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CHAPTER

3

PRENATAL SCREENING IN THE LIGHT OF SELF-DETERMINATION

Abstract: *Information is of great importance for exercising self-determination in prenatal screening. The Dutch Health Council, the Dutch Government and Parliament attach great importance to standardised information and a non-directive attitude of those who supervise the pregnant woman within the scope of the national prenatal screening programme. However, to ensure the self-determination of the pregnant woman it is important that the provision of information about prenatal screening is perceived as a social-dialogic process that goes further than just providing factual information. Furthermore, it is imperative to dispense with the age limit for the reimbursement of the combined test, so that the pregnant women actually have freedom of choice in decisions surrounding prenatal screening for Down syndrome.*

Rachèl van Hellemond, Carla van Os, Aart Hendriks & Martijn Breuning, 'Prenatale screening in het licht van zelfbeschikking', *Tijdschrift voor Gezondheidsrecht* 2012, p. 463-474.

3.1. INTRODUCTION

Prenatal screening can provide the pregnant woman⁹⁹ with information about (the risk of) abnormalities in their unborn child. Based on the results, they can decide if they want to continue the pregnancy or not.

Providing access to such information, and thereby to these diagnostics and screening methods, is not a 'free-standing' obligation. According to the settled case law of the European Court of the Human Rights (henceforth: ECtHR) the State is obliged to inform citizens adequately of serious (health) threats.¹⁰⁰ Parents not infrequently experience having a child with serious anomalies, such as the syndrome of Down (trisomy 21, henceforth: Down syndrome), as a threat, about which they wish to be informed in good time.

In accordance with the case law of the ECtHR, but also of the Dutch Supreme Court,¹⁰¹ the pregnant woman must have timely access to relevant information on which she can decide if she wants to continue with the pregnancy or not.¹⁰² At the same time individuals have the right to be spared information that they do not appreciate. Both rights, to know and not-to-know, are part of self-determination, a notion which underpins all human and patient rights.¹⁰³ Individual self-determination assumes that individuals are able to make free choices. This imposes requirements on the information which they (can) have access to and to the decision-making process.¹⁰⁴

In the decision-making process of the pregnant woman about participating in prenatal screening programmes various dimensions of self-determination play a role; self-determination as the right 'to be left alone', self-determination 'as freedom to choice' and as a 'claim to self-development'.¹⁰⁵ In order to make use of all these dimensions of self-determination, adequate information is of essential importance. Furthermore, the way in which the screening programme is implemented must be critically examined.¹⁰⁶ In this chapter we examine the guarantees for self-determination within the scope of the national programme of prenatal screening for Down syndrome. Down syndrome is a congenital disorder which is associated with intellectual disability as well as medical problems and physical characteristics. The prevalence of this disorder among all

⁹⁹ We mean by the term 'pregnant woman' also the (possible) partner.

¹⁰⁰ More detailed Hendriks 2010, p. 57-68; see also ECtHR 28 February 2012, *Kolyadenko et al./ Russia*, no. 17423/05.

¹⁰¹ Hoge Raad der Nederlanden.

¹⁰² ECtHR 26 May 2011, *R.R./ Poland*, no. 27617/04; HR 18 March 2005, *NJ* 2006, 606; HR 23 November 2003, *NJ* 2002, 386/387.

¹⁰³ Hendriks 2008, p. 2-18.

¹⁰⁴ Stirrat & Gill 2005, p. 127-130; Van Os & Hendriks 2010, p. 180-186.

¹⁰⁵ R.E. van Hellemond, A.C. Hendriks & M.H. Breuning, 'Vrijheid, blijheid? Het reguleren van DNA-diagnostiek in de zorg vanuit mensenrechtelijk perspectief', *Nederlands Tijdschrift voor de Mensenrechten (NTM/NJCM-Bulletin)* 2010, p. 7-24.

¹⁰⁶ Leenen et al. 2007, p. 189-190.

pregnancies with a gestation period of more than twenty weeks in the Netherlands is 15.7 per 10,000 births. Furthermore, it should be noted that 42% of the children with Down syndrome are detected prenatally and in three-quarters of these cases it is decided to terminate the pregnancy.

In our research for the safeguarding of self-determination, we examine not just the case law of the ECtHR and the relevant national legislation, but also the (legal) conditions and basic assumptions which according to the Dutch Health Council, the Government and Parliament apply to the provision of information to pregnant woman regarding prenatal screening for Down syndrome. Particular attention is given to the age limit applied, that means the minimum age of the pregnant woman for having the prenatal screening costs reimbursement by a Health Insurance Company.

The structure of this chapter is as follows. After a short description of prenatal screening and the relevant legal framework, we examine, in section 3.3. The right of the pregnant woman to self-determination from a constitutional perspective. In section 3.4. we analyse the significance that the Dutch Health Council and the Government attach to self-determination within the scope of prenatal screening for Down syndrome. In section 3.5. we analyse the justification for erecting a financial threshold on the basis of age regarding the national prenatal screening programme. In section 3.6. we discuss the implementation of the current national prenatal screening programme in relation to self-determination and we offer a few recommendations for improvement. We end this chapter in section 3.7. with conclusions.

In this contribution we do not pay attention to the application of (new) technique(s) in which (cell-free) fetal DNA in the maternal blood can be examined for Down syndrome. The (future) use of non-invasive prenatal screening and diagnostics in which fetal DNA is examined for Down syndrome or other diseases and disorders, raises different legal issues than prenatal screening and diagnostics by means of the combined test, amniocentesis and the chorionic villus testing.¹⁰⁷

3.2. THE FRAMEWORK OF THE DUTCH PRENATAL SCREENING PROGRAMME

3.2.1. Prenatal screening

The possibilities for the pregnant woman to seek advice about possible handicaps and diseases in the child before the delivery have increased considerably. The most well-known and used tests are prenatal screening for Down syndrome and the prenatal screening for physical defects (the anomaly scan). Both are part of the national programme for prenatal screening. Midwives, gynaecologists and general practitioners

¹⁰⁷ Herderschee 2011; Van Osselen 2011; Verweij et al. 2012; De Jong et al. 2011, p. 657-663.

draw the attention of all pregnant women in respectively the first and second trimester of the pregnancy to the possibility of these forms of screening. Prenatal screening in the Netherlands is seen as providing good care as part of the general provision of information to the pregnant woman.¹⁰⁸ The aim of these screenings is to inform the pregnant woman concerning possible anomalies in the unborn child, also with a view to making a decision about continuing or terminating the pregnancy.

The combined risk assessment test is used for prenatal screening for Down syndrome in week 9-14 of the pregnancy. It is possibly preceded by a family history and an ultrasound (in week 9-12). This non-invasive test consists of a blood test of the pregnant woman and measurement of the skin fold in the foetus neck. This is conducted with an ultrasound scan. The risk of having a child with Down syndrome can be calculated with the results of these tests, in combination with the age of the pregnant woman and the length of the pregnancy.¹⁰⁹ The percentage of the pregnant women that take part in this form of screening is 25-30%.

In prenatal screening for physical anomalies in the form of a structural ultrasound scan (US), better known as the 20-week scan,¹¹⁰ the structure and development of the organs¹¹¹ of the foetus is checked, plus the size of the unborn child and whether there is sufficient amniotic fluid. The participation percentage in this examination is approximately 80%.

The structural US is included in the basic health insurance package of the Health Insurance Act (Article 10)¹¹² and is reimbursed to all pregnant women. However, to participate in prenatal screening for Down syndrome there is a financial threshold. Women younger than 36 years do not get this screening reimbursed via their health insurance, as opposed to the pregnant woman of 36 years and older, (Article 2.4 (1a) Decree Health Care).¹¹³ This is different when from the (family)history of the pregnant woman, younger than 36 years, it emerges that there is an increased risk of having a child with a (genetic) disorder. In such situations the combined test is reimbursed due to the existence of a medical indication.

3.2.2. Prenatal diagnostics

Prenatal screening is sometimes confused with prenatal diagnostics. Prenatal diagnostics, unlike prenatal screening, takes place as a result of specific indications of

¹⁰⁸ Kamerstukken II 2003/04, 29 323, no. 1; Kamerstukken II 2003/04, 29 323, no. 3; Centraal Orgaan and RIVM 2011, p. 23.

¹⁰⁹ The combined test also gives information regarding the risk of having a child with the Patau'syndroom (trisomy 13) or Edward's syndrome (trisomy 18). If the pregnant woman will remain of this information she has to state this prior to the screening.

¹¹⁰ An ultrasound scan sends high-frequency sound waves that are reflected by tissues and organs. The reflected sound waves are made visible on a screen.

¹¹¹ The foetus is examined for various physical defects, among other things, the heart, the skull, lungs, kidneys and bones, and also characteristics of Down syndrome.

¹¹² *Stb.* 2005,358 (Zorgverzekeringswet).

¹¹³ *Stb.* 2005, 389 (Besluit zorgverzekering).

an increased risk of the (possible) presence of a (genetic) disorder.¹¹⁴ If it is determined there is an increased risk of Down syndrome, prenatal diagnostics is often offered in the form of a chorionic villus testing or amniocentesis. For these invasive tests a puncture is necessary. This puncture, as opposed to the combined test and the structural US, can interfere with the pregnancy, and can lead to a miscarriage.¹¹⁵

The human rights relevance of the difference between screening and diagnostics lies in the fact that the screening is offered to all individuals of the section of the population group concerned (in this case pregnant women) without having a medical indication for it. This makes specific demands on the safe-guarding of self-determination in whether or not to participate in the screening.

3.2.3. Legal framework

The Dutch Act on population screening (WBO) lays down quality criteria for the offer and practicing of (prenatal) screening. The permit system of the WBO applies to offer and performing prenatal screening for Down syndrome, because it is a population screening for the risk of a disorder for which no treatment or prevention is available.¹¹⁶

According to the WBO the Minister of Health, Welfare and Sports grants a licence when the population screening is scientifically sound, the screening is in accordance with the professional medical practice standard and the expected benefits offset the risks.¹¹⁷ Moreover, the decision regarding granting a licences is open to objection and appeal (Article 7:1 General Administrative Law Act),¹¹⁸ in which when failing to give a timely decision and after a declaration in breach the applicant could claim a penalty payment (Article 4:17 et seq Awb).

The aim of the WBO can be deduced from the balance between benefit and risk and the definition of population screening: promoting public health and gaining health benefits.¹¹⁹ In the case of prenatal screening the question can be asked what needs to be protected, the health of the pregnant woman, the unborn child or both the pregnant women and the foetus.¹²⁰ The fact is that with the WBO the screening of unborn life has acquired a place in a law which is meant to protect the health of those who have been born already.¹²¹

Before granting a licence the Minister is advised by the Dutch Health Council.¹²² The Dutch Health Council has advised the Minister a number of times regarding the

¹¹⁴ > 0.5 by the combined test.

¹¹⁵ 0,3 tot 0,5% of the pregnancy ended in a miscarriage after an invasive tests. Downsyndroom. Prenatale Screening (version 2011), RIVM March 2011; www.rivm.nl/pns/Images/Down%20folder%20NED%20%28mrt%202011%29_tcm95-57264.pdf

¹¹⁶ Art. 2(1) WBO.

¹¹⁷ Art. 7(1) WBO.

¹¹⁸ *Stb.* 1992, 315 (Algemene wet bestuursrecht).

¹¹⁹ Art. 1(c); Art. 7(1c) WBO; Aartsen 1996, p. 71-84.

¹²⁰ Van Os & Hendriks 2010.

¹²¹ Olsthoorn-Heim 1996, p. 57.

¹²² Art. 6 WBO.

national programme for prenatal screening.¹²³ We examine this in more detail in the next section.

To summarize, under the WBO a licence is required for offering and performing prenatal screening. A risk indicated test – combined test - for Down syndrome is offered to all pregnant women within the framework of the national prenatal screening programme. This takes place in week 9-14 of the pregnancy. The pregnant woman of 36 years and older and the pregnant woman with a medical indication have the choice between the combined test or to immediately undergo prenatal diagnostics – chorionic villus testing or amniocentesis.¹²⁴ The combined test, unlike the structural ultrasound scan (US), in principle is not reimbursed by the health insurance to the pregnant woman younger than 36 years (Article 2.4 (1a) Decree Health Insurance).

3.3. CONSTITUTIONAL FRAMEWORK

According to the ECtHR Self-determination – commonly referred as ‘personal autonomy’ – is an important aspect of the private life of individuals.¹²⁵ Self-determination, or individual autonomy, is ‘*an essential corollary of the individual’s freedom of choice*’,¹²⁶ a view which denotes self-determination as ‘freedom of choice’. In this respect, self-determination also includes the right to respect decisions about whether or not to become pregnant¹²⁷ and the right to choose the circumstances to have children.¹²⁸

The notion of self-determination ‘as a right to be left alone’, in other words the right to organise one’s own life without intervention by others,¹²⁹ also means the freedom of pregnant women to decide for themselves about participating in prenatal screening. The self-determination of the pregnant woman thereby also encompasses ‘the right to freedom of choice’ and a ‘claim right’, namely the desire for information and help for ‘self-development’ about whether or not to continue the pregnancy. These freedoms presume, according to the ECtHR in the *R.R.* case, that if required, the pregnant woman is to be given access to comprehensive, reliable and timely information, including information about the health of the foetus.¹³⁰ This ‘freedom of choice’, as a separate dimension of self-determination in addition to ‘the right to be left alone’ and ‘right

¹²³ GR 2007a; GR 2006a; GR 2004; GR 2001b.

¹²⁴ KNOV, Standpunt prenatale diagnostiek, Bilthoven: KNOV 2005.

¹²⁵ ECtHR 29 April 2002, *Pretty/ the UK*, no. 2346/02; ECtHR 11 July 2002, *Christine Goodwin/ the UK* (GC), no. 28957/95.

¹²⁶ ECtHR 29 April 2002, *Pretty/ the UK*, no. 2346/02, para. 61; ECtHR 28 November 1984, *Rasmussen/ Denmark*, no. 8777/79, para. 54.

¹²⁷ ECtHR 10 April 2007, *Evans/ the UK* (GC), no. 6339/05, para. 71.

¹²⁸ ECtHR 14 December 2010, *Ternovszky/ Hungary*, no. 67545/09, para. 22.

¹²⁹ There are various designations of this dimension of self-determination, see for example Dupuis 2004, p. 56-58; Beers 2009, p. 29.

¹³⁰ ECtHR 26 May 2011, no. 27617/04, *R.R./ Poland*, para. 197-199.

to self-development', provide specific responsibilities for the doctor regarding the counselling of the patient in making choices which fit in with him or her.¹³¹ However, it cannot be concluded from above that the right to personal autonomy is absolute.¹³² In the case *Ternovzky* the ECtHR considered that '*the mother is entitled to a legal and institutional environment that enables her choice, except where other rights render necessary the restriction thereof.*'¹³³ In other words, the being able to exercise self-determination by pregnant women, in particular for their self-development, should be legally and socially guaranteed, but can be restricted as far as this is necessary for safeguarding other rights and interests.

At a national level this view of self-determination underpins Article 11 Dutch Constitution.¹³⁴ It is also elaborated in the Medical Treatment Contract Act.¹³⁵ In this view the possibility of rejecting an offer of treatment and/or care is an expression of self-determination. The Dutch Supreme Court ruled that not fulfilling the information obligation by a healthcare worker to the pregnant woman entails the risk that the patient cannot make use of her self-determination in the way she wishes, 'and consequently entails the risk that the patient makes a choice which (s)he would not have made if (s)he was well-informed.'¹³⁶

3.4. GUARANTEEING SELF-DETERMINATION AND PRENATAL SCREENING

3.4.1. The Dutch health council and informed consent

Consent

In the opinion of the Dutch Health Council, the offer of prenatal screening for Down syndrome should be presented in such a way that the pregnant woman could make a decision based on 'informed consent' in order to realise self-determination. In its advisory reports the Dutch Health Council emphasizes that due to the unsolicited offer – 'uninvited force into someone's life' – the offer of prenatal screening for Down syndrome requires strict quality norms for the provision of information and the consent procedure.¹³⁷ The offer of prenatal screening for Down syndrome demands explicit consent for receiving objective information. The consent requirement does not just look at the performing of the screening, but also at the information given about the prenatal screening – a combination of the right to information (Article 7:448 BW) and the right of not-to-know (Article 7:449 BW).

¹³¹ MacLean 2006, p. 321-338.

¹³² ECtHR 16 December 2010, A.,B. & C./ Ireland., no 25579/05.

¹³³ ECtHR 14 December 2010, *Ternovszky/ Hungary*, no. 67545/09, para. 24.

¹³⁴ Kamerstukken II 1978/79, 15 463, no. 1-2, p. 5.

¹³⁵ Art. 7:448; 7:450 BW.

¹³⁶ HR 23 November 2001, *NJ* 2002, 386/387, para. 5.3; HR 18 March 2005, *NJ* 2006, 606.

¹³⁷ GR 2004, p. 138.

Phased information

The Dutch Health Council stipulates that making a well-considered choice about prenatal screening for Down syndrome requires time for consideration. Accordingly, and to prevent an information overload, the Dutch Health Council pleads, just like Government and Parliament, for a phased, uniform and standardised approach¹³⁸ of ‘informed consent’ concerning the decision-making process around prenatal screening.¹³⁹ This process consists of three phases, namely a) the phase in which the pregnant woman is asked if she wants to receive information about prenatal screening; b) the phase in which providing information has the aim to give the pregnant woman a choice between whether or not to make use of prenatal screening for Down syndrome; c) the phase after establishing a higher risk of Down syndrome; the information from the health care worker will then concern possible follow-up diagnostic tests.¹⁴⁰ During this decision-making process the health care worker should continually check if the pregnant woman is sufficiently informed to prevent her from making a choice which is not in accordance with her norms and values.¹⁴¹ This notes self-determination as a form of freedom of choice, which calls for counselling and protecting.

Guideline

In 2008 the then Minister Klink (CDA) of Health, Welfare and Sports informed Parliament about a guideline of quality requirements for the counselling of pregnant women. This guideline was established as a result of the call from the Parliament to inform expectant parents about prenatal screening in a standardised and non-directive way. The National Institute for Public Health and the Environment (RIVM) published a brochure and developed a choice-indicator (www.ikkiesbeter.nl) for pregnant women which should help them to choose whether or not to take part in the prenatal screening programme. According to the Minister, the most important objective of the prenatal screening – the informed choice of expectant parents – is guaranteed by these measures.¹⁴²

3.4.2. Analysis

In prenatal screening for Down syndrome, the Dutch Health Council, as well as the Government and Parliament, emphasize the realisation of an informed choice. To safeguard the self-determination of the pregnant woman in the decision-making process surrounding prenatal screening he argues for a phased and standardised ‘informed consent’-approach. The Dutch Health Council argued for standardised and non-directive attitude of those who inform the pregnant woman about prenatal screening and throughout the counselling.

¹³⁸ GR 2006a, p. 12-13.

¹³⁹ GR 2001b, p. 27.

¹⁴⁰ GR 2006a, p. 11-13; GR 2001b, p. 29.

¹⁴¹ GR 2004, p. 59.

¹⁴² Kamerstukken II 2007/08, 29 323 and 22 894, no. 49.

This approach offers good opportunities to establish quality requirements in the decision-making process and so promote the self-determination of the pregnant woman. A possible disadvantage of standardisation is that the health care worker does not feel free to tune the information to the individual and does not check enough if the way of informing also fits in with the person who has to process the information. Not everyone will find that (the same) factual, objective information sufficient to be able to make a choice. Standardisation that is too strict can therefore clash with the legal requirement that the health care worker should be guided by that which the patient in that specific case in all reasonableness should know (Article 7:448 (1) BW) and with the requirements of good health care worker practices (Article 7:453 BW). Consequently an important responsibility rests with the health care worker to check if the information is understood by the person concerned and if this information forms a good basis for making an informed decision. Important indications for the necessity for differentiation can also be found in a recent study by Erasmus University Rotterdam. Factors such as the level of education, cultural background and religion distinguish determine the extent to which women with 'informed consent' take part in prenatal screening.¹⁴³

3.5. SELF-DETERMINATION AND AGE LIMITS

3.5.1. Justification age limit

In 2003 the then Secretary of State for Health, Welfare and Sports Ross-van Dorp (CDA) argued for restraint regarding the offer of prenatal screening, on the one hand to prevent medicalization and on the other hand 'not proceed further down the road of a misleading idealised image, namely human enhancement'.¹⁴⁴ She therefore made a distinction between the offer of prenatal screening for Down syndrome reimbursed by the insurance company and providing information about the combined test to all the pregnant women. Pregnant women, younger than 36, would have to pay for the prenatal screening themselves.¹⁴⁵ Ross-van Dorp underpinned this distinction between information and offer with a reference to the research report '*Opgelucht maar ook aangedaan*'.¹⁴⁶ This, while the researchers raised the question if it is realistic to expect that good information about the possibility of prenatal screening for Down syndrome can compensate the infringement of autonomy. The financial threshold on the basis of age is a restriction of the access to prenatal screening which affects the self-determination of pregnant women.

¹⁴³ Van Agt et al. 2012, p. 4.

¹⁴⁴ Kamerstukken II 2003/04, 29 323, no. 1, p. 8.

¹⁴⁵ Kamerstukken II 2003/04, 29 323, no. 3, p. 2.

¹⁴⁶ Geelen et al. 2004.

3.5.2. Age limit dispute

The age limit regarding the offer and the reimbursement of the combined test is medically and socially controversial. Although the risk of having a child with Down syndrome increases in with years of age, the Dutch Health Council advised, already in 2001, not to apply an age limit to prenatal screening.¹⁴⁷ The combined test without an age limit gives the most favourable combination of false positive/false negative test results and detection-miscarriage ratio. Furthermore, most of the pregnant women are younger than 36 years, the combined test during the first trimester of the pregnancy will thus reduce the number of pregnant women that have to undergo an invasive test at a later stage of the pregnancy, for example as a result of the structural US.

3.5.3. Quiet introduction ultrasound at 20 weeks

The final cabinet standpoint that pregnant women must be informed about the possibility of prenatal screening for Down syndrome, but that for the reimbursement of this screening an age limit will apply, was announced to the Parliament in a letter dated 15 September 2005.¹⁴⁸ A month later a letter followed in which it was announced that the structural US for all pregnant women would be reimbursed.¹⁴⁹

While there were many and frequent discussions about the introduction of a national screening programme for Down syndrome, and the age limit associated with reimbursing, the reimbursement of the structural US for all pregnant women was quietly accepted. That is remarkable, given the fact that the decision-making process surrounding the structural US is complex due to the nature of the test. The decision-making process of prenatal screening for Down syndrome is compared to the structural US more transparent because yet one anomaly is screened.¹⁵⁰ Moreover, in the structural US the pregnant woman is put under greater pressure of time because in accordance with the Termination of Pregnancy Act it is no longer permitted to terminate the pregnancy later than a few weeks after the structural US.

3.5.4. Analysis

Yet, in contrast to the structural US, an age limit applies to the reimbursement of prenatal screening for Down syndrome. A clear and unequivocal justification for the age limit is absent. The question must be asked whether an age limit for prenatal screening conflicts with the constitutional notion of self-determination in relation with

¹⁴⁷ GR 2001b, p. 13-15.

¹⁴⁸ Kamerstukken II 2004/05, 29 323, no. 15.

¹⁴⁹ Kamerstukken II 2005/06, 29 323, no. 17.

¹⁵⁰ The combined test also gives information regarding the risk of having a child with the Patau syndrome (trisomy 13) or Edward's syndrome (trisomy 18). If the pregnant woman will remain of this information she has to state this prior to the screening. See about the complexity of the decision making process ; Dondorp et al. 2010; vorige.nrc.nl/opinie/article2484612.ece/Echo_zorgt_voor_onverwachte_dilemma_s; De Kort 2008, p. 36-37; Oepkes 2008, p. 38-40.

the principle of non-discrimination due to the financial threshold for access to 'health information'. If women younger than 36 years (have to) waive the prenatal screening with the combined test for financial reasons, also because they can be informed 'free' about it in the twentieth week of the pregnancy, it restricts their self-determination without good justification and in a seemingly discriminatory way.

3.6. IS IT ENOUGH?

3.6.1. Self-determination and standardised information

As we saw in the previous sections the information given to pregnant women about prenatal screening is standardised. Furthermore, Government, Parliament and professional associations set great store by the principle of non-directivity. Standardised information guarantees minimum quality requirements of the information for prenatal screening and is in accordance with the procedural norm of Article 8 ECHR. Nevertheless, a quarter of the women that participate in prenatal screening appear not to do this on the basis of an informed choice.¹⁵¹ In practice it was found that pregnant women do not only need to have information so that they can make an informed decision about rejecting (information about) prenatal screening for Down syndrome (self-determination as 'right to be left alone'). The pregnant women say that they also want to receive information that is related to the implications of prenatal screening, namely the consequences of the test results and the choices arising from that about the continuation or termination of the pregnancy (self-determinations as freedom 'to choice' and as 'self-development').¹⁵² Illustrative are the experiences of parents of a child who has Down syndrome that took part in prenatal screening. In a survey only 32% of these parents stated that they remembered having received information regarding Down syndrome. Moreover, a quarter of this group found that the information was insufficient. The parents mostly had the feeling of being alone in the decisions about screening and about whether or not to continue the pregnancy.¹⁵³ We emphatically note, however, that these figures are based on the experiences and memories of the parents.

Moreover (expectant) parents stated that they would also like to know more about the experiences of living with a child with Down syndrome, the psychosocial aspects of it.¹⁵⁴ In addition to factual information the pregnant women also want support in taking decisions regarding the period after the combined test based on the interpretation of the test results. Furthermore, they expect the experts to state their opinion about

¹⁵¹ Van Agt et al. 2012, p. 3.

¹⁵² Geelen 2004.

¹⁵³ De Graaf et al. 2010, p. 37-48.

¹⁵⁴ De Graaf et al. 2010, p. 37-48.

the seriousness of the situation, and the health care worker to advise the pregnant woman from his professional experience with regard to further diagnostics and the continuation or termination of the pregnancy.¹⁵⁵

From the above it can be concluded that a standardised 'informed consent' approach as transfer of knowledge and information does not give an absolute guarantee of the pregnant woman being able to exercise self-determination and the freedom to choose with regard to prenatal screening. Should not be given more attention to individualised information tailored to the pregnant woman (Article 7:448 (1) BW)? After all, not every pregnant woman needs the same assistance to make the choices concerning prenatal screening. Furthermore, the need for information of those involved is strongly influenced by factors as knowledge and education, previous pregnancies, the circumstances in which the family lives, the presence of other children and the phase in the decision-making process of the screening. It seems advisable that the health care worker, who cares for the pregnant woman in the first trimester of the pregnancy, first and foremost finds out if the information regarding prenatal screening is understood by the pregnant woman, in order that this information actually helps her to make choices.¹⁵⁶ Furthermore, the health care worker could be guided by the question which information, tailored to her individual needs, the pregnant woman needs in order to be able to make a decision and the purpose of the information. This implies a concept of professional responsibility from midwives, gynaecologists and general practitioners that goes beyond non-directivity. The safeguarding of self-determination via giving information and offering support is more than the provision of information about facts.¹⁵⁷ There must be the opportunity to exchange feelings, ideas, doubts and dilemmas between the pregnant woman and those who supervise the pregnancy as professionals. Communication perceived as a social-dialogical process guarantees the material norm of self-determination better than a standardised and non-directive form of provision of information.¹⁵⁸

3.6.2. Self-determination and the age limit

In view of self-determination it is important for the pregnant woman to receive information about the health of her unborn child as early as possible in the pregnancy. The sooner the risk of a (genetic) abnormality is detected the more time the pregnant woman is given for making choices after screening. It can be assumed that the barrier to participate in prenatal screening is higher if the pregnant woman has to pay for it, also because not reimbursing screening from the basic health insurance package of the Health Insurance Act seems to suggest that it is not necessary.¹⁵⁹

¹⁵⁵ Slagboom 2011, p. 21-22.

¹⁵⁶ Coggon & Miola 2011, p. 523-547.

¹⁵⁷ Van der Stouwe 2008, p. 43.

¹⁵⁸ Geelen 2004, p. 52; Van der Stouwe 2008, p. 43.

¹⁵⁹ Zeeman 2008, p. 40.

If strict requirements apply to the information about screening due to the unsolicited offer, and having time for reflection is an important condition for being able to take a well-considered choice, then it seems that not reimbursing screening for Down syndrome to pregnant women younger than 36 years is an unnecessary restriction of self-determination, in terms of ‘freedom to choice and self-development’.

The procedural norm concerning self-determination of the pregnant woman as a ‘right to be left alone’ is adequately safeguarded with the current screenings policy. In contrast, the material norm does not appear to be sufficiently safeguarded. Prenatal screening for Down syndrome and the structural US are part of the provision of information and good care for pregnant women. Not reimbursing prenatal screening for Down syndrome to pregnant women aged less than 36 years seems to be inconsistent policy, which is at odds with Article 8 ECHR. In our view the pregnant women under 36 years have just as much right as pregnant women of 36 years and older to adequate and sound information given in good time about the risk that their foetus is affected with syndrome of Down. The decision of the Minister of Health, Welfare and Sports regarding reimbursement of the structural US shows that this can be arranged with a single letter to the Parliament. From a health and human rights standpoint this benefits the self-determination of all pregnant women in the dimension of ‘freedom to choice and freedom of development’.

3.7. CONCLUSION

Pregnant women have the right to self-determination and thereby have the right to make their own choice regarding their pregnancy and to undergo prenatal screening. Information is of great importance for exercising self-determination in prenatal screening. This information, according to the ECtHR, must be complete, reliable and timely accessible. In the advisory reports of the Dutch Health Council regarding prenatal screening for Down syndrome, self-determination in the dimension of providing possibilities for making informed choices predominates. Besides factual information it seems that in practice pregnant women especially have needs for professional counselling by health care workers in applying the information to their own situation. In respect of self-determination the professional groups and implementing agencies should reformulate the principle of non-directivity regarding the provision of information about prenatal screening. It should be formulated in such a way that it (better) expresses that informing pregnant women about prenatal screening is a social-dialogical process that goes beyond just giving factual information. Furthermore, it is important that the Minister of Health, Welfare and Sports reconsiders the age limit for the reimbursement of prenatal screening for Down syndrome from the primary health care package, so that not just the procedural norm of Article 8 ECHR is guaranteed –

the access to prenatal screening and receiving information about it – but that also the material norm for all pregnant women is guaranteed: actually having and experiencing freedom of choice.