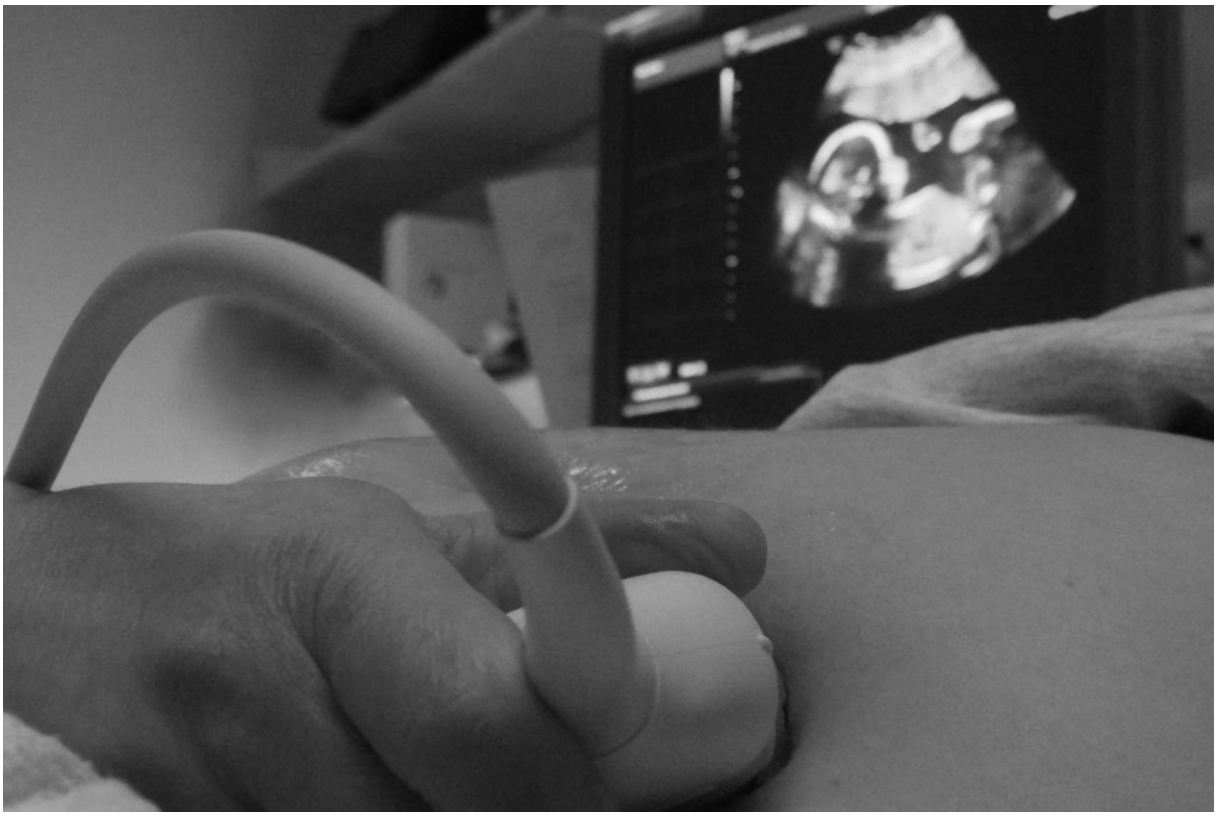
Kristine Flo Halle and Maria Fjose

Early prenatal screening in Iceland and Norway

Background and current situation



Graduate thesis 2016
Faculty of Medicine and Health Sciences, NTNU

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Norwegian University of
Science and Technology

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Preface

On our academic pathway to become doctors, this is the first time we have gotten the opportunity to explore a field in depth. This project has given us the chance to evolve our understanding of antenatal care and early prenatal diagnosis. This is a theme that has been source for debate for decades, and is still in the limelight. We have been given the chance to meet lot of different people, and their point of views have given us deeper insight.

This project took us to Iceland, a country of volcanos, geysers and pleasant people. Our knowledge about the people, health care system and the screening program, would not have been the same without this journey. We are so thankful to all people we got to meet and who wanted to talk to us. It was a great personal experience.

There are many people who deserve our acknowledgement. Most of all we want to thank our supervisors; Johann Sigurdsson and Linn Getz. We could not have had better guidance through this project. Always accessible and well-informed, ready to give us the advices we need. We are so grateful.

We also want to thank our collaborators in Iceland; Hildur Kristjansdottir, Amalia Bjornsdottir and Margret Olafia Tomasdottir, for their good help with part two of our project.

And at last, sincere thanks to all our participants. We couldn't have carried out this project without your willingness to share your experiences and thoughts around this subject.

Maria and Kristine, 30.11.2016

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Abstract

In our project, the aim has been to explore early prenatal screening in Iceland and Norway. Seen from the outside, these two countries have a lot in common. They are both Nordic democratic welfare states, with several common historical and cultural roots. Despite this, there are significant differences in the use of prenatal screening (1). An interesting question is, whether the differences in Iceland and Norway can be seen as an incidental result of different political systems and laws, organisation of the health care system, or whether we are in fact facing deeper cultural differences. To gain deeper insight into these topics, we have performed a project with two distinct elements. Using data from an empirical study, we have tried to explore *the use of early ultrasound and prenatal screening among Icelandic women, and what characterises those who choose to undergo the screening.* To put the empirical study in a perspective, we have done some field work both in Iceland and Norway.

The design of the report

To distinguish the two elements of the project properly, we have divided the report in part one and part two. These two parts are made in a way so they can be read separate. With other words, they will both contain their own introduction, background, method, findings/results and discussion. Part two will hopefully lead to a publication, and is therefore designed as a scientific paper.

Part one – exploring the field

The essence of part one is the field work, with semi-structured interviews of health personnel, professionals and pregnant women in Iceland and Norway. Our focus was their personal experience and thoughts around prenatal screening and antenatal care. For a better understanding of the situation in the two countries, we have tried to explain how the health care system works, what diagnostic methods that are used and the regulation of the screening, in the background. We have also mentioned the most common anomalies the screening is searching for, and how abortion in the two countries is regulated.

Part two – empirical study

Part two is an analytical cohort study based on the Childbirth & Health study done in Iceland. The use of early ultrasound and prenatal screening among Icelandic women was in focus here. Also, what characterises those who choose to undergo the screening and their feelings around it, was in our interest.

Part 1: Exploring the field

Introduction

In the Nordic countries today, pregnant women and their unborn child receive antenatal care according to public regulations. This system is free of charge, and the goal is to ensure a safe pregnancy and optimal health for both mother and child. The original aim of antenatal care was to minimize risk factors related to the pregnancy as such (2). Sonography scans have, for many years, played an important role in antenatal care in many countries. How these scans are performed and the number of scans the women are offered, however differs considerably, even across the Nordic countries (1). The purpose of the sonography scan, and what the examination is supposed to reveal, has gradually become more complex. On one hand, the focus is on factors related to the pregnancy, like determination of the term date, the number of embryos and the location of the placenta. On the other hand, the scan has made it possible to discover factors related to the foetus. Under this comes anatomy, development and potential indicators of malformations or syndromes. Among these are chromosomal aberrations, including Trisomy 21 (Down´s syndrome). Prenatal diagnostics have over the last decades evolved a lot. New technology makes it possible to describe the foetus in greater detail. This opens for new possibilities in terms of diagnostics and treatment, but also lead to an ethical debate; who gets to decide what is a worthy life?

Background

Congenital anomalies

The sonography scan in both first and second trimester have the intention, like mentioned above, to discover factors related to the pregnancy as well as the foetus. The search for congenital anomalies is one of the aims. Chromosomal anomalies are described further below. Structural anomalies can be categorised due to their different dysmorphologies. It can be the absence of a structure that is normally present, herniation through a structural defect, presence of an additional structure and so on (3). The most common development anomalies are heart defects and neural tube defects (4). Anencephaly is a dramatic example of an absent structure, where great parts of the brain are missing, due to a defect in the central nervous system. Other structural anomalies are renal agenesis, where one or both of the kidneys are missing, and defects in the gastro intestinal tract (3).

The most common chromosomal anomalies

Trisomy is a form of chromosome anomaly, where the foetus is born with three copies of a chromosome instead of two. There are mainly three forms of trisomy the child can be born with; trisomy 21, 18, and 13 (5).

What is trisomy 21?

Trisomy 21, called Down´s syndrome, is the most common of the chromosome anomalies. In recent years, about one child per 700-800 has been born with Down´s syndrome in Norway (5). In 2014, 74 children were born with Downs syndrome (6). The probability of having a child with Down´s Syndrome increases with the age of the mother (5). Persons with Down´s syndrome have different degrees of disability. They have a global development delay, with mild to moderate intellectual disability. They also have a higher frequency of congenital heart defects, and other organ problems, involving the gastro intestinal tract, ears, eyes, the thyroid gland and the haematological system, The average life expectance is 50-60 years, and it increases (7). The impact of Downs Syndrome is individual. Some are considerably handicapped, while others can live independently as adults (8).

What is trisomy 18 and 13?

Trisomy 18 and trisomy 13 are both rare chromosome anomalies causing serious and usually lethal disorders. One per 6000-8000 is born with trisomy 18 every year, and there are more girls than boys. Between one per 10 000 to one per 20 000 is born with trisomy 13 every year (9, 10). The median lifetime for both trisomy 18 and 13 are 10-14 days. 10 % are still alive after one year (5).

What is prenatal screening?

Prenatal screening involves examination of foetal cells, the foetus itself or a pregnant woman, with the purpose to get information about the foetus´s genetic characteristics, or to detect or exclude disease or development anomalies (5). This is the general definition, independent of which method is used. Prenatal screening has undergone rapid development during recent years. There is a trend to go from invasive testing, such as amniocentesis and chorion villi-sampling, to non-invasive testing involving sonography with or without accompanying blood tests (combined testing) and Non-invasive prenatal testing (NIPT). NIPT is based on investigation of foetal genetic material in peripheral maternal blood, further described below (11).

What is sonography when used in prenatal screening?

It is important to differ between sonography used in the normal antenatal care and sonography as a part of targeted, foetal screening (12). The sonography that is routinely done on all pregnant women, primarily aims to determine that the foetus is alive, the term date, the number of embryos, location of the placenta and examine the foetus's general anatomy and development. When it comes to twin pregnancies, it is important to distinguish between whether there are one or two placentas, also called mono- and dichorionic pregnancies. This is of importance, because the risk for different complications (like twin-transfusion-syndrome) is higher in a monochorionic pregnancy (13). The determination of whether the pregnancy is mono- or dichorionic, is more accurate in the sonography scan in week 10-14 than in week 18-20, when the established routine scan is performed (14).

Targeted foetal screening is currently done by sonography in the first trimester, typically between weeks 11-14. The main focus is the nuchal fold. This is a measurement

of the maximal thickness of the subcutaneous translucency between the skin and the soft tissue overlying the cervical spine. Increased thickness of the nuchal fold is seen as a so-called "soft marker" for chromosome malformations, especially Down´s Syndrome (trisomy 21) (15). Soft markers are minor anatomical variations, indicating an increased likelihood that the foetus has a chromosomal aberration or other defects such as a heart anomaly (16).

What is the combined test?

The combined test is the most common test used in targeted foetal screening in the Nordic countries (1). It is a combination of both the early sonography scan with the nuchal fold measurement, and a blood test. Blood markers that are used, are PAPP-A (pregnancy-associated plasma protein A) and free beta-hCG (human chorion gonadotropin). In a combined risk estimate, these two tests, and the mothers age, give a sensitivity on 90-95% to discover trisomy 21 (5). The risk estimate is based on the so called multivariate Gaussian distribution described by Wald et al (1996), using the "alpha" software (17), and is given to the pregnant woman as a ratio. For example, the woman can get to know that there is a 1/2000 risk for the child to have Down´s Syndrome. A risk that is 1/250 or higher is categorized as "increased", and these women are therefore offered an invasive diagnostic procedure to rule out or verify the trisomy (5).

What is invasive prenatal screening?

There are two invasive tests in prenatal screening, amniocentesis and chorion villi-sampling. Amniocentesis is a test of the amniotic fluid, done by inserting a needle through the abdominal wall of the mother (11). Cytogenetic and enzymatic analysis can be done on cells obtained from the amniotic fluid, to find chromosome malformations. Levels of alfa-fetoprotein (AFP) and acetylcholinesterase (AChE), can be measured to diagnose neural tube defects (such as spina bifida and anencephaly) and anterior abdominal wall defects (such as gastroschisis) (18).

The chorion villi sampling (CVS) is a sample taken from the placenta, and can be done both transabdominal and transcervical (through the vagina and cervix) (11). This test can be performed earlier than the amniocentesis, i.e. in the first trimester.

Amniocentesis is usually done between pregnancy week 14-20, and CVS between week 9-13. The CVS is suited for discovering chromosomal aberrations, but cannot diagnose neural tube defects (18).

Both the amniocentesis and the CVS increase the risk for a spontaneous abortion, and the risk is approximately 0,5-1,0% (19).

What is NIPT?

Non-invasive prenatal testing (NIPT) is of many seen as the future, and is now under consideration to become a part of the targeted foetal screening in all Scandinavian countries (11). The method is based on the fact that maternal plasma (blood) contains cell free DNA (cfDNA) from the foetus. With other words, that the DNA is not bound to the nuclei of the cells. All pregnant women will have a small part of the foetus´s cfDNA in their blood, and this fraction increases throughout pregnancy. It is therefore possible to analyse the genetic characteristics of the foetus by only taking a regular blood test of the mother by venipuncture. There are a wide range of possibilities with NIPT. So far, there are four possible areas of utilization: determination of sex, detection of single gene disorders, detection of aneuploidy (abnormal chromosomal number) and RhD-typing of the foetus (11). RhD-typing of the foetus is already introduced in Norway and is in use. The use of NIPT to detect chromosome malformations is under consideration, and will in case of introduction be considered as part of the prenatal screening.

The method that is used to analyse the foetal DNA when it comes to detecting chromosome malformations, is “massive parallel shotgun sequencing” (MPSS), and is a type of DNA-sequencing. The sequenced foetal DNA is then compared to a reference sequence. If the foetus for example has Downs Syndrome, there will be an excess of fragments from chromosome 21. This result, together with foetal fraction of DNA (cfDNA), the mothers age and pregnancy length, will estimate the risk for the foetus having a chromosome malformation. NIPT has higher accuracy than the combined test, and the hope is that it can lower the use of invasive tests with associated risk for unintended foetal loss (11).

Pregnancy and foetal screening in Norway and Iceland

The system in Norway

As part of the antenatal care, all pregnant women in Norway have been offered a sonography scan in week 17-19 since 1986 (12). This is not seen as explicit prenatal screening, although the scan will involve an examination of the foetus's size and anatomy. Soft markers of potential foetal defects, might also be identified. As mentioned above, the sonography scan focuses on correct determination of the term date, the number of embryos and the location of the placenta. For women with a normal and uncomplicated pregnancy, this is the only sonography scan. There is also something called *sonography scan on medical indication,* and it is not seen as prenatal screening. A medical indication could be bleeding, pain, worry of the mother or suspicion of foetal growth restriction (12).

Prenatal screening, i.e. foetal testing with the explicit aim to detect anomalies, is in Norway regulated by the Law of biotechnology (Bioteknologiloven). It is available for pregnant women above 38 years of age at term and other specific risk groups, like those who have given birth to a child with a chromosome anomaly, spina bifida or congenital hypothyroidism (12). The screening is also available after individual assessment on social grounds (1). The method that is used is currently the combined test (ultrasound and maternal blood test) in week 11-14 of pregnancy.

The system in Iceland

As in Norway, all pregnant women in Iceland have access to free antenatal care which involves regular visits to midwifes at community health care centres, general practitioners (GPs) and obstetricians if needed. When it comes to prenatal screening, Iceland however differs significantly from Norway. From 2006, all women have been offered information about the combined test in week 11-14 (20). The process however, started already in 1999, when pregnant women above 35 years old were offered the nuchal fold-measurement. Around the same time, the maternity hospital suggested that there should be a systematic screening for all women in the first trimester of pregnancy. This started a heavy debate among professionals and in mass media, later published in series of papers in two issues in the Icelandic Medical Journal (21, 22).

In the end, the academic environment concluded that the prenatal screening should be available for all pregnant women, but not considered part of the routine antenatal care. Therefore, the expecting couple have to ask for the test and pay a fee, currently 93 Euro (ISK 11.636, NOK 834) (23).

The nuchal fold measurement is carried out in two places in Iceland: in Akureyri Hospital in the north and in the Landspitali University Hospital in Reykjavik. The combined test is only done at Landspitali University Hospital. In the guidelines from the Directorate of Health (24), it is stated that the combined test should be an informed choice. This underlines the responsibility of the health professional providing care to the woman to explain all available options in a nondirective way (20). A big difference from Norway is that there is no formal referral or gatekeeper system in Iceland. In other words, the patients can contact private specialists directly and book an appointment themselves, without having the general practitioner as the connecting link.
Therefore, before signing up for antenatal care in the public system, a large number of Icelandic women have already, by their own initiative, had their pregnancy confirmed by vaginal sonography, done by private gynaecologists (20). Icelandic women thereby appear to have a more technical approach to confirmation of pregnancy than Norwegian women.

Participation in early pregnancy screening

Iceland

As said, all pregnant women in Iceland are supposed to receive information about the possibility for early pregnancy screening by the combined test, in order to promote an ”autonomous reproductive choice”. According to the National Birth Register from Landspitali University Hospital (25) a total of 3623 women underwent combined testing in pregnancy week 11-14 in 2009. This can be estimated to be around 73% of all pregnancies that year. Similar figures for 2014 (26), showed that around 80% of all pregnant women chose the combined test.

Norway

In Norway, like mentioned above, the Law of Biotechnology regulates access to prenatal screening and diagnostic procedures, including the combined test. Key actors in the field

(Torbjørn Eggebø and Pepe Salvesen, specialists in obstetrics and gynaecology at St. Olavs Hospital) report a tendency that more and more women want information about the foetus already in the first trimester of pregnancy, where there is currently no routine examination in offer. The solution for many has been the private market, where clinics offer sonography scans against payment. If the health personnel who do the scan find something that could be considered abnormal, the woman will be referred to a public hospital for further examination (27, 28). This can therefore be described as the "backdoor" into the system.

Institutions that perform prenatal examinations in Norway have to be approved by the Directorate of Health (Helsedirektoratet). Some private institutions are not approved, but are still doing the first trimester-sonography scan. This is called "wildscreening" (29). The extent of the wildscreening is not known, but it is assumed that it is more common among women who live in urban areas. An estimate to determine the number of women who have done a sonography scan in a private clinic during the first trimester, was done in 2014 and 2015. This was performed by asking women who came to the routine sonography in week 18, whether they had been to a scan before. In Trondheim the number was 85%, in Oslo 79% and in Bergen 69% (29).

The private market for sonography is growing fast, something that has made it very accesible for many women. A quick internet search, tells us that one can get an early ultrasound the same day in the bigger cities in Norway. The prize varies, but lays around 1100 NOK (120 euro) (27, 28). The availability can most likely explain why there are more women in the cities than in the countryside, who choose to do an early ultrasound.

Information about screening and knowledge among pregnant women

How do pregnant women experience the sonography scan and the screening program, and what do the women want to know? Is the knowledge about the sonography scan good enough?

Expectations among pregnant women

Pregnant women's expectations regarding sonography screening have been reported in several publications (30-34). To affirm general well-being of the child, was the most

prominent expectation reported in a study of second trimester ultrasound from 2008, done by Georgsson and Waldenström (30). But what reasons do women state for undergoing a first-trimester sonography? A Danish study reports how women's background factors affected their preferences when it came to first-trimester sonography scan. The women's income affected their reasons for choosing an early sonography scan. Women with low income, reported that they mainly wanted to "see the baby" and get a sonography picture. In the high-income-group, women more often wanted to check that everything was normal, and that the pregnancy proceeded as it should (33). When the researchers looked at the whole group of women together, the most common stated reasons for wanting prenatal screening, was to check for foetal malformations (60% of the women), to see that everything was normal (55% of the women), and for own reassurance (44%) (33).

Knowledge among pregnant women

In a systematic review by Garcia et al. from 2002, the researchers concluded that sonography scanning is very attractive for pregnant women and their families, but that knowledge about the purpose of the sonography and the technical limitations of the scan, is often lacking (34). The same conclusion was made by Lalor et al. in their study from 2007. They found that the women lacked knowledge when it came to the limitations and capability of the scan, like what the scan could reveal when it came to chromosomal anomalies. About one in three of the women in the study, believed that the scan could detect Downs syndrome and other chromosome anomalies. This suggest that many women lack adequate knowledge about the test, since the diagnosis Downs Syndrome must be verified through an invasive test. Their conclusion was that women receive insufficient information from health personnel to make an informed decision about their pregnancy (31).

Information received about screening

Information is important when women are going to make decisions in their pregnancy. What information they get, influences their knowledge and their possibility to make an autonomous reproductive choice. A lot has been written during the last decades about this topic, both by social scientists, philosophers and health personnel. We will only mention one study here:

What do the women themselves think of the information? This question was studied by Georgsson and Waldenström in 2008. They asked how the women experienced the information received in relation to the screening. 88% were satisfied with the information about *why* the screening was performed, and 87% with the information about *how* it was performed. Only 58 % said they had received sufficient information about the risks associated with the screening programme (30).

Induced abortion: laws and regulations

Prenatal screening leading up to so-called selective abortion (due to specific characteristics of the foetus), is seen as a key factor in the so-called "Sorting society" (no: Sorteringssamfunnet) Abortion is, like prenatal screening, strictly regulated.

Norway

In Norway, abortion is regulated through Act on Abortion (Abortloven)(35). Shortly put, women have self-determined abortion until the end of pregnancy week 12. With other words, no specific grounds for abortion are required, and the woman can make the decision herself. Between week 12 and 18, permission for abortion may be granted when certain requirements are met. Under this comes that the pregnancy and childbirth can cause unreasonably strain on the woman`s physical or mental health, that there is a major risk that the child suffers from a serious disease as a result of its genotype, or that the woman became pregnant as a result of a sexual abuse crime. After week 18, there must be particularly compelling reasons. If there is reason to believe that the foetus is capable of survival, permission for an abortion will not be granted (35). A viable foetus is defined as older than 21 weeks and six days (36). With other words, an abortion is possible until the end of pregnancy week 21.

Iceland

Iceland and Norway are quite similar when it comes to the regulation of abortion. The biggest difference is that in Iceland the woman must have a social or medical reason for wanting the abortion also throughout the first trimester of pregnancy (1). In practise, however, all women who apply will be granted permission for an abortion at least until the end of week 16.

Fieldwork method - explorative interviews

In our interviews with health professionals and pregnant women in Iceland and Norway, we applied a method inspired by the *semi-structured interview* or *in-depth interview*, as described by professor Axel Tjora in the book "Kvalitative forskningsmetoder i praksis" (37). It is important to emphasise that our aim was not to conduct a full-blown, analytical qualitative study. Our aim was to familiarise ourselves with our research topic by talking quite systematically with some persons who know a lot about prenatal diagnostics and/or have come in close contact with it as providers or recipients. For this purpose, a qualitative interview approach was considered suitable. Tjora writes that the aim of the in-depth interview is to create a situation where the participants are having a quite free conversation around a specific theme. The researcher has decided this theme in advance. Using open questions, instead of closed, the semi-structured interview gives the informants the possibility to delve deeply where they have a lot to tell. By creating a relaxed atmosphere, the goal is to let the informant reflect around own opinions and experiences related to the topic (37).

Participants

Health professionals were contacted through their work institution, facilitated by our supervisors. We talked to two health professionals in Iceland, and three in Norway (including one ethicist). The Icelandic pregnant women who participated in our study, were recruited through contact persons at health care centres in Iceland. The Norwegian women were found through personal contacts. In all, seven women were interviewed in Iceland and four in Norway.

The interviews

Interviews with health professionals/academics and pregnant women were conducted in Iceland and Norway in September-October 2016. Our questions were prepared in advance and formed the basis of the interviews. All interviews were taped, and passages we considered most interesting were subsequently transcribed (in comparison to a complete qualitative study where we would have transcribed the whole material). The interviews in Iceland were done in both English and Norwegian, according to the wishes of the participants. In Norway we interviewed both women and health professionals in Norwegian.

We met the professionals in the institution where they worked. These interviews lasted from 20 to 75 minutes and focused on how the system works and the professional's opinion of the system.

We met the Icelandic women in health care centres. In Norway, the women could decide time and location themselves. These interviews lasted from 16 to 30 minutes and started with open questions around the pregnancy. Then we asked the women about their experiences and thoughts around the prenatal screening in their country. Since the systems in the two countries differ, the questions were adapted for each setting.

Ethical considerations

All participants were informed about the purpose of the interviews and consented in advance. The interviewed persons in this study involve healthy pregnant women and health professionals who reflected upon their work. We had decided beforehand not to include women who might find themselves in a stressful life situation due to medically induced uncertainty about the unborn baby's health. As a further precaution, we chose to present the women under pseudonyms in our report. The health professionals all agreed to be quoted under their names.

Analysis of the interviews

The main researchers (KFH, MF) listened to the taped interviews several times, with the aim to understand the participant's true reflections and thoughts as well as possible. As indicated above, we then transcribed passages we found particularly relevant and interesting in light of our research questions. Since the report is written in English, we have translated the Norwegian interviews. In this way, some nuances might have been lost. We have done our best to reproduce the thoughts and opinions as precisely as possible.

Findings in the interviews

Overview:

- Health professionals/academics in Norway
    - Three professionals: Torbjøn Eggebø, Pepe Salvesen and Berge Solberg
- Health professionals in Iceland
    - Two professionals: Kristin Rut Haraldsdottir and Hulda Hjaltadottir
- Pregnant women in Iceland
    - Seven women (table following below)
- Pregnant women in Norway
    - Four women (table following below)

Professionals in Norway

To get an impression of the situation in Norway, we have interviewed three professionals on the theme. Two of them are specialists in obstetrics and gynaecology at St. Olavs Hospital, Torbjørn Eggebø and Pepe Salvesen. The third person is Berge Solberg, professor in Medical ethics. His PhD from 2003 dealt with the ethics of prenatal screening.

The situation in Norway today – what do you think of it?

When we asked the experts about their opinion of the system in Norway today, they had different approaches to the topic. One argument they all agreed on, was the importance of autonomous choices: in a democracy like Norway, all citizens should have the same rights, and be able to make the important decisions themselves:

> *Torbjørn Eggebø: "I think it is a weird law in Norway, that allows some women prenatal screening and not everybody. That is not fair."... "With the laws we have in Norway today, we can´t say that the women have autonomous choices when it comes to prenatal screening."*

> *Pepe Salvesen: "I think that the women themselves should decide, when the technology exists and there are no risks with the non-invasive tests."*

The Norwegian professionals also talked about how it is a good thing that there has been a debate in Norway. That it is a complex subject, and how it is important to think about the possible consequences before changing the system:

> *Pepe Salvesen: "The positive side, is that the society in Norway tries to take both the choice of the woman and the right of people with a disability, into consideration. The debate is alive, that is positive."*

> *Berge Solberg: "We are in a historical situation in Norway now, because we have been holding back, and once we stop holding back, it will be impossible to go back again."*

The early screening in week 12 – what do you think about it?

On this subject, the gynaecologists focused on the medical benefits with an ultrasound examination in week 12. Among these, the detection of twin-pregnancies and determination of term date were mentioned. In addition, early detection of conditions that are not compatible with life, was discussed:

> *Torbjørn Eggebø: "We want to take the focus away from trisomy 21." … "The sonography scan is important for so many other things. That´s why we want it. And the ones who want to know whether the child has trisomy 21 or not, should have this option. It should be a choice for the women, and not a political resolution. I want a society with autonomous choices."*

> *Pepe Salvesen: "You can discover things that are important to know, at an earlier stage. If the women choose to terminate the pregnancy because of a severe anomaly, it is better for the women to get to know this at an earlier stage, like in week 12, compared to week 18-19. My opinion is that we should do more ultrasound in Norway than we do today"*

> *Berge Solberg: "We have to try to present the prenatal screening in a way so that people don't feel that it is a hunt to find children with Downs syndrome. We have to have another focus."*

One of the arguments against the 12-week scan, came from Berge Solberg. He took it from the mothers' perspective, and how pregnant women who are informed about an increased risk of a foetal anomaly, will be pressured to make a choice they might in fact not want to have. The lethal conditions that were mentioned by the gynaecologists, will in many cases result in a spontaneous abortion after some time, irrespective of the woman's choice. An important question then is: what´s the worst scenario for the mother? To choose to terminate a pregnancy she knows is likely to end anyway, or to go through a spontaneous abortion later in pregnancy?

> *Berge Solberg: "It´s a hard decision to make when it comes to abortion, and in some cases, maybe it is better to let the nature decide."*

Berge Solberg also argued that introduction of a screening programme could set the standard for a society in a way considered to represent the norm for what people should do. Maybe the choice is thereby not so autonomous after all?

> *Berge Solberg: "If you don't want the routine sonography, people might ask: why? What is wrong with you, why don't you do like everyone else? This is one of the difficult questions we are afraid people will begin to ask, if we introduce prenatal screening in week 12. What if the society judges you if you get a handicapped child, because you didn't want the test? We don't want to have it like that. The medical technology is not always for the best."*

Also the previously mentioned term "sorting society" came up in our interviews. This is a term frequently used in the Norwegian debate, often with lots of emotions involved:

> *Berge Solberg: "The other side is the "sorting society". What is wrong with sorting? Is it contrary to human thoughts? Do we send a negative signal to the families that live with a child with Downs?" … "The society today is actually more welcoming of people who are different than before. Today we have people with Downs syndrome in TV-shows, theatres, in the movies."*

Still, they were all clear about what they wished as a final outcome of the prenatal screening-debate:

> *Torbjørn Eggebø: "We, who are foetal medicine physicians, wish that the first trimester-examination should be legal for everybody in Norway as well."*

> *Berge Solberg: "I think we live in a part of the world where there is an own logic in the society. We are getting more and more freedom to make our own decisions, and when something is stopping us from making a free choice, then there must be a really good reason for it. If not, you cannot stop people from doing it." … "But the information that is to be given has to be very good, so that nobody feels this is something they necessarily have to do. It is an individual choice. People are different."*

What justifies the Norwegian age limit of 38-years?

The current age limit in the Law of Biotechnology was set in 1981 by the health minister of the time, Torbjørn Mork, together with the introduction of amniocentesis in Norway(38). Here is Torbjørn Eggebø´s explanation for it:

> *"He chose the age limit based on economics. How many can we afford to offer this?" … "This is how the 38-years age limit came to Norway, and it stills lingers... So this was a random decision, more than 30 years ago. It has no technical basis. The risk for having a child with trisomy increases gradually with age, and there is no reasonable cut-off when the woman is 38."*

Our two other professionals agree with Eggebø:

> *Pepe Salvesen: "That is just foolish" … "Age is a very poor screening test."*

> *Berge Solberg: "We have no good arguments for keeping the age limit, besides for not wanting everyone to have the screening."*

Why do you think the system in Norway differs from the other Nordic countries?
Like mentioned in the background, Norway has a more conservative approach to prenatal screening in general, and in particular the aspects concerned with foetal diagnosis, than the other Nordic countries. We have played with the thought, whether this has a cultural or a political background. Our professionals seem to agree on that this is caused mostly by politics and a strong Christian Party (KRF – Kristelig Folkeparti) in Norway, compared to for example our neighbours, Denmark. They also considered the possibility of a change in the regulation of prenatal screening, with a possible change of government:

> *Berge Solberg: "One of the reasons for the extensive debate in Norway, is that we have quite strong political voices, like the Christian party (KRF)- that are against prenatal screening. We also have many famous people who have appeared in the media, and talked about Downs syndrome and the positive sides that are against a sorting society."*

> *Torbjørn Eggebø: "KRF stopped a study about prenatal screening at St. Olavs around 2000..."*

What is your impression of the women´s wishes?
The two gynaecologists offered no comments around this question. Berge Solberg commented on some Norwegian studies, where the majority of women answered that they would not want the combined test to be offered to all pregnant women. He pondered around, that maybe the women would not do the same as they say in a research study, if they were put up with a choice in their own personal life. From both Denmark and Iceland, we have seen that most women choose the to do the screening, when they have the option:

> *Berge Solberg:* "When it comes to what women do and think, it is probably not that different in the different countries" … "One thing is what people say, but it is something else what people do…"

What do you think about the future? Do you think the system will change?

When asking about the future, the NIPT was the theme of subject. When it comes to NIPT, it is alone (without an ultrasound examination) more accurate in discovering chromosome malformations than the combined test is. This way, if the aim were to screen for Down's syndrome, one option might be to have a screening in week 12 with only a blood test and no ultrasound. Our three professionals were all of the opinion, that this was not the preferable solution. Especially the gynaecologists, thought that the ultrasound examination is the most important part of the 12-weekscreening, and can´t be replaced by the NIPT test alone. But the topic might still remain ethically heated:

> *Pepe Salvesen: "I don't think we should do NIPT, if we haven´t done a sonography first" … "I think we should use NIPT as a secondary test" … "When we find something wrong, we can use NIPT instead of using a needle on the women (CVS)" … "NIPT is also expensive".*

> *Torbjørn Eggebø: "NIPT is the future, and will make the combined test less important. It will probably oust the invasive tests as well."* … "*I think it should come as a supplement to KUB." …" NIPT is more precise when it comes to discover trisomy's, but the test lacks all the other things of importance, like how the foetus is doing."*

> *Berge Solberg: "Politically, this is a very difficult question. NIPT is even more directed towards Downs syndrome, than the combined test."*

Professionals in Iceland

To get an impression of the situation in Iceland, we interviewed a midwife, Kristin Rut Haraldsdottir, and Hulda Hjaltadottir, who is a gynaecologist. They both work at the public hospital in Reykjavik, Landspitali University Hospital.

What information do you give to the pregnant women about the early screening and the combined-test?

One of the topics of importance, is how well informed the women are in this situation, and what information the health personnel find important to promote. We got to know that most of the women get information at the health care centre, from a midwife or a general practitioner (GP), before they come to the hospital for screening. Hulda tried to give us an impression of what she focuses on, when she talks to the pregnant women at the hospital:

> *Hulda: "Have you heard of the combined test? Do you know what we are testing for? Have you heard about chromosome-anomalies? This test can give you a risk estimate for your pregnancy. If you are in a high risk group, you will be offered an invasive procedure, and that is not without risk. I usually tell them, "if you are not going to do anything with the result, you should not go through with the screening at all". I try to take the time to tell the women this."*

How much do you talk about the consequences of the test before doing it?

One important aspect is how well informed the women are of the consequences of the test. Do they know that sometimes there are false positive and false negative results? Do they know the risk of unintended foetal loss after an invasive diagnostic procedure?

> *Krisitin Rut: "Many of them have already gotten information when they come here. But I tell them, that it is a 90 % chance that the result of the ultrasound is correct. And that we cannot say it for sure before they have gotten the result from the blood test. If they are at risk and want to have an CVS, they are offered genetic counselling and a conversation with a doctor in the unit, or they go straight to the CVS."*

Hulda: "I always try to take my time to talk to the women about the risk. I have the impression that many women think: "I just want to know that everything is OK with the baby." Then I try to tell them that this screening does not guarantee that everything is OK, it just excludes some specific anomalies."

Do you have the impression that the women really understand the risk?

Hulda: "Yes, at least when it comes to the chorion villi-sample. I tell them that it is a 1% chance for a miscarriage after the procedure, and usually make an example like: If you have 100 women doing the procedure, one of them will have a miscarriage. But I also tell them, that afterwards we don't know if the miscarriage would have happened anyway or if it was because of the procedure."

What is your understanding about the expectations of the women?
What do most women really want to know?

On this question, they both agreed that the women are coming to the screening for reassurance.

Kristin Rut: "They say that they are excited to know the sex, but mostly I think they want to know if everything is ok."

Hulda: "They want to know that everything is fine, and that is not realistic."

What is your personal opinion about the early screening-program?

In Iceland the prenatal screening is available for all pregnant women. We talked to the women and asked them what they thought of the screening. We also wanted to know the thoughts of the health personnel. Throughout the conversation, they both seemed very positive to the screening:

Kristin Rut: "I think everyone should have the offer."

Hulda: "I have worked both before and after the combined test, so I am able to compare. I think we have come closer to a real risk."

Hulda is referring to the system they had before in Iceland, where all women over the age of 35 got the offer to go through with amniocentesis. The way it is today by doing the combined test first, less women have to go through the invasive procedures.

What are the positive sides?

On this question, we saw that the Icelandic professionals had quite the same responses as the Norwegian gynaecologists. They both use the argument, that there are some things that are easier to discover in week 12, and also that it is may be better for the women to get to know the bad news earlier than in week 17-19, when the established second trimester ultrasound screening is carried out.

> *Hulda: "You can find the most serious anomalies already in week 12. With that I mean those who are not compatible with life, like trisomy 13 and 18. We can also find almost everybody with trisomy 21. I have the impression; it is not a that big shock for the woman to get this bad news in week 12, then in week 20. It is so hard for the women in week 20, because most of them have started to feel the foetus kicking."*

> *Kristin Rut: "We see more things now at the 12 weeks' scan, than we did in the beginning, because now we have more practice and the machine is better. We are finding a lot of problems, like anencephaly. We will find it at the 20-week scan too, but you know, you cannot live with it. We can also find gastrocele, and missing limbs." … "It is better to pick it up at 12 weeks than at 20 weeks."*

Another aspect, came from Kristin Rut: Both in Denmark and Iceland, the numbers of women who previously went through amniocentesis, were high. The introduction of the combined test has lowered the use of invasive tests substantially:

> *Kristin Rut: "Instead of sending all women over 35 years to an amniocentesis, they now do the screening on everyone, and less women are actually doing the amniocentesis, because now we can do better risk estimates on beforehand."*

Are there any negative sides?

On this question, both the professionals found it difficult to come up with anything negative. Kristin Rut have meet a lot of pregnant women, and have experienced how people change their way of thinking, when they are in the situation themselves:

> *Kristin Rut: "You don't know what you are going to do before you are pregnant and are in that situation."*

Hulda had a more medical approach to the question:

> *Hulda: "If I had to choose between the one in week 20 and in week 12, I would have chosen the one in week 20, because you get more information. But I would prefer to have both of them. Especially when it comes to twins, there are a lot of things you can find out in week 12, that you can´t find out in week 20. If they are mono- or dichorionic. There is a huge difference in risk between those two situations. That is the one thing that you can´t find out in week 20. I can´t think of something negative with having the 12-week scan, right now. The only thing is when there are couples who have said that they only want to see the foetus and nothing more, and then you discover something very serious. Then it is very difficult to know what to do."*

We asked more specifically about the risk of findings of uncertain significance (sometimes called "soft markers") or false positive results in screening, i.e. a false alarm that something is wrong with the foetus. We also wondered about false negative result, i.e. the birth of a handicapped child after a normal screening result. Hulda agreed that these situations are in fact a negative aspects of the screening program:

> *Hulda: "I am sure that some pregnant women will start to think differently about their foetus after the screening, especially when there are findings with uncertain importance. That is the negative side."*

The situation of false negative results can be dramatic for both parents and professionals:

Hulda: "We had two false negatives last year, and that was very hard. They were angry, even though they had the baby in their arms. And we had to go through the screening, and see if we had overlooked something."

In Norway we often use the term "sorting society" in the debate. What do you think about that? Is that a part of the debate in Iceland?

Both of the professionals found the age limit (38 years) in Norway strange. The gynaecologist also criticises the way things work with pregnant women who have attended a private clinic. They can come through a "backdoor" into the system:

Kristin Rut: "If you are able to have a handicapped child, you are more likely to do it at 38 years old than 21." ... "Why can a woman who are 39 years old, go to an abortion with a baby with Downs, and not the women who are 35? If that is the argument, then nobody should have the possibility."

Hulda: "I think it is very weird the way it is done in Norway. That the age decides it." ... "Some people still choose to go to a private clinic and do the sonography, and if they find out they are at higher risk, they come to the hospital through "the backdoor". That is wrong. Everything works fine as long as you are older than 38."

Hulda have worked one year in Norway, at the hospital in Stavanger, and has experienced the system in Norway herself:

Hulda: "It is less controlled in Norway. It should be standardized, and everybody should have the option." ... "If you come through the backdoor, they often came directly to the gynaecologist, without any information about the sample taking or the risk, and I found that that worked out poorly." ... "The ones who came through the backdoor, had not an exact measurement of the nuchal fold, they had not taken the blood test and everything was very unclear. Almost everybody ended up with the chorion villi sample, even those who maybe should not have had it."

Prenatal screening has created an intense debate in Norway. We wondered, if the theme had led to discussion in Iceland as well. Kristin Rut could tell us this:

Kristin Rut: "We had a lot of debate here in Iceland too. We first had an age limit of 35 years and older. Everyone over 35 years were offered an invasive test. But a lot of women complained. Everyone, also women with a lower age, wanted the offer. After some debate, the law changed, and now we are offering everyone a combined test. We are doing fewer invasive tests today than we did then. Now only the pregnant women with an actual risk, get the CVS."

"The sorting society" is the most used expression in the debate in Norway, with Down´s syndrome in focus. The professionals had these comments on this theme:

Kristin Rut: "It should be up to each and every one to decide. Some have a big net around them, family, friends and so on, to help them if they get a disabled child, some have not." … "Down´s Syndrome is not Down´s Syndrome. Some are really well and some are really sick, but it should be up to the parents to make a decision about it."

Hulda saw the more negative sides of the screening, and came with any example from Denmark, where a striking majority of pregnant women chooses to do the test, and fewer are born with Down´s syndrome today than earlier. Can it be that the high participation rate is a reflection of too much socio-cultural pressure:

Hulda: "There are some people (Authors comment: 15% in Iceland) who choose to not do the screening, and I think that is a good thing. In Denmark there are 98% who do the screening, and I find that strange. It should be an option to say no."

In the end of the interviews we touched thse theme NIPT, which many believe is the future of prenatal screening:

Kristin Rut: "The newest test now is the NIPT. It is very accurate when it comes to chromosome anomalies, and some people say "then you skip the sonography" – No, you should not do that, because then you miss a lot of things that we can discover on the scan".

Hulda:"This blood test is going to change the practice in Norway, I think!" … "This is much more specific and sensitive than the combined test."

Pregnant women in Iceland

Pseudonym	*Age*	*Parity*	*Pregnancy week*	*Work*	*Relationship status*	*What examination*
Eygló	28	1	37+4	Kindergarten	Married	Combined test
Hanna Birna	25	0	38+6	Nurse	Boyfriend	Combined test
Dagrún	32	1	7	University teacher	Married	Not done it yet
Elísabet	36	2	40+1	Teacher	Married	Only ultrasound
Hólmfríður	40	2	Already given birth	Social worker	Married	Combined test
Heiða	28	0	19	Professional athlete	Fiancee	Combined test

We talked to six pregnant women in Iceland. They varied in age from 24 to 40 years old, and from pregnancy week 7 to some weeks after birth. Two of them had two children from before, two had one child and two was pregnant for the first time. One of them had previously gone through a miscarriage. The combined test was chosen by four of the women, one had not done it yet and one had chosen to only do the sonography scan. From those who did the combined test, all of them had a negative result (meaning that everything looked normal).

Why did you want the screening?

Four of our six women had the screening in week 12. When asking why they wanted this, the sudden thought from most of them, was about the wellbeing of the foetus:

> *Hanna Birna: "It was my first pregnancy and everything was so new. I wanted to know that everything was OK" … "I was really scared it was something wrong with the baby. It was so comforting to see that everything was working."*

Preparation was also frequently mentioned. They said they wanted to know on beforehand, if something was seriously wrong with the foetus:

> *Eygló: "If it has something, I want to know it. Then I am prepared,"*

In Norway, one of the arguments against introduction of the screening, is that we don't want the society to set the norm for what people should do. When talking to the women, we found a wide variety in how much they had thought through the screening themselves beforehand. Some of them were well informed and made the choice they thought were best for themselves. Others again, swum with the stream:

> *Heiða: "I feel like everyone here in Iceland do it, so that was why we did it, that is just something everyone does."*

What does the result of the screening mean to you?

When asking about what the result would mean to them, the women were divided in opinions. Some said that they most likely would choose an abortion, others said that was something they could not know before being in the situation themselves, while some said they would keep the child anyway. Nevertheless, numbers from the Icelandic Birth register, showed that all women with a positive test for Down's syndrome in 2014, chose an abortion (25).

Comments from the women who did not want an abortion:

> *Eygló: "This is just life, if it was something wrong, it is just for us to deal with it."*

Dagrún: "To tell the truth, I think I would have kept the child, even with Downs Syndrome. I am almost sure I would... But I would like to know it."

One of the pregnant women we talked to, was a nurse, and had worked with children who had spent a lot of time in the hospital. This experience had made a huge impression on her, and was one of the reasons why she wanted the screening:

Hanna Birna: "I remember thinking, I would not know what to do, if the result was bad." … "I am a nurse, so I have seen a lot of sick babies. I don't think it´s a great life..."

Why did you not want the screening?

The one who had chosen not to participate in the screening, was in her third pregnancy, and had not attended screening in her two former pregnancies either. She was of the opinion that it should be a free choice for everybody, but for her there was only one right thing to do:

Elísabet: "If I have a baby with Downs, it´s still a product of me."

One of our pregnant women did not choose screening in her first pregnancy, but she did now, in her second pregnancy. She explained why she did not want it in the first pregnancy:

Dagrún: "I did not want to be put up with the choice… Because I had a friend who did it. They said that her child had a heart defect that was very common among people with Downs, and that it was very likely that her child also had Downs." … "She was just crying throughout pregnancy. Then it turned out, it was only a heart defect. The baby did not have Downs."

In her second pregnancy, she got information from her midwife, that the invasive tests could verify whether the child had Downs or not. Then she chose to go through with the screening.

Where did you get information about the screening?

On this theme, most women had no clear answer. The screening is something that is talked about, and most of them had known about it a long time before they were pregnant themselves. Sources that were mentioned, were Facebook, friends, family, google and the health service. One of the women mentioned that it is frequently discussed in so called "pregnancy groups" on Facebook:

> *Eygló: "A lot of groups on Facebook are talking about this. Some are against it and some are not."*

How was the information given by the health care service?

To make an autonomous choice, sufficient and good information from the health care service is of importance. The general impression from the pregnant women, was that the information could have been better. The ones that were well-informed, had read it themselves or asked the midwifes specifically about it. Some had also gotten written information from the health care center. Especially information about what happens after a positive screening result, was lacking. Most had not heard about the invasive tests, and how they are necessary to verify chromosome malformations.

> *Heiða: "I guess they did not really talk about, if there are bad results, like what you can do. I remember reading about it later, but I did not know that before (Authors comment: doing the combined test). Maybe that information could have been better. When you get to the hospital, they just do it. They don't ask any questions."*

> *Hanna Birna: "I got a lot of papers, and I read them."*

They also reflected upon, how many who, after a negative screening, expect the "perfect" baby. That there should be better information when it comes to what the screening actually can discover and what it can´t:

> *Dagrún: "I think people should have more information. There are so many malformations that they can´t scan for"*

Others again, were satisfied with the information:

Hólmfríður: "The information from the midwife on the screening was good. She explained what the numbers and the risk estimates meant."

What is your personal opinion about the screening program in Iceland?
On this question, all were in agreement. They were of the opinion that it should be the woman´s choice whether she wanted the screening or not. Also the one who chose to not do the screening herself, was of this opinion. In general, they were all very satisfied with both the screening and the antenatal care.

Elísabet: "I think it´s great! That´s up to one self to make a decision."

Heiða: "I think it's a nice thing to offer it early. If people think it is too big to take on, and it is very likely the child has Downs."

Dagrún: "I think it is brilliant that you have the possibility!" … "You just want to know what is ahead."

When asking more specific if they could think of anything negative about offering the screening, most of them had no comments. Nevertheless, one of them mentioned how they had heard that stress could affect the foetus:

Heiða: "I know that stress and stuff is bad, so if you get bad results, it might not be good for the baby."…"It´s not like I am against it or with it, I just think it´s ok to offer it."

In Norway it is not an option to do the combined test, before the woman is above 38 years old. The first ultrasound-examination for women in general, is in week 18 of pregnancy. What do you think about that?
We were met by surprise, when telling about the situation in Norway. The Icelandic women found the Norwegian system unfair, especially when it came to the age limit. Many questioned the "sorting society", and how we could use that as an argument, when the women above 38 where allowed to "sort out". They were also talking about how reassuring it was to see the foetus already in week 12, and how they would be nervous if

they had to wait until week 18. The lethal conditions were also mentioned, and how stressful it would be to get that kind of information in the second trimester.

> *Hanna Birna: "But then the child is so big! I don't see why you can´t do the 12-week sonar. If the doctor can see that it won´t be a good life, I think it's better to have the option not to give birth to it." … "The scan should be an offer in Norway, but maybe not specifically for Downs."*

> *Eygló: "I would be a lot more nervous, because it is a long time to wait" …"You want to see that it is moving, and that there is something in there, because you can't feel it on that time."*

> *Elísabet: "I think people should have the option, if they want to know."*

Can you tell us about your personal experience (emotions, and thoughts) around the ultrasound examinations in your pregnancy?

Without doubt, this was the question that stirred up most emotions among the women. The confirmation that the foetus was alive, that everything seemed to be OK and the sound of the heartbeat, were mentioned as the highlights of the examination. The women also told us about stress around the child´s health, that disappeared after being to the sonography.

> *Elísabet: "I thought it was amazing! Tears appeared in my eyes. And the sound of the heart beat was amazing."*

> *Hanna Birna: "It was so magical, to see a baby. I did not have a belly, so it was so surreal. I really loved that"*

> *Heiða: "I loved it. I would like to walk around with a heart monitor all the time"*

> *Hólmfríður: "I was not really nervous about that (screening), but I think most woman that carries a child worries a bit." … "It was good to know that everything was fine."*

But we found other reactions, too: One of the women told us how she found the foetus´s face looking abnormal, both at the 12- and 18-week sonar. Even though the midwife told her that everything looked perfectly fine, that was a stress she was not able to get rid of.

Pregnant women in Norway

Pseudonym	Age	Parity	Pregnancy week	Work	Relationship status	What examination
Evelyn	24	0	37+3	University student	Live-in partner	Sonography week 12 +18
Ingrid	30	1	9-10	Pharmacologist	Live-in partner	Sonography week 12
Karoline	29	0	10	Psychologist	Married	None
Kaja	33	2	27	Physiotherapist	Married	Sonography week 12 + 18

We interviewed four pregnant women in Norway. They varied in age from 24 to 33 years old, and were in pregnancy week 10 to 37. Two of them were nullipara, one had one child, and one had two children from before.

When and which ultrasound/examinations have you gone through in this pregnancy?

All followed the normal antenatal care, and had done or were planning to attend the routine ultrasound in week 18. In addition, three of four had done a sonography around week 12. One of these had been on a medical indication (bleeding) and two were performed by private midwifes.

Some Norwegian women choose to go to a private clinic to do an ultrasound before week 18. Have you heard about this? Have you considered it?

The women were all well informed about the possibility to do a sonography in the private market. Their general impression was that most women nowadays do it:

> *Kaja: "It is seven years since I was pregnant for the first time, and then it was not that common as it is today. Today, I almost feel that everyone does it."*

The two women who chose the private market themselves, stated different reasons. One had not planned the pregnancy, and wanted the sonography to determine how many weeks pregnant she was. She also stated that she had not lived adequately from a preventive perspective, because the pregnancy was unknown to her, and wanted to ensure that the foetus was healthy. The other woman was curious about the foetus´s health and found the waiting period too long.

> *Evelyn:" I thought it was too long to wait until week 18, to know anything..."*

She also said how she found it assuring, to have seen a healthy and alive foetus, before telling friends and family about it.

One of the women who did the sonography in week 12, remembered how it was in her earlier pregnancies when she only had the routine sonography:

> *Kaja: "In my first pregnancy, I only had my hopes and thoughts, and believed that everything was going to be fine." … "If I did know about any risk factors in my family, I think I would have taken the early sonography in all of my pregnancies."*

The pregnant woman who was planning to only have the routine sonography (now in pregnancy week 10), explained it like this:

> *Karoline: "I don't think I want to do it, because everything has been fine this far... But if I had had some miscarriages, I would probably do it." … "I have friends who have done it, but they are mostly couples that have been through miscarriages before." … "I really understand the need to see the baby, because you get really*

impatient." … "It is quite a long time to wait, because you don't know whether it is alive or not."

One of our pregnant women, had experienced bleedings in the pregnancy, and therefore gotten the sonography on medical indication. Her thoughts around the private market were positive:

Ingrid: "If I hadn't gotten the sonography now, on medical indication, I would easily pay 1000 NOK, to do it private." … "I get the impression that everybody else do it too" … "I do it mostly because I want to "see" that there is a baby in there, and that it is doing alright. I have not been that stressed for anomalies."

Can you tell us about your personal experience (emotions, and thoughts) around the sonography scan?

The two women who had done the early sonography in the private market, where in accordance about the experience. They were both satisfied with having the possibility to see a healthy foetus. Still, they found the sonography a little rushed, and were disappointed with the information given from the midwife:

Evelyn: "It was kind of weird, but also very nice, to see a little person in there. She could have explained more. We had paid 1000 NOK to go there..."

Our women were in general very satisfied with the 18-week routine sonar:

Evelyn: "The sonography in week 18 was more proper. It was in the hospital, and she explained much more. That was good, especially for my boyfriend."
Ingrid: "I thought it was really nice, one of the best things I have experienced in life." … "But I was really stressed before she said that everything was fine."

In some countries, like for example Denmark, all women are offered an early screening in week 12. This can make it easier to discover chromosome anomalies, like Downs Syndrome. What do you think about that?

On this theme, the women had a wide range of thoughts. They shared many of them, but on the question if they wanted it or not, they were divided. Some were positive and stated these reasons for it:

> *Kaja: "If I had the possibility, I think I would do it, for the reassurance." … "I believe, that if you find something like Downs, it can be nice to know about it, so you can prepare yourself. I also think it is a good thing, that everybody can make an individual choice if they want to continue with the pregnancy or not."*

> *Ingrid:"I think that is positive, because it is nice to get to know if there is something seriously wrong with the baby before it is too big." ... "I think, if the baby has a severe anomaly, and is only going to sit in a wheelchair and be multi-handicapped the rest of its life, then I don't see any reasons for the baby to live." … "Then I don't believe it is a worthy life."*

We asked the women who were positive to an introduction of the 12-week sonar in Norway, why they wanted it:

> *Evelyn: "I am against doing an abortion because of syndromes." … "But I also think that if you really don't have the resources to take care of the baby (Authors comment: she obviously referred to a sick baby as she said this), then it would be good to know."*

> *Kaja: "In the beginning of pregnancy, it is not a lot of follow up. When you are in week 18 (Authors comments: referring to the 18-week scan), you are soon halfway through your pregnancy… I think a lot of women want to get some follow up before this stage, and then an early sonography would be nice."*

Another perspective that came up, was about anxiety among pregnant women. How many are not able to enjoy the pregnancy, before having confirmed that the foetus is alive. One of our pregnant women, was of the opinion that a sonography in week 12, would help the mother relax:

Ingrid: "There is also a lot of uncertainty for the mother, to wait until week 18. It is a long time. I believe that having an early sonography, makes the mother more relaxed and able to be happy for the pregnancy."

Some were more sceptical to the screening, but positive to the sonography alone:

Evelyn: "It sounds kind of scary, that you get this risk estimate. But I am very positive to the sonography alone." … "I think that can lead to more abortions. I don't know if I would want to know that kind of risk estimate… Then I guess I would go around and think about it."

She also indicated that the system in Norway today, is not good enough:

Evelyn "It is kind of weird that so many do the early US, and then it is not controlled by the government."

Even though some of the women wanted the opportunity, they reflected upon the criticisable sides of the screening:

Kaja: "I don't think everyone realises that it can be a lot of things that can be wrong with the baby, even though everything looks fine in week 12."

Karoline: "If you are going to do something like that, I think you have to reflect and be aware of what you going to put yourself through, and know that it will be a big decision to make."

One who was against the screening, reflected upon how making this kind of choices, is not necessarily for the best:

Karoline: "I initially think, that it is nice to not know, because then you don't have to make up your mind about it, and make a choice." … "You have to make a choice that not only involves you, but also your partner and your family. In that way it would be easier not to have the option."… "In the same way, I can understand that people

want to know." ... "Maybe it should be optional, but then you still have to make the choice yourself."

In the political debate about early screening we have the expression sorting society. Do you have any thoughts around this?

On this question, the women had different thoughts. Some were against a society with sorting, and some had a more realistic approach to the theme. This shows that although the screening in week 12 has a focus on chromosome anomalies, it doesn't mean that the women choose an early sonography necessary for this reasons.

Ingrid: "I know that people with Downs can have a really good life, and whether it is OK to sort out all of them, I would question that." … "But, to sort out foetuses who are not going to have a worthy life, I think it´s OK."

Evelyn: "This is what I am against, like: Okay, you are sick. Let's get rid of you. That is just stupid. They have the right to live as well." … "I think it is better then, to have the time to adjust and to be able to do it." (Authors comment: She is here speaking of taking care of baby with findings on the scan) …"The way it is now – that you can design your own baby – that is just wrong."

Kaja: "I think the result will be more sorting, because people can make a decision on an earlier stage in pregnancy. But I think that it will anyway be an individual choice, and every couple have to decide for themselves." … "Everyone wants a healthy child"

Discussion

The aim of the fieldwork part of our project was to get a broad overview of current practices regarding early prenatal screening in Iceland and Norway. We found that the topic is debated in both countries. Nevertheless, there seem to be some significant differences in the legislation, practice, culture and political climate surrounding the topic in the two countries. In Iceland, we found a relatively uniform practice where most women chose to attend early ultrasound screening in the public system at an affordable price. In Norway, we observe a notable tension between the established national system which does not endorse early foetal screening, and actual practices where women to an increasing extent seem to enter the system through private "backdoors". In that way, they can circumvent current legislation. There is increasing availability of prenatal screening in many countries, and we think it is important to follow the development with an open mind and critical eyes.

The included informants

In our fieldwork, we talked with only a handful of informants in the two countries. The field is complex and foetal diagnosis is a very personal theme. We will not try to draw many general conclusions from our interviews. We are nevertheless fascinated by the richness of the material we ended up with. Several issues that are well-known from previous research and debates about prenatal diagnosis, are highlighted in our material.

Researching the field on the internet, we noticed that particularly in Norway, there are professional voices both for and against targeted foetal screening. However, we did not come in contact with any professional who clearly argued against. It would have been interesting for us to get a deeper understanding of both sides.

As previously outlined, we intentionally avoided to interview pregnant women with positive screening results (meaning findings that indicate that the foetus might have disease or malformations). These women would most likely find themselves in a difficult, emotionally and ethically loaded situation. This would be a vast and sensitive research topic in itself, and inclusion of such women would have required a more comprehensive consent procedure.

Thematic findings

During our field work we touched a lot of interesting themes. Here are some of the topics that attracted our attention:

- *What do expectant parents want from ultrasound in early pregnancy?*
- *The idea of a "free reproductive choice": Ideal or reality?*
- *Does the information prior to screening do justice to disabled people?*
- *Postponing the news until after the screening: "The tentative pregnancy"*
- *The emotional impact of false positive results*
- *The implications of false negative results - wrongful birth?*
- *Are there good enough medical or moral reasons for including early ultrasound in the public system?*
- *The political climate and discussion in the mass media*

What do expectant parents want from ultrasound in early pregnancy?

After talking to our pregnant women, it became quite clear that most of them wanted general reassurance that there was a healthy foetus growing inside of them. These expectations have been found in several previous studies (30, 39, 40). Since the vast majority of foetuses appear to be healthy, ultrasound in pregnancy often deliver according to these expectations. This way it is often experienced as something magical and spectacular for the parents. To hear the heartbeat for the first time, was by one of our pregnant women described as the happiest moment of her life. This can maybe explain why so many choose to do the early prenatal screening in Iceland, and why so many Norwegian women have started to use the private market to get an early ultrasound. Nevertheless, one can question whether the expectant parents are well-enough informed about what the ultrasound (and the blood test) can reveal and not.

Hulda Hjaltadottir (Icelandic gynaecologist) told us how many expectant parents want to know that "everything is fine", and how she found this problematic. She emphasised the importance of sufficient information when it comes to what the test actually is able to discover. That even though everything looks normal on a 12- or 18-week scan, there is no guarantee from the health service that the baby turns out healthy. We will come back to the topic of false negative and positive results below.

The idea of a "free reproductive choice": Ideal or reality?

In contemporary society, information is generally considered a good in itself. In relation to foetal screening, the implications of the information are far from trivial: It might involve decisions about life and death of an unborn baby - a baby that was wanted and welcomed until the moment of screening. Beyond decisions related to pregnancy termination, it is often argued that it is valuable to be able to prepare for the birth of a disabled child. It is however evident that choices which can arise in relation to prenatal diagnosis can be very hard to make. They touch upon deep personal as well as societal and spiritual values. Nevertheless, as ethicist Berge Solberg pointed out, society seems to bend it course towards so called autonomous choices, even in the field of reproduction. But how autonomous is it possible for expectant parents to be? And what about the autonomy of the foetus?

As a whole, our interview objects seemed to be quite in agreement on reproductive choices. Both the health personnel and most of the pregnant women believed it should be up to oneself to decide when it comes to prenatal screening. Only one of the pregnant women said that she found it better not to have the choice whether to go through prenatal screening or not. Her argument for this, was that she saw this as a choice that affected not only her and her partner, but also their family. Because of this, she found it to be too big to take on. Berge Solberg also mentioned how it may be worse for the mother's health to have to make the choice, instead of letting nature decide.

After talking to the Icelandic women, we got the impression that most of them had decided whether they wanted the screening or not, before the first contact with the health care service. With other words, the health service seemed to have little impact on their decision making. The same observation was made by Gottfredsdottir et al., in a study from 2009, where the authors studied parents in Iceland who accepted nuchal translucency-screening (20). Without drawing any strong conclusions, we sensed a tendency that at least some of the women chose the screening based on the herd instinct. That the 12-week scan had become almost like a norm in the society, and something one is supposed to do. This makes it even more important to emphasise proper and sufficient information, so that expecting couples can make the choices that are best for them. Recently, a web-based decision aid has been tested in Sweden. Results

from this study showed that the women´s awareness was enhanced, and indicates that this might be one way to proceed (41).

Does the information prior to screening do justice to disabled people?
According to the women and the health personnel we talked to, the information about the screening itself seemed to be OK. Nevertheless, we encountered a psychology student in Iceland (not one of our formal informants) who had worked with disabled children. She believed there also should be information about how life with a disabled child is. Working with disabled children had enriched her life. She wanted to draw more attention to the positive sides of living with a child with Downs Syndrome or other disabilities. One can also get the same impression from women who have given birth to children with Downs Syndrome. Their experiences evidently vary a lot, but some parents of disabled children say that they are happy they were not confronted with the choice. This is because their disabled child has provided them with an appreciation of life they think they would never have experienced in any other way. One Norwegian mother came with the proposition, that parents with a positive finding indicating that their child has Downs Syndrome, should be given the possibility to meet a person with the disability. In that way, the expectant parents might be able to understand how life with disability can indeed be good and meaningful (42, 43).

The emotional impact of false positive results:
One of our Icelandic informants declined prenatal screening in her first pregnancy, because she had witnessed how a friend's pregnancy had been overshadowed by worries that the child might have Down's syndrome. Ultrasound findings of uncertain significance (for instance so-called "soft markers") have for years received considerable attention from the methodological viewpoint. The difficult human experience of receiving such information has also gained some attention, as highlighted by Getz and Kirkengen (16). There exists a substantial literature about the foetal impact of significant maternal stress in general (44). Whether stress induced by uncertain findings at prenatal screening can negatively affect the foetus, is not known, as far as we know.

Postponing the news until after the screening: "The tentative pregnancy"

The term "tentative pregnancy" describes the situation where a woman waits to acknowledge her pregnancy until after the prenatal screening (45). This topic was quite thoroughly explored some years ago (46) and we won´t delve deeply into it here. Nevertheless, we find it worthy to mention, as this was something we encountered quite frequently in our interviews. As previously described, one woman directly told how she found it reassuring to have the confirmation that all seemed to be OK with the foetus before she told friends and family about the pregnancy.

The implications of false negative results - wrongful birth?

The situation of false negative results (i.e. where the prenatal screening fails to discover an existing anomaly) can be dramatic for both parents and professionals. The Icelandic Gynaecologist Hulda told us about parents who had gone through the screening without any findings, and then the baby turned out to have Downs Syndrome. She described the parents as shocked and very angry at the doctors. The professional's reaction was to conduct a thorough re-examination of the recorded screening procedure, to see if anything had been overlooked. It is fair to assume that the failure of the screening had fundamental impact on the relation between the newborn and its parents. In the absence of a screening programme, the parents' strongest feeling would probably have been of a different nature. Now, someone could be blamed, and the parents expressed anger towards the health service. A study by Hall from 2000 (47) of parents with children with Downs Syndrome looked on the psychological consequences of a false negative screening result. The results showed that those who had gone through a false negative screening test experienced more parenting stress and were more likely to blame others for the outcome, compared to parents who had declined the test. From the United States, we have the term "wrongful birth", in which the parents of a congenitally disabled child sue the health professional for not having been able to discover the genetic or congenital malformation (48). These are thought-provoking scenarios about which we have found little scientific knowledge. Are we facing a future where the search for the perfect child has gone too far?

Are there good enough medical or moral reasons for including early ultrasound in the public system?

According to the obstetricians we talked to, there is. They argue, among other things, with the benefits of discovering twin pregnancies and heart defects early. The Knowledge Centre for the Health Services (Kunnskapssenteret) however concluded differently in their report in 2012. They found that there is no documented health-related benefit of an introduction of early ultrasound screening for everybody (49). It seems evident that the debate about early pregnancy screening is about more than evidence in a narrow, medical sense. In 1986, Norwegian authorities faced a similar situation regarding implementation of the second trimester ultrasound screening (50). Its introduction into the public healthcare system was not supported by convincing medical evidence, but the screening was still implemented as ultrasound scanning had widely become part of what one might call the culture of pregnancy.

The political climate and discussion in the mass media

During the last decade, screening for foetal malformations has periodically been discussed in the mass media in Norway. As the only Nordic country without a routine offer of early ultrasound for all pregnant women, the situation in Norway has become exceptional. One of the most used expressions in the debate is “the sorting society”. This expression came into use already in 1993 by Hilde Frafjord Johnson in an interview with the newspaper Aftenposten. Later the expression has been used a lot in the political debate and in the heated discussion around early ultrasound in media (51). As we described in the introduction of the fieldwork, this is an interesting situation. Our interviews did not bring us much closer to understanding why the development in Norway is different from the Nordic neighbours. In order to understand more, one might have to dig deeper into both political and historical perspectives, which are beyond the scope of our project.

The latest wave of the Norwegian foetal screening debate took place in the autumn 2016, when we were working on this project. The arguments then circled around the newest test, NIPT. In October, NRK Troms wrote about the University hospital in Tromsø, and their application for introduction of NIPT. The argument the hospital used, is that the new non-invasive test is simple in use and have no risk of terminating the

foetus (52). This created an immediate response from the chairman of the Norwegian board for Downs syndrome in NRK Troms some days later. She said that she was worried about the tendency in the society today, and expressed her concerns around the expectations the women can feel. Media writes frequently about different opportunities with prenatal screening, and some can feel a pressure to go through with the procedure. She claimed that the society is creating a sorting society (53).

Final comment

We hope that this report from our fieldwork around prenatal diagnosis has convinced you as reader that prenatal diagnosis is an important and interesting topic. It has been the topic of considerable research throughout the last decades – our report just presents the top of the iceberg regarding existing publications and references. However, both society and technology are continuously changing, which means that prenatal diagnosis will present new questions to new generations of citizens and researchers. In the following second part of our report, we will present a recent empirical study in which we have had the opportunity to take part.

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The picture on the front page is taken by the authors (KFH,MF) and is from the maternity outpatient clinic at St. Olavs Hospital, autumn 2016.

Draft of publication for a peer reviewed journal.
Some search for optimal supporting references remains, as well as final text polishing

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Use or overuse of early ultrasound and prenatal screening among pregnant women in Iceland

Analytical study based on the Childbirth and Health Cohort Study

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ABSTRACT

Background: The use of ultrasound scanning in early pregnancy is increasingly common, but little is known about its actual prevalence and the associated decision-making.

Objective: To study the use of early ultrasound with and without formal foetal screening among pregnant women in Iceland. Furthermore, to analyse women´s decision making related to early screening, perceived information received, and concerns related to the unborn child's health.

Design: Cross sectional and analytical cohort study.

Setting and subjects: Primary health care centres in Iceland. Questionnaire study among 1111 women attending prenatal care in early pregnancy in 2009-10.

Main outcome measures: Total number of ultrasound scans, participation in foetal screening, socio-demographic characteristics, perception of pre-screening information, reasons for attending or declining prenatal screening, concerns related to the foetus' health.

Results: A total of 95% had undergone ultrasound scans in early pregnancy. The mean number of scans was 2.0 per woman, and 63% underwent two or more scans. 78% of the women went through combined foetal screening. Decision-making regarding the prenatal screening was mainly informed by sources outside of the healthcare system. Most women felt that they got sufficient general information about the scope of the prenatal screening test but information regarding potential risks was frequently perceived as insufficient.

Conclusions: Ultrasound scans in pregnancy are in high use in Iceland and have apparently become a profiled part of the pregnancy culture. Whether this is a favourable development or a sign of undue medicalization, can be debated. Information prior to screening might be improved.

KEYWORDS*: Pregnancy, early prenatal screening, combined test, informed choice, risk*

Introduction

Ultrasound scans play an increasing role in antenatal care and culture in industrialized societies. The purpose of such scanning can be complex. For many expecting parents, confirmation of the pregnancy and a "first encounter" with the child-to-be are a central motivation. From the health care point of view, surveillance of pregnancy-related risk factors is in focus (determination of the term date, number of embryos and location of the placenta). Another aim might be foetal screening, i.e. to examine the foetus for potential structural malformations, diseases or syndromes, including Trisomy 21 (Down´s syndrome) (1). Prenatal screening typically involves visual examination of the foetus by scanning, combined with biomarkers in the pregnant woman‘s blood („combined test"). A more recent method involves examination of free foetal DNA in maternal blood, so-called Non Invasive Prenatal Testing (NIPT) (2). Due to the diversity and complexity of prenatal test procedures, provision of information prior to scanning/testing can be a demanding issue.

Why do women attend ultrasound scans in pregnancy?

Several studies have shown that visualization of a living, thriving foetus can often represent the most prominent reason for attending an ultrasound scan (3, 4). In a Danish study, 60% stated that their main reason was to check for foetal malformations, 55% wanted to see that everything was normal, and 44% said they did the test for their own reassurance (5). Since the ultrasound scan as such has a strong appeal to many people, it can be hard to disentangle the professional medical aims of a scan from the human wish to simply „see" the foetus. Technology might thereby contribute substantially to shape the culture surrounding even low-risk pregnancies, for better or worse (6)

Foetal screening and informed participation

Many countries have introduced national foetal screening programmes at an affordable price or free of charge (7). In several countries, including Iceland, pregnant women are informed about early foetal screening by the so-called combined test (an algorithm based on foetal nuchal translucency measured by ultrasound, maternal age and a maternal blood tests in pregnancy week 11-14(8)). The test sensitivity for Down‘s syndrome in the combined test is 90-95%. In the presence of an increased risk, the

pregnant woman is offered an invasive diagnostic procedure which involves approximately a 1% risk for unintended pregnancy loss. The cut-off point for offering invasive testing is typically 1/250 (9).

In relation to screening programmes in general, potential participants should receive correct and balanced information to enable informed participation (10). Foetal screening involves complex technology and is inherently value-laden (4, 11). A Swedish study from 2008 showed that 88% of the women were satisfied with the information about *why* the screening was performed, and 87% with the information about *how* it was performed. However, only 58 % said they had received sufficient information about the risks associated with the screening programme (3). In a study by Edvardsson et al from 2016, the midwifes' point of view was explored. Their findings indicate that Swedish midwifes want better information-giving to improve informed consent (12).

Current practice in Iceland

Iceland had 320,000 inhabitants at the time of the present study. 70% lived in the greater capital area. The health care system resembles the other Nordic countries (13, 14), with some variations. Primary health care is considered to be the first place of contact for the patients. Private medical practises with elaborate technological equipment are however common, including gynaecologists with ultrasound equipment. Furthermore, there is no formal referral or gatekeeper system in Iceland (15). At present, patients pay 9.6 Euro (1200 ISK) to visit a GP and 46 Euro (5700 ISK) for a visit to a medical specialist.

Icelandic primary healthcare is carried out by GPs, nurses, midwives and other auxiliary staff, all paid by fixed salaries by the state. Antenatal care for healthy women in a normal pregnancy is considered a part of the primary health care, and is therefore carried out in the health care centres (16). The maternity care in the healthcare centres is free of charge and usually starts no later than week 12 of pregnancy. The midwives, obstetricians and GP´s work closely with the obstetrical units at the nearest hospital, where more specialized care is provided for women who are considered to be of high risk during pregnancy.

Before signing up for antenatal care in the public system, a high number of Icelandic women will have their pregnancy confirmed by ultrasound in the practice of a gynaecologist. The gynaecologist receives reimbursement from the National Health

Insurance system (17). This scan does not represent a formal foetal screening test, and the gynaecologist will inform the pregnant women about the availability of foetal screening (the combined test in week 11-14) at the national university hospital in Reykjavik or Akureyri hospital in North Iceland.

Regardless of where they first seek antenatal care, all pregnant women have since 2006 been informed about their possibility to have the combined risk estimate for foetal malformations or chromosome aberrations (18). This screening is only an offer and not part of the antenatal care. Therefore, the expecting couple currently have to pay 93 euro for the examination (ISK 11.636) (19). National guidelines in Iceland recommend one ultrasound scan in week 17-19, but also state that all eligible women who show up for antenatal care should receive information about the week 11-14 screening programme (16).

Based on the above facts, there is good reason to believe that many women undergo at least two ultrasound scans already in early pregnancy. Furthermore, we have little knowledge about the expectant parents' information level and decision-making related to the foetal screening programme.

Study aim

The aim of the present study was to explore the use of early ultrasound and foetal screening among pregnant women in Iceland. Furthermore, we explored where the women sought/got information about prenatal screening, their decision-making process, perception of the information received, and the impact of screening on their concerns related to the foetus' health.

Study population and methods

This study is a part of the Icelandic Childbirth and Health Study (C&H study), carried out in 2009-11 (20). It is a population-based cross-sectional cohort study of pregnant women attending routine antenatal care at primary healthcare centres. We used consecutive convenient sampling methods, stratified according to residency. This was to attain a distribution similar to the one in the entire country, with the ratio 70:30 for urban and rural residency respectively. The study is described in more detail elsewhere (20).

Participating women answered a comprehensive questionnaire around pregnancy week 16 (phase I, with 1111 participants, constituting 23% of all pregnancies in 2009), at 5-6 months postpartum (phase II; 765 participants), and 18 to 24 months after delivery (phase III, 657 participants or 59% of the original sample). The questions included socio-demographic and obstetric background, use of health care services including ultrasound scans and screening for foetal malformations, perception of received information, decision-making related to prenatal tests, emotional well-being and pregnancy-related worries. The present analysis is based on study phases I and II.

Education was categorized in the following manner: elementary school covering 10 years (primary), college or similar covering 3- 4 years after elementary school (secondary), and technical education/university less than 4 years and university more than 4 years (higher education).

General validity of the dataset

Evaluation was done for possible self-selection bias caused by dropout after phase I compared with those who participated in both phase I and II, as recommended by Fewtrell et al (21). This analysis showed that those who participated in both phases were at baseline older ($p < 0.001$) and with a higher educational level ($p = 0.001$), compared to those who participated only in phase I. No difference was found regarding residency, civil status or parity.

Statistical analysis

We used Statistical Package for Social Sciences (SPSS) for Windows version 22.0 for statistical analyses. Descriptive data are presented as frequency and percentage. For continuous variables, we used conventional methods for calculation of mean values and standard deviation (SD). We used Pearson's Chi-Square test to assess significance between groups on demographic variables. Binary logistic regression analyses were used to estimate the association between groups, both crude odds ratio (OR) with 95% confidence intervals (CI). We considered a two-tailed value of $p < 0.05$ to be significant.

Ethical considerations

The study was approved by the National Bioethical Committee in Iceland (VSNb2008010023/03-1) and reported to the Data Protection Authority (S3695/2008

LSL/). The study was also approved by the professional authorities of the health care centres approached.

Results

Socio-demographic characteristics of participants at entry are shown in Table 1. Most participants were well-educated, with 59% having higher education (more than 14 years). A total of 69% lived in the capital area, and 93% lived with a partner (data not shown in table).

A total of 95% (95% CI 93.1% - 95.8%) had undergone early ultrasound in pregnancy. The mean number of scans per woman before 19th week of pregnancy was 2.0 (N = 880; SD $\pm$ 1.2; range 0-12). Figure 1 shows the percentage cumulative frequency of the number of ultrasound scans in pregnancy. As shown, 63% underwent two or more scans and 7% had four or more scans.

Seventy-eight percent had participated in foetal screening for anomalies in week 11-14 (Table 1). As shown, those who were pregnant for the first time, had higher education, were older and lived in the urban area, were more likely to have the combined prenatal screening test. Among women above 35 years, 88% went through screening. Also in the youngest age group (18-24 years), as many as 74% attended.

To test potential recall bias regarding the number of early scans, we compared the reported number of scans reported by the women in phases I and II. When the routine second trimester scan is excluded, the number of reported scans were similar (figure 1).

After becoming pregnant, most women consulted a gynaecologist (Table 2). These women were more likely to choose the combined screening test, compared to women who attended GP´s or midwifes as the first contact ($p< 0.001$).

Figure 2 illustrates how the decision of whether to attend prenatal screening for foetal anomalies was made. It appears that the decision was reached within the family, often considered as “the obvious thing to do”. The decision as such was rarely explicitly influenced by a healthcare professional.

According to recruitment methods and national guidelines, all women (expectant parents) should receive a brochure about the combined test when they first enter the healthcare system with a new pregnancy. Further information can also be sought at the

screening site. Table 3 shows the women's opinions regarding the amount of information given/received, both regarding the screening test and subsequent diagnostic tests with associated risks. Most women who participated in the foetal screening were satisfied with the information they got about the test as such, but less satisfied with the information about it's potential risks.

In 3.5% of the cases, the woman reported that the combined foetal screening test had indicated an increased risk for foetal anomalies. Figure 3 shows to what extent the screening had affected the women´s concerns regarding the health of their child-to-be. In 61% of cases, the woman reported reduced concerns. However, 10% of the women reported increasing concerns.

Regarding experiences of the screening, most women (92%) reported a very positive experience. This is shown in figure 4:

As illustrated in Table 1, 22% of the included women did not attend screening for foetal malformations.

Figure 5 illustrates the reasons women reported for their decision. About 50% stated their personal values and beliefs here, 40% stated that they did not want to face a potential decision of whether or not to terminate their pregnancy and 40% reported that they did not consider themselves in an at-risk situation (more than one response was possible).

Discussion

The Childbirth and Health Study is a comprehensive primary care cohort study on pregnancy and childbirth in Iceland. We found that around 95% of all participating women had early ultrasound, and 78% attended screening for foetal anomalies in week 11-14. As expected, foetal screening attendance was highest among older women, but attendance was 75% or higher in all age groups. Women with higher education and closer distance to the screening units were more likely to attend the combined foetal screening. Although ultrasound before week 19-20 is currently not included in routine perinatal care in Iceland, 63% of the women attended two or more scans during this period. To what extent the widespread use of ultrasound to confirm low-risk pregnancies represents use or overuse of medical resources, remains open for debate.

Strengths and weaknesses of the study

The main strength of this study is the relative size of the original sample, encompassing 23% of all pregnant women in Iceland in 2009. The original sample has been considered relatively representative for pregnant women in Iceland (20, 22). However, women with higher education might be somewhat overrepresented (20). This might lead to overestimation of the average number of ultrasounds among pregnant Icelandic women in general.

Comparison with other studies

To our knowledge, no other studies have documented the percentage of Icelandic women who take ultrasound in their early pregnancy. Based on the National Birth Register from Landspitali University Hospital (23), it can be estimated that 73% of all pregnant women in Iceland underwent combined testing in pregnancy week 11-14 in 2009. This figure is slightly lower than our finding of 78%, a fact which can potentially be explained by a certain overrepresentation of educated women in our material, as mentioned above. More recent figures from the national Birth Register in Iceland indicate that 80% of women currently attend the combined screening test (23).

We have not obtained international data for comparison of Icelandic women‘s use of early ultrasound in pregnancy. Regarding the Nordic setting, a Danish study from 2008 found that the number of women who chose to have a risk estimate increased from 63% in 2005 to 84% in 2006 (24). More recent numbers suggest that over 90% of Danish women undergo the combined test (25)(*)

Norway has no formalized offer of early foetal screening. Experts in foetal medicine however report that a high number of pregnant Norwegian women seek out a private clinic and have an early ultrasound performed there. If the scan is suggestive of anything abnormal, the woman is referred to an authorized department for foetal medicine. This pathway has been described as a „backdoor“ to early foetal screening (**).

*(**No good reference yet, only personal communications from key informants. We can look for adequate references before submission of the paper.)*

Our study indicates that the decision to attend screening was mainly made within the family and not directly initiated by a healthcare professional. Furthermore, the second

most frequent reason given for attending screening, was that women found it „obvious to go". This suggests that prenatal testing has become part of a wider culture of pregnancy. The question of whether the choice should be considered individual and autonomous can evidently be raised, even in the North European setting. Like Williams (11) pointed out, some of the general criticism of prenatal screening is that the women might not perceive that they do have a free choice.

Regarding the received information about screening, many women in our study found that information regarding the potential risks associated with the screening programme was deficient. Similar findings have been reported from Sweden (3).

The main stated reason for declining the combined test in our study, was the women's values and beliefs. Secondly, many said that they did not consider themselves at risk. That "termination is not an option", and that the invasive test could increase their risk for miscarriage, were the reasons found by Ternby et al (26).

Conclusions

Ultrasound scans in pregnancy are in high use in Iceland and have apparently become a profiled part of the pregnancy culture. Whether this is a favourable development or a sign of undue medicalization, can be debated. Information prior to foetal anomaly screening might be improved.

Acknowledgements

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Conflicts of interest

None declared

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(*) We would like to add info about Sweden and Finland, but find confusing information. Details here will be sorted out before submission of the paper. So far we find the following;

Sweden (2013):
https://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/s12884-016-1165-8
In 2013 there were different laws in the different counties of Sweden. In some counties the combined test (KUB) was an offer to everybody, in some counties it was regulated through certain guidelines and in other counties it was prohibited for everybody. In one of the counties where the combined test was offered to everybody, the uptake among pregnant women was 80%. On a national scale, the uptake was about 36,2%.

Sweden (2014):
https://www.nordforsk.org/en/publications/publications_container/legislation-on-biotechnology-in-the-nordic-countries-2013-an-overview-2014
This source from 2014 claims that all Swedish women are offered the combined test. We have to find out whether it has been a change of the law between 2013 and 2014.

Finland (2015):
https://www.ncbi.nlm.nih.gov/pubmed/27859455
NIPT was introduced in Finland in 2015, and reduced the uptake of invasive tests with about 50%. The uptake of first and second trimester screening in Finland is overall more than 90%, in HUS (HUS area approximately 95%.

Legends to figures

Figure 1. Cumulative percentage of the number of ultrasound scans before pregnancy week 19 (phase I, N= 1038). For validation, recalled number of ultrasounds among respondents after delivery (phase II; N = 763).

Figure 2. The women's main reason for choosing to undergo prenatal screening (more than one option possible).

Figure 3. The women`s perception of whether the screening affected their potential concerns about whether something was wrong with the child.

Figure 4. The women´s overall experience with the combined screening test.

Figure 5. Reasons for declining the combined screening test (N = 234; more than one option possible).

Figures

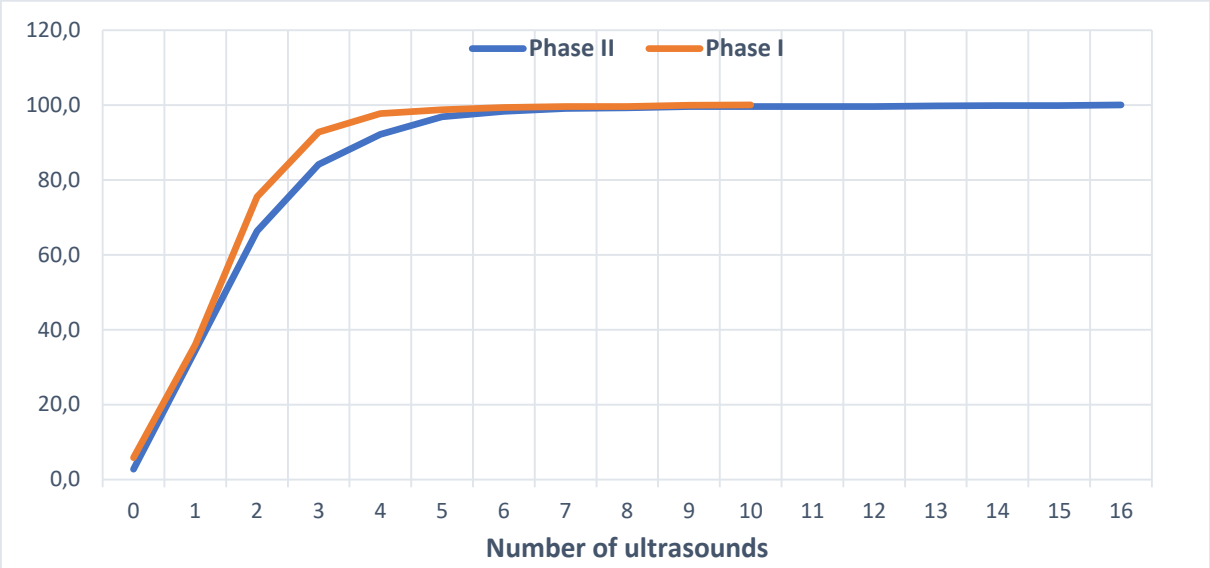

Figure 1. Cumulative percentage of the number of ultrasound scans before pregnancy week 19 (phase I, N= 1038). For validation, recalled number of ultrasounds among respondents after delivery (phase II; N = 763)

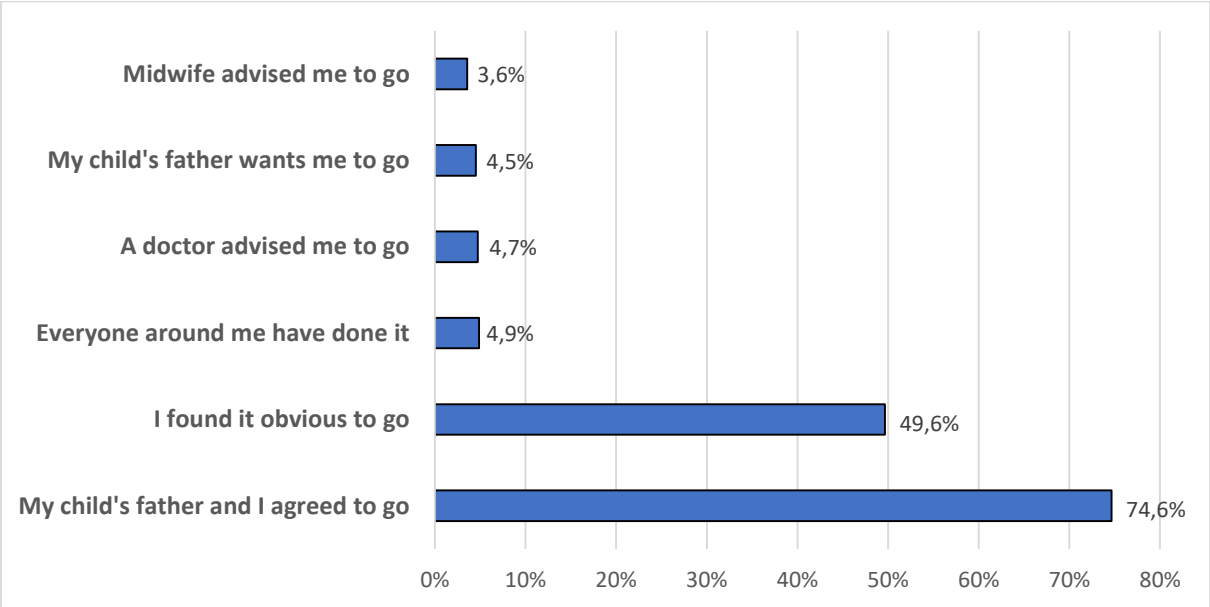

Figure 2. The women's main reason for choosing to undergo prenatal screening (more than one option possible).

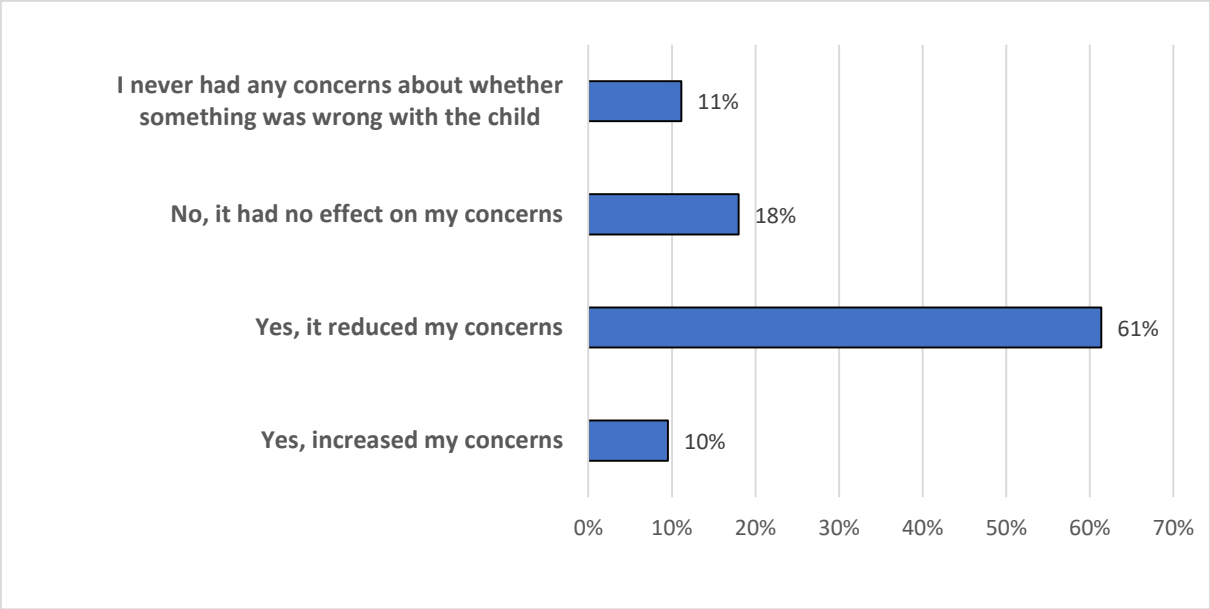

Figure 3. The women`s perception of whether the screening affected their potential concerns about whether something was wrong with the child

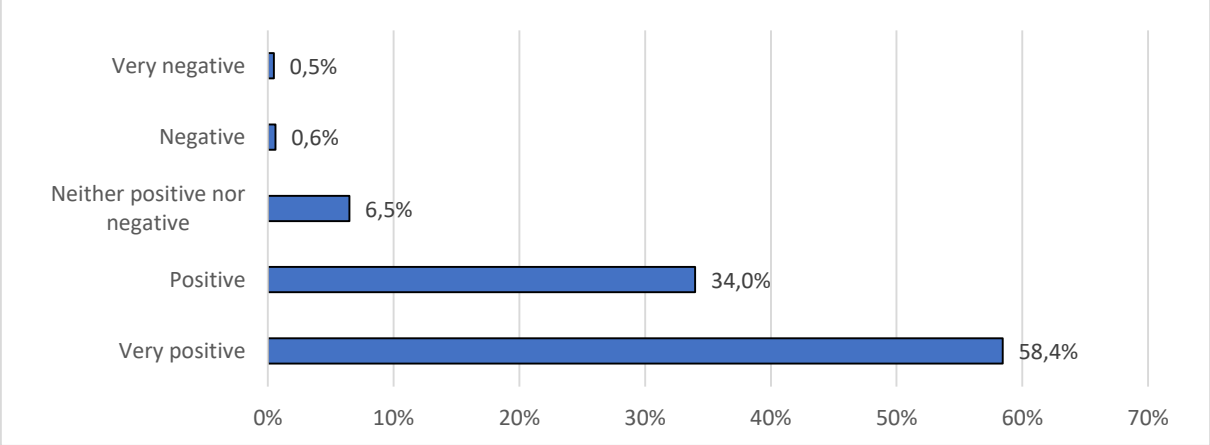

Figure 4. The women´s overall experience with the combined screening test

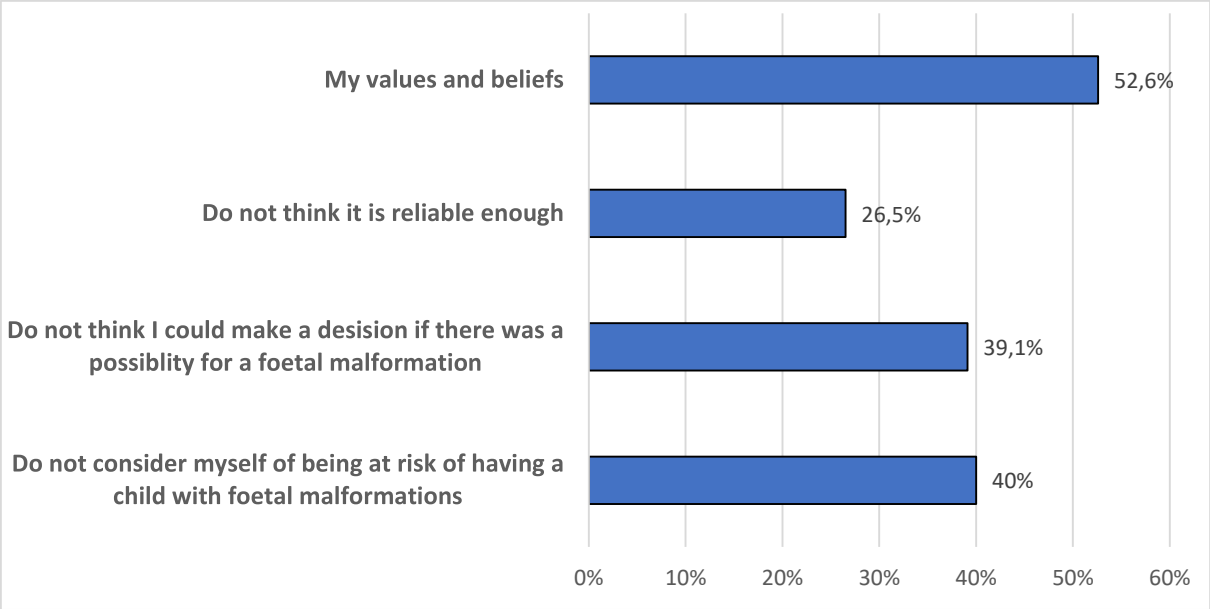

Figure 5. Reasons for declining the combined screening test (N = 234; more than one option possible)

Tables

Table 1. Characteristics of participants, percentages (absolute figures within brackets), odds ratio (OR) and 95% confidence intervals (95%CI) for those who chose combined prenatal screening test for foetal anomalies in the Childbirth and Health Study, Iceland.

		Combined prenatal screening test at week 11-14			
	All (Number	**%**	**OR**	**95%CI**	**P-value of significance**
Total	1111	78.3 (862/1101)			
Parity at study entry					
Primipara	439	82.3 (359/436)	1	Ref.	
Multipara	671	75.6 (503/665)	0.67	0.49-0.90	.009
Education					
Primary (10 years)	123	73.0 (89/122)	0.53	0.34-0.83	.006
Secondary (4 years**)**	291	67.9 (195/287)	0.42	0.30-0.58	.009
Higher (> 14 years)	695	83.5 (577/691)	1	Ref.	
Age (years)					
18-24	186	75.0 (138/184)	0.39	0.23-0.69	.001
25-34	733	76.5 (557/728)	0.43	0.27-0.69	<.001
≥35	192	88.4 (168/190)	1	Ref.	
Region					
Urban	763	86.5 (656/758)	1	Ref.	
Rural	347	60.1 (206/343)	0.23	0.17-0.32	<.001
I have tried to get pregnant for more than a year					
Yes	147	83.0 (122/147)	1	Ref.	
No	959	77.6 (737/950	0.71	0.45-1.12	.140
Assisted pregnancy such as in vitro fertilization or artificial insemination					
Yes	67	85.1 (57/67)	1	Ref.	
No	1039	77.9 (802/1030)	0.62	0.31-1.23	.168

Table 2. Type of health care provider at first visit in pregnancy, and odds (OR) for decision regarding combined prenatal screening test at week 11-14.

	All (Number	Combined prenatal screening test at week 11-14			
		%	OR	95%CI	P-value of significance
Midwife	320	71.3 (228/320)	1	Ref.	
General practitioner	129	72.9 (94/129)	1.08	0.69-1.71	.730
Gynaecologist	609	83.3 (507/609)	2.01	1.45-2.77	<.001
Others	42	76.2 (32/429	1.29	0.61-2.73	. 504

Table 3. Perception of information given and odds (OR) for decision regarding combined prenatal screening test at week 11-14. Percentages, absolute figures within brackets, odds ratios (OR) and 95% confidence intervals (95% CI).

	%	OR	95%CI	p-value
Information about availability of early prenatal ultrasound screening				
Enough or too much	79.2 (718/906)	1	Ref.	
Not enough	75.0 (39/52)	0.79	0.41-1.50	.465
No information	72.0 (85/118)	0.67	0.44-1.04	.075
Information about availability of combined test screening				
Enough or too much	79.6 (747/938)	1	Ref.	
Not enough	66.7 (46/69)	0.51	0.30-0.87	.012
None	73.0 (54/74)	0.69	0.40-1.18	.176
Information on the potential side effect of combined prenatal screening test				
Enough or too much	76.6 (399/521)	1	Ref.	
Not enough	80.7 (117/145)	1.28	0.81-2.02	.296
No information	80.3 (331/412)	1.25	0.91-1.72	.168
Information on the potential risk associated with foetal prenatal diagnosis				
Enough or too much	78.0 (397/509)	1	Ref.	
Not enough	81.7 (125/153)	1.26	0.80-2.00	.326
No information	78.2 (326/417)	1.01	0.74-1.38	.947
Information about ultrasound scan in week 19-20				
Enough or too much	75.7 (617/815)	1	Ref.	
Not enough	85.5 (130/152)	1.90	1.17-3.06	.009
No information	91.2 (103/113)	3.31	1.69-6.45	<.001