

# Novel quality assessment method for the health educational component of counselling about prenatal screening

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## ABSTRACT

*Objective:* Informed decision-making on participation in prenatal screening (PS) for Down's, Edwards' and Patau's syndrome and structural anomalies is the cornerstone of the prenatal screening program in the Netherlands. Since the introduction of the Non Invasive Prenatal Test (NIPT) in the Netherlands counseling on PS became more complex. The importance of adequate counseling and the absence of a quality assessment method for the counseling urged to develop a new assessment method that could assess the quality of the 'health educational' part of the counseling for prenatal screening.

*Methods:* the reliability of this assessment method was studied in two hospitals and one ultrasound centre. On the basis of 56 transcribed audio-recordings of counseling sessions concerning the combined test and/or the second trimester Fetal Anomaly Scan an item scoring was conducted on each record by three different assessors by using two developed assessment tools for CT and FAS counseling.

*Results:* the intraclass correlation coefficients of the three assessments of the counseling about PS showed to be significantly above 0.80 ( $p < 0.001$ ), which indicates excellent agreement between the assessments.

*Conclusion and practice implications:* This method proved to be a reproducible and feasible assessment method and is useful in a broader health care perspective.

## INTRODUCTION

The Dutch Ministry of Health, Welfare and Sports (VWS) granted eight regional centers (RC's) a permit for coordination and quality assessment of prenatal screening with regard to the Population Screening Act in 2007.<sup>1</sup> The screening program consists of counseling for screening for Down's, Edwards' and Patau's syndrome and screening for structural fetal anomalies and the actual execution of the prenatal screening tests, being the first trimester combined test (CT), Non Invasive Prenatal Test (NIPT) (since April 2017) and the second trimester fetal anomaly scan (FAS). Every obstetric caregiver that wishes to perform one of the previously mentioned tasks has to be certified to do so<sup>2-5</sup> and must have a quality contract with a RC. The RC's are responsible for the regional coordination and quality of prenatal screening in their targeted region in the Netherlands. There are nationwide uniform quality requirements for prenatal screening on the content of the counseling, basic qualifications of the counselor on knowledge, skills and conditions for offering counseling.<sup>2-6</sup>

The concept of counseling in the national prenatal screening program implies that all women will be informed, both written and verbally, in the first trimester of their pregnancy on the option for prenatal screening and the implications and the possible advantages and disadvantages of prenatal screening.<sup>1,2</sup> The purpose of this counseling is to enable the pregnant woman to freely make an informed decision on whether or not to participate in prenatal screening.<sup>1-3</sup> The counseling for prenatal screening occurs in midwifery practices, sonographic centers and hospitals.

By national evaluations and scientific research it was evident that there are specific points of attention regarding counseling, such as (1) the relatively frequent insufficient counseling of multiparous pregnant women, (2) the fact that non-western and low-educated pregnant women more often make an uninformed decision and (3) that from the perspective of the pregnant woman during counseling more attention should be paid to the screening procedures and the social and risk aspects of the screening which contribute to an informed decision.<sup>7-10</sup>

Since April 1st 2017 the NIPT is available in the Netherlands in a study setting (TRIDENT 2). The NIPT, besides the combined test, is available as an optional first trimester screening test primarily for Down's, Edwards' and Patau's syndrome. Due to the availability of the NIPT in the Netherlands the procedure of provision of prenatal screening becomes complicated and requires for a higher standard of counseling and therefore more knowledge and skills on prenatal screening.

### Quality assessment counseling

The quality of counseling is assessed by the RC's through written audits in which questions regarding organization of the counseling and the level of training of the counselor

were included. Besides this, counselors were also assessed on the number of counseling sessions per year. Moreover, informed decision making of pregnant women about participation in prenatal screening was evaluated on a national level.<sup>9, 11</sup> International research shows several methods to measure the quality of counseling: (1) evaluating client satisfaction focuses on the experience and opinions of the client with use of the Client Satisfaction Questionnaire and Service Satisfaction Scale<sup>12</sup>, (2) evaluating informed decision making after counseling through questionnaires, but occasionally also through audio recordings<sup>11, 13, 14</sup> and (3) evaluating the standards of care by assessing if the counseling session is up to the latest standard.<sup>12</sup> The before mentioned proceedings give outcomes on quantity of the counseling, the quality of the organization of the counseling and informed decision making of pregnant women rather than the quality of the content of the counseling.

The absence of an assessment tool on the content and the increased interest for the quality of the counseling was the motivation to develop a novel method to assess the quality of the 'health education' component of the counseling. The developed method was based on the assessment of the content of audio-recordings of counseling sessions. With our study we will answer the question whether a 'New assessment method counseling for prenatal screening' offers the possibility of providing a reproducible and reliable assessment of the information provision of a counseling session. With regard to the aim of this study, this article will not comment on the quality assessments of the content of the conducted counseling sessions.

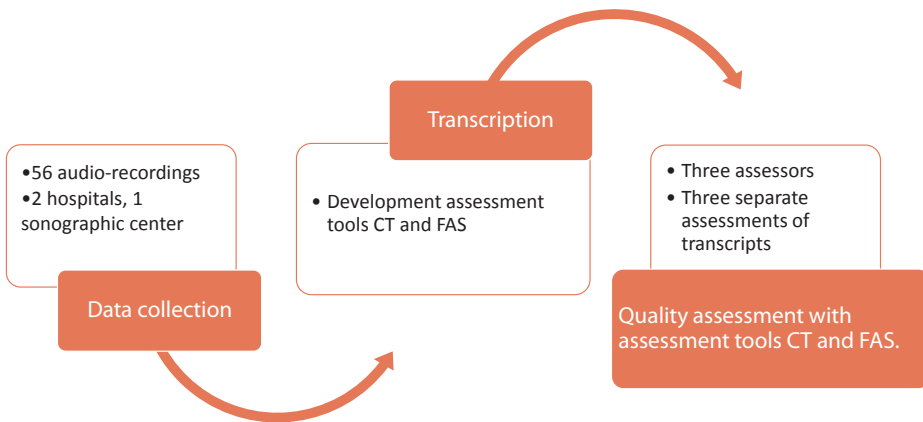
## METHOD

The study regarding the assessment method was conducted in the screening region of Southwest of the Netherlands. Ten counselors working in two hospitals and one ultrasound center were prepared to take part in the study.

Use of audio-recordings was preferred above video-recordings for several reasons: (1) making audio-recordings diminishes privacy related issues of the counselor and the pregnant woman, (2) an audio-recording of the counseling session is an adequate source for enabling assessment of the health education component of the counseling and (3) the counselor is able to make the recording herself. The method in this study consisted of the following phases (see also figure 6.1):

- A) Inclusion pregnant women: in the period February to April 2016 the to be counselled pregnant women within the participating organizations were notified with regard to the study through an information letter, through which from both the pregnant woman and the counselor written informed consent was obtained.

- B) Recording counseling session: using a voice-recorder the counselor recorded the counseling session.
- C) Registration counseling and pregnancy details: several anonymous details were registered [date counseling, gravidity, age and Dutch language proficiency of the pregnant woman [good, average, none]].
- D) Transcribing audio-recordings: the recordings were transcribed and the timeframe was registered.
- E) Assessment audio-recordings: the transcripts were assessed with use of the assessment frameworks for the CT and the FAS counseling. For each counseling session the outcomes of the assessment per item, sub-item and the total overall score were registered in the study dataset as well as the timeframe of the assessment.



**Figure 6.1** Study design: Novel quality assessment method for counseling about prenatal screening.

CT: Combined Test

FAS: Fetal Anomaly Scan

### Assessment framework

The assessment framework consisted of two assessment tools for a qualitative measurement of the quality of the content of the counseling for the CT and the FAS. See supplements 6.1 and 6.2 for the assessment tools CT and FAS. The assessment tool for the counseling of the CT was based on the nationally implemented checklist of what an adequate counseling session for screening on Down's, Edwards's and Patau's syndrome should consist of.<sup>5</sup> For the development of the assessment tool for the FAS, a checklist of what an adequate counseling session for the FAS should consist of developed by the SPSZN was used, as such a checklist was lacking on a national level. The checklists consisted of items which indicated the minimum information to be given during a

**Table 6.1** Baseline characteristics

		N	(%)
<b>Organisation</b>			
Counselling sessions		56	(100)
Counsellors		10	(100)
Location counselling session	Ultrasound center	20	(36)
	Hospital	36	(64)
Profession counsellor	Midwife	6	(11)
	Nurse	30	(54)
	Sonographer	20	(35)
Time frame counselling session	Median 9,22		
	0-5 minutes	12	(21)
	>5-12 minutes	21	(38)
	12-23 minutes	23	(41)
Type counselling	FAS	9	(16)
	Combined test	1	(2)
	Both	46	(82)
<b>Pregnant women</b>			
Gravidity	Primigravida	19	(34)
	Multigravida	37	(66)
Age	<36	47	(84)
	≥36	9	(16)
Dutch language proficiency	Good	53	(95)
	Average	1	(2)
	None	2	(4)

counseling session. With use of the assessment tools counseling for the CT and the FAS, a set score could be assigned on the level of the discussed items and sub-items. The assessment tool clearly stated, word by word, what was needed to be discussed in order to be assigned a certain score. For the CT counseling a maximum score of 14 points could be assigned and for the FAS counseling a maximum score of 12 points could be assigned. Within an item, it was possible to assign a part of the maximum points when only a part of the sub-items were discussed.

### Statistical analysis

In order to gain insight into the characteristics of the study dataset, descriptive statistical analysis was conducted. The same method was used to analyze the differences in

assessments of the counseling sessions. To analyze intra-observer variability between the three assessors, the Intraclass Correlation Coefficient (ICC) analysis method was used for which a minimum sample size of 50 is required.<sup>15</sup> Analysis of the determinants regarding the feasibility, such as timeframe of transcription and quality assessment per audio-recording, were conducted with use of descriptive statistical frequency analysis. All analyses were conducted in IBM SPSS statistics software version 21 (SPSS Inc., Chicago, IL, USA). A p-value of <0.05 was considered significant in this study.

## RESULTS

Of the participating hospitals and ultrasound center 58 audio-recordings of counseling sessions regarding the combined test and/or the FAS were retrieved. Two audio-recordings were excluded from the study. One due to missing characteristics of the pregnant woman and another one because it concerned a post test counseling session.

**Table 6.2** Quality assessments Combined test and Fetal Anomaly Scan counselling

	<b>Max. Score</b>	<b>Median</b>	<b>(min-max)</b>
<b><i>Total item score CT counselling</i></b>	14	9.15	(3.28-13.09)
- Information CT	2	2.00	(0.67-2.00)
- Chance of trisomy 18 and trisomy 13	2	1.00	(0.00-2.00)
- Information down syndrome, trisomy 18 and 13	2	1.00	(0.33-2.00)
- Further research	2	1.67	(0.00-2.00)
- NIPT	2	1.60	(0.00-2.00)
- Provision of RIVM flyer <sup>1</sup>	1	0.00	(0.00-1.00)
- Referral letter	1	1.00	(0.00-1.00)
- Communication test results	2	0.33	(0.00-1.33)
<b><i>Total item score FAS counselling</i></b>	12	4.33	(1.73-8.24)
- Purpose FAS	2	0.96	(0.00-2.00)
- Limitations FAS	2	0.33	(0.00-2.00)
- Sonographic markers / additional findings	1	0.00	(0.00-1.00)
- Time frame FAS	2	0.33	(0.00-2.00)
- Further research	1	0.67	(0.00-1.00)
- Communication test results	2	0.33	(0.00-1.33)
- Provision RIVM flyer <sup>1</sup>	1	0.00	(0.00-1.00)
- Referral letter	1	1.00	(0.00-1.00)

CT: Combined Test

FAS: Fetal Anomaly Scan

<sup>1</sup> In practice the flyer is not standard provided during the counseling session.

Table 6.2 shows the median score of the assessments of the counseling items due to the inventory assets of the method. The median overall score of the counseling for the combined test is 9.15 of a maximum score of 14. The counseling for the FAS reached a median score of 4.33 of a maximum score of 12.

Table 6.3 shows that the coefficients of the three assessments by the three assessors for the counseling for the CT and the FAS were significantly above 0.80 which indicates excellent agreement between the assessments. Additionally, on item level the agreement between the three assessors and the assessor pairs were generally high with significant coefficients of over 0.70. Several assessed items, with a coefficient of <0.70 on all levels of analysis, showed a disagreement between the assessments. The CT counseling agreement between the assessors was least significant for the item 'communication of

**Table 6.3** Intraclass Correlation Coefficient analysis

	A1/A2/A3	
	ICC	P-value
<b>Total Combined test counselling</b>	0.88	0.001
- Information CT	0.10	0.289
- Chance of trisomy 18 and trisomy 13	0.86	0.001
- Info down syndrome, trisomy 18 and trisomy 13	0.93	0.001
- Further research	0.90	0.001
- NIPT	0.89	0.001
- RIVM flyer	0.94	0.001
- Referral letter	0.88	0.001
- Communication of results	0.47 <sup>1</sup>	0.003
<b>Total Fetal Anomaly Scan counselling</b>	0.82	0.001
- Purpose FAS	0.97	0.001
- Limitations FAS	0.76 <sup>2</sup>	0.001
- Sonographic markers	0.95	0.001
- Time frame FAS	0.30 <sup>3</sup>	0.001
- Further research	0.93	0.001
- RIVM flyer	0.94	0.001
- Referral letter	0.22	0.006
- Communication of results	0.57 <sup>1</sup>	0.001

CT= Combined test, FAS= Fetal Anomaly Scan

B1= Assessment 1, B2= Assessment 2, B3= Assessment 3.

Coefficient  $\geq 0,70$  adequate agreement between the assessments <sup>[11]</sup>

<sup>1</sup> Significant inadequate agreement between 1 assessor pair, <sup>2</sup> between 2 assessor pairs and <sup>3</sup> between 3 assessor pairs.



results'. The items 'time frame FAS', 'referral letter' and likewise the 'communication of results' significantly showed the largest difference in assessments for the counseling of the FAS.

Table 6.4 gives an overview of the feasibility determinants for the execution of the assessment method. For each minute of an audio-recording of the counseling, the median time investment for transcription was close to 10 minutes.

**Table 6.4** Time investment assessment method counseling

<b>A. Transcribing</b>	<b>Median</b>	<b>min-max</b>
Per transcript (total minutes)	97.50	(10.00-195.00)
Per minute counseling	9.61	(5.75-21.74)
<b>B. Assessments content counseling</b>	<b>Median</b>	<b>min-max</b>
Per transcript (total minutes)	12.80	(1.70-20)
Per minute counseling	1.28	(0.67-3.20)
Assessments CT counseling n=47	9.15	(3.28-13.09)
Assessment FAS counseling n=55	4.33	(1.73-8.24)

CT: Combined test

FAS: Fetal Anomaly Scan

## DISCUSSION AND CONCLUSION

### Discussion

To our knowledge this is the first developed and evaluated method that was able to assess the quality of the content of the health educational component of the counseling based on audio recordings. This method offered the ability to assess the conversation held in the counseling session in a standardized and a reproducible manner. The primary outcomes of the assessment were the quality assessments for the health educational part of the counseling, and the secondary outcome was an evaluation of counselor specific characteristics and any shortcomings in the counseling. The method was therefore complementary regarding the developed observation method with which the communication skills of the counselor can be studied.<sup>8</sup>

The method assessed the quality of the 'information supplying component' (health education) of the counseling while the 'support in decision-making' is not part of the assessment. Considering the purpose of this study and the low representativeness of the sample size, this article will not supply quality assessments on the content of the conducted counseling sessions. The required sample size of 50 counseling sessions to enable execution of a valid ICC was reached with a sample of n=56.<sup>11</sup> Based on the significant agreement between overall assessments for both tests of the counseling

supplied by the three assessors, the reliability of the method has been established. The outcomes confirm that for the overall assessment for each type of counseling it does not matter which assessor has executed the assessment. However, on a few items there was less of an agreement between supplied assessments by the assessors, with the item assessments for the FAS counseling showing the least agreement. Based on further study of the sub-items for both assessment tools, it appears that a lack of explicitness in the sub-items is the cause. The study findings give implications for improvement of the method. The items and sub-items with the lowest level of agreement are ought to be made more explicit in their description in the assessment tools. This will further optimize the method.

The assessment method was based on audio-recordings of the counseling session conducted by the counselor. Transcription of the audio-recordings contributed to a reliable assessment of the counseling. Solely use of the audio-recordings is less objective to determine on which parts of the conversation the scored and assessed items are based. Furthermore the listening and elaborating by the counselor themselves of the conducted counseling session will lead to further insight and awareness on the quality of the conducted counseling session and create a learning experience. For this reason it is, not only with regard to the feasibility of this method from the perspective of the auditor, recommended to enable transcription by the counselor, despite the timely investment.

Based on the transcripts, the counseling can be evaluated accordingly to the described method, which will enable the auditing organization to report on the quality of the counseling.

## CONCLUSION

The developed assessment tool showed to be an adequate instrument to assess the quality of the 'health education' component of the counseling session in a uniform and reproducible manner. The method additionally offers the ability to gain insight in the structure of the counseling and shortcomings in the transmission of information. Hereby a reliable method is available to primarily assess the health educational part of the counseling on an individual level and secondary give the opportunity to inventory the omissions in the counseling in national perspective.

### Practice implications

Implementation of this new assessment method for counseling is feasible seeing (1) the method and the used assessment tools are transmissible and useful in a broader health care perspective, (2) the used assessment tools are easily adjustable and (3) the time investment for the counselor and auditor is realistic. Implementation of the

assessment method appears to be worthwhile. This method could be used as a quality evaluation of the counseling session and can, after professional development adjusted to the outcomes of the assessment, result in contribution to improvement in the quality of the counseling.

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## SUPPLEMENTS

## SUPPLEMENT 6.1 - ASSESSMENT TOOL COUNSELING COMBINED TEST

Score-code	Item	Required content	Score	Comments
S_1_CT	Wish for information Combined test	Do you wish to get information about screening for Down syndrome?	N.A.	This question is likely to be asked prior to the counselling session.
S_2_CT	Information Combined test: blood test, Nuchal translucency (NT) measurement to enable pregnant woman to make an informed decision.	CT: (1) blood test at 9-14 weeks pregnancy. (2) NT measurement for child during ultrasound within week 11-14 of pregnancy.	2 themes mentioned 1 theme mentioned -	(1): score when blood test and a timeframe is mentioned. (2): Timeframe of 12 weeks is adequate. = 2 points (good) = 1 point = 0 (inadequate)
S_3_CT	Combined test: Besides chances for DS, also chances for trisomy 13 (patau and 18 (edwards).	(1) Besides chances for DS results too show chances for t18 (edwards) and t13 (patau). (2) Pregnant woman will only get all three results if she wishes to.	2 themes mentioned 1 theme mentioned -	= 2 points (good) = 1 point = 0 (inadequate)

## SUPPLEMENT 6.1 - ASSESSMENT TOOL COUNSELING COMBINED TEST (continued)

Score-code	Item	Required content	Score	Comments
S_4_CT	Information trisomy 21, 13 and 18.	T21 (Down): (1) It is a congenital disease (2) Caused by extra chromosome 21. (3) Slow and limited development of the child. T18 (edwards)/T13 (patau): (4) Caused by extra chromosome 18/13. (5) Most children pass away during the pregnancy or within the first year after birth. (6) severe mental disability and specific physical abnormalities.	all 6 themes mentioned 5 themes mentioned 4 themes mentioned 3 themes mentioned 2 themes mentioned 1 theme mentioned	When pregnant woman does not wish to receive information on T13 & T18, then maximum points must be divided over T21.  (1): chromosomal abnormality = adequate = 2 points (good) = 1.66 points = 1.33 points = 1 point = 0.5 point = 0.33 point = 0 (inadequate)
S_5_CT	Information various result options and potential referral for further research.	(1) The results of the blood test + NT + age + exact length of the pregnancy = result of chance (no certainty) (2) With a chance of 1:200 or higher for DS: further research. (3) Further research consists of NIPT, Chorionic villus sampling, amniocentesis. (4) Chorionic villus sampling and amniocentesis gives definitive result.	All 4 themes mentioned 3 themes mentioned 2 themes mentioned 1 theme mentioned	= 2 points (good) = 1.5 points = 1 point = 0.5 point = 0 (inadequate)

## SUPPLEMENT 6.1 - ASSESSMENT TOOL COUNSELING COMBINED TEST (continued)

Score-code	Item	Required content	Score	Comments
S_6_CT	Information Non Invasive Prenatal Test	(1) With higher chance opportunity to take part in NIPT study. (2) Take blood to test DNA child for DS, Edwards and Patau syndrome. (3) Advantage NIPT: no risk of miscarriage. (4) Disadvantage NIPT: no 100% certain result. (5) Further research.	All 5 themes mentioned 4 themes mentioned 3 themes mentioned 2 themes mentioned 1 theme mentioned	(2): Mention of blood test + three syndromes = adequate (3): Mention of non-invasive as part of name NIPT = inadequate
L7_CT	Offering support to the pregnant woman to digest the information and come to a decision.	(1) Answer options: - Contact via call; - Extra consultation; - Decision making support / website; - Other.	N.A. (No scoring, but inventory)	
S_8_CT	Mention of flyer 'Information about Down screening'	Has the flyer been mentioned yes/no?	mentioned not mentioned	= 1 point (good) = 0 (inadequate)

## SUPPLEMENT 6.1 - ASSESSMENT TOOL COUNSELING COMBINED TEST (continued)

Score-code	Item	Required content	Score	Comments
S_9_CT	If pregnant woman decides to take part in the prenatal screening programme, a referral letter must be given in which is stated that the counselling session has been conducted.	(1) Referral letter given/explained (2) Digital referral in the patient system in the case that the CT will be executed internally. (3) In the case that pregnant woman does not yet commit to taking part in the CT, explain further steps and when her final decision is due.	given/registered/ explained  not given /not registered/not explained	1 point can be scored when one of the situation applies.  When pregnant woman decides not to do the CT, no referral letter can be given. In that case score 1.
S_10_CT	If pregnant woman decides to take part in screening programme, mention how she will receive the results from the Combined test.	(1) Explanation of how the results are communicated. (2) Explanation of who will communicate the results.	2 themes mentioned 1 theme mentioned If pregnant woman hasn't decided whether or not to take part yet.	When pregnant woman has decided not (yet) to take part in the CT score 2 for item S_11_CT  = 2 points (good) = 1 point = 0
S_11_CT	If pregnant woman hasn't decided whether or not to take part yet.		Yes No	= 2 points = 0
<b>CALCULATION</b>				
			Max 14 points	
			Total score: 1,4 = final score	



## SUPPLEMENT 6.2- ASSESSMENT TOOL FETAL ANOMALY SCAN

Score-code	item	Required content	Score	Comment
S_1_FAS	Wish for information Fetal Anomaly Scan	Do you wish to get information about the FAS?	N.A.	This question is likely to be asked prior to the counselling session.
S_2_FAS	Information goal Fetal Anomaly Scan	(1) neural tube defect (open spine, spinal cord or brain) (2) development of organs (3) other physical abnormalities (4) growth of the child (5) amount of amniotic fluid	5 themes mentioned 4 themes mentioned 3 themes mentioned 2 themes mentioned 1 theme mentioned -	= 2 points (good) = 1.6 points = 0.96 points = 0.8 points = 0.4 points = 0 (inadequate)
S_3_FAS	Limitations of the Fetal Anomaly Scan	(1) FAS is not able to find all abnormalities (2) No certainty for healthy/unhealthy child	2 themes mentioned 1 theme mentioned -	= 2 points (good) = 1 point = 0 (inadequate)
S_4_FAS	Chance of unexpected findings (Sono-markers)	Mention that during the FAS unexpected findings can be found.	Mentioned not mentioned	= 1 point (good) = 0 (inadequate)
S_5_FAS	Timeframe Fetal Anomaly Scan	(1) Between 18-22 weeks of pregnancy. (2) Best before week 21.	2 themes mentioned 1 theme mentioned -	= 2 points (good) = 1 point = 0 (inadequate)
S_6_FAS	Information further research	Further research: expert ultrasound	mentioned not mentioned	= 1 point (good) = 0 (inadequate)

**SUPPLEMENT 6.2- ASSESSMENT TOOL FETAL ANOMALY SCAN (continued)**

Score-code	item	Required content	Score	Comment
S_7_FAS	If pregnant woman decides to take part in screening programme, mention how she will receive the results from the Fetal Anomaly Scan	(1) Explanation of how the results are communicated. (2) Explanation of who will communicate the results.	2 themes mentioned 1 theme mentioned - This option must be chosen as well in the case that the pregnant woman hasn't decided whether or not to take part yet)	When pregnant woman has decided not (yet) to take part in the CT score 2 for item: = 2 points (good) = 1 point = 0 (inadequate)
I_8_FAS	Offering support to the pregnant woman to digest the information and come to a decision.	Answer options: - Contact via call; - Extra consultation; - Decision making support / website; - Other:	N.A. (No scoring, but inventory)	
S_9_FAS	Mention of flyer Fetal Anomaly Scan	Has the flyer been mentioned yes/no?	mentioned not mentioned	= 1 point (good) = 0 (inadequate)
S_10_FAS	If pregnant woman decides to take part in the prenatal screening programme, a referral letter must be given in which is stated that the counselling session has been conducted.	(1) Referral letter given/ explained (2) Digital referral in the patient system in the case that the FAS will be executed internally. (3) In the case that pregnant woman does not yet commit to taking part in the FAS, explain further steps and when her final decision is due.	given/registered/ explained not given /not registered/ not explained	= 1 point = 0

## SUPPLEMENT 6.2- ASSESSMENT TOOL FETAL ANOMALY SCAN (continued)

Score-code	item	Required content	Score	Comment
S_10_FAS	No referral letter is given when the pregnant woman has not decided whether or not to take part.		1=No referral letter due to no decision 0=Referral letter given/ no referral letter given when decision has already been made.	= 1 point = 0
<b>CALCULATION</b>				
Max 12 points				
Total score: 1,2 = final score				