As part of a thorough validation of present selection of archetypes I decided to evaluate all archetypes according to proposed requirements by Kalra et al. This due to the distinct nature and identification of the requirements and due to the fact that Kalra et als article is newer compared to Leslies criterias. My assumption was that criterias of

Leslie have been evaluated when designing the quality requirements. Results of quality validation can be found in Chapters 9.6.1. – 9.6.1.3.

8.4   Domain Knowledge Governance

Several authors propose and discuss the need for a formalised way of creating and reviewing archetypes to ensure high level of quality. It is also noted that without a proper coordinated quality management of archetype development, the sheer number of archetypes will possibly jeopardize semantic interoperability (Garde et al., 2007; Garde et al. 2007b; Kohl et al., 2008; Moreno et al., 2011; Nasjonal IKT, 2012).

8.4.1   Structure for cooperative development – keeping pace?

If one is to see beyond this primary challenge there is the need for a thorough quality management of all developed archetypes, for national and international developed archetypes alike. The key to ensure high quality is "…a clear process for authoring, updating, managing and disseminating archetypes, as well as archetype version control"(Hovenga et al., 2007:10). A structure formalising the cooperative development has been put forward, ensuring high clinical involvement with professional committees, clinical review boards and finally a design committee (Kohl et al., 2008). The aim is a transparent, repeatable collaborative involvement by many actors with different backgrounds to achieve consensus in the definition of clinical concepts, including quality control measures.

The proposed development structure has, as said, an aim of publishing clinically valid and technically correct designed archetypes. The challenge however is to gain enough input to the finalisation and publication of archetypes. My investigation in the present archetype selection for this current project shows that only 1 is published and 19% have status Team Review. The rest have either status Review Suspended or Draft (80%), which means in effect that they are not under any sort of revision. The low number of published and in review archetypes is a challenge, as needs for already existing archetypes continually increase as number of archetype related initiatives rise. When the governance model is not keeping up with archetype development activities, this causes challenges for new projects.

Moreno et al. (2011) concluded that there is a need for increasing the community of experts involved in development process as current activity provided by the experts cannot address all archetypes that are in the repository. Kalra et al conclude that within domain knowledge management "the experience and evidence base for the quality assurance and quality labelling of archetypes is not yet strong enough to support a formal certification process" (2012:49).

8.4.2 Information governance requirements
Challenges in domain knowledge governance are several as previous chapters show. Nevertheless, users that design or modifies archetypes should provide the different teams and review boards with archetypes of high quality, not only as to clinical content but also with needed information enabling the domain knowledge governance board to do their part of the job.

Kalra et al (2012) have in their article identified governance requirements for archetypes. In my work I have, when one quality requirement in effect consists of several components, broken down the requirements in to single measurable components. This is shown in the table with subsequent numbers added after a punctuation mark. Where my evalution saw the need for further presision of a requirement, this was also included and can be found in list with the same breakdown structure and (n) for new behind.

Information governance requirements (archetypes shall) :	
QR12	include information about author (person or organisation) that has taken primary responsibility for its creation
QR12.1(n)	Include contact information (e-mail) to authors
QR12.2(n)	Include contact information (e-mail) to translators
QR13	Include time of its creation
QR13.1	Include location/jurisdiction of its creation
QR13.2(n)	Include time of translation
QR14	Include information about the person/organisation that has coordinated the inputs into its design basis
QR15	Include references to former versions of archetypes when modifications result in revised versions

QR16	Not revision may render any non-conformant any instance of EHR data that conformed to previous version (when archetypes is revised)
QR17	Reference a clear statement of any copyright that apply to it
QR17.1	Reference a clear statement of any usage restrictions that apply to it
QR17.2	Reference a clear statement of any licence information that apply to it
QR18	List and date stamp any approvals and endorsements for its use
QR18.1(n)	List and date stamp any approvals and endorsements of translations
QR19	Include a time-stamped indication of its intended deprecation from future use by any jurisdiction, optionally with an explanation
QR19.1	Include an explanation for deprecation of use

Table 5 - Information governance requirements (Kalra et al, 2012)

As part of the quality assurance of present archetype selection performed, the archetypes have been evaluated according to proposed information governance requirements. The results form quality assurance work can be found in Chapters 9.6.2 - 9.6.2.6.

9   Implementation of openEHR design process

For the proposal of archetypes in a future Norwegian antenatal health record, the openEHR core design steps have been followed and the results are described. Conformance to quality requirements will be discussed in addition to evaluation of clinical content coverage in former developed archetypes relevant for antenatal health care.

9.1   Gathering of content

Clinical content for proposed archetypes for antenatal health care record has primarily been obtained from the existing paper based antenatal health record and from the National Clinical Guideline for Antenatal Care. In addition hearing responses to a revised and electronic version of antenatal health record and forms used to report to national Medical Birth Registry of Norway have been utilised in search for clinical content relevant for archetypes (Folkehelseinstituttet, 2013; The Norwegian Institute of Public Health, 2012; Svarlien, 2008). Elements from the two forms used for reporting to the Medical Birth Registry have been included due to the fact that many of the received responses, as summarised by commented on the need for harmonising the structures between antenatal health record and the Medical Birth Registry (Svarlien, 2008). Furthermore, the ambition of this project has been to gain further insight into health care professionals attitudes to the paper based record, positive and negative experiences as well as their perception of necessary clinical information and functionality in an electronic antenatal health record. Inputs gained through focused interviews with midwives and doctors are included in the review for clinical content. Scanned versions of the two report forms can be found in Appendix 4 and 5.

9.1.1   Content of paper based antenatal health record
The paper based antenatal health record was last updated in 1985 and it contains patient demographics, status about previous pregnancies, current pregnancy status as well as information of the women's illnesses, hereditary or not, that may come to affect the pregnancy (see Appendix 2 for a scanned version of the paper based antenatal health record). The record itself contains both persistent data, for instance patient demographics and status about previous pregnancies, as well as specific information

recorded at each check-up. The health record does not give an indication at what time the different information should be filled out. The more recent National Clinical Guideline for Antenatal Care (2005) has omitted of some of the tests and observations that are indicated on the health record. The guideline also includes additional information to be provided to the pregnant women as well as new evaluations are to be performed. See Chapters 3 and 4.3 for details on antenatal health care and the documentation process.

9.1.2   Focused interviews

The interviews had the aim of investigate further into the areas concerning user processes with the paper based antenatal health record, the health care professionals experiences in using the record as well as their proposals of amendments and needed new functionality. In regards to clinical content, the latter categories are relevant, namely the responders views and suggestions of amendments as well as their perceived needs for new clinical content.

As a contribution to proposed revision of clinical content, the results of 4 interviews are included in the gathering of clinical content. Even though the responders collectively represent health care facilities in antenatal health care (1 GP, 1 specialist and 2 midwifes in specialist hospital), the results cannot be evaluated as representative. Nevertheless, the results after coding show that the responses in interviews are in line with former response hearings. The results were evaluated to be indicative and relevant for present work.

9.1.2.1 Clinical content – results from interviews

Each occurrence of relevant sections in each interview has been coded. In addition, all responses to former hearings also have been codified using the same codes. For codes representing clinical content, code presence show compliance:

	Adherence to guidelines	Historical information	Need for update	New functionality	Quality	Reporting	Risk assessment	SF curve	Structuring	Too much information
Specialist_Trondheim	1	1	1	1	1	1	1	1	1	1
Responses to reports	1	1	1	1	1	1		1	1	1
Midwife_Hospital_Oslo	1	1		1	1	1	1	1		
Midwife_Hospital_Oslo	1		1	1	1	1		1		1
GP_Oslo	1		1	1	1	1			1	1

Table 6 Clinical content - code presence

Codification of each occurrence gives a weighted presence result of each of the codes. The codes with high numbers represent elements that were repeated and stressed as important by the responders (description of codes can be found in Appendix 6).
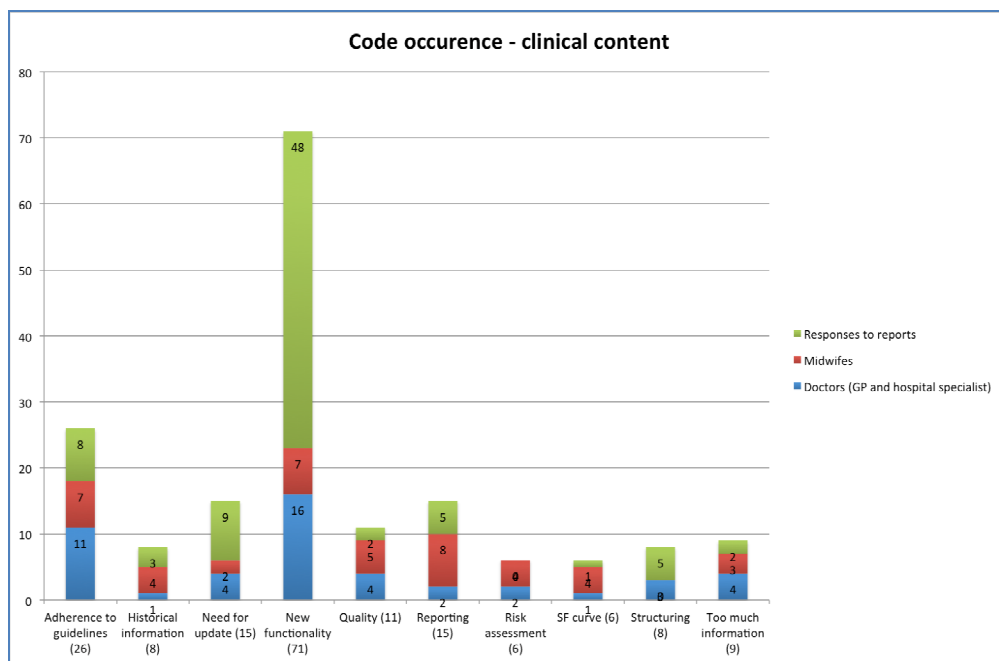

Figure 6 Code occurrences, clinical content

As the graph shows, both the interviews as well as former hearing responses give a clear indication that there is a need for new functionality in addition to the notion of adherence to the National Clinical Guideline for Antenatal Care. Further analysis shows that these two codes in fact overlap, as most of the proposed new functionality already is described in the guideline. The remaining issues dealt with the reduced quality in

present health record when focusing on reuse of information (both for communicative purposes as well as for reporting) and the need of having historical information readily available at each check-up. Finally many comments dealt with the fact that current record provides slots/spaces encouraging more tests to be executed that what is in line with the guideline. An overall conclusion from the interviews is that new content should reflect what is described in the National Clinical Guideline for Antenatal Care and that elements that isn´t directly described in the guideline should be omitted.

9.2   Identification of clinical concepts and mapping (step 1 and 2)

A high level gathering shows that there are a total of 7 high-level clinical concepts relevant for an antenatal health care record. At this high-level the established clinical concept correspond to what is present in the paper version of the record. (See Appendix 10 for mind maps for each of the high-level concepts).
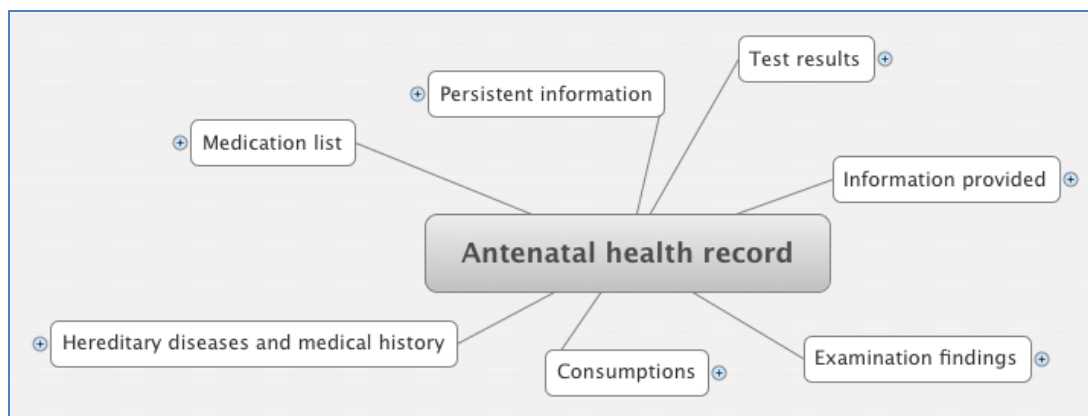

Figure 7 High-level gathering of clinical concepts

From the gathering of information it has become clear that it is within these high-level concepts there is the need for inclusion, omission and alteration of information when comparing existing health record with the guidelines and reporting demands. A total of 52 discrete clinical concepts were identified and 100 potential archetypes were mapped to these.

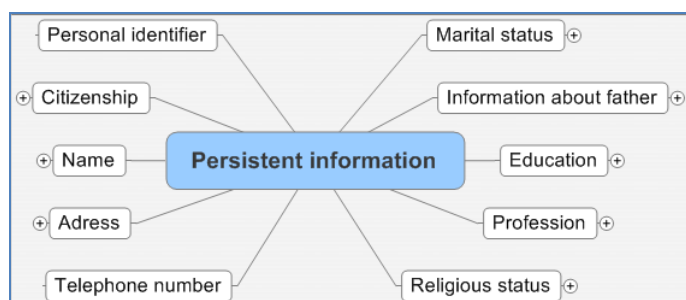### 9.2.1 Concepts and archetypes omitted from further analysis

Figure 8 Persistent information

The high level concept *Persistent information* consists of different information elements that are likely to be consistent throughout the pregnancy. The information is used for identifying the personal details of the mother (to-be): name, address, unique identifier etc. In addition information is gathered about the father of the unborn child.

Investigation in the different CKMs for archetypes matching criteria for these demographic types of information has been performed. However, as the aim of this thesis is focussing on the clinical concepts, i.e. concepts regarding the woman's prior health history (when relevant for current pregnancy) as well as her and her baby's (-ies) current state of health, I have not performed further analysis for concepts and corresponding archetypes in the group Persistent information. In addition, an assumption is that most of this information will be obtained through integrations with local EHR systems. The need for quality archetypes is nevertheless present, but this has not been a focus in current thesis.

9.2.2 Clinical concepts

Based in the remaining 6 high-level clinical concepts, further work was done to detail and identify all discrete, separate clinical concepts. There has been a challenge to ensure that all relevant concepts are included, as some of the forms (the paper based antenatal health record) have not been updated in many years, and there are inconsistencies between concepts in the paper based health record and forms used in reporting to national Medical Birth Registry. I have, where inconsistencies have been identified, based inclusion of clinical content on what is described in the National Clinical Guideline for Antenatal Care and in the report form used to the national registry. This because the forms are more up-to-date than the paper based antenatal health record.

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9.3 Evaluation of mapping (step 3)

In the work of mapping clinical concepts to existing archetypes, there are three different challenges that have to be taken into consideration. Some of the archetypes completely cover all items in a clinical concept and archetypes are reusable without any adjustments. Secondly there are archetypes that cover some, but not all, items in clinical concepts. In the latter case a broader evaluation considering how complete coverage of clinical content could be achieved was done. The opportunities can be summarised as:

– Additions to existing archetypes,

– Development of archetype specialisations

– Development of new archetypes

– Inclusion of clusters or other types of archetypes in subscribing archetypes

A final evaluation regards whether items could be added in local templates rendering previously developed archetypes untouched with additions/constrictions only locally applicable. These different challenges are also identified by Buck et al (2009).

A third aspect is the fact that for some of the clinical concepts there are more than one archetype present that partly cover identified clinical content. As there are more than one CKM, there have been developed archetypes that cover local (national) specifications that may be structured somewhat differently than to other national demands. Examples of this are the *OBSERVATION.menstrual_cycle* and *OBSERVATION.menstruation* archetypes found in NEHTAs and openEHR CKMs respectively. The archetypes both cover the need for recording onset of last menstruation; in addition they have overlapping as well as non-overlapping elements.

The challenge when aiming for reuse of archetypes in Norway is therefore deciding what extra information elements are of interest. This challenge is also identified with the archetypes used for recording the use of substances, tobacco and alcohol. Regardless of present challenges, the archetypes in present selection cover identified clinical content, but the differentiated design of overlapping archetype has challenged which ones should be utilised. After careful consideration a decision was made to utilise archetypes developed in the Northern Territory Antenatal project when evaluating

archetypes. The archetypes conform more to Norwegian requirements for clinical content than archetypes found in openEHRs CKM. When utilising one primary source the abovementioned challenges were solved to a large degree. In chapter 9.4 needed adjustments are described in detail.

9.4 Needed modifications of existing archetypes (step 4)

As work progressed it became clear that the focus of this thesis would be the clinical content documented in each antenatal check-up. A decision was therefore made to focus only on the archetypes that were mapped to underlying concepts found in the high-level clinical concept Examination findings. These concepts would naturally belong together in a document section.
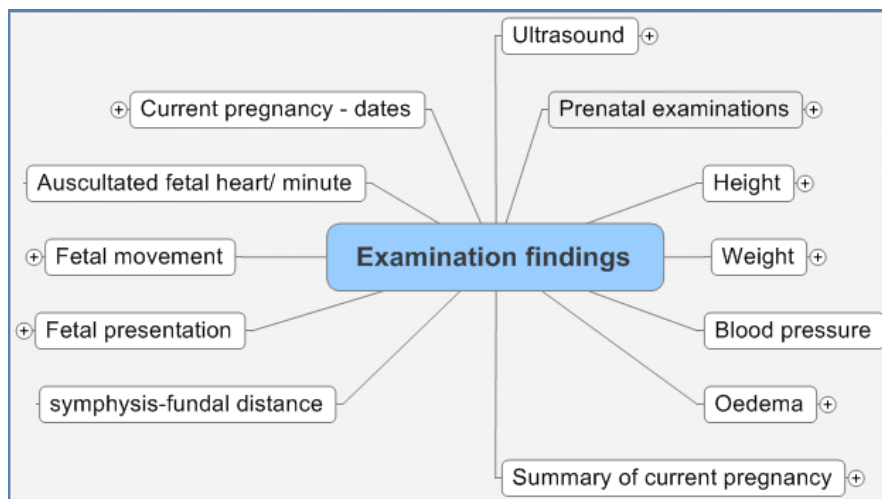

Figure 9 Clinical content in Examination findings

Some of the information visualised in figure 9 is not documented in every check-up; for example are Ultrasounds done once in guideline adherent antenatal health care and a summary of current pregnancy is documented at the end of pregnancy.

A further selection was therefore made focussing on the archetypes needed for representing the clinical content of:

- Current pregnancy – dates   - Fetal movement
- Auscultated fetal heart/minute   - Fetal presentation
- Symphysis-fundal distance/measure - Height
- Blood pressure   - Weight
- Oedema

The archetypes developed within the Northern Territory Antenatal project is used as primary source. There are however two exceptions; the two CLUSTERs (dimensions and oedema) were obtained from openEHRs CKM. Of a total 12 translated archetypes, eight have been translated within present work. One archetype: SECTION.antenatal has had alterations to fit Norwegian needs. The alterations require new version of the archetype so it will not be directly compatible with NEHTAs version, if approved in the Norwegian CKM. The alterations are additions rather than removal of information. As will be shown with the developed template, adding constraints at template level covers the additional Norwegian requirements of structure.

	Translated concept	Concept archetype	Identifier	Translated in present work	Need for alterations
Cluster	Dimensjon	Dimensions	dimensions.v1	–	–
	Ødem	Oedema	oedema.v1		–
Evaluation	Klinisk sammendrag	Clinical Synopsis	clinical_ synopsis. v1	yes	–
Observation	Blodtrykk	Blood pressure	blood_pressure.v1	–	–
	Vekt	Weight	body_weight.v1	–	–
	Funn ved fysisk undersøkelse	Physical Examination Findings	exam.v1	yes	–
	Fosterhjertelyd	Fetal Heart Rate	fetal_heart.v1	yes	–
	Fosterbevegelse	Fetal Movement	fetal_movement.v1	yes	–
	Svangerskap	Gestation	gestation.v1	yes	–
	Høyde/lengde	Height	height.v1	–	–
	Urinanalyse	Urinalysis	urinalysis.v1	yes	–
Section	Svangerskaps kontroll	Antenatal	antenatal.v1	yes	yes

Table 7 Overview translated archetypes

9.5 Creation of new archetypes (step 5)

For the clinical concepts within Examination findings, evaluation shows no need of development of new archetypes. Present selection with constrictions at template level cover required clinical content. With aggregation of translated archetypes in developed template, required clinical content can be documented in a section equivalent to Examination findings.

9.6 Evaluation of archetypes – quality requirements

As described the proposal is a high reuse of existing archetypes. The ongoing NT Antental project (chapter 4.2.1) has provided a large range of archetypes and together with existing archetypes found in openEHR CKM the coverage in a complete electronic antenatal health record in Norway is high.

As part of the evaluation all relevant archetypes have undergone a quality assurance check with an evaluation of quality requirement fulfilment. A spreadsheet was established, with columnheadings representing the quality requirements as described by Kalra et al (2012), see Tables 4 and 5 for details. For the complete antenatal health record, a total of 100 potential archetypes were examined as to their fulfilment of the quality requirements. Appendix 7 shows the complete list of archetypes and primary source CKM for each. As stated, NEHTAs CKM was used as primary source but 49 of evaluated archetypes also exist in openEHR CKM. In the following requirement validation there will be deviations in results compared to utilising the openEHR CKM as primary source.

When importing an archetype into a CKM accuired from another source, there is the option whether to include translations or not. A translated archetype in one CKM might therefore not have translations in another. Present work has not investigated translatory statuses across different CKMs. Additionally, other deviations will occur in the validation reports, as these reports validate the technical quality of the archetypes in the CKM source in use. If changes/ amendments/updates have been done in one repository and not in the other, technical validation reports will differentiate.

9.6.1 Quality requirements performance

The quality assuranse shows that non of the evaluated archetypes meet all proposed quality requirements. It is not directly stated by Kalra et al (2012) as to when in a development process the requirements should be met. Of the included archetypes in present selection only 1 have status Published. 32 have the status of either Team review or Review suspended, showing that initial design work has been finalised and the authors have released proposal for archetype. One would assume that once an archetype is released for team review, all needed quality measures have been taken and that quality requirements should have been fulfilled.

In the following a detailed analysis of each proposed quality requirement and fulfilment is described.

9.6.1.1 Unique identifiers with fluctuating publication statuses
There are three requirements that all reviewed archetypes meet.

These are:

- sufficient precision (QR1),
- the class is specified (QR9) and
- unique identifier (QR10).

There are some challenges regarding the unique identifiers however. There are currently activities concerning archetypes in approximately 24 countries with several initiatives within the different countries as well (openEHR, 2014; Klein, 2013). Archetype management is both a national as well as an international challenge, as archetype related projects and initiatives are ever growing. Governance challenges regarding numerous sites gathering and publishing archetyped clinical content (CKMs) is therefore present. The evaluation shows that there is a challenge concerning archetype content and governance in the different CKMs in archetypes with same unique identifier. The content is not collectively updated. The different instances have same unique identifier, but their status in the different CKMs however are not the same.

Of the 100 archetypes evaluated in present selection, 49 exist in the CKMs of NEHTAs and openEHR. Of these 18 of the archetypes have conflicting publication statuses.
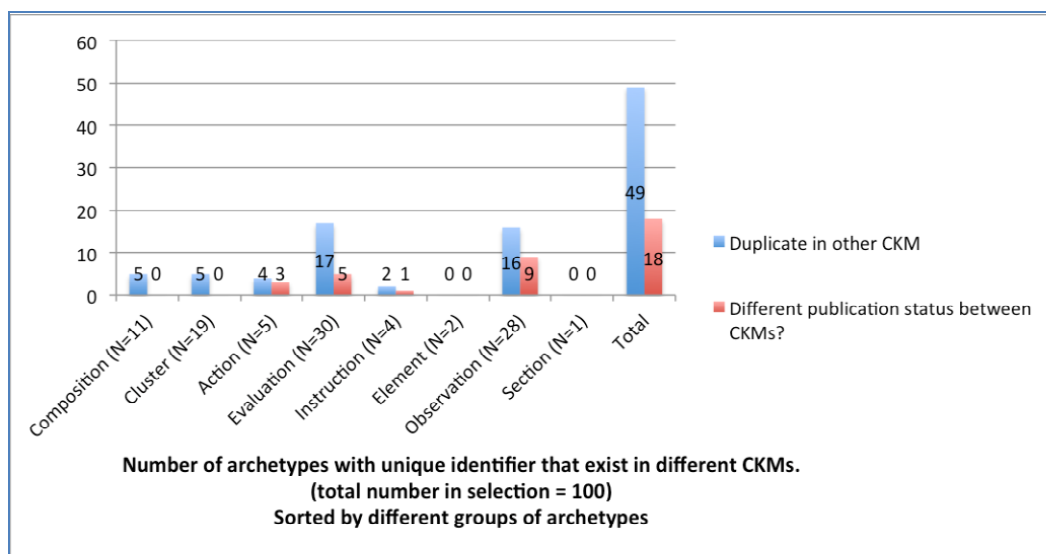

Figure 10 Duplicate archetypes in different repositories

This fluctuation between publication statuses is a challenge. Not so much due to the publication status itself, but because of the amendments and adjustments that may have occurred in on repository and not in another.

When looking in the two major CKMs the publication status of one specific archetype EVALUATION.clinical_synopsis.v1 is:

	openEHR CKM	NEHTA CKM
Created on	27.07.2009	08.11.10
Last modified on	31.10.13	24.01.11
Content Status	Published	Team review
Total number of reviews	58	31
Initial review round initiation date	10.08.09	16.12.10
Latest review round completion date	22.01.10	05.02.11

Table 8 Statuses in CKMs - EVALUATION.clinical_synopsis.v1

The dates shows that EVALUATION.clinical_synopsis initially was developed in openEHR CKM. After latest review round completion it was added in NEHTAs CKM.Further quality management has been performed in both CKMs. To what extent the number of reviews actually include same amendments in both CKMs have not been thoroughly scrutinised for all the archetypes that coexist in several CKMs. For present archetype however it is clear that amendments in openEHRs repository after publication are translations. In NEHTAs repository there are modifications of content and while translations are not available.

The challenge with having archetypes with same unique identifiers in different repositories is, as shown above, that amendments and alterations can be performed in on repository while not in another. This might in return give non compliant archetypes with same unique identifier. Recently this challenge has been adressed: some of newly uploaded archetypes in openEHR CKM have a direct link to the original source of the

archetype. This fasilitates the access to archetypes with unique identifiers in several CKMs, while alterations and quality management solely is performed in the one (figure 11). This linkage between CKMs does not exist in any of the evaluated archetypes. Thus, the challenges adressed above are still present.

Garde et al (2007) state, in the discussion about collective effort to ensure international semantic interoperability, that one comprehensive repository is key. Further; one repository will provide needed mechanisms to make comprehensive domain knowledge governance both feasible and efficient. Although I agree to this statement, in my view the functionality for remote management solves the challenges to some extent. Still, challenges will still remain. Will the owners of sovereign CKMs adopt the functionality of remote management? Will primary developers be able to manage reviewers in sovereign CKMs? And if so, what is really the purpose of having different CKMs?
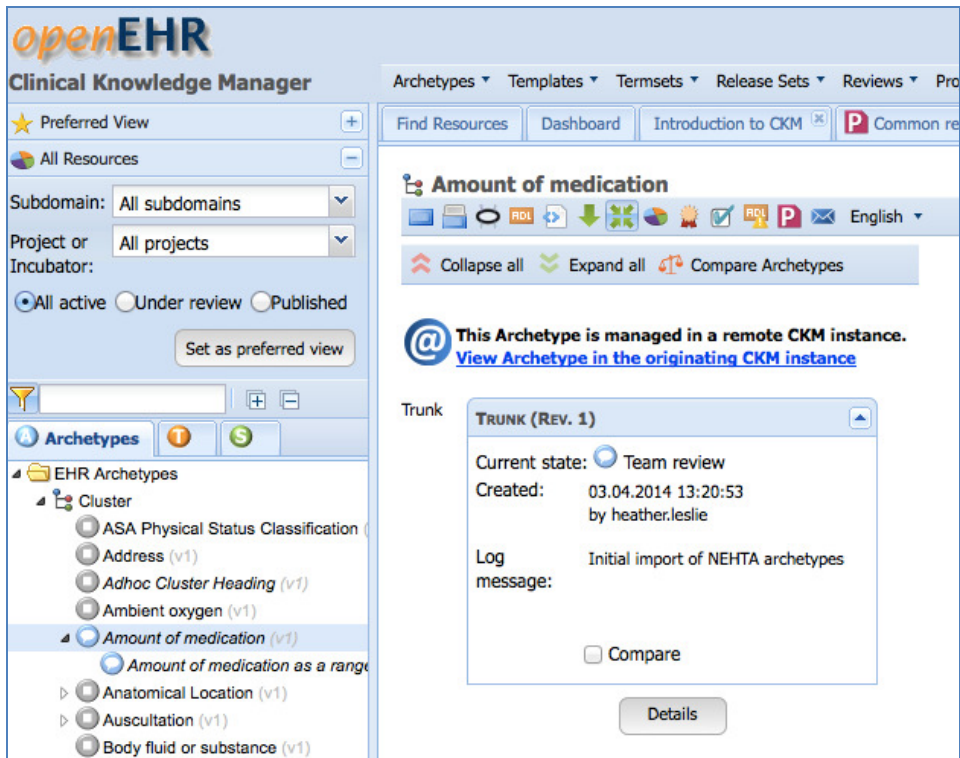

Figure 11 Remote management of archetypes

9.6.1.2 Quality requirements "shooting out of cannon into sparrows"?
Most of the archetypes do not fulfil the requirements for Clinical scope (QR2), Clinical scenario/workflow (QR3), Speciality/discipline/group (QR4) and Published evidence

(QR7). During the evaluation questions arised concerned the necessity for all archetypes to include information about intended clinical scope/scenario/workflow as well as speciality/discipline/groups. Archetypes of good quality should be unambigous, thorough, distinct and comprising all needed data for clinically meaningful concepts. And as such be applicable in various scenarios, workflows and by all different specialities and groups (Rosenälv and Lundell, 2012; Buck et al., 2009). I posed my questions to dr. Dipak Kalra in a private e-mail. Although he somewhat agreed to my hesitation, he problematised it as to "...the critical issue whether the particular scenario or workflow has an important impact on what is documented and provides an important context for subsequent interpretation" (Kalra, 2013). Further discussions should be taken in revisions of quality requirements, but present proposal is to amend requirements to comprise the need of clarification and thorough description only when archetypes have a narrow use case. This to ensure that other users of the archetype understand different user situations in which the archetype may appropriately be used.

No matter how the quality requirements 2,3 and 4 should be amended, present evaluation show partial fulfillment of these three requirements. Only 9% in present selection fulfil criteria of including information about clinical speciality. 78% has described clinical scope and finally 77% have included information about clinical scenario/workflow. The relatively high percentage of 78% and 77% resepectively indicates that my immediate notion of these requirements being too extensive may not perceived as such by archetype developers. Clinical workflow may vary in different clinical settings and countries, even though the actual clinical information that is to be captured is the same. This calls for the need of having clinical scenarios and scope included in archetype metadata.

Interestingly enough only 9% of evaluated archetypes include information about clinical speciality. It is difficult to establish the reason for this low percentage, but one can assume that either the archetypes are found to be relevant to all clinical specialities or that relevant specialities are implied by clinical scope and scenario. Present evaluation has not however found implication of this information present, so assumptions are made that the archetypes are made to be relevant to all clinical specialities.

When analysing these requirements fulfilment one should also consider the types of archetypes present. There are archetypes which are designed to be re-usable chunks of information designed to represent same structure in different client archetypes. These reusable chunks or fragments are called clusters. Subscribing archetypes are often of Entry-type (Rosenälv and Lundell, 2012; Leslie and Heard, 2008; Michelsen et al., 2005). Other types are of a technical support nature, for example Elements. The different Entry type archetypes comprise most of the clinical information, and it is therefore natural that the majority of present archetypes that fulfil present requirements are Entry-type archetypes (figure 12). Clusters also have a high degree of requirement fulfilment. One can assume that this is due to the fact that clusters are designed for specific purpose within different projects, so clinical information in their metadata has been seen as necessary to ensure correct usage.
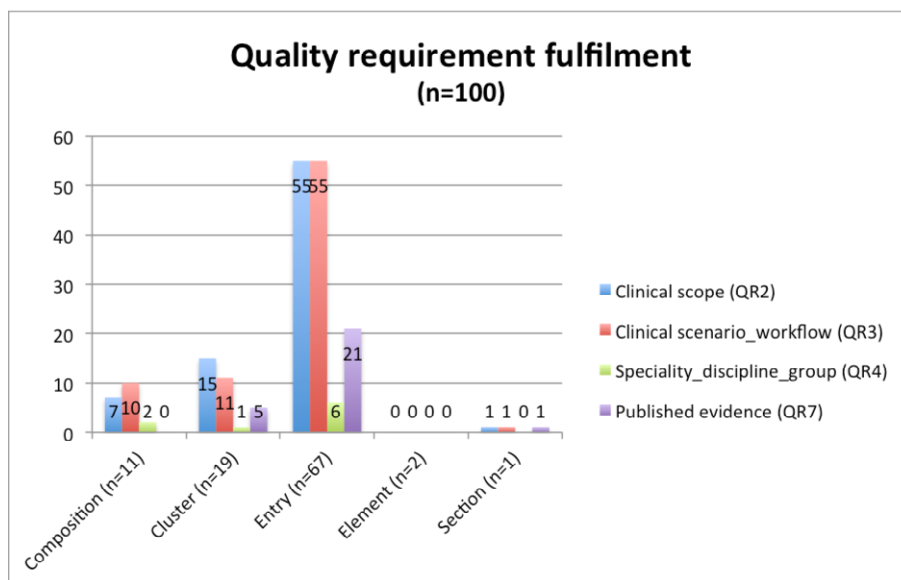

Figure 12 Quality requirement fulfillment (QR 2,3,4 and 7)

The lack of fulfilment of providing published evidence in archetype metadata (QR 7) indicates that many of present archetypes are designed based on expert input or pragmatic usage experience. This was concurred by dr Kalra (2013). There are many archetypes that never will have published evidence. One example is Action.health_education.v1 archetype that "only" structure the way, when and by whom patient information is given. For the archetypes containing clinical content however, the aim should coincide with general criterias; all clinical documentation and EHRs as a

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whole should be based on formal evidence based documentation, of which clinical guidelines is one example (Kalra, 2013; Marcos et al., 2013; Helse- og omsorgsdepartementet, 2012; Kalra et al., 2012; Carlsen and Bringedal, 2011; Marcos and Martinez-Salvador, 2011; Hovenga et al., 2007; Backe and Jacobsen, 1994). The informants in the interviews all focused on the demand that clincial content in antenatal health care should be complicant to National Clinical Guideline for Antenatal Care. And as such they all uniformily concur to general views about the topic. In conclusion, it is my view based on present evaluation, that the requirement should be mandatory for ENTRY types while voluntary for others and I prospose a discussion concerning this in future revisions of quality requirements..

9.6.1.3 Information models and content validation

Dual-model methodology separates the reference model (RM) and knowledge model into two with an aim of empowering health care professionals to design and include all relevant clinical information in one model. The knowledge model is then utilised by technical vendors/staff in designing the system at run-time. Still, clincal experts need to have knowledge of which reference model to use and more importantly which RM that was used by others when designing their archetypes. Reference models have slight variations in context properties and the different archetype elements are instantiations of chosen reference model. The 8th quality requirement specifying which EHR information model used is important. The requirement itself does not clearly specify how the information should be provided, but in discussion with dr. Dipak Kalra (2013) the intention was that the information should be found in archetype metadata, easily available to all potential users. In the review only 10% of the archetypes had included this information in the meta-data. However, the information can easily be found in the archetype identifier itself. If the identifier of the archetype starts with **openEHR-EHR** it is based on the openEHR information model. In present selection all archetypes are based on the openEHR information model, hence all identifiers start with: *openEHR-EHR.*

The CKMs provide functionality for technical validation of archetypes. The validation reports show irregularities to the reference model (RM) as well as content style validation. The CKMs are based on the openEHR RM, hence validation to openEHR RM is performed described in reports that are easily understandable for non-technical users.

Most of the errors in validation reports for present selection are due to inconsistencies in cardinality between RM and designed features in the archetypes (30%). 18% have errors due to irregularities in format of dates in the metadata. The latter is of minor concern when we talk about quality requirements.

Quality requirement 11 state that information in an archetype shall be capable of being represented using the information model specified in Section 7 of ISO EN 13606 part 2. The challenge is that the standard does not make clear how conformance should be demonstrated. I also consulted dr. Kalra on this issue and he confirmed that how one should demonstrate conformance was something they "… were not able to specify properly and clearly when we originally developed this standard" (Kalra, 2013)[13]. In present quality assurance I have not been able to assess whether selected archetypes conform to ISO EN 13606.

9.6.2   Governance requirements performance

The quality assurance work has also been performed for the information governance requirements. Results show that non of present selection meet all of the proposed quality requirements. In the following the detailed investigation and the results are described.

9.6.2.1 Maturity of archetypes

In a study examining the archetype development process, Moreno et al (2011) problematised the high number of draft archetypes present in archetype repositories. Their view was that compared to number of draft archetypes, the level of activity combined with low number of clinical experts, heavily challenge the speed of archetypes publicised. Their view was to increase the community of experts in order to speed up processes. The article does not include the number of archetypes with different publication status´; hence comparison with present numbers is not feasible. However, when comparing publication status in present selection with publication statuses in openEHR and NEHTA CKMs one can see that numbers coincide. Not surprisingly the numbers found for present archetype selection are more in line with publication status in NEHTAs CKM. The reasoning for this is that antenatal related archetypes were extracted from NEHTAs CKM.

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[13] Dipak has led the development of the world's first formal standard for electronic health record communication. This series of five inter-related standards, has been published as ISO EN 13606 Parts 1-5, between 2008 and 2010.
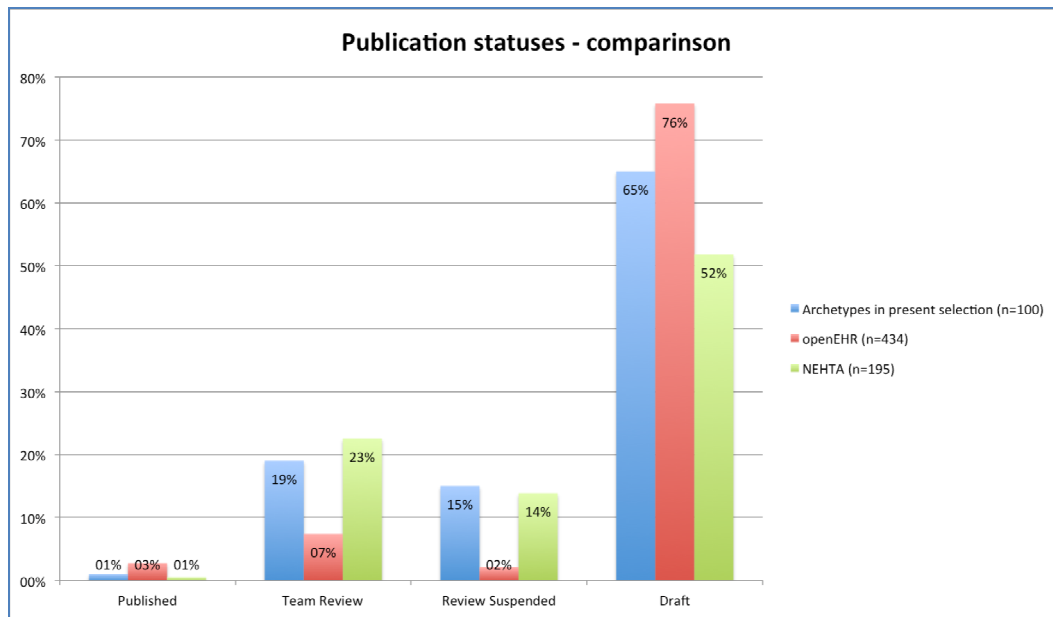
Figure 13 Comparison of publication statuses

The total number of registered users in openEHR is 1142, while in NEHTA 298 (as of April 2014). Moreno et al (2011) link low publication numbers with low numbers of expert reviewers. In openEHRs CKM registered reviewers are 30% of total number of users, in NEHTA 48%. This may give an answer to why NEHTA has a more active community compared to openEHR. Present numbers represent same challenges as Moreno et al describe.

9.6.2.2 Authors, organisations and coordinated input

All but one archetype include information about the author(-s) and organisations, as well as contact information to the authors (98,7%). The original requirement (QR 12) only stated that archetypes shall *include information about author (person or organisation) that has taken primary responsibility for its creation.* I find that not only information about authors, name and possibly role, is sufficient. How to get in contact with the authors is relevant, i.e. the additional requirement Q12.1n was added. Information about coordinated input (QR 14) was included in 75% of archetypes.

9.6.2.3 Time of creation and jurisdiction

All but three archetypes include information about time of creation in metadata (QR 13). The information for the remaining three still is available in the CKMs Status-tab. The Status-tab however does only show time of inclusion of specific archetype in present CKM. So, as discussed earlier the challenge is to know actual time of creation

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when an archetype has been copied from another archetype repository. Time of creation should therefore be information that is included in archetype metadata.

As for requirement QR13.1 *Include location/jurisdiction of its creation* approximately 13% have included information about what country the archetype author has. None of the archetypes however clearly include information about what location and/or jurisidiction the archetype has been developed for. It may be argued that all archetypes included in NEHTAs repository indirectly show location/jurisdication as NEHTA is the lead organisation supporting a national vision for eHealth for Australia. Still, as shown many times in this thesis, archetypes are found in several archetype repositories with same unique identifier, so location and jurisdiction should be found in the metadata. This requirement is closely linked to QR18 – 19.1, namely information about approvals, endorsements and deprecations of different archetypes. It is my assumption that approvals, endorsements and deprecations can be made applicable for countries as a whole. It will not suffice to include this kind of information pr translation, as one language may be spoken in several countries. Portuguese for instance is official language in 10 different countries and territories[14] and arabic is official in a total of 25 sovereign states[12]. Some countries may challenge this as some countries have a high degree of soveregnity for their states (for example USA). What impact different national legislations has not been investigated in this thesis. It is therefore only my assumptions that soveregnity of states in one country may have impact on the challenge in including approvals, endorsements and possibly deprecations of use nation for nation. One thing is clear however, including this kind of information pr translation will not suffice.

9.6.2.4 Translations
Not all archetypes have been translated (any language, not norwegian exlusively). The total number of translated archetypes are 23. This means that for QR12.2n, QR13.2n and QR18.1n the maximum number of archetypes that could meets these criterias could never be higher than 23% of total. Of the 23% however, only 22% have a complete contact list for all translators included (QR12.2n). None of the archetypes have included information about time for translation (QR13.2n) or endorsements of translations (QR18). Quality assurance work of translations should be part of national quality

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[14] Reference: Wikipedia.org

assuranse work in each country, as spelling and grammar varies even in worldwide spoken languages. Available tools do not provide designated slots for this kind of information. In future revisions of archetype metadata, I propose that designated sections supporting translation governance work is included. One may assume that some of the different national archetypes repositories have come in place in order to provide national translation and quality assuranse activities. This is not however noted in any document or article that involves local or national activities as far as I have found.

9.6.2.5 Reference to former versions and deprecation from use

The requirements clearly state that archetypes should clearly reference former versions (QR15) and any non-conformances to previous versions (QR16). The fact that all archetypes present in this thesis are in version 1 gives a natural explanation to why none meet these two criterias. The challenge however, as discussed in previous chapters, are that same archetypes may be found in several CKMs with different publication statuses and possibly differentating content. The criterias does not clearly state that versioning have to be between finalised and published versions but it is my assumption that this is the intended meaning. When widely adopted, references to former versions automatically are stored in the CKM. The newly adopted solution for remote management of archetypes will however solve some of the challenges. If remote management is not adopted however, the issue again rises.

Quality requirements detailing date stamps for approvals/endorsements and endorsements (QR18, QR19, QR19.1) have not been met by any of the archetypes. One can argue that once an archetype have reached published status, this is an indication of approval/endorsement. The tools provided however does not include specific sections where this kind of information can be included. As medical practices may vary somewhat in different regions and countries, designated sections for endorsements or deprecations from use should be included for all translations of an archetype. The argument depicted above, that national translation and quality assuranse acitivites may be one of the reasons why several archetype repositories exist, may also be influenced of the need to endorse which archetypes that meet the different national standards and requirements.

9.6.2.6 Copyright, usage restrictions and licence information

Copyright information is included in all archetypes. The notion of copyright is interesting to investigate further however. OpenEHR Foundation clearly state that a CC-BY-SA licence applies to all clinical documents (i.e. archetypes and templates). The licence allows to share and adapt any material for any purpose as long as the terms of attribution (give credit, link and indicate if changes were made) and share alike (distribution of adjusted material under same licence as the original) are met. In addition the licence state that there can not be applied any legal terms or technological measures that legally restrict others from doing anything the licence permits (Creative Commons, 2014).

Given that the complete list of archetypes has included copyright information, and 49 archetypes are present in two or more CKMs, a comparinson of registrered copyright information was performed. All of the 49 duplicate archetypes have differentiating copyright information: in NEHTAs CKM copyright is set for National E-Health Transition Authority and in openEHRs the openEHR Foundation. It is interesting to see how copyright information is handled as it seems to an information of CKM ownership, not so much copyrights[15]. The question therefore should maybe be that the Copyright-information in the CKMs should be amended to owner of respository? However with the newly adopted remote management of archetypes, copyright information is transferred from CKM responsible for the archetype into the connected CKM (Figure 11). This functionality supports the idea of keeping Copyright as data element.

The requirements also state that archetypes should reference a clear statement of usage restrictions (QR17.1) and licence information that apply to them (QR17.2). The CC-BY-SA licence clearly state that, when the terms of attribution and ShareAlike are met, no additional restrictions can be added: "You may not apply legal terms or technological measures that legally restrict others from doing anything the license permits" (Creative Commons, 2014). This thesis does not contain a thorough investigation of legislative and licencing implications for archetype development and sharing of information. It has not been the aim for this thesis to investigate this, nor does the author have knowledge

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[15]   Copyright is a form of intellectual property, applicable to any expressible form of an idea or information that is substantive and discrete. The contemporary intent of copyright is to promote the creation of new works by giving authors control of and profit from them (Wikipedia, 2014)

to perform such an investigation. Still, it is my understanding that the quality requirements conflict with the licence that applies to openEHR.org clinical documents. My recommendation therefore is of a thorough investigation of how the licence applies to archetype development. Either these requirements should be omitted completely or be revised to comply to licence criteria's.

9.7 Creation of templates

A template defines data sets for any particular use case and are formal specifications defining specific aggregations of archetypes. Additional constraints can be included, such as including mandatory items or omissions of content. Embedded templates can be part of larger templates or complete content can be collected within one large.

9.7.1 Proof-of-concept

As a proof-of-concept with direct reuse of previously developed archetypes, a test template was established for *Examination results*. This template can serve as an embedded template in a complete template for antenatal health record. As previously discussed, the evaluation shows that previously established archetype represent required clinical content. For section Examination results, 11 of a total 12 archetypes were evaluated to cover clinical content requirements. One archetype needed additions to comply with Norwegian demands: the archetype SECTION.antenatal. Section archetypes correspond to document headings and little clinical content is directly defined in these archetypes. They consist of allocated slots for other supplier archetypes. In other words, alteration of this archetype does not imply needed additions or removal of clinical content. On the basis of current design of antenatal health record and more importantly due to the National Clinical Guideline for Antenatal Care, the revision of Section.antental archetype was performed. In the revised version clinical content recorded at every check-up from week 24 of pregnancy is included. Some information elements are not mandatory (for instance auscultation of the fetal heart) according to the guideline. Health professionals can evaluate inclusion of these elements at every check-up. A decision was made to include these elements in developed template.

9.7.2 Experiences with template design

Although I had some technical challenges initially with the Template Designer, these were solved and I could commence the actual design. The huge and time-consuming

effort determining what clinical information to include had already been performed by those who had designed the archetypes, so when it comes to template design I found it a time-affordable activity. A midwife was briefly consulted during the design of the template, providing some alterations and new requirements from initial design. The test template developed shows that the previously developed archetypes could represent required clinical content for a Norwegian antenatal health record.

The complete developed template can be found in Appendix 8.

9.7.3 Translation of archetypes for Norwegian antenatal health record

In order to develop a template for use in Norway, archetypes had to be translated. Eight archetypes were translated in current work; four were already translated in other Norwegian initiatives. The translations were done in the Norwegian CKM, which supports translatory activities quite well. However, when translating archetypes out of context i.e. not having a clear view as to where the different data elements will be used, the translations sometimes had a peculiar feel when using them in a template. Functionality within Template Designer allows alterations of attribute name so that the peculiarities could be adjusted to present context. However, it is crucial to know that adjustments of attribute names should not come into conflict with intended use of attribute. Nasjonal IKT (2012) found examples where same attribute was given different names in different templates, leaving the users confused. In present template, alteration of attribute name was done in some instances.
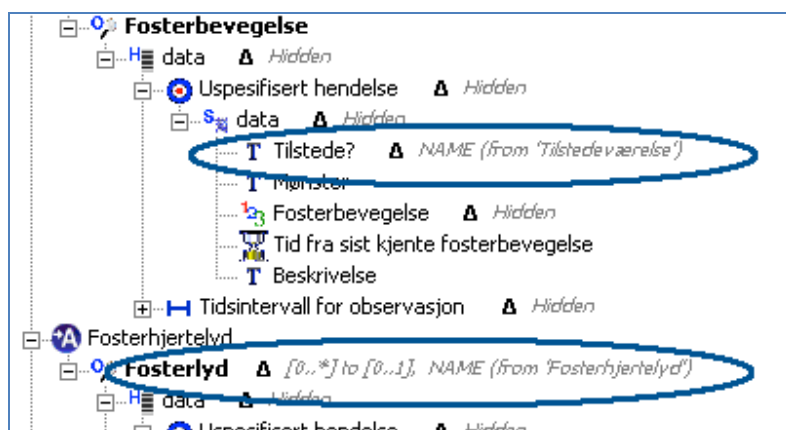

Figure 14 Changing attributes in templates

In *Fosterbevegelse* (Fetal Movement) the archetype translation was *Tilstedeværelse (English: Presence)*. The attribute name was changed to *Tilstede? (English: Present?)*. Same content is conveyed, but new attribute name felt more familiar by the midwife. The same was done with *Fosterhjertelyd* (Fetal Heart Rate). The translation in archetype adheres to terms used in Clinical Guideline for Antenatal Care. However, when showing the template to the midwife she commented that the word used in clinical practice is not *Fosterhjertelyd* but *Fosterlyd (English: Fetal sound)*. The midwife also commented on other terms but the translations were not altered. This because they adhere with earlier translations performed by Nasjonal IKT (2012). I had an aim of following the line of Nasjonal IKT that previously translations of attributes should be reused when they occur in different archetypes. This way attributes will have a coherent translation throughout.

9.7.4 Constraints and omissions of content
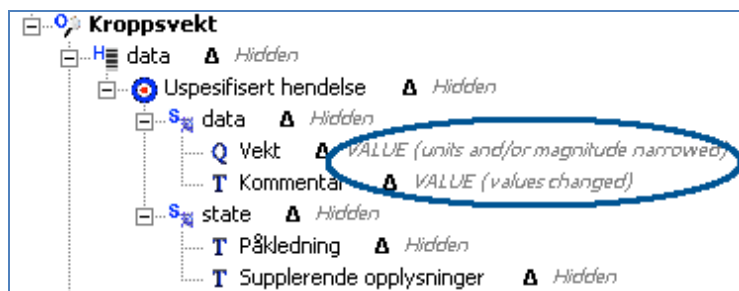
Figure 15 Hiding data elements in templates

When utilising archetypes in a template, constraints can be added and archetype content can be omitted. With the archetype *Kroppsvekt* (Weight) all data elements that have *Hidden* behind are omitted from the template. In data element *Vekt* units were narrowed so that only *kg* is an available unit (leaving out *lb*).
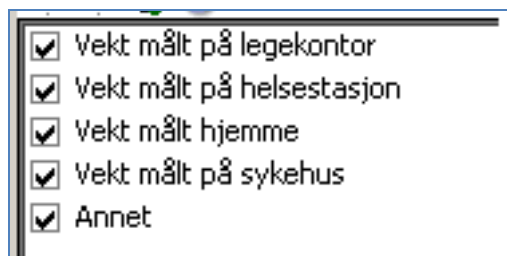

Figure 16 Added dropdown list in template

In the element *Supplerende opplysninger* a predefined dropdown list was established. The consulted midwife commented on the benefits of knowing what device that is used at every weight measurement. Having a predefined dropdown prompts the user to fill this out and will potentially increase the clinician's potential of evaluating the weight measurement. There is an archetype CLUSTER.device that could have been utilised. However, when evaluating it in relation to this specific use-case the data elements did not comply.

9.7.5   Implications for use in Norway

Proposed template covers only one small part of a complete antenatal health record. The proof-of-concept however holds; undoubtedly there is huge potential for reusing previous developed archetypes conforming to the requirements in a Norwegian record. The challenge is not what clinical content that should be included, but how it should be done. The challenge with antenatal health records is that they comprise persistent information and new information, and all should be conveyed to clinicians collectively. Thomas Beale (2013) formulated the challenge as: what reference models structures to use? Should each check-up data be a bunch of Observation archetypes or should there be a bunch of standing orders with each observation ordered for specific points of time? Should this be included in a persistent Composition?

I do not have enough knowledge to evaluate the different designs properly. Nevertheless, the challenge is there and I am grateful to know that the NT Antenatal project currently is working on solving the challenge. Developing such combination archetypes greatly challenges archetype developers and in turn the system developers at run-time.

This current proof-of-concept however shows that shared venture with reusable archetypes means that in time also a Norwegian project with novice archetype developers may contribute in proof-testing these challenging archetypes. Supplier archetypes contain needed clinical information, how to convey them to the users is the challenge.

10 Discussion

The discussion consists of three parts, each of which is connected to the scientific questions. The first part discusses lessons learnt from previous projects and how these lessons can be utilised in a realisation of an electronic health record for antenatal health care. Part two discusses practical experiences with archetype development and implications for present case. Part one and two serves as background facilitating the discussion in part three: how can clinicians´ work processes and demands for clinical content be realised with archetypes and templates. For ease of reading, the scientific questions are included.

Scientific question 1:

What has caused the failure or success of solutions developed for antenatal health care nationally and internationally? What lessons can be learnt?

10.1 Lessons learnt from prior system development projects

The prior projects and system developments initiatives evaluated in present work collectively show that developing electronic support systems for antenatal health care is not an easy task. All of prior projects have aimed at providing the information to the pregnant women; some by utilising smart cards or memory sticks other by including information in national health portal. In that respect all of the previous solutions were a success in terms of patient satisfaction (Berg, 2001). The different solutions did impose challenges for the health personnel however, demanding extra efforts for double documentation and re-entry of information after the check-ups had been performed. This may have contributed to lack of clinical user satisfaction. Although not clearly discussed in the reports found in literature review, my perception is that one primary reason for the different systems not being used is that there was not enough emphasis on integrating the systems with current work processes. System implementation has to take into account the socio-technical changes its introduction imposes. Maybe the socio-technical challenges were not identified clearly enough and handled to a degree needed prior to the systems introduction.

In general, when implementing electronic health records there are high demands for interoperability and single-sign-on support connecting EHR systems. These are important factors that can minimise clinical workload of having to re-enter information and having to login to all different systems that are used in clinical work practice every day. As stated, previous projects all had elements of re-entry of information or additional work relating to copying information on USB-sticks etc. Although logging on to a new system or copying information to memory sticks are not big tasks, results show that this may have been the straw that broke the camels back. Eltvik and Torsvik have in their thesis summed up needed activities for successful systems implementation as: "It is useful to involve end users well ahead of implementation [and] it is useful to focus on clinical work processes and workflow as early as possible" (2013:148–149).

10.1.1 Current work practices with paper based antenatal health record and local EHR systems

The findings from interviews and responses to former hearings show that clinicians, although mostly positive to an electronic counterpart to the paper based antenatal health record, have clear demands that a new system should be incorporated or tightly integrated with their everyday electronic health record system. In addition there are demands that a new system should adhere to existing clinical work process as well as contribute to the process by providing clinical decision support functionality.

In the present thesis work I have interviewed clinicians and they have been questioned about their current use of antenatal health records. Shared responses were that basic information relevant for the pregnant women as well as the collaborative actors within antenatal health care is documented on the paper. There are some challenges with current design however; it is restrictive as to what information that can be documented and there is no room for structured documentation of planned activities. The restrictive design reduces the possibility of documenting evaluations in the more elaborate way. All of the users also answered that this basic information also was re-entered in their local electronic health record system. Hence, there is double documentation being carried out every day in antenatal health care. This work practice is well incorporated in daily work routine and in general the users seem quite ok with documenting the information twice. They find that this double documentation creates additional work,

but they also evaluate the design of the paper based health record to support a quick and thorough clinical evaluation of pregnancy, given that all actors actually document on the record. The act of double documentation is therefor accepted as the outcome of the work contributes to clinical assessments of good quality. These findings are not new; they are thoroughly described in previous reports.

As a final note, the general practitioner commented that the local EHR system is used as legal documentation in case of any complaints regarding antenatal health care provided to an individual. The documentation in the local EHR system is therefore not merely done as a "nice-to-have" activity; it is a necessity and a legal obligation (Helseregisterloven, 2001; Helsepersonelloven, 2001; Forskrift Om Pasientjournal, 2001).

10.1.2 Technical solution for an antenatal health record
In summary, the demands for an electronic counterpart for the paper based record is a system that is tightly connected to the local EHR system, supporting clinical work processes as well as supporting the need for retrieval of relevant information provided by other actors in other parts of antenatal health care. The demands for documentation of health care in health care records are regulated in legislation. The Clinical Guideline for Antenatal Health Care proposes that information should be documented in a structured way by using the paper based antenatal health record. Even though the use of the paper based record is not based in legislation, i.e. the use of it is voluntary; the use is about 100%.

The preliminary projects proposed technical solution was an establishment of an electronic collaborative solution for antenatal care for all involved actors, based on one common module (Svarlien, 2008). The proposed legislative revisions of The Personal Health Data Filing System Act and Patient Health Record Act (Helse- og omsorgsdepartementet, 2013) provide opportunities for collaborative solutions. While recognising how the proposed amendments can support such solutions for all health actors within antenatal health care, the proposal is still being processed and this will not be discussed further in this thesis.

However, before a decision of *how* a technical solution for an electronic antenatal health record should be, the literature study and results from the interviews performed in present work show that there is a need for a thorough evaluation of the primary intentions of an antenatal health record. Present findings show that a clear purpose of use for the electronic antenatal health care record is not clearly established. The guideline proposes the use of a structured record, but the intended further use of the record is somewhat unclear. Below there are listed 3 different proposals for purposes for an antenatal health record. The proposals are merely suggestions. However, in different ways they include the variants of intended use found in literature and through the interviews.

These proposals are meant to be used as a basis upon which further discussions and concrete decisions can be made.

> **Purpose 1:** *The electronic antenatal health record shall only contain basic information relevant for cooperating health care personnel in antenatal healthcare. The electronic antenatal health record shall serve as a communication tool between all relevant actors in antenatal health care. Thorough documentation of all relevant information shall be performed in local electronic health record, while an overview of relevant information shall be included in the communication tool. Reporting activities (to health registries and ancillary functions) shall be performed in the local electronic health record, not in the antenatal health record.*

Provided development based on Purpose 1, the electronic antenatal health record will only contain basic information, much like todays paper record. If filled out properly, todays design and information content supports this goal quite well for the 75% of pregnancies that have an uncomplicated progress. In the interviews, current view of paper based health record fits well with Purpose 1: *the record is an instrument where some of the relevant information is transferred from one healthcare provider to another (interviewed medical specialist).* With such a solution the need for double documentation will prevail. However, the solution can be designed based on current paper based record as the preliminary report has identified (Svarlien, 2008). The

archetypes found in present work are evaluated to cover all identified clinical concepts for an antenatal health record with intended use as described in Purpose 1.

There are challenges with such a solution; who shall evaluate what *relevant information* consists of? Reponses to former hearings clearly show that the notion of relevant information is not consistent by all relevant actors within antenatal health care. In the preliminary report (Svarlien, 2008) it is stated that an electronic solution demands a common dataset with definitions of content. Discussions of content and how information should be reused may represent a challenge for a development project, it was concluded. This concurs with responses to former hearings and current challenges with the paper based antenatal health record. Responses in interviews indicate that midwifes have a somewhat different opinion as to what information is relevant compared to the interviewed medical clinicians. A technical solution supporting intended use as described in Purpose 1 could perhaps export publically identified *relevant information* from the local EHR systems reducing the need for double documentation while serving the communicative aspect with the antenatal health record.

> **Purpose 2**: *The electronic antenatal health record shall be a comprehensive health record containing all relevant documentation in a pregnancy. This includes (but is not limited to); the woman's prior health status, relevant family history that can impose risks in a pregnancy, prescriptions, clinical assessments and results from tests and investigations that have been performed. The antenatal health record shall facilitate future development of clinical decision support systems (CDSSs). All reporting activities (to health registries and for ancillary functions) shall be performed within the electronic antenatal health record.*

Provided the development should be based on Purpose 2, clinical content requirements will be greatly heightened, as the record should support detailed clinical documentation for every pregnancy. In fact, such a record will become a complete EHR system in itself. The record will include a complete documentation for all pregnancies, including the 25% of pregnancies where prior diseases/illnesses or complications during pregnancy demands documentation of information that greatly exceeds what is found in todays

paper based record. If Purpose 2 encompasses intended use of an electronic antenatal health record, double-documentation will be avoided, as the antenatal health record is in fact a complete health record. All actors within antenatal health care will have access to all relevant information, provided accessibility for all involved actors.

Reporting activities will be heavily supported, although this is not the primary goal for an electronic antenatal health care record. Nevertheless, there are national goals and statements that regard this reuse of data as a positive feature in electronic health records. This concur to former responses to hearings as well as it was identified by interviewed health personnel.

> **Purpose 3:** *The electronic antenatal health record shall contain basic information relevant for the pregnant women, to support the women's empowerment. Empowerment shall be supported by providing information of clinical findings from the individual check-up, and an overview of relevant information regarding pregnancy in general shall be provided in adherence to National Clinical Guideline for Antenatal Health Care.*

Following Purpose 3, the electronic antenatal health record will fulfil the national initiatives of providing information to all patients with an aim of supporting patient empowerment and including the patients more actively in daily health care activities. The interviewed clinical specialist commented that current antenatal health record is documentation *for the women, showing that provided health care is in line with guideline proposals.* What the health care actors perceive as relevant information however will vary greatly from the pregnant women's view. Patients (and here; pregnant women) in today's healthcare have high expectations as to having access to all relevant information. Tools for "translating" medical expressions for laymen are easily accessed, thus a development solely with a purpose of providing information to pregnant women in layman "language" may be perceived as condescending and a unnecessary task by many.

As the three proposals presented above indicate, there is a need for a thorough discussion resulting in a conclusive intention for the use of an electronic antenatal

health record. The proposals can serve as a basis for further discussions. The results from the literature review and interviews show that intended use of antenatal health care records are not clearly defined, at least there is not one common purpose of use that is identified by the users of the record.

A discussion regarding intended use and purpose of the electronic antenatal health care record should provide clear conclusions. Legal obligations regarding health care documentation should be evaluated in each of the proposals, with a clear view on how reuse of information can be supported, how clinical work and decision processes can be supported, how all relevant information can be provided to all actors (including the pregnant women) as well as how double documentation efforts can be reduced. When a clear purpose of use is identifies, the work regarding the realisation of an electronic solution for antenatal health care should commence.

The findings in this thesis with the demand for a discussion regarding purpose of use are highly relevant; the brand new National Plan of Action for health proposes an assessment and investigation into how antenatal health care record can be realised in a common solution for both primary and specialist care. This will in turn facilitate a better and quicker access to information for all health personnel, it will increase patient security and it will provide a better utilisation of resources it is stated (Helsedir., 2014).

10.1.3 Possibilities for re-use of information

Current views on electronic system development in health care are that systems should be developed with additional reuse of content for in mind. The perceived benefits of this are recognised by many including the interviewed health care professionals. The National Plan of Action in health also recognises reuse of information in the national strategy for Norway (Helsedir., 2014). The aim with the dual-model initiative is to facilitate reuse of information, without compromising the primary concern of system development; creating ICT support systems for health personnel in their daily clinical activities. Health care records are used to document provided health care. In addition, the information within electronic health records is reused in communicative aspects, both within the system, between different health care professionals as well as externally outside system boundaries, in supporting ancillary functions, as well as for reports to national health registries.

In order to support communication, either within an EHR system or between different systems, a fundamental prerequisite is some degree of standardisation and structuring (Pirnejad et al., 2008; Stefanelli, 2004; Coiera, 2003). The Norwegian government has a national vision that information in health registries shall be automatically retrieved from the EHR systems. In order to realise this vision one has to plan for secondary use of data when starting to design health information systems (Helse- og omsorgsdepartementet, 2012).

Advocates for archetypes and structured clinical content have an additional agenda however, namely providing health care personnel the opportunity of designing and detailing needed clinical content. By doing this the argument is that the end result (i.e. the developed system) will cover clinicians requirements for clinical content. It is "... useful to identify core concepts and to ensure common perceptions of these for all actors" (Eltvik and Torsvik, 2013:149), while the preliminary report commented that there are challenges in establishing one common dataset due to; "... there has not been a decision as to who should collect and unify the definitions, there lacks an overview of definitions used in different EHR systems and that the definitions are determined only by one part" (Svarlien, 2008:14).

Even though there have been identified challenges as to identifying core concepts and definitions of them, this thesis demonstrates how this can be done. Discussions about method of work, the results and proposed further actions are discussed subsequently.

<div align="center">
Scientific question 2:

What practical experiences regarding development of archetypes are there and how are these relevant?
</div>

10.2 Lessons learnt from prior projects

Different articles and project descriptions show a differentiation as to the practical path utilised when working with archetypes. Some project base the clinical content on existing health records, either electronic or paper based ones (Santos et al., 2012; Buck

et al., 2009). Others based archetype and template development on clinical processes giving the result of process-specific templates defined with reference templates. Each reference template was populated with clinical content relevant for each specific context (Rosenälv and Lundell, 2012).

The archetype development projects and prior proof-of-concepts projects evaluated in this thesis single out one crucial factor as regards archetype development; the clinicians have to be engaged in the development of structured clinical concepts (Nasjonal IKT, 2012; Santos et al., 2012; Buck et al., 2009; Leslie et al., 2009; Hovenga et al., 2007). Only with the engagement of clinicians can complete and clinically relevant archetypes be developed. In addition of creating quality archetypes, the clinicians will have the opportunity of designing and detailing their needed clinical content. By doing this the end result (i.e. the developed system) have great chances of covering and encompassing all clinicians requirements for clinical content.

Several projects also identify the need of having qualified technical staff supporting the clinicians in the archetype development process. In Brazil, the clinicians opted for using a spreadsheet, while technical staff performed the technical design. The Norwegian proof-of-concept also saw benefits of having health care staff with prior knowledge to ICT, in order to facilitate the archetype development process (Nasjonal IKT, 2012). Leslie summarised the challenge as that clinical staff must be supported so they "...can be able to make some sense of a computable representation of clinical content" (2009:126). The archetype development process described in Chapter 8, propose utilisation of mind-maps in the development process. Several projects comment the positive attribution mind-maps had in the archetype development processes.

10.2.1 Time usage

Critical comments regarding development processes of acknowledged standards are that they are very time-consuming. The standards organisations themselves agree in that they should continually improve their timeliness and performance to ensure that end results meet the expectations of the users. An in-house study performed within ISO shows a reduction of standards development time by 30% from 2002 to 2009 (Holmblad, 2011). Still, the average time is 32,8 months.

It is challenging to perform a direct comparison between development time of standards and archetypes, as the end results of these two processes are different. Creating and developing archetypes can also be considered a time-consuming activity. As Santos et al (2012) described, they used 120 days to define data elements and identification of the clinical concepts. The research into existing archetypes, to check for overlaps etc., time usage was 45 days. To my knowledge no other article or project description has described time usage to same extent as Santos et al. However, knowing that the project designed all needed archetypes prior to searching for already developed archetypes, one can argue that overall time usage in that specific project may have been reduced if research in archetype repositories were done prior to development. The article does not however describe if there were overlapping archetypes, so this argument must be regarded as a qualified guess.

In the future new projects should report time usage, like Santos et al have done, in order to facilitate further evaluate use of time in different standardisation activities. In theory, archetype projects in the future should require less use of time in developing archetypes, as there will be more published archetypes available (hopefully). It will be interesting to see whether this will become true.

10.2.2 Involvement of health professionals

As stated numerous times, in order to develop archetypes representing clinical concepts of good quality, that are unambiguous, thorough and distinct comprising all needed data for clinically meaningful concepts, clinicians have to be actively involved in the development process. Present project has not had clinical involvement, the focused interviews excepted. The proposed clinical content is derived from existing paper based record as well as numerous sources like report forms and earlier responses to hearings. The interviewed clinicians all stressed that an antenatal health record must conform to the National Clinical Guideline for Antenatal Care.

The archetypes proposed in this project represent the identified concepts derived from the identified sources. The work presented in this work should be considered as the first-step of the evaluation of clinical concepts needed in an antenatal health record. It may be that stakeholders within antenatal health care do not agree with proposed content. However, it is my view that the strength of present proposal is that all data

elements identified in the documents and in the interviews are represented. Additionally, many of the proposed archetypes are developed within the NT Antenatal health care project in Australia. Present project provides therefore, in my view, a solid base on which further discussions and quality assurance work as to applicability for Norway can be based on. However, prior to further work regarding clinical content commences, the discussion regarding what intention of electronic antenatal health care record has to be done. The chapter *Technical solution for an antenatal health record*, shows that the premise for the health record has to be distinctly identified. When this is done, further work with clinical content for the record can be facilitated. For example: if Purpose 1 describes primary intent of the antenatal health care record, the evaluation shows that proposed archetype selection represent needed clinical content. If Purpose 2 represents primary intent of the record, proposed archetypes only somewhat cover needed clinical content and further analysis has to be performed.

10.2.3 Involvement of stakeholders

The great potential for re-use of information that dual modelling and archetypes represent has been discussed. The Swedish project IFK2 identified the need of developing new archetypes to support content extraction when reporting to registries. They found that direct reuse of existing archetypes did not provide sufficient data collection needed for reporting activities (2010, summarised in Nasjonal IKT, 2012).

Stakeholders in antenatal health care are represented by (non-exhaustive list):
– The Norwegian Institute of Public Health which are responsible for several national health registries of which National Birth Registry of Norway is one
– Other quality registries and medical registries that may utilise information from the antenatal health record
– Health professionals involved in in vitro fertilisation
– Health professionals involved in genetics
– Postnatal health care stakeholders. Both in maternity wards and primary health care
– The pregnant women,
– And administrative stakeholders.

Even though archetypes alone will not resolve all needed reuse of clinical content there should be an aim of supporting reuse activities as much as possible. In order to fully

support this, all the stakeholders to antenatal health records should be involved in quality assurance work of clinical content and attributes.

10.2.4 Translation of archetypes

A total of 8 archetypes have been translated in this project. I have not seen any articles or prior projects discussing experiences regarding translator activities with archetypes, other than the Norwegian report *Nasjonal IKT Tiltak 41* (Nasjonal IKT, 2012)*. In their report they discuss how they in some instances found the need to utilise descriptive translations to represent same content as original language. In the project, they also deliberately tried to reuse same translations for each occurrence of term in all archetypes. The aim of current project was to reuse the translations performed in the Nasjonal IKT project but it proved to be a challenge retrieving these earlier translations. I had to examine all previously translated archetypes to identify whether a term had occurred in any other archetype. This was quite time-consuming work and I am not currently sure that all previously translated terms have been reused. A significant tool for translation activities would have been if one could extract all previously translated terms from the CKM repository. It is my clear opinion that this would enhance consistent translations in all archetypes.

Present project had a distinct ambition to create a demonstration template to complete the proof-of-concept for direct reuse of archetypes in a Norwegian setting. When creating this demonstration-template, the quality of the translations was put to a test. The test showed that several terms had quite a peculiar feel to them when aggregated into a template. The content was clearly understood, but the phrasing and chosen words did not comply in every instance. This shows that there is a challenge in translating archetypes properly when not having the actual use-case clearly visioned. The challenge is that each archetype may be reused in several settings, challenging having a specific use-case in mind.

Scientific question 3:

Can previously developed archetypes cover clinical content and work process requirements in Norwegian antenatal health care?

In this quality case study a comprehensive data elements collection has been gathered. The collection has in turn been utilised in searching for existing archetypes. The work has been twofold; firstly an investigation and evaluation regarding clinical coverage was performed. Then a thorough qualitative evaluation of the archetypes was performed, utilising identified Archetype Quality Requirements.

10.2.5 The evaluation of clinical content coverage in candidate archetypes

Based on a clinical content assessment performed based in Purpose 1 (an electronic representation of an antenatal health record based on existing paper based record updated with additions/alterations identified in the guideline) my investigation shows that in most part all required clinical content and attributes already are described and included in existing archetypes. The exceptions are; confirmation of last menses date ("date certain"/"date not-certain") and precise location of placenta. Regarding "date certain" and "date not-certain" my proposal is to include this as predefined text in templates. Precise location of the placenta, as has been proposed by the interviewed GP, has not been covered in the evaluated archetypes due to a simple reason; my previous investigation overlooked the archetypes CLUSTER.anatomical_location.v1 and the specialisation CLUSTER.anantomical_location-precise.v1. The failure of not identifying these two candidate archetypes shows that in search for previously developed archetypes, failures to detect all relevant archetypes may occur. Present archetype selection is the result of an investigation that has solely been performed by me. To heighten the quality of investigations into formerly developed archetypes, it is my proposal that several individuals should perform investigative work. After the different "investigators" have explored archetype repositories and summoned their findings, omissions like demonstrated here most probably would not occur.

10.2.6 Proposals for future work

The performed investigation and evaluation of previously developed archetypes relevant in an antenatal health record, as has been done in this thesis, provide a unique

basis for a future development of a Norwegian antenatal health care record encompassing all needed clinical content. The proposal is to reutilise previously developed archetypes, many of which are developed by antenatal and maternity care experts in Australia. When aggregating archetypes in templates, data elements and clinical content that not is to be utilised in Norway can be hidden and additional constrictions can be added resulting in comprehensive fit-for-purpose health record.

By having this rich repository of archetypes future projects have a great advantage as to being able to reduce efforts and time-use in the standardising activities. It is my view that the core development steps as described in chapter 8 should be utilised. I have not had the possibility of evaluating whether the archetypes developed in the Brazilian project can be regarded as being of higher quality or encompassing more clinical content than archetypes found in NEHTAs and openEHRs repositories do. Nevertheless, it is my clear opinion that the additional time I assume was put into the effort of developing all new archetypes prior the examination for existing could be better used for quality evaluation of existing archetypes.

10.2.7 Evaluation as regards work processes

An investigation into how antenatal health care is performed and how the documentation activities in the check-ups have been performed. Although prior projects have described documentation processes in antenatal health care thoroughly, I have not found descriptions regarding the complete set of information that is documented both in the local EHR systems as well as on the paper based record. The description of clinical documentation activities should be further examined in future projects. Current work processes may change and new solutions that support these activities will further impact work processes. The practical implications of new solutions should clearly be identified and evaluated, as success of projects and systems can be evaluated by the user acceptance. With a thorough evaluation of clinical documentation processes hopefully double-documentation can be reduced and chances for positive end user experiences enhanced.

The need for embracing the socio-technical complexity within health care and standardisation work has been described and discussed. The arguments sum up to be that standards should incorporate clinical work practices and the electronic health

records should support clinical processes. Clinical guidelines convey the best available evidence in the field of study and they shall have focus on clinical practice and implementation of them. The National Clinical Guideline for Antenatal Health Care details how antenatal care should be provided and it proposes appropriate interventions to different clinical problems. There are different ways one could say electronic systems should support clinical work processes. One way is to developing clinical decision-support systems (CDSSs) that support health professionals in deciding what health care to perform in any given clinical problem or clinical finding. By sending proposals CDSSs can support clinicians in the evaluation of needed clinical activity based on a test result or measurement, or prompts at specific times for additional tests or measurements. The development of CDSSs is a challenging task and further evaluation about this topic has not been performed in this thesis.

Disregarding CDSSs there are potentials with archetypes as to how information from previous pregnancies directly can be reutilised in the health record in current pregnancy. If a woman has previously been pregnant, information regarding blood type will exist in her former antenatal health record. This is information that directly can be utilised in a current pregnancy; *if she was Rh factor positive then, she is Rh factor positive now (*interviewed medical specialist*)*. Summary of previous pregnancies can directly be included in the current antenatal health record as well as family history. Additionally, one could establish a system that reuses gestation information as a source for issuing information about what actions that should be performed in the individual check-ups and what information the guideline proposes should be given to the women at specific times.

Inclusion of work practice support systems is not as of yet widely developed, but preliminary projects show that archetypes also can be utilised in that respect. Within antenatal health care there are challenges as the actors within the domain are dispersed in many different legal entities and that the pregnant women shall have access to the information. In Norway legislation has prevented the creation of systems that cover demands for cooperative work and information sharing, but the current amendment proposals have the aims for positively influence development of collaborative and

shared systems to be used within health care (Helsedir., 2014; Helse- og omsorgsdepartementet, 2013).

10.2.8 Quality of archetypes

With a basis in proposed Archetype Quality Requirements (Kalra et al., 2012) the identified archetypes relevant for a Norwegian antenatal health record have been evaluated (disregarding the two clusters mentioned in Ch. 10.2.4). To my knowledge, a practical utilisation and discussion regarding the proposed quality requirements have not been performed prior to present work. During this work it became clear that several of the requirements had to be splitted. It was hard to determine whether a requirement was met or not, when the requirement itself contained several elements that individually could or could not be fulfilled. The different elements found in some of the requirements have therefore been split. This is indicated with a punctuation mark and a subsequent number. Other requirements were added, as I evaluated the requirement list not being complete in its original form. This is been indicated with a (n) behind quality requirement number.

Some of the findings discussed must be regarded as new design requirements for the CKMs. This is true for these quality requirements:

- **QR 8:** Specify the EHR information model
- **QR 13, 13.1 and 13.2(n):** Include time and location/jurisdiction of its creation, and time of translation
- **QR 17:** Reference a clear statement of any copyright that apply to it
- **QR 18 and 18.1(n):** List and date stamps for endorsements and approvals of use, endorsements and approvals of translations
- **QR 19 and 19.1:** List and date stamps for deprecations of use with explanation

As of now these requirements are not represented with designated areas in archetype metadata. Adding these in the CKM may contribute to inclusion of this specific information in the archetypes and thus heightening the overall quality of the archetypes.

In addition to propose new or refined requirements, there are findings that should be regarded as proposals for revisions of the existing quality requirements. The table

below summarises the proposed breakdown structure, new requirements as well as the proposed evaluation regarding specific requirements, marked with **x**.

Information governance requirements:		Break down into measurable components	New requirement	Evaluation of requirement should be
QR3	Specify for which clinical scenario or workflow it is intended for			x
QR4	Specify any particular speciality, discipline or professional groups			x
QR5	Include or reference minimum one term from an internationally registered terminology system			x
QR11	Information in an archetype shall be capable of being represented using the information model specified in Section 7 of ISO EN 13606 part 2			x
QR12	include information about author that has taken primary responsibility for its creation	x		
QR12.1(n)	Include contact information (e-mail) to authors		x	
QR12.2(n)	Include contact information (e-mail) to translators		x	
QR13	Include time of its creation	x		
QR13.1	Include location/jurisdiction of its creation	x		
QR13.2(n)	Include time of translation		x	
QR14	Include information: person/organisation that has coordinated the inputs *Revise requirement* – inclusion of complete stakeholder representation		x	x
QR17	Reference a clear statement of any copyright that apply to it	x		
QR17.1	Reference a clear statement of any usage restrictions that apply to it	x		x
QR17.2	Reference a clear statement of any licence information that apply to it	x		x
QR18	List and date stamp any approvals and endorsements for its use	x		
QR18.1(n)	List and date stamp any approvals and endorsements of translations		x	
QR19	Include a time-stamped indication of its intended deprecation from future use by any jurisdiction	x		
QR19.1	Include an explanation for deprecation of use	x		

Table 8 Collated list of proposed amendments of quality requirements

I have thoroughly discussed that requirement 3,4 and 5 are relevant information to be included in many archetypes. But, as there are many archetypes that one never will be able to specify clinical workflow, scenario, speciality, discipline or professional group (for instance several Cluster archetypes and Elements), my proposal is to refine the requirements and target these to specific classes of archetypes. Without such a refinement, there will always be several archetypes that never will pass a quality requirement check, like the one performed in this thesis. Regarding QR 11; how to represent the information model of ISO EN 13606 has not yet been specified (Kalra 2013). In my view, although not negative to having such a requirement, this requirement should be omitted until a detailed description of how such a representation should be performed has been published. Quality requirements 17.1 and 17.2 are shown to be in clear opposition to CC-BY-SA licence terms. The licensing of openEHR artefacts is based on the principles of CC-BY-SA licence terms. The quality requirements should therefore be adjusted so that they do not come into conflict with licencing terms.

10.2.9 Quality management

There are many facets and discussions regarding the performance of quality management. Findings in this thesis do not contribute with new knowledge in that regards, other than as a confirmation of previous findings in other studies and articles. However with the new remote management, several challenges regarding archetypes with unique identifiers in several archetypes repositories may be aided. Still, new functionality also raises new challenges as to the actual adoption of this functionality. Are the creators of archetypes capable of providing such service to all other CKMs, and are the owners of each CKM comfortable of having content of which they cannot govern themselves? Present study has not further performed such an evaluation, but a clear description as to how this will be utilised should be made available.

As a final note, I have to question whether numerous archetype repositories is the way to go regarding archetype development and management. My assumption is that demands for local/national CKMs stem from a need and wish to have some degree of ownership of the data within the CKM. Still, the aim of openEHR is to support worldwide sharing of structured clinical data, and the CC-BY-SA licence terms support

this. Perhaps one CKM for the whole world will be too big, but I welcome such a discussion. As shown in chapter 9.6.2.1 *Maturity of archetypes* there is a need of increasing the number of clinical experts in order to speed up the evaluation and publication process of archetypes. Maybe each country could have prime responsibility of a Project or Incubator? If all openEHR users used the one CKM, there is a great potential for raising the numbers and hence, speed up the archetype development process.

10.2.10 Do the quality requirements impose quality?

The aim for utilising the archetype quality requirements in this project was to identify archetypes fulfilment of the requirements, as well as to identify whether the requirements actually reflect quality of archetypes. The thorough evaluation performed shows that there is room for improvements in both the design of CKM to incorporate data descriptions as well as there is identified proposals for revisions and additions to the requirements. What is left is an evaluation; do the quality requirements actually impose quality on archetypes?

In my view, the answer is both yes and no. There are great challenges in defining quality and my knowledge is not vast enough to assess whether quality is found in each and every instance. However, thru the work a sensation has grown; has my evaluation really identified whether the archetypes encompass all needed clinical content? Hovenga et al (Hovenga et al., 2007) identified the need of developing new archetypes to fulfil needed clinical content for reporting issues. The structure of archetypes has the capacity of being reutilised in many aspects, as discussed earlier. However, when evaluating the quality requirements there is great focus on the clinicians. Of course the clinicians are the foremost stakeholders for clinical content and actual use of archetypes. Still, to ensure reusing capabilities of archetypes there are several more stakeholders that should be included. In a future Norwegian project my proposal is to identify all stakeholders and involve them throughout the archetype development process. Leslie has described a candidate framework which identifies the need for stakeholder involvement throughout the "life-span" of an archetype (Leslie, 2011).

In QR 14 (Include information about the person/ organisation that has coordinated the inputs into its design basis) Kalra et al somewhat encompass this criteria but the validation shows that the stakeholders that contribute in archetype design mostly

consists of health professionals. After having concluded the validation of archetypes, my conclusion is that further additions to the requirements will contribute positively to the quality of archetypes. The stakeholder aspect should be included in both archetype metadata and in quality requirements for archetypes. This proposal is in line with Leslies proposal in her framework.

11 Conclusion

In this thesis I have investigated how the dual-model approach with archetypes and templates can be utilised within antenatal health care records. The primary aim of this study has been to investigate how health care professionals can be aided in the daily health care provision for pregnant women both in regards to clinical content in electronic support systems but also how a technical design model can be utilised for the establishment of needed clinical content. The results from this study include proposals for future development projects within health care domain in Norway in general, and for antenatal health care in special. Proposals for design requirements to the archetype repositories are identified and proposals to further refinement of archetype quality requirements are discussed.

11.1 Significant findings - within antenatal health care in Norway

Regarding previous projects within antenatal health care, the evaluation show that this area of health is a challenging area to support with electronic support systems like an electronic health record. There are stakeholders both within primary and specialist care. The pregnant women are key stakeholders within antenatal health care, who also shall have access to the documented information. With the retrieval of information, both with a literature study and interviews of health care professionals, it has become clear that intended use of an electronic antenatal health care record is not properly established. The health care professionals are to document all clinical investigations, evaluations and findings in a health record. The National Clinical Guideline for Antenatal Health Care proposes the utilisation of structure documentation. During the investigation however I have not found any documentation of the intended use for this structured documentation. **A significant finding of this study is that a thorough investigation and clarification process regarding intended use of an electronic antenatal health record should be performed.** To start off such a discussion, three enticing statements have been provided, all of which encompass different views of intention of use that have been found present in present work. A discussion and conclusion should encompass what health care documentation shall be performed in an antenatal health care record compared to a general use health care record, how reuse of

information should be supported, how clinical work and decision processes can be supported, how relevant information shall be provided to all actors (including the pregnant women) as well as how double documentation efforts can be reduced. When such a conclusion has been met, further work as to how such a support system should be developed can commence. A development project will then have a clearer view as to what clinical information that should be included and how such a system can support the collaboration between different actors within antenatal health care.

The evaluation of previous projects and development of systems for antenatal health care included in this study, show that they often impose a lot of additional work on behalf of the health care professionals. Often this has been the reason as to why the systems no longer are in use. A projects or a systems success can be evaluated in many different ways; for instance that they are finalised on time, that budgets have been kept or by end users satisfaction. The most apparent result found in investigated projects is however that user dissatisfaction has contributed in the termination of use. To enhance the potentials for user satisfaction one has to include end users early in development projects.

With early inclusion, the end users can clearly identify what clinical content is needed as well as work processes can be identified. However, the end users are not the only relevant stakeholders to be included in such a process. This qualitative case study shows the **importance of involving all stakeholders as early as possible in development projects in general as in archetype development specifically**. It is also important to sustain stakeholder involvement throughout the development cycle to ensure that the interests for all stakeholders are met and thus enhance reuse of clinical information. In antenatal health care stakeholders represent (non-exhaustive list) national health registries, medical health registers, health care professionals working within in vitro fertilisation and genetics, post natal primary care, administrative personnel as well as the pregnant women. **This study proposes that a future development project for antenatal health care involves all relevant stakeholders in early stages and throughout the project**. The result of early involvement will enhance possibilities for reuse of information in several aspects.

Finally, this project has identified data elements from several relevant sources. These data elements have been evaluated and are found to exist in the already developed archetypes included in present archetype selection. In addition, a demonstration as to their applicability in a Norwegian setting has been demonstrated with the design of a template. Preliminary projects have identified the establishment of common clinical concepts with clear definitions as a potential challenging area in a development project. **The proposal from present project is to reuse previously developed archetypes in a future electronic antenatal health record.** Antenatal and maternity experts have developed these archetypes and with a reutilisation of these efforts for clinical content identification and attribute identification can be reduced significantly. In addition, potentials for reuse in communication activities can be heightened for Norway as well as internationally.

11.2 Significant findings - within dual-modelling community in Norway

The use of archetypes and templates in Norway is at the starting point. Present project has identified challenges as regards archetype management. These findings are not new, they are confirmations of findings from previous studies. However, the findings are significant for the establishment of archetype management within the Norwegian archetype repository. In order to support archetype evaluation and publication there **is a need for active and high numbers of clinical reviewers**. The number of registered reviewers in openEHRs and NEHTAs CKM compared to number of published archetypes indicate that number of reviewer should not be lower than 50% of total registered users in a CKM.

This qualitative proof-of-concept demonstrates how previously developed archetypes describe needed content for an antenatal health care record and how these can be aggregated in templates. A significant finding from present project is that **translators should have potential use-cases of an archetype in mind when performing translations**. When aggregating translated archetypes in templates results show that performing translations without use-case in mind gives a somewhat peculiar feel to the Norwegian text. A proposed solution aiming at the establishment of consistent translations in all archetypes is **to develop and publish a demonstration archetype that includes approved translations of most commonly used terms in archetypes.**

This project has demonstrated how one researcher may overlook relevant archetypes when searching and examining previously developed archetypes. As a final note the proposal is to **always include more than one "investigator" when performing searches for previously developed archetypes**. This will in turn reduce changes of not detecting all candidate archetypes, as happened in this project.

11.3 Significant findings - within international dual-modelling community

To my knowledge, no other project has actively utilised proposed Archetype Quality Requirements in an evaluation of candidate archetypes in a project. In present project this has been performed and thru this work there is identified proposals for future adjustments in both the design of CKMs as well as for the Archetype Quality Requirements.

11.3.1 Requirements for CKMs

The quality requirements proposed identify several key elements that should be representing in archetypes. In order to support the documentation of the information, my proposal is to **include designated fields for these in the CKM**. Having the information available in metadata of archetypes may in turn contribute to the inclusion of this information in archetypes and thus heightening the overall quality of archetypes. This can in turn support the overall quality management of archetypes and their publication process.

11.3.2 Refinement, additions and evaluation of Archetype Quality Requirements

In order to properly use the quality requirements in evaluation of archetypes, my proposal is to **break down the requirements into single measurable components**. In addition I have proposed **inclusion of new requirements** in order to have a complete quality evaluation of the archetype metadata both in original language (English) and for all translations. Finally, the evaluation shows that in order to impose quality in archetypes, the dimension regarding **stakeholder involvement should become more prominent**.

11.4 Proposals for future work

This project has shown how focused interviews can contribute into understanding how clinical work processes are and what information is relevant in clinical practice.

However, the material derived from the interviews does not represent all stakeholders in antenatal health care. The primary care aspect, with local health centres has not been interviewed. In addition, stakeholders with different health record support systems should be involved. As described, there are different electronic solutions in use in Trondheim, Bergen and Oslo and this project did not succeed in having representatives from each region in the interviews. The potentials for having different clinical work processes in these different areas are quite high. The proposal for future work is therefore to ensure that all stakeholders, including same group of stakeholders but in different areas/regions in Norway are included.

The developed template has had a quick quality check by a midwife. However, in general health care professionals have not been involved in the evaluation of present work. Inclusion of, and evaluation by, health care professionals should be a part of a future project.

Finally this project has not tested and demonstrated how archetypes and templates can be constrained by using standards. I propose that this should be an area for further investigation in future projects.

12 References

Anell, A. and Glenngård, A.H. (2012) "Sweden. Health System Review". Vol.14, No. 5. *Health Systems in Transition. European Observatory on Health Systems and Policies.*

Bach, G., Yang, J., Alsaker, M. and Vestad, A. (2005) "Elektronisk 'helsekort' for den gravide. Gravidkortet, elektronisk løsning for effektiv og sikker deling av informasjon om graviditet". *KITH Rapport R 01/05.*

Backe, B. and Jacobsen, G. (1994) "General Practitioners´compliance with Guidelines for Antenatal Care." *Scand J Prim Health Care* 12: 100–105.

Bansler, J. P., Havn, E.C., Johannsen, N. and Winthereik, B.R. (2007) "Elektronisk svangrejournal i Fyns Amt. Evaluering af et pilotprosjekt". København: Center for Informations- og Kommunikationsteknologi, Danmarks Tekniske Universitet. http://www.dtu.dk/upload/centre/cict/publications/working%20papers/cictwp114.pdf.

Beale, T. (2002) "Archetypes: Constraint-Based Domain Models for Future-Proof Information Systems". *OOPSLA Workshp on Behavioral Semantics: Serving the Customer.* http://www.openehr.org/shared-resources/publications/archetypes.html.

Beale, T. (2013) "Antenatal Health Records in Norway... and Archetypes", June 4. (e-mail)

Berg, M. (2001) "Implementing Information Systems in Health Care Organizations: Myths and Challenges." *International Journal of Medical Informatics* 64 (2-3): 143–56.

Buck, J., Garde, S., Kohl, C.D. and Knaup-Gregori, P. (2009) "Towards a Comprehensive Electronic Patient Record to Support an Innovative Individual Care Concept for Premature Infants Using the openEHR Approach." *International Journal of Medical Informatics* 78 (8): 521–31.

Cambio Healthcare Systems. 2012. "Welcome to the E-Health Generation. Welcome to Cambio COSMIC". Homepage. *Cambio Healthcare Systems.* http://www.cambio.se/zino.aspx?articleID=15036. Accessed: 02nd Dec 2012

Carlsen, B. and Bringedal, B. (2011) "Attitudes to Clinical Guidelines--Do GPs Differ from Other Medical Doctors?" *BMJ Quality & Safety* 20 (2): 158–62. doi:10.1136/bmjqs.2009.034249.

CEN, European Committee for Standardization (2012) "CEN - European Committee for Standardization: What Is a Standard?" Homepage. http://www.cen.eu/cen/NTS/What/Pages/default.aspx. Accessed: 08th Nov 2012

Chen, R., Klein, G.O., Sundvall, E., Karlsson, D. and Åhlfeldt, H. (2009) "Archetype-Based Conversion of EHR Content Models: Pilot Experience with a Regional EHR System." *BMC Medical Informatics and Decision Making* 9 (1): 33.

Coiera, E. (2003) *Guide to Health Informatics.* 2nd ed. London.

Creative Commons (2014) "Creative Commons — Attribution-ShareAlike 3.0 Unported — CC BY-SA 3.0". Homepage. *Cc - Creative Commons.* Accessed: 19th Jan 2014. http://creativecommons.org/licenses/by-sa/3.0/.

Ebbing, M. (2014) "Sentrale helseregistre - styrker, svakheter, koblingsmuligheter". *Lecture presented at the HEL-8020, UiT 2014,* March 31, Tromsø. Accessed: 17th April 2014 http://www.kvalitetsregistre.no/getfile.php/Norsk/Dokumenter/Ebbing-Sentrale%20helseregistre.pdf.

EFTA (2013) "EEA Agreement". Homepage. *The European Free Trade Association*. November 25. http://www.efta.int/eea/eea-agreement. Accessed: 25th Nov 2013

Ellingsen, G., Monteiro,E. and Munkvold, G. (2007) "Standardization of Work: Co-Constructed Practice." *The Information Society* 23 (5): 309–26.

Eltvik, N.E. and Torsvik, M. (2013) "Implementering av elektroniske støtteverktøy i helsetjenesten. Faktorer som er viktige for å styrke implementering, basert på funn fra case i maritim spesialisthelsetjeneste." Msc. Health Informatics, Trondheim: Norwegian University of Science and Technology.

European Union, European Commission and Directorate-General for the Information Society and Media (2009) *Semantic Interoperability for Better Health and Safer Healthcare: Research and Deployment Roadmap for Europe. Semantic Health Report January 2009*. Luxembourg: EUR-OP.

Fawdry, R., Bewley, S., Cumming, G. and Perry, H. (2011) "Data Re-Entry Overload: Time for a Paradigm Shift in Maternity IT?" *JRSM* 104 (10): 405–12.

FHI (2009) "Gode helseregistre - bedre helse. Strategi for modernisering og samordning av sentrale helseregistre og medisinske kvalitetsregistre 2010-2020. Hovedrapport fra forprosjektet Nasjonalt helseregisterprosjekt". Oslo: Helse- og omsorgsdepartementet.

Folkehelseinstituttet, Avdeling for medisinsk fødselsregister (2013) "Melding til MFR av graviditet etter assistert befruktning (ART)". Folkehelseinstituttet. Accessed: 4th Sept 2013. http://www.fhi.no/dokumenter/87ace3edca.pdf.

Forskrift Om Pasientjournal (2001) http://lovdata.no/dokument/SF/forskrift/2000-12-21-1385.

Garcia, D., Moro, C.M.C., Cicogna, P.E. and Carvalho, D.R. (2013) "Method to Integrate Clinical Guidelines into the Electronic Health Record (EHR) by Applying the Archetypes Approach." In *Studies in Health Technology and Informatics*, 192: MEDINFO 2013:871–75. Copenhagen.

Garde, S., Hovenga, E.J.S., Gränz, J., Foozonkhah, S. and Heard,S. (2007b) "Managing Archetypes for Sustainable and Semantically Interoperable Electronic Health Records." *Electronic Journal of Health Informatics* 2 (2): e3.

Garde, S., Knaup, P., Hovenga,E. and Heard, S. (2007) "Towards Semantic Interoperability for Electronic Health Records." *Methods of Information in Medicine* 3 (46): 332–43.

Hanseth, O., Jacucci,E., Grisot,M. and Aanestad, M. (2003) "Reflexive Standardization. Interpreting Side-Effects and Escalation in Standard-Making." Standard Making: A Critical Research Frontier for Information Systems. MISQ Special Issue Workshop.

Hasley, S. K. (2011) "Decision Support and Patient Safety: The Time Has Come." *American Journal of Obstetrics and Gynecology* 204 (6): 461–65.

Heard, S. (2011) "Northern Territory Pregnancy Care Record - Health Information Models - openEHR Wiki". Homepage. *openEHR - Northern Territory Pregnancy Care Record*. June 5 2011. Accessed: 2nd Dec 2012

http://www.openehr.org/wiki/display/healthmod/Northern+Territory+Pregnancy+Care+Record.

Helse- og omsorgsdepartementet (2011) "Sammendrag av høringsgrunnlag for Nasjonal helse- og omsorgsplan (2011 - 2015) Fremtidens helsetjeneste: trygghet for alle". Sammendrag av høringsgrunnlag. Fremtidens helsetjeneste. Oslo: Helse- og omsorgsdepartementet. https://fremtidenshelsetjeneste.regjeringen.no/.

Helse- og omsorgsdepartementet (2013) *Høring - forslag til ny pasientjournallov og ny helseregisterlov*. Oslo.

Helse- og omsorgsdepartementet (2012) "Meld. St. 9 (2012–2013) Én innbygger - én journal. Digitale tjenester i helse- og omsorgssektoren." Melding til Stortinget 9. Oslo: Helse- og omsorgsdepartementet.

Helsedir (2005) "National Clinical Guideline for Antenatal Care (short Version)". Nasjonale faglige retningslinjer IS-1339E. Helsedirektoratet.

Helsedir. (2012) "Overtidige svangerskap - Helsedirektoratet.no". Homepage. *The Norweigan Directorate of Health*. September 6 2012. Accessed: 25th Nov 2013. http://helsedirektoratet.no/folkehelse/gravid/overtidige-svangerskap/Sider/default.aspx.

Helsedir. (2013) "Nasjonale faglige retningslinjer for antibiotikabruk i primærhelsetjenesten". National clinical guideline IS-2030. Nasjonale retningslinjer. Oslo: Helsedirektoratet.

Helsedir. (2014) "Nasjonal handlingsplan for e-helse (2014-2016)". IS-2179. Oslo: Helsedirektoratet.

Helsedirektoratet (2005) "Nasjonal faglig retningslinje for svangerskapsomsorgen". Nasjonale faglige retningslinjer IS-1179. Oslo: Sosial- og helsedirektoratet.

Helseregisterloven (2001) *The Personal Health Data Filing System Act*. http://lovdata.no/dokument/NL/lov/2001-05-18-24/KAPITTEL_2?q=virksomhetsovergripende+helseregistre*#KAPITTEL_2.

HOD (2009) "St.meld. nr. 12 (2008-2009) En gledelig begivenhet". St.meld 12. Oslo: Helse- og omsorgsdepartementet.

Holmberg, G. (2012) "Trial with optical memory cards at Löwenströmska Sjukhuset", E-mail dated: 19th Nov 2012.

Holmblad, J. (2011) "Roadmap to Success. How to Improve the Standards Development Business." *ISO Strategy 2011-2015*, January.

House of Commons (2011) "The National Programme for IT in the NHS: An Update on the Delivery of Detailed Care Records Systems." Report of Session 45th Report of Session 2012-12. London: Hous of Commons Committee of Public Accounts.

Hovenga, E.J.S., Garde, S., Carr, T. and Hullin, C.M. (2007) "Innovative Approaches and Processes for Capturing Expert Aged Care Knowledge for Multiple Purposes." *Electronic Journal of Health Informatics* 2 (1). e5: 13.

ISO (2008) "Health Informatics - Electronic Health Record Communication - Part 1: Reference Model". EN ISO 13606-1. International Standard. Switzerland: ISO.

ISO (2012) "ISO Standards - What Is a Standard?" Homepage. Accessed: 8th Nov 2012. http://www.iso.org/iso/home/standards.htm.

Johnsen, J. R. (2006) "Health Systems in Transition: Norway." Health Systems in Transition. Copenhagen: WHO Regional Office for Europe.

Johnson, R. B. and Onwuegbuzie, A. J. (2004) "Mixed Methods Research: A Research Paradigm Whose Time Has Come." *Educational Researcher* 33 (7): 14–26.

Kalra, D. (2013) "Archetype Quality Questions". E-mail dated 25th Nov 2013.

Kalra, D., Tapuria, A., Austin, T. and De Moor, G. (2012) "Quality Requirements for EHR Archetypes." Edited by J. Mantas. *Quality of Life through Quality of Information*. European Federation for Medical Informatics and IOS Press, 48–52.

Kawamoto, K., Del Fiol, G., Lobach, D.F. and Jenders, R.A. (2010) "Standards for Scalable Clinical Decision Support: Need, Current and Emerging Standards, Gaps, and Proposal for Progress." *The Open Medical Informatics Journal* 4 (1): 235–44.

Klein, G. (2013) "Prosjekt med arketyper og kliniske maler i andre land - Hva kan vi lære av andre?" presented at the DIPS-forum, June 4, Tromsø. http://www.dips.no/nor/dips_forum/tromso-2013/foredrag-dips-forum-2013.

Kohl, C.D., Garde, S. and Knaup, P. (2008) "Facilitating the openEHR Approach – Organizational Structures for Defining High–quality Archetypes." In , 136:437–42.

Krossen, H. E. and Roland, B. (2007) "Fra veske til skjerm - Elektronisk helsekort for gravide". IS-1432. Oslo: Sosial- og helsedirektoratet.

Kuziemsky, C. E. and Varpio, L. (2010) "Describing the Clinical Communication Space through a Model of Common Ground: 'you Don't Know What You Don't Know'." *AMIA Annu Symp Proc.2010*, November, 407–11.

Lehr, W. (1992) "Standardization: Understanding the Process." *Journal of the American Society for Information Science*.

Leslie, H. (2011) "Archetype Quality II | Archetypical". Blog. *Archetypical*. June 19. Accessed: 21st Apr 2014. http://omowizard.wordpress.com/2011/06/19/archetype-quality-ii/.

Leslie, H. (2013) "Antenatal Health Records in Norway.. and Archetypes", October 3. E-mail.

Leslie, H. and Heard, S. (2008) "Building an Archetype." *Ocean Informatics Website*. Accessed: 9th Oct 2012. www.oceaninformatics.com/Media/docs/2008-06-Building-Archetypes-5c9eaef0-62de-47c6-a155-2ff853e0045f.pdfabout:blank.

Leslie, H., Heard, S., Garde, S. and McNicoll, I. (2009) "Engaging Clinicians in Clinical Content: Herding Cats or Piece of Cake?" In *Medical Informatics in a United and Healthy Europe - Proceedings of MIE 2009. THe XXIInd International Congress of the European Federation for Medical Informatics*, edited by Klaus-Peter Adlassnig, Bernd Blobel, John Mantas, and Izet Masic, 125–29. Studies in Health Technology and Informatics. IOS Press.

Lov om helsepersonell m.v. (helsepersonelloven). 2001. http://lovdata.no/dokument/NL/lov/1999-07-02-64.

Marcos, M., Maldonado, J.A., Martínez-Salvador, B., Boscá, D. and Robles, M. (2013) "Interoperability of Clinical Decision-Support Systems and Electronic Health Records Using Archetypes: A Case Study in Clinical Trial Eligibility." *Journal of Biomedical Informatics* 46 (4): 676–89.

Marcos, M. and Martinez-Salvador, B. (2011) "Towards the Interoperability of Computerised Guidelines and Electronic Health Records: An Experiment with openEHR Archetypes and a Chronic Heart Failure Guideline." In *Knowledge Representation for Health-Care*, 6512:101–13. Lecture Notes in Computer Science. Lisbon, Portugal: Springer-Verlag Berlin Heidelberg.

Michelsen, L., Pedersen, S. S., Tilma, H. B. and Andersen, S.K. (2005) "Comparing Different Approaches to Two-Level Modelling of Electronic Health Records." In , edited by Rolf Engelbrecht, 116:113–18. IOS PRESS. http://booksonline.iospress.nl/Content/View.aspx?piid=4353.

Moreno, A., Berry, D. and Parra, C. (2011) "A Study of Archetype Development Processes." In *User Centred Networked Health Care*, edited by Anne Moen, Stig Kjær Andersen, Jos Aarts, and Petter Hurlen, 169:3. Studies in Health Technology and Informatics. Oslo.

Nasjonal IKT (2011) "Forprosjekt - Pasientrettede IT-systemer. Nasjonal IKT, tiltak 38". Tiltak 38. Trondheim: Nasjonal IKT.

Nasjonal IKT (2012) "Prosjektrapport Nasjonal IKTs tiltak 41. Bruk av arketype-metodikk til definisjon, tilgjengeliggjøring og bruk av kliniske informasjonsmodeller i helseinformasjonssystemer". Project report 41. Nasjonal IKT tiltak. Trondheim: Nasjonal IKT.

Nasjonal IKT (2007) "Prosesstøttende EPJ systemer - bakgrunn, definisjon og målsetninger". Tiltak 10. Trondheim: Nasjonal IKT.

Nasjonal IKT and Kompetansesenteret for IT i helsesektoren (2009) "Tiltak 27 - Forprosjekt for nasjonal definisjonskatalog for kliniske variabler i elektronisk pasientjournal og tilknyttede fagsystemer. Rapport fra arbeidsgruppen". Project report. Nasjonal IKT and KITH.

Novick, G. (2008) "Is There a Bias against Telephone Interviews in Qualitative Research?" *Research in Nursing & Health* 31 (4): 391–98.

openEHR (2014) "openEHR - Who Is Using openEHR?" January 12. Accessed: 12th Jan 2014. http://www.openehr.org/who_is_using_openehr/index.

Phelan, S. T. (2008.)"The Prenatal Medical Record: Purpose, Organization and the Debate of Print Versus Electronic." *Obstetrics and Gynecology Clinics of North America* 35 (3): 355–68.

Pirnejad, H., Niazkhani, Z., Berg, M. and Bal, R.A. (2008) "Intra-Organizational Communicationin Healthcare." *Methods of Information in Medicine* 47 (4): 336–

Rønneberg, U. and Fjeld, A. S. (2005) "Hvilke muligheter og utfordringer står man overfor ved integrering av e-kommunikasjon som funksjon i et e- helsekort for gravide? Et prosjekt med brukervurdering av en fremtidig IKT-løsning i svangerskapsomsorgen." Masteroppgave. Ålborg.

Rosenälv, J. and Lundell, K-H. (2012) "The Swedish Strategy and Method for Development of a National Healthcare Information Architecture." In *Large Scale Projects in eHealth*, 8. IOS Press.

Santos, M. R. dos, Bax, M.P. and Kalra, D. (2012) "Dealing with the Archetypes Development Process for a Regional EHR System." *Applied Clinical Informatics* 3 (3).

Shuy, R. W. (2003) "In-Person versus Telephone Interviewing." In *Inside Interviewing: New Lenses, New Concerns*, by James Holstein, edited by Jaber F. Gubrium, 175–94. California: Sage Publications.

Siemens (2012) "Obstetrix -ett komplett processtödjande journalsystem för mödravård och förlossning". Homepage. Accessed: 2nd Dec 2012 http://www.nwe.siemens.com/sweden/internet/se/Healthcare/IT-losningar/Obstetrix/Pages/Obstetrix.aspx.

Sjetne, I.S., Kjøllesdal, J.G-, Iversen, H.H. and Homboe, O. (2013) "User experiences of pregnancy, birth and postnatal care. National results". PasOpp-report 4- 2013. PasOpp. Oslo: Nasjonalt kunnskapssenter for helsetjenesten.

Sommerville, I. (2011) *Software Engineering*. 9th ed. Boston: Pearson.

Standard Norge (2012) "Homepage - Norsk Standard". Homepage. Accessed: 13th Nov 2012. http://www.standard.no/no/.

Stefanelli, M. (2004) "Knowledge and Process Management in Health Care Organizations." *Methods of Information in Medicine* 43 (5): 525–35.

Stoltenberg, C. (2011) "When the Whole Population Contributes to Knowledge: On Health Registries in Norway". Presentation presented at the MIE 2011, August 30, Oslo.

Sundvall, E. (2013) "Scalability and Semantic Sustainability in Electronic Health Record Systems". Doctoral thesis, Lindköping: Lindköping University.

Svarlien, A. B. (2008) "Forprosjekt: Elektronisk Helsekort for gravide EHG". KITH Rapport 24/08. Trondheim: KITH.

The Norwegian Institute of Public Health (2012) "Medisinsk fødselsregister - Folkehelseinstituttet." November 22. Accessed: 27th Nov 2012. http://www.fhi.no/eway/default.aspx?pid=233&trg=MainArea_5661&MainArea _5661=5631:0:15,3278:1:0:0:::0:0.

Tjora, A. (2011) *Kvalitative forskningsmetoder i praksis*. Oslo: Gyldendal Akademisk.

Vestad, A. and Svarlien, A.B. (2009) "Nye samhandlingsløsninger - konseptbeskrivelse med utgangspunkt i helsekort for gravide". R 01/09. Trondheim: KITH.

Wäckerle, A., Blöchlinger-Wegmann, B., Burkhardt, T., Krähenmann, F., Kurmanavicius, J. and Zimmermann, R. (2010) "Notes on a Stick: Use and Acceptability of Woman-Held Maternity Notes." *European Journal of Obstetrics & Gynecology and Reproductive Biology* 153 (2): 156–59.

Wisdom, J. P., Cavaleri, M.A., Onwuegbuzie, A.J., and Green, C A. (2012) "Methodological Reporting in Qualitative, Quantitative, and Mixed Methods Health Services Research Articles." *Health Services Research* 47 (2): 721–45.

Wollersheim, D., Sari, A. and Rahayu, W. (2009) "Archetype-Based Electronic Health Records: A Literature Review and Evaluation of Their Applicability to Health Data Interoperability and Access." *Health Information Management Journal* 38 (2): 7–17.

Appendix 1 - List of terms

Clinical guideline	A set of systematically developed statements to assist the decision of health care parties about health care activities to be provided with regard to a health issue specified clinical cirucumstances (CEN, 2005)
Clinical information	Information about a peron, relevant to his or her health or healthcare (ISO, 2008)
Electronic health record extract	Part or all of the electronic health record of a subject of care (ISO 2008)
Electronic health record system (EHR)	System for recording, retrieving and manipulating information in electronic health records (ISO, 2008)
Electronic patient record	Repository of information regarding the health of a subject of care, in computer prossesable form (CEN, 2005)
Elektronisk helsekort for gravide	The Norwegian name used in reports when talking about the electronic version antenatal health record (*Helsekort for gravide*)
Healthcare	Services related to the health of an individual (CEN, 2005)
Healthcare organisation	Organisation involved in the direct or indirect provision of healthcare services to an individual or to a population (ISO 2008)
Healthcare professional	Person authorized by law or official regulatioins to be involved in the direct provision of health care activities (CEN, 2005)
Healthcare provider	In this thesis, healthcare provider is used with the same meaning as healthcare organisation. See definition under Healthcare organisation
Healthcare service	Service provided with the intention of directly or indirectly improving the health of the person or populations to whom it is provided (ISO 2008)
Helsekort for gravide	The Norwegian name for the paper version of antenatal health record. Direct translation: "health record card for pregnant women"
Mödravärdjournal	Swedish term for antenatal health records, encomprises often antenatal as well as labour and postnatal information

National clinical guideline	In principle, national clinical guidelines can be regarded as recommendations and advice, and should be based on sound, updated professional advice. Guidelines are meant to be aids for professionals in the assessments they must make in order to achieve sound professional standards and provide high quality services (Helsedir.,2005) (see Clinical guideline)
Patient	Synonym for a subject of care (ISO, 2008)
Personal health record	Health record for which the subject of care or a legal representative of the subject of care is the data controller (ISO 2008)
Semantic interoperability	Ability for data shared by systems to be understood at the level of fully defined domain concepts (ISO 2008)
Shareable electronic health record	Electronic health record with a standardised information model which is independent of electronic health record systems and accessible by multiple authorized users (ISO, 2008)
Shared care	Oganisational principle where two or more health care providers jointly co-operate to provide health care activities to a subject of care for a continuing health issue (Cen, 2005)
Silo-system	An electronic system (can be a system for health records) that that is unable to engage communicatively with other electronic systems. I.e. if the two systems are based upon different, non-compatible standards
Standard	Document, established by consensus and approved by a recognized body, which provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context (ISO 2008)
Subject of care	Person scheduled to receive, receiving, or having received healthcare (ISO 2008), in other words; patients
Svangrejournal	The Danish word for antentatal health record

Appendix 2 – Antenatal health record (scanned)

Appendix 3 – Details from Clincial Guideline for Antenatal Health Care

Details from *Retningslinjer for svangerskapsomsorgen* (Helsedirektoratet 2005, 44–45).

	Week of pregnancy
Identification of high-risk pregnancies	´8-12
Hyper-tension and/or heart disease	x
Kidney- and/or urinary tract disease	x
Severe asthma and/or lung disease	x
Physical disabilities	x
Epilepsy and/or neurological disease	x
Diabetes	x
Endocrine disease	x
Hematological interference	x
Autoimmune disease	x
Cancer	x
HIV	x
Substance abuse	x
Other diseases	x
BMI <18,5 or BMI >30	x
Mental illness	x
The pregnant considered vulnerable, exposed for traumatic experiences	x

Other special conditions	´8-12
Earlier caesarean	x
Severe pre-eclampsia, HELLP (hemolyse elevated liver enzymes low patelet count) or eclampsia	x
Three or more spontanious abortions, earlier premature birth og spontanious abortions in second trimester	x
Neonatal death or still-born	x
Previous children with born anomalies	x
Earlier SGA (small for gestagation age) or LGA (large for gestagation age) children	x
Hereditary diseases	x
Female genital mutilation	x
Primary infection herpes genitales	x
About the routine examinations	x

	Week of pregnancy

Provide information about:	´8-12	18	24	28	32
Lifestyle considerations (diet, physical activity, alcohol)	x				
Smoking cessation programs	x				
Social security rights	x				
About recommended routine examinations	x				
The pregnant should gain understanding about the purpose of each examination and test before consent is given	x				
Folate, preferably 4 weeks prior to pregnancy and first 12 weeks of pregnancy	x				
About the storing of the health record	x				
That all testresults will be documented on the "helsekortet" and that the woman should understand the results	x				
Offer of genetic prenatal diagnosis and genetical consultations when needed	x				
Breast feeding					x
Anameia screening	x			x	

	Week of pregnancy								
Recommendation of sceening and test for:	8-12	18	24	28	32	36	38	40	41
Blood grouping and antibodies	x			(x)		(x)			
Thrombocyte antibodies	x								
Rubella (German measles)	x								
HIV	x								
Syphilis serology	x								
Hepatites B and C on indication	x								
Screening for asymptomatic bacteriuria on indication	x								
Ultrasound in preganancy week 17-19	x								
Weight (BMI)	x			x	x	x	x	x	x
Height (BMI)	x								
Proteinuria	x		x	x	x	x	x	x	x
Glucosuria	x		x	x	x	x	x	x	x
Blood-pressure	x		x	x	x	x	x	x	x
Risk of sickle cell anaemia and thalassaemia	x								

	1	2	3	4	5	6	7	8	9
Genital chlamydia women < 25 years or on indication	x								
Ultrasound		x				(x)			
Synphysis-fundal (SF) distance			x	x	x	x	x	x	x
Fetal movements				x	x	x	x	x	x
Auscultation of the fetal heart			x	(x)	(x)	(x)	(x)	(x)	(x)
Fetal presentation						x	x	x	x
Referral for postterm evaluation at obstetric out-patient clinic or maternity unit									x

Appendix 4 –Melding om avsluttet svangerskap

Appendix 5 – Melding - Graviditet etter assistert befruktning

Melding til MFR av graviditet etter assistert befruktning (ART)

+ Fylles ut av avdelingen/klinikken for alle behandlinger ved første ultralydundersøkelse

Avdeling/klinikk

+ | Ikke skriv her

Kvinnens navn og adresse

På grunn av optisk lesning av skjemaene må fødselsnummer påføres her selv om det eventuelt også står på påklistret merkelapp.

Fødselsnummer:

Infertilitetsårsaker:
(Kryss evt. i flere rubrikker)

1. ☐ Tubefaktor
2. ☐ Endometriose
3. ☐ PCOS
4. ☐ Amenoré/anovulasjon
5. ☐ Redusert ovarialrespons
6. ☐ Sædfaktor
7. ☐ Kreft hos mann
8. ☐ Annet, spesifiser
9. ☐ Uforklarlig

Hovedårsak til infertilitet:
(Kryss kun av i én rubrikk)

1. ☐ Tubefaktor
2. ☐ Endometriose
3. ☐ PCOS
4. ☐ Amenoré/anovulasjon
5. ☐ Redusert ovarialrespons
6. ☐ Sædfaktor
7. ☐ Kreft hos mann
8. ☐ Annet, spesifiser
9. ☐ Uforklarlig

Ikke skriv her

Infertilitetsvarighet:
Hvor mange år har paret forsøkt å få barn før første behandling?

Metode ved denne behandlingen:

Fersk syklus:
1. ☐ IVF
2. ☐ ICSI-ejakulert sæd
3. ☐ ICSI-frossen sæd
4. ☐ ICSI-TESA/TESE
5. ☐ ICSI-PESA

Fryse-syklus:
1. ☐ Cryo-IVF
2. ☐ Cryo-ICSI-ejakulert sæd
2. ☐ Cryo-ICSI-frossen sæd
3. ☐ Cryo-TESA/TESE
4. ☐ Cryo-PESA

Tilleggsprosedyre:
☐ PGD   ☐ Annet, spesifiser:

Ikke skriv her

Antall befruktede egg innsatt v/denne behandlingen:

A: Fersk syklus   B: Fryse-syklus

Totalt antall innsettinger for å oppnå aktuell graviditet:

A: Fersk syklus   B: Fryse-syklus   Totalt antall

Fersk syklus:
Dato for egguttak:

Fryse-syklus:
Dato for innsetting:

Dato for innsetting:

Frosset på: Dag

Dato for første ultralydundersøkelse:

Status ved første ultralydundersøkelse:

Antall fostre:

Antall fostre med sikker hjerteaksjon:

Sendes til MFR straks etter første ultralydundersøkelse

Dato og underskrift (lege), stempel

Wittusen & Jensen art. 836.412 – V7_0 – 04.2013

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Appendix 6 – Codes description

Codes used	Description of code
Adherence to guidelines	Comments concering the need for an antenatal health care record to reflect and be adherent to national guidelines
Historical information	Need for access to historical information (for instance about previous pregnancies, medical history etc)
Need for update	The need for an update of clinical information elements to be included in the antenatal health record
New functionality	Proposals for new functionality or new information elements to be included
Quality	Comments about reduced quality in antenatal health record, also in reporting to MFR
Reporting	Positive statements regarding the use of the antenatal health record for reporting
Risk assessment	Information from antenatal health record used as risk assessment (screening)
SF curve	Comments about SF curve
Structuring	Comments on the need for structuring of information, for different purposes (reporting, gaining a quick overview of situation, reduction of free-text comments etc)
Too much information	Comments regarding the notion of too much information is available in present paper version

Appendix 7 – Complete list of validated archetypes

Archetype identifier	Concept archetype	Source	Status in source	Duplicate in	Status in other CKM
ACTION.health_education.v1	Health Education	NEHTA NT Antenatal	Team Review	openEHR	Draft
ACTION.informed_consent.v1	Informed Consent	NEHTA	Team review	openEHR	Draft
ACTION.medication.v1	Medication Action	openEHR	Draft	NEHTA	Team Review
ACTION.referral.v1	Referral	NEHTA NT Antenatal	Draft	–	–
ACTION.review.v1	Review	NEHTA NT Antenatal	Draft	openEHR	Draft
CLUSTER.amount-range.v1	Amount of medication as a range	NEHTA	Team Review	–	–
CLUSTER.amount.v1	Amount of medication	NEHTA	Team Review	–	–
CLUSTER.cessation_attempts.v1	Cessation attempts	NEHTA	Draft	openEHR	Draft
CLUSTER.change.v1	Change	openEHR	Draft	–	–
CLUSTER.consent_details.v1	Informed Consent Details	NEHTA	Draft	openEHR	Draft
CLUSTER.dimensions.v1	Dimensions	NEHTA	Draft	openEHR	Draft
CLUSTER.document_entry_metadata.v1	Document Entry Metadata	NEHTA NT Antenatal	Draft	–	–
CLUSTER.education.v1	Education and Training	NEHTA	Review suspended	–	–
CLUSTER.household.v1	Household	NEHTA	Review suspended	–	–
CLUSTER.housing.v1	Housing	NEHTA	draft	–	–
CLUSTER.imaging.v1	Imaging Details	openEHR	Draft	–	–
CLUSTER.lab_result_annotation.v1	Laboratory result annotation	openEHR	Draft	–	–
CLUSTER.medication_admin.v1	Medication administration	openEHR	Draft	NEHTA	Draft
CLUSTER.medication_amount.v1	Medication amount	openEHR	Draft	–	–
CLUSTER.menstrual_cycle.v1	Menstrual Cycle	openEHR	Draft	–	–

		NEHTA NT Antenatal	Draft	openEHR	Draft
CLUSTER.oedema.v1	Oedema	NEHTA NT Antenatal	Draft	openEHR	Draft
CLUSTER.palpation_of cervix.v1	Palpation of Cervix	NEHTA NT Antenatal	Team Review	–	–
CLUSTER.palpation_of_fetus.v1	Palpation of Fetus	NEHTA NT Antenatal	Team Review	–	–
CLUSTER.palpation_of_uterus.v1	Palpation of Uterus	NEHTA NT Antenatal	Team Review	–	–
COMPOSITION.adverse_reaction_list.v1	Adverse Reaction List	NEHTA NT Antenatal	Draft	openEHR	Draft
COMPOSITION.encounter-antenatal.v1	Antenatal Visit	NEHTA NT Antenatal	Draft	–	–
COMPOSITION.family_history.v1	Family History	NEHTA NT Antenatal	Draft	–	–
COMPOSITION.lifestyle_factors.v1	Lifestyle factors	NEHTA NT Antenatal	Draft	–	–
COMPOSITION.medication_list.v1	Medication List	NEHTA NT Antenatal	Draft	openEHR	Draft
COMPOSITION.obstetric_history.v1	Obstetric History	NEHTA NT Antenatal	Draft	–	–
COMPOSITION.pregnancy_summary.v1	Pregnancy Summary	NEHTA NT Antenatal	Draft	–	–
COMPOSITION.problem_list.v1	Problem List	NEHTA NT Antenatal	Draft	openEHR	Draft
COMPOSITION.referral.v1	Referral document	openEHR	Draft	NEHTA	Draft
COMPOSITION.social_summary.v1	Social Summary	NEHTA NT Antenatal	Draft	–	–
COMPOSITION.vaccination_list.v1	Vaccination List	NEHTA NT Antenatal	Draft	openEHR	Draft
ELEMENT.last_normal_menstrual_period.v1	Last Normal Menstrual Period (LNMP)	openEHR	Draft	–	–
ELEMENT.menstrual_cycle_day.v1	Current Day of Menstrual Cycle	openEHR	Draft	–	–
EVALUATION.adverse_reaction.v1	Adverse Reaction	NEHTA NT Antenatal	Team Review	openEHR	Review
EVALUATION.alcohol_use_summary.v1	Alcohol Use Summary	NEHTA NT Antenatal	Team Review	–	–

EVALUATION.check_list-medication.v1	A check list for medications	openEHR	Draft	–	–
EVALUATION.clinical_synopsis.v1	Clinical Synopsis	openEHR	Published	NEHTA	Team Review
EVALUATION.employment_summary.v1	Employment Summary	NEHTA	Review suspended	–	–
EVALUATION.exclusion-adverse_reaction.v1	Exclusion of an Adverse Reaction	NEHTA NT Antenatal	Draft	openEHR	Draft
EVALUATION.exclusion-family_history.v1	Exclusion of Family History	NEHTA NT Antenatal	Draft	openEHR	Draft
EVALUATION.exclusion-medication.v1	Exclusion of a Medication	NEHTA NT Antenatal	Draft	openEHR	Draft
EVALUATION.exclusion-problem_diagnosis.v1	Exclusion of a Problem/Dagnosis	NEHTA NT Antenatal	Draft	openEHR	Draft
EVALUATION.exclusion-procedure.v1	Exclusion of a Procedure	NEHTA NT Antenatal	Draft	openEHR	Draft
EVALUATION.exclusion.v1	Exclusion Statement	NEHTA NT Antenatal	Draft	openEHR	Draft
EVALUATION.family_history.v1	Family History	NEHTA NT Antenatal	Review suspended	–	–
EVALUATION.goal.v1	Goal	openEHR	Draft	NEHTA	Draft
EVALUATION.immunisation_summary.v1	Immunisation Summary	NEHTA NT Antenatal	Draft	–	–
EVALUATION.menstrual_cycle_summary.v1	Menstrual Cycle summary	NEHTA NT Antenatal	Draft	–	–
EVALUATION.nutrition_summary.v1	Nutrition Summary	NEHTA	Review Suspended	–	–
EVALUATION.obstetric_summary.v1	Obstetric Summary	NEHTA NT Antenatal	Team Review	openEHR	Draft
EVALUATION.pregnancy_bf_status.v1	Pregnancy/Breast Feeding Status	NEHTA NT Antenatal	draft	openEHR	Draft
EVALUATION.pregnancy.v1	Pregnancy Summary	NEHTA NT Antenatal	Team Review	openEHR	Draft
EVALUATION.problem_diagnosis.v1	Problem/Diagnosis	NEHTA NT Antenatal	Team Review	openEHR NasjonalIKT	Team Review Draft
EVALUATION.relationship_summary.v1	Relationship summary	NEHTA	Review suspended	–	–
EVALUATION.religion.v1	Religion	NEHTA	Review suspended	–	–
EVALUATION.risk-family_history.v1	Risk of condition based on family history	openEHR	Draft	NasjonalIKT	Draft

EVALUATION.risk.v1	Evaluation of risk of condition	openEHR	Draft	NEHTA	Draft
EVALUATION.social_summary.v1	Social Summary	NEHTA NT Antenatal	Review suspended	–	–
EVALUATION.substance_use_summary-alcohol.v1	Alcohol Use Summary	openEHR	Draft	–	–
EVALUATION.substance_use_summary-tobacco.v1	Tobacco Use Summary	openEHR	Draft	NasjonalIKT	Draft
EVALUATION.substance_use_summary.v1	Substance Use Summary	openEHR	Draft	NEHTA	Review Suspended
EVALUATION.tobacco_use_summary.v1	Tobacco Use Summary	NEHTA NT Antenatal	Team Review	–	–
EVALUATION.vaccination_summary.v1	Vaccination Summary	openEHR	Draft	–	–
INSTRUCTION.medication.v1	Medication instruction	NEHTA NT Antenatal	Team Review	–	–
INSTRUCTION.request-lab_test.v1	Laboratory Test request	openEHR	Draft	–	–
INSTRUCTION.request-referral.v1	Referral request	NEHTA	Draft	openEHR	Draft
INSTRUCTION.request.v1	Healthcare service request	openEHR	Draft	NEHTA	Team Review
OBSERVATION.alcohol_audit.v1	Alcohol Use Disorders Identification Test (AUDIT)	NEHTA NT Antenatal	draft	–	–
OBSERVATION.alcohol_use.v1	Alcohol Use	NEHTA	Team Review	openEHR	Initial
OBSERVATION.apgar.v1	Apgar score	NEHTA NT Antenatal	Review suspended	openEHR	Published
OBSERVATION.blood_match.v1	Blood matching	openEHR	Draft	–	–
OBSERVATION.blood_pressure.v1	Bloodpressure	NEHTA NT Antenatal	Review suspended	NasjonalIKT	
OBSERVATION.body_mass_index.v1	Body mass index	NEHTA NT Antenatal	Review suspended	openEHR	Published
OBSERVATION.body_weight.v1	Weight	NEHTA NT Antenatal	Review suspended	NasjonalIKT	
OBSERVATION.edinburg_pnd_scale	Edinburgh postnatal depression scale	NEHTA NT Antenatal	draft	openEHR	Draft
OBSERVATION.exam.v1	Physical Examination Findings	NEHTA NT Antenatal	Review suspended	openEHR	Draft
OBSERVATION.fetal_heart.v1	Fetal Heart Rate	NEHTA NT Antenatal	Team Review	openEHR	Draft
OBSERVATION.fetal_movement.v1	Fetal Movement	NEHTA NT	Review Suspended	openEHR	Draft

		Antenatal			
OBSERVATION.gestation.v1	Gestation	NEHTA NT Antenatal	Draft	–	–
OBSERVATION.height.v1	Høyde	NEHTA NT Antenatal	Review suspended	NasjonalIKT	
OBSERVATION.imaging_exam.v1	imaging examination result	openEHR	Draft	NEHTA	Team Review
OBSERVATION.lab_test-blood_match.v1	Blood matching	openEHR	Draft	–	–
OBSERVATION.lab_test.v1	Laboratory test	openEHR	Draft	–	–
OBSERVATION.menstrual_cycle.v1	Menstrual Cycle	NEHTA NT Antenatal	Draft	–	–
OBSERVATION.menstruation.v1	Menstruation	openEHR	Draft	–	–
OBSERVATION.pathology_test-blood_glucose.v1	Blood Glucose Test Result	NEHTA NT Antenatal	draft	openEHR	Draft
OBSERVATION.phq.v1	Patient Health Questionnaire (PHQ)	NEHTA NT Antenatal	draft	–	–
OBSERVATION.pregnancy_test.v1	Pregnancy test	NEHTA NT Antenatal	Draft	openEHR	Draft
OBSERVATION.progress_note.v1	Progress Note	NEHTA NT Antenatal	draft	–	–
OBSERVATION.pulse.v1	Pulse	NEHTA NT Antenatal	Team Review	openEHR	Team Review
OBSERVATION.substance_use-alcohol.v1	Alcohol Consumtion	openEHR	Draft	–	–
OBSERVATION.substance_use-tobacco.v1	Tobacco Use	openEHR	Draft	–	–
OBSERVATION.substance_use.v1	Substance Use	openEHR	Draft	–	–
OBSERVATION.tobacco_use.v1	Tobacco Use	NEHTA	Team Review	openEHR	Initial
OBSERVATION.urinalysis.v1	Urinalysis	NEHTA	Team Review	openEHR	Draft
SECTION.antenatal.v1	Antenatal	NEHTA NT Antenatal	Draft	–	–

Appendix 8 - Complete results after validation of archetypes

The tables below show results from the evaluation of all archetypes in selection (n=100) as to their fulfilment of Archetype Quality Requirements (Kalra et al, 2012).

- Numbers shown are the results after an evaluation of 100 archetypes. I.e., in **Constraint pattern requirement (QR1)**, 83 of 100 archetypes fulfil the requirements.

- However, there are some requirements that only are valid for translated archetypes. For these, the numbers show requirement fulfilment based on 23 archetypes (=the number of translated archetypes). I.e. in **Contact information to translators (QR12.2n)**, 4 of 23 archetypes fulfill the requirement.

Summarised, basis numbers found and utilised in tables below, and in thesis are:

- Archetypes in selection:	100	- Translated archetypes (all languages):	23
- Number found in two CKMs:	49	- Different publication status in number found in two CKMs with:	18
- Number with RM validation warnings (in primary source):	30	- Number with content validation warnings (in primary source):	19

Constraint pattern (QR1)	Clinical scope (QR2)	Clinical scenario_ workflow (QR3)	Speciality_dis cipline_group (QR4)	Terminology (QR5)	EHR instances (QR6)	Published evidence (QR7)	EHR information model (QR8)	Class in model (QR9)	Identifier unique (QR10)	ISO EN 13606 compatibl e (QR11)
83 %	78 %	77 %	9 %	8 %	100 %	27 %	10 %	100 %	100 %	0 %

Information author/org (QR12)	Contact information to authors (QR12.1n)	Contact information to translators (QR12.2n)	Information time (QR13)	Information location/jurisdiction of creation (QR13.1)	Information time for translation (QR13.2n)	Person/org coordinated inputs (QR14)	References to former versions (QR15)	Not non-conformances (QR16)
100 %	99 %	17 %	97 %	11 %	0	68 %	n.a.	n.a.

Copyright (QR17)	Copyright information different in duplicate CKM?	Usage restrictions (QR17.1)	Licence information (QR17.2)	Date stamps approvals/ endorsements (QR18)	Endorsements of translation (QR18.1n)	Date stamps deprecations from use (QR19)	Explanation of deprecations of use (QR19.1)
100 %	90 %	0	0	0	0	0	0

Appendix 9 – Test template for Examination results

Historikk

Aktuelle svangerskap

Svangerskapslengde	[_____]
Tid fra unnfangelse	[_____]
Kommentar	[_____] 🔍
Beregning basert på	[_____ ▼]

Funn

Blodtrykk

Systolisk	[_____] mm[Hg]
Diastolisk	[_____] mm[Hg]

Symfyse-fundusmåling

Lengde	[_____] cm
Fortolkning	[_____] 🔍

Fosterbevegelse

Tilstede?	[_____ ▼]
Mønster	[_____ ▼]
Tid fra sist kjente fosterbevegelse	[_____]
Beskrivelse	[_____] 🔍

Fosterlyd

☐ Er hjertelyd tilstede?

Frekvens	[_____] /min
Konklusjon	[_____] 🔍

Urinanalyse

Glukose	[_____ ▼]
Protein	[_____ ▼]
Leukocytter	[_____ ▼]
Kommentar	[_____] 🔍

Blodprøvesvar

Prøvetype	[_____] 🔍
Prøvesvar	[_____]
Klinisk fortolkning	[_____] 🔍

Kroppsvekt

Vekt	[_____] kg
Supplerende opplysninger	[_____ ▼]

Ødem

Grad	[_____ ▼]
Kommentar	[_____] 🔍

Notater

Klinisk Sammendrag

Beskrivelse	[_____] 🔍

Neste kontroll

Henvisninger og/eller rekvireringer

Type henvisning	[_____] 🔍
Beskrivelse	[_____] 🔍
Siste mulige dato for gjennomføring av undersøkelsen	[_____ ▼]
Status på henvisning	[_____] 🔍

Appendix 10 – Data elements used in evaluation (mind maps)

Examination findings

- **Ultrasound**
  - Yes — Stated with encoder OID=1101
  - No — Stated with encoder OID=1101
  - Number of ultrasounds
- Pregnancy by Assisted reproduction technology (ART)
- **Prenatal examinations**
  - yes
    - type of prenatal examinations
    - Pathological findings
      - yes — specify
      - no
  - no
- **Height**
  - Height prior to pregnancy
- **Weight**
  - Weight prior to pregnancy
  - Weight during pregnancy
- **Blood pressure**
- **Oedema**
  - 0
  - 1
  - 2
  - 3
- **Summary of current pregnancy**
  - Bleeding prior to 13th week
  - Bleeding prior to 12th week
  - Bleeding between 13 – 28 weeks
  - Bleeding after 28 weeks
  - Bleeding after 29 weeks
  - Haemoglobin under 10,0 g/dl
  - Haemoglobin < 9.0 g/dl
  - Haemoglobin over 13,5 g/dl after week 20
  - Light hypertension
  - Light pre-eclampsia
  - Sever pre-eclampsia
  - Pre-eclampsia prior to week 34
  - Glucosuri
  - Viral infection
  - gestational diabetes
  - HELLP syndrome
  - Eclampsia
  - Trombosis – treated
  - Infections — specify
  - other
  - Comments
- **symphysis–fundal distance**
- **Fetal presentation**
  - Cephalic vertex position
  - Breech position
  - Transverse position
- **Fetal movement**
  - Fixed position
    - yes
    - no
- **Auscultated fetal heart/ minute**
- **Position of placenta**
- **Current pregnancy – dates**
  - Last period
    - numerical date
    - Certain
      - Yes — Should be stated with yes or no encoder OID=1101
      - No — Should be stated with yes or no encoder OID=1101
  - Date of term — Should be calculated from Last Period and Certain/Not certain. Should be presented as dd.mm.yy
  - Clinical status
    - Date of check–up
    - Weeks according to uterus — numerical
    - Cor/pulm/mammae
    - Cytological test — Res., ref
    - Date of term – corrected
      - Should be presented as dd.mm.yy
      - Date of correction
    - Predicted date of term — Automatic calculation of predicted date of term based on manually calculated date of term. Should be presented as dd.mm.yy
    - Number of fetus
  - Week of pregnancy — Week/days should be automatically estimated either by predicated date–of–term or date proposed from ultrasound

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Test results

- **Vaccination status**
  - Rubella
    - Yes — Should be stated with yes or no encoder OID=1101
    - No — Should be stated with yes or no encoder OID=1101

- **Blood and pathology test results**
  - Date of test — should be presented as dd.mm.yy
  - Syphilis serology
  - Blood type — Should be registered with encoder OID=9160
  - Rehsus positive — Should be registered with encoder OID=9160
  - Rhesus negative — Should be registered with encoder OID=9160
  - Blood type antibodies
    - yes
      - Should be stated with yes or no encoder OID=1101
      - Comments (free-text)
      - reference number reply report
    - no
      - Should be stated with yes or no encoder OID=1101
      - reference number reply report
  - Rubella antibodies
    - Proven
    - Not proven
    - reference number reply report
  - HIV
    - Positive
    - Negative
  - Comments
  - Locally analyzed test results
  - Haemoglobin

- **Urine**
  - glucose
    - yes — Should be stated with yes or no encoder OID=1101
    - no — Should be stated with yes or no encoder OID=1101
  - protein
    - yes — Should be stated with yes or no encoder OID=1101
    - no — Should be stated with yes or no encoder OID=1101
  - white cells
    - yes — Should be stated with yes or no encoder OID=1101
    - no — Should be stated with yes or no encoder OID=1101

Information provided

- Genetic prenatal diagnosis and genetical consultations when needed
- Recommended routine examinations
- Purpose of each examination and tests before consent is given
- Anemia screening
- Antenatal courses
  - Yes — Stated with encoder OID=1101
  - No — Stated with encoder OID=1101
- Referral status
  - referred
    - Yes
    - No
  - to hospital
  - to specialized out-patient clinic
 - to operation
- Storage of the antenatal health record
- Social security rights
- Folate
- About documentation of testresults and what the results mean
- Breast feeding

Consumptions

- Alcohol consumption
  - Daily
  - Sometimes
  - Never
- Smoking consumption
  - Daily
  - Sometimes
  - Never
  - Number of cigarettes
    - At 1st visit
    - At 36 weeks
  - Written information
    - yes
    - no
  - informed concent from mother
- Drug consumption
  - Drug abuse
    - yes
      - Should be stated with yes or no encoder OID=1101
    - no
      - Should be stated with yes or no encoder OID=1101

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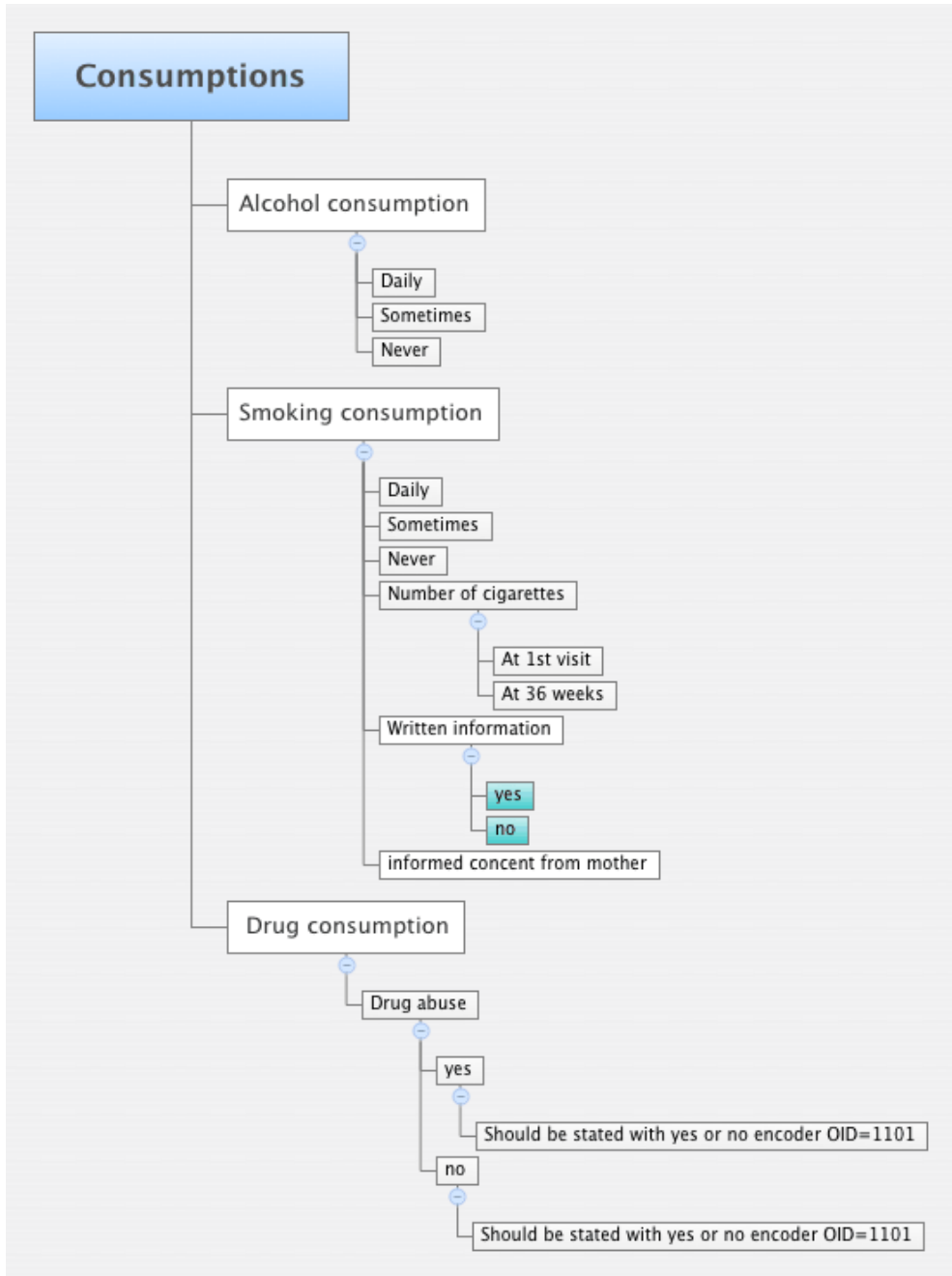
Hereditary diseases and medical history

- **Previous pregnancies – summary**
  - Number of previous pregnancies
  - Number live-born
  - Number still-born
  - Number abortions – spontaneous
  - Number abortions – provoked
  - Number ectopic
  - Comments – free-text

- **Hereditary diseases**
  - Not known — Should be registered with yes/no. No= no one known
  - Yes, see comments
  - Parents are siblings
  - Parents are related — Specify

- **Previous medical history**
  - Not applicable — Should be registered with classifications (ICD-10 or ICPC-2
  - Heart disease — Should be registered with classifications (ICD-10 or ICPC-2
  - hypertension — Should be registered with classifications (ICD-10 or ICPC-2
  - Kidney /urinary tract — Should be registered with classifications (ICD-10 or ICPC-2
  - Diabetes — Should be registered with classifications (ICD-10 or ICPC-2
  - Allergies — Should be registered with classifications (ICD-10 or ICPC-2
  - Epilepsy — Should be registered with classifications (ICD-10 or ICPC-2
  - Gyneacoligal diseases/operations — Should be registered with classifications (ICD-10 or ICPC-2
  - Mental illness — Should be registered with classifications (ICD-10 or ICPC-2
  - Astma — Should be registered with classifications (ICD-10 or ICPC-2
  - Urinary infection – recurrent — Should be registered with classifications (ICD-10 or ICPC-2
  - Rheumatoid arthritis — Should be registered with classifications (ICD-10 or ICPC-2
  - Other, comments (free-text) — Should be registered with classifications (ICD-10 or ICPC-2

Medication list

- **Current medication list**
  - Yes — Stated with encoder OID=1101
    - daily
    - sometimes
    - include list in comments
  - No — Stated with encoder OID=1101

- **Nutritional supplements**
  - vitamins
    - Prior to pregnancy — Regular intake — yes / no
    - During pregnancy — Regular intake — yes / no
  - Folic acid
    - Prior to pregnancy — Regular intake — yes / no
    - During pregnancy — Regular intake — yes / no