



**HAL**  
open science

## Is the non-respect of ethical principles by health professionals during first-trimester sonographic Down syndrome screening damaging to patient autonomy?

Romain Favre, Virginie Guige, Anne-Sophie Weingertner, Christophe Vayssière, Monique Kohler, Israël Nisand, Christian Hervé, Grégoire Moutel

### ► To cite this version:

Romain Favre, Virginie Guige, Anne-Sophie Weingertner, Christophe Vayssière, Monique Kohler, et al.. Is the non-respect of ethical principles by health professionals during first-trimester sonographic Down syndrome screening damaging to patient autonomy?. *Ultrasound in Obstetrics and Gynecology* = *Ultrasound in Obstetrics & Gynecology*, 2009, 34 (1), pp.25-32. 10.1002/uog.6327. inserm-00415138

**HAL Id: inserm-00415138**

**<https://inserm.hal.science/inserm-00415138>**

Submitted on 17 Sep 2009

**HAL** is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

# **Is the non-respect of ethical principles by doctors during Down's syndrome screening by first-trimester ultrasound damaging to patient autonomy?**

## **Authors**

Romain Favre, MD \*

Virginie Guigue, MD \*

Anne-Sophie Weingertner, MD \*

Christophe Vayssière, MD \*

Monique Kohler, MD \*

Israel Nisand, MD \*

Christian Hervé, MD \*\*

Grégoire Moutel, MD \*\*

\* Département d'échographie et de Médecine fœtale. 19 rue Louis Pasteur, CMCO-SIHCUS. Schiltigheim / Strasbourg France.

\*\* Laboratoire d'éthique médicale et médecine légale, Faculté de médecine, Université Paris 5, 45 rue des Saints Pères, 75006 Paris & Institut International de Recherche en Ethique Biomédicale (IIREB).

**Key words:** Prenatal diagnosis, Down syndrome, nuchal translucency, informed consent, patient autonomy.

**Address:** Romain Favre. 19 rue Louis Pasteur. CMCO-SIHCUS. Schiltigheim/Strasbourg. France. Tel : 00 333 88 62 83 29 – 06 21 72 05 53

Email: [romain.favre3@orange.fr](mailto:romain.favre3@orange.fr)

## **Abstract.**

**Objectives.** Health professionals' understanding involved in the practice of first-trimester ultrasound were evaluated by three questions: how much does the medical population know about Down's syndrome screening by nuchal translucency?, what is the personal position of doctors with respect to this screening test?, what position does the doctor occupy with respect to his or her patients?

**Methods.** We studied the medical population in the east part of France by a questionnaire.

**Results.** We sent 460 questionnaires to medical correspondents. 276 responded (60 %). Three independent factors seemed to affect interview quality: speciality ( $p < 0.001$ ), the type of hospital ( $p < 0.032$ ) and the duration of medical practice ( $p < 0.015$ ). Two independent factors affected the level of medical knowledge concerning first-trimester ultrasound scans: speciality ( $p < 0.031$ ) and site of practice ( $p < 0.034$ ). Two independent factors affected the attitude of doctors to first-trimester ultrasound scans: the site of practice ( $p < 0.034$ ) and the type of medical practice (public/private), ( $p < 0.05$ ). Two independent factors affected the attitudes of doctors to their patients: speciality ( $p < 0.001$ ) and the age of the doctor ( $p < 0.02$ ).

**Conclusion.** The answer to the question "*Are ethical principles respected when women are proposed ultrasound screening during the first trimester of pregnancy?*" is clearly "no" and that a major effort is required to ensure that the decisions made by patients are based on a real possibility of choice.

## **Introduction**

Many studies have demonstrated first-trimester ultrasound screening for Down's syndrome to be valuable (1, 2). However, certain inherent problems resulting from the early stage at which diagnosis is made are rarely considered: some concern the patients — concerns about possible miscarriage, the use of chorionic villus sampling for sex selection — whereas other concern the professionals involved more specifically — the high level of acceptability of early abortion, social and medical pressure and pressure from insurance companies (3). In this context, we are beginning to see the emergence of studies (4, 5) dealing with the new issue of real consent and real autonomy in practices relating to first-trimester ultrasound scans. F.A. Chervenak pointed out that the most important ethical principle is medical competence (6). He identified respect for autonomy — respecting the beliefs and values of patients — as the second most important ethical principle. Next in order comes justice, corresponding to equal access to medical resources.

Most pregnant women undergo an ultrasound scan during the first trimester, as part of the routine follow-up of their pregnancy. The principal objective of this examination is to date the pregnancy. Nicolaides *et al.* (1) showed that nuchal transparency measurements were highly sensitive for the screening of Down's syndrome. This discovery conferred a new objective on this ultrasound scan. However, women are not always informed about these diverse approaches to ultrasound scans in early pregnancy. The widespread use of this examination, in the absence of real consent and real understanding of the issues involved by patients, has led to debate in France about possible eugenic aspects of the banalisation of this prenatal screening examination (6, 7). This question is of particular importance in France, the only country in which first-trimester ultrasound scans are carried out systematically, nationwide, and in which this examination is entirely reimbursed by the national health insurance system and perceived as obligatory by patients (5).

We addressed three questions, to evaluate health professionals' understanding of the ethical stakes involved in the practice of first-trimester ultrasound scans: 1) How much does the medical population know about Down's syndrome screening by ultrasound? 2) What is the personal position of care staff with respect to this screening test? 3) What position does the doctor occupy with respect to his or her patients?

We formulated two hypotheses:

1. The knowledge of the doctors conditions decisions taken with the patient. Poor knowledge may affect the quality of the information transmitted. This lack of information may result in the patient's autonomy not being respected during the practice of first-trimester ultrasound scans.
2. The doctor's position with respect to screening may also strongly influence patients, again damaging the respect of patient autonomy.

## **Materials and methods**

We investigated ethical aspects of first-trimester ultrasound scans. Measurement of nuchal translucency on such scans has been shown to be useful for Down's syndrome screening. This measurement is carried out during the first-trimester ultrasound examination, which takes place between the 11<sup>th</sup> and 14<sup>th</sup> weeks of amenorrhoea.

Doctors' knowledge and positions with respect to this test, together with their positions with respect to their patients, were evaluated by means of questionnaires, which were sent to 460 doctors regularly corresponding with our hospital structure.

The methodology used was validated by our team (5): a questionnaire for the evaluation of doctors' knowledge, their attitude to the test and their attitude to their patients. This questionnaire had five parts:

- A. The first part of the questionnaire (questions 1 to 7) provided a description of the doctor - age, sex, type of medical practice (public/private), type of hospital structure (university/regional hospital), duration of medical practice (<5 years, 5 to 10 years, >10 years) and location of practice (small town, medium-sized or large town). We analysed the effects of these seven parameters on the three variables tested: level of knowledge, attitude to the test and attitude to patients.
- B. The second part (questions 8 to 11) generated a medical quality score for the interview (IMQS). Four questions were asked. These questions evaluate the quality of the medical interview preceding the examination and generate a score indicative of this quality. The median score was calculated and used to define a threshold below which the information interview was considered deficient and above which it was considered satisfactory.

- C. The level of doctors' knowledge was assessed as described by Michie and Marteau (8, 9), through 10 questions (questions 12 to 21). These questions focused on the recommendations of scientific societies (16). A total score was calculated for each doctor, together with a median score for the entire population of doctors, the maximum possible score was 20. Doctors were classified into two populations as a function of the frequency of correct responses: the level of knowledge was considered good for doctors with a total score higher than the median.
- D. Based on the same approach (8, 9), the fourth part of the questionnaire evaluated the doctor's perception of this test. We used this part of the questionnaire to gauge the doctor's personal opinion (differentiating clearly between this opinion and what he or she said to the patients (questions 23 to 26). These four questions were used to calculate a mean score for each doctor and the median for the whole population of doctors was then determined. Doctors with scores below this median value were considered to be opposed to this test. Conversely, doctors with scores greater than the median were considered to be in favour of this screening approach. This evaluation was compared with the response to a direct question (question 27), making it possible to consider alternatives, with comments.
- E. The last part of the test evaluated the doctors' attitudes to their patients. These questions were posed so as to make it possible to define two opposing attitudes: an "autonomist" attitude and an "automatist/directive" attitude. We deliberately avoided the use of the term "paternalist", as this term implies a protective attitude towards patients. The automatist attitude arises partly due to medicolegal pressure, attempts to make practices systematic and a lack of discussion. Directive attitudes arise from the doctor's firm convictions and a refusal to accept that the patients are able to understand the issues involved. A score was

calculated based on the responses to these four questions (questions 28 to 31). Higher scores were associated with a more autonomist approach, whereas lower scores were associated with autonomist/directive approaches.

We adapted the three-dimensional diagram designed by T.M. Marteau (8), using this attitude of doctors towards their patients as the third dimension (Figure 1). The doctor's approach may favour the obtainment of real consent from the patients and the respect of ethical principles or may make it more difficult to obtain such consent. This diagram reveals the existence of several possible situations. Only the doctors in cells 1 and 2 are really in a position to favour the obtainment of real consent from their patients, respecting ethical principles in terms of competence and the autonomy of patients. *These doctors are well informed, may or may not be in favour of the test, but adopt an autonomist approach.* In all other situations, the doctor does not facilitate the obtainment of real consent from patients. The least acceptable situations in terms of ethics concern the doctors in cells 7 and 8, who adopt a directive approach but lack competence.

We used  $\chi^2$  tests to compare individual variables between categories, Student's t tests and analyses of regression to evaluate the relative contributions of certain parameters and the links between them. We incorporated the following parameters into the regression analysis, to investigate the influence of each factor on knowledge, attitude to the test and attitude to patients: the sex and age of the doctor, the doctor's speciality and type of practice, the type of hospital, the duration of practice, the location of practice and the score obtained for the medical interview preceding the examination (IMQS). A significance threshold of 0.05 was used (SPSS 16.0).



## **Results**

We sent 460 questionnaires to medical correspondents involved in obstetric follow-up. Those who responded that they were not directly involved in the follow-up of their pregnant patients were excluded. In total, 276 responded to the questionnaire, corresponding to 60% of the practitioners consulted after three attempts at contact over a period of six months. These doctors comprised 226 specialist gynaecologists/obstetricians (81.9%), 46 general practitioners (16.7%) and four midwives (1.4%). The mean age of these practitioners was 48.8 years (range: 24 to 68 years). This sample included 160 men and 116 women. Of these subjects, 156 (56.5%) worked in private practice and 120 (43.5%) worked in hospitals (85 in regional hospitals and 35 in university hospitals). Most (232; 84%) had been in practice for more than 10 years and 29 (10.5%) had been in practice for five to 10 years. Only 15 (5.4%) had been in practice for less than five years. The site of practice was a small town (<10,000 inhabitants) for 45 subjects (16.3%), a medium-sized town (between 10,000 and 100,000 inhabitants) for 125 subjects (45.3%) and a large town (>100,000 inhabitants) for 106 subjects (38.4%).

### ***Evaluation of the interview preceding the ultrasound examination (IMQS)***

This first analysis dealt with the way in which the doctor presented the screening test to the patient. Most doctors (257; 93.1%) provided some explanation, but 19 (6.9%) provided no prior explanation. The explanation of the test took about five minutes for 145 subjects (52.5%), between five and 10 minutes for 18 subjects (6.5%) and more than 10 minutes for 18 subjects (6.5%). Only 95 doctors used documentation or some other support when giving explanations (34.4%). The majority of doctors (183; 66.3%) were aware of the optional nature of this examination. However, 93 doctors considered this ultrasound examination to be obligatory (33.7%). A score relating to the quality of this interview was established. For 215

doctors, this score was greater than the median (77.9%), whereas it was below the median for 66 doctors (21.1%)

### ***Evaluation of the level of knowledge about ultrasound scans***

This part of the study involved the evaluation of medical knowledge concerning the first-trimester ultrasound scan. The first question concerned the sensitivity of the test: *How effective is screening for Down's syndrome by ultrasound scan during the first trimester?* The actual sensitivity of ultrasound scan alone has been estimated at 75%. Only 113 subjects gave a correct response (47.7%), with 39 doctors failing to respond to this question and 124 (52.3%) replying incorrectly.

The second question concerned the notion of positive predictive value: *What is the probability of the foetus having Down's syndrome if the nuchal translucency is thick?* Only 45 doctors (23.5%) correctly appreciated the performance of nuchal translucency measurement, which has a positive predictive value of 3% in the general population. No response to this question was obtained from 38 subjects. Most of the subjects gave an incorrect evaluation of the test, 182 (76.5%). The risk of Down's syndrome is strongly overestimated by most doctors.

The next three questions dealt with technical aspects. Three responses were proposed for question 3: *First-trimester ultrasound scan should measure the nuchal translucency for a height corresponding to the following craniocaudal length?* The correct response was given by 147 subjects (54.6%), whereas 122 subjects (45.4%) gave an incorrect response and seven doctors did not respond (2.5%). Question 4 was *"What is the optimal position of the calipers for measuring nuchal translucency?"* Seven subjects did not answer this question, 214 (79.6%) knew the technical criteria and 55 (20.4%) gave an incorrect response. Question 5 asked *"Which measurement of nuchal translucency should be retained?"* The correct answer was the largest measurement. Six subjects gave no response, 186 (68.9%) responded correctly

and 84 (31.1%) gave an incorrect response, despite the existence of an international consensus concerning these criteria.

Question 6 dealt with the approach to be adopted: *When should the taking of a sample be suggested?* None of the proposed answers to this question was correct. Nonetheless, 91 (35.5%) of the subjects responded correctly. However, 165 (64.5%) answered incorrectly and 20 doctors (7.2%) gave no response.

Question 7 evaluated the doctors' understanding of the concept of "multiple of the median" (MoM). Several possible responses were suggested to this question: *Why should MoM be used in preference to absolute values for nuchal translucency?* In total, 44 subjects (15.9%) did not respond to this question. Only 88 doctors (37.9%) responded correctly, with the majority of doctors (144; 62.1%) answering incorrectly.

Question 8 concerned the natural course of foetal Down's syndrome. Doctors were expected to respond that there was a high probability of spontaneous miscarriage. In response to the question *"What is the natural fate of fetuses with trisomy 21?"*, 37 subjects (13.4%) did not respond. Only 101 subjects (42.3%) knew that almost 50% of pregnancies in which the foetus is trisomic end in spontaneous miscarriage. The majority of those questioned (138; 57.7%) were unaware that this was the case.

Question 9 evaluated the notion of foetal death due to intervention: *What is the frequency of miscarriage associated with the sampling of chorionic villus sampling?* Thirteen (4.7%) doctors did not respond, whereas 194 doctors (73.8%) gave a correct evaluation (of the order of 1 to 2%) and 69 doctors (26.2%) underestimated the risk.

Question 10 dealt with the notion of specificity: *In screening for Down's syndrome by early ultrasound scan, what is the probability of being considered at low risk?* In total, 54 doctors (19.6%) did not respond. Only 77 doctors (34.7%) knew that 95% of the population is

at low risk by definition. Most doctors did not seem to have understood the notion of low risk, with 145 incorrect responses (65.3%) obtained.

The mean value obtained was  $9.17 \pm 4.75$ , and the median value was 10. Ninety-eight doctors (35.5%) obtained scores above this median value and were considered to have a good level of knowledge. However, 178 doctors (64.5%) obtained scores below the median value and were considered to be poorly informed.

### ***Evaluation of the attitudes of doctors to first-trimester ultrasound scans***

Four propositions for question 11 were used to calculate an overall score (8). The maximum possible score was 28, and the mean score was  $22.8 \pm 4.8$ . Using a threshold value of 14 (the median), 255 doctors (92.4%) were considered to be in favour of this examination, whereas 21 (7.6%) were considered to be opposed. These findings correlated well with the response to question 12, which provided doctors with an opportunity to provide a written response concerning their views. The response to question 12 showed that 242 (87.7%) doctors were in favour of this examination, 12 (4.3%) were opposed and the remaining 22 (8%) had a more equivocal opinion. The comments made included the following: *"It's what the patient wants that must be taken into account"*, *"it's our duty to present the test, changes in the medicolegal situation have made it essential to offer this test"*, *"it takes time to explain these data to the parents, who then become very anxious"*, *"nuchal translucency screening is positive when the disease is lethal"*, *"if there is trisomy 21!!! Should we eradicate these patients?"*, *"what happened to tolerance?"*, *"I'm uncomfortable with the eugenic changes in our profession and in French society, which has a real problem dealing with handicap"*, *"the medicolegal risk is more important than the ethical problem."*

### ***Evaluation of the attitude of doctors to their patients***

The last four questions, questions 13 to 17, were designed to analyse the attitudes of doctors to their patients. Higher scores for these questions indicated that the doctor tended to allow patients to make their own choices, whereas lower scores indicated that the doctor played a much greater role in the decision-making process, probably guiding his patients in their choices.

Question 13 concerned the objective of this test: *In your opinion, what is the main aim of prenatal diagnosis by ultrasound during the first trimester?* Three responses were proposed: 1) to allow the patient to have an abortion if an abnormality is found. This proposition was selected by 102 doctors (37%); 2) to optimise perinatal management. This proposition was selected by 46 doctors (16.7%); 3) to provide the couple with information. This option was selected by 128 doctors (46.4%). The other three questions dealt with the discussion before the examination of the possibility of an abnormal test, a normal test and the possibility of Down's syndrome. The mean score obtained was  $8.83 \pm 2.39$  and the median score was 6. All doctors with a score of at least 6 were considered to have an autonomist approach to their patients. This was the case for 224 doctors (81.2%), the other 52 (18.8%) being considered to have an autonomist/directive approach.

We classified the doctors according to a multidimensional approach (table 1). We found that only 88 doctors (cells 1 and 2; 31.9%) had an approach facilitating the obtainment of real consent from their patients and respecting the ethical principles of competence and patient autonomy. The other 188 did not clearly respect the principles of autonomy and the 42 doctors (15.2%) in cells 7 and 8 were both poorly informed and had a directive approach.

We carried out a linear regression analysis of the factors potentially influencing these elements of doctor-patient relations. This analysis included eight variables: age group, sex, type of practice (private/hospital), type of hospital, speciality, number of years of practice, site of practice and IMQS.

- Three independent factors seemed to affect interview quality: speciality ( $t = -5.287$ ,  $p < 0.001$ ), the type of hospital ( $t = 2.16$ ,  $p < 0.032$ ) and the duration of medical practice ( $t = 2.458$ ,  $p < 0.015$ ).
- Two independent factors affected the level of medical knowledge concerning first-trimester ultrasound scans: speciality ( $t = -2.173$ ,  $p < 0.031$ ) and site of practice ( $t = 2.126$ ,  $p < 0.034$ ). IMQS was at the limits of significance ( $t = 1.973$ ,  $p < 0.050$ ).
- Two independent factors affected the attitude of doctors to first-trimester ultrasound scans: the site of practice ( $t = -2.126$ ,  $p < 0.034$ ) and the type of medical practice (public/private), which was at the limits of significance ( $t = -1.968$ ,  $p < 0.05$ ).
- Two independent factors affected the attitudes of doctors to their patients in the context of first-trimester ultrasound screening: speciality ( $t = -4.377$ ,  $p < 0.001$ ) and the age of the doctors ( $t = -2.316$ ,  $p < 0.02$ ).

Finally, three independent factors influenced whether *doctors did or did not respect ethical principles in their dealings with their patients in the context of first-trimester ultrasound examinations*: the quality of the interview before the examination, IMQS ( $t = 3.030$ ,  $p < 0.003$ ), speciality ( $t = -1.996$ ,  $p < 0.05$ ) and site of practice ( $t = 2.363$ ,  $p < 0.02$ ).

In conclusion, patients followed by a specialist, who took care over the interview before the examination and worked in a large town, were significantly more likely to have the opportunity to exercise their autonomy.

## **Discussion**

The three fundamental ethical principles identified by F.A. Chervenak (3) — medical competence, respect of autonomy and justice (equal access to medical resources) — are not clearly respected in practice for the first-trimester ultrasound scan.

We observed that doctors had a poor understanding of the statistical notions of sensitivity, predictive value and low risk. Less than half the doctors had understood the notion that ultrasound had a sensitivity of 70 to 75% for a false-positive rate of 5%. Most of the subjects studied overestimated the performance of nuchal translucency screening. Only 23.5% correctly appreciated the value of this sign. Finally, only a third of those questioned realised that 95% of patients are, by definition, at low risk.

The assimilation of technical information seemed to be better, but remained suboptimal, with 45% of doctors unable to identify the correct time for this examination to be carried out, 20% not knowing how to measure nuchal translucency and 31% not knowing which measurement should be retained.

The risks involved with chorion villous sampling were also frequently underestimated, by 26% of those questioned.

These findings indicate that a non-negligible number of doctors do not transmit correct information to their patients. This is confirmed by knowledge scores being below the threshold for 64.5% of doctors. Thus, the first principle — medical competence — is not satisfied by all professionals. General practitioners had less precise knowledge than specialists and doctors from small towns had less precise knowledge than doctors from larger towns.

We used Marteau's diagram (8) modified for the investigation of doctors' attitudes. We introduced a third variable - the attitude of the doctor to the patient ("autonomist" or "automatist/directive"). We found that only a minority of doctors (31.9%) respected the autonomy of their patients. The largest group of doctors (46%) corresponded to those in

favour of the test and autonomist, but poorly informed (cell 5). This confirms the idea that only high-quality information based on competence can guarantee the validity of consent. By contrast, 52 doctors (18.8%) took a directive approach and did not provide the patients with good information about the implications of this examination. Most worrying of all, 15.2% of the doctors were found in cells 7 and 8, indicating a directive approach combined with poor knowledge.

Overall, three independent factors were found to be linked to a position that favours the autonomy of patients: a high-quality interview (high IMQS) before the examination ( $p < 0.003$ ), specialist ( $p < 0.05$ ) and doctor practising in a large town ( $p < 0.02$ ). However, respect for autonomy is not really possible when 30% of doctors believe this test to be obligatory.

The principle of justice is poorly respected, with inequalities of access to care from professions of equal competence. This problem of inequality of access to care was not addressed directly here, but is nonetheless evident from our results. It is of particular importance to public health, leading to increased litigation and regulation of this activity. The lack of competence has been aggravated by a decrease in the number of ultrasound operators following the Perruche trial (10, 17). This legal decision has greatly increased insurance costs for ultrasound operators, in some cases causing these individuals to stop practising. In the Seine Saint-Denis area, one gynaecologist said "*There are no more private ultrasound operators. It can take more than two months to get an ultrasound scan done. Logically, there must be a large number of women no longer having ultrasound scans to measure nuchal translucency... By contrast, women in the more chic districts of Paris are continuing to benefit from ultrasound scans.*" (17).

Thus, there seem to be two different ways to be born: some newborns arrive without the "quality" of their physical or intellectual faculties having been checked, whereas others



arrive after active checking. Natural, ordinary birth is reserved for more disadvantaged populations, whereas the children of wealthier families must undergo a large number of antenatal examinations before being given the "green light" allowing them to be born (17). This may lead to a form of eugenics, made accessible to wealthier populations by medicine. This trend was also identified by E. Dormandy (11), who demonstrated a lower frequency of prenatal diagnosis in populations of disadvantaged women and women from ethnic minorities, with significantly lower levels of informed consent, despite all patients being strongly in favour of antenatal screening.

The non-respect of the three fundamental principles limits the freedom of choice of patients. This freedom is also decreased by biomedical and societal constraints (12). Our work confirms that biomedical constraints hinder the free choice of patients. The medical authoritarianism determining whether or not this screening is prescribed in about 15% of cases provides a clear illustration of this problem.

Bouffard's approach to societal constraints appears particularly relevant when applied to our problem concerning screening for Down's syndrome. The first factor is the lack of support provided to families with affected children. This point has also been highlighted by D. Sicard (7). Other factors include the fragility of families and of family assistance, based on the resources of the couple or of single parents. Moreover, despite the expression of intentions to the contrary, our society accords no role to disabled individuals, who are violently rejected (17). All these factors weigh heavily in the balance when parents are confronted with choices and impose a type of medical practice. The patient-doctor relationship therefore appears to be subject to pressure from society. This same issue has been addressed by our Canadian colleagues (14). English-speaking ethicists (6, 13, 14) have highlighted the non-directive nature of antenatal counselling, whereas we seem to be dealing with a very different situation in France.

This major change in our society today requires us to consider how real free and informed choice really is, without calling into question the individual decisions of couples or the legitimacy of abortion. Indeed, we must ask ourselves whether our society, beyond its agreed discourse, provides any real alternatives. A reflection on handicap and the conditions in which disabled children are managed is essential if we want parents to have real possibilities to make honest choices and if we want to avoid the deleterious results of automatic screening and its consequences.

## **Conclusion**

Our findings confirm the two initial hypotheses. Our results show that the answer to the question "*Are ethical principles respected when women are proposed ultrasound screening during the first trimester of pregnancy?*" is clearly "no" and that a major effort is required to ensure that the decisions made by patients are based on a real possibility of choice and, thus, an understanding of a medical prescription with potentially serious consequences.

Consent may be obtained under diverse constraints or may be the result of diverse pressures. Under such circumstances, the consent obtained does not respect the principle of autonomy in that the patients can see no real alternative. According to Geneviève Fraisse "*To accept is to adhere, to permit is to support*" (15). This reflection highlights the essential difference between acceptance and consent that must be worked on in medicine. Acceptance involves passive submission to an authority, whereas consent is a free and responsible act.

## References

1. Snijders R.J.M., Noble P., Souka A. Nicolaides K.H. UK multicentre project on assessment of risk of trisomy 21 by maternal age and fetal nuchal-translucency thickness 52 10 – 14 weeks of gestation. *Lancet*. 1998; 351: 343 – 6.
2. Snijders R.J.M., Nicolaides K.H. *Ultrasound markers for fetal chromosomal defects*. 1996. The Parthenon Publishing Group. London
3. Boss J.A. First trimester prenatal diagnosis: earlier is not necessarily better. *J. Med. Ethics*. 1994; 20 (3): 146 - 51.
4. Chasen S., Skupski D., McCullough L. and Chervenak F. Ethical issues in first-trimester screening. *OBGYN. net Conference Coverage*. Reprinted with permission of [COGI](#), Washington DC, June 2002.
5. What about the informed consent in first-trimester ultrasound screening for Down syndrome? R. Favre, G. Moutel, N. Duchange, C. Vayssière, M. Kohler, N. Bouffet, M-Ch. Hunsinger, A. Kohler, C. Mager, M. Neumann, C. Vayssière, B. Viville, C. Hervé, I. Nisand. *Fetal Diagn. Therap.* 2008; 23: 173 - 184
6. Chervenak F.A., L.B. McCullough. Implementation of first-trimester risk assessment for trisomy 21: Ethical considerations. *Am. J. Obstet. Gynecol.* 2005; 192: 1777 – 1781.
7. Alberganti M., J-Y. Nau. La France au risque de l'eugénisme. Propose de Didier Sicard. *Le Monde* 2007 ; Lundi 5 février : 14.
8. Marteau T.M., Dormandy E., Michie S. A measure of informed choice. *Health Expectations*. 2001; 4: 99 – 108
9. Michie S., Dormandy E., Marteau T.M. Informed choice: understanding knowledge in the context of screening uptake. *Patient Education and Counselling*. 2003; 50: 247 - 253.
10. Moutel G., Francois I., Moutard M-L., Hervé C. The Perruche decree, an opportunity to question the acceptance of a handicap and the relationship between physicians, justice and society. *Presse Med.* 2002; 31: 632-635.

11. Dormandy E., Michie S., Hooper R., Marteau T.M. Low uptake of prenatal screening for Down syndrome in minority ethnic groups and socially deprived groups: a reflection of women's attitudes or a failure to facilitate informed choices? *Int. J. Epidemiol.* 2005; 34: 346 – 352.
12. Bouffard C. Le respect des principes bioéthiques est-t-il possible dans les conditions actuelles de prestation des services génétiques québécois de médecine prédictive associée à la reproduction ? 2004 :119-144, in C. Hervé, B. M. Knoppers, P. A. Molinari & G. Moutel (dir.), *La place de la bioéthique en recherche et dans les services cliniques*. Paris, Dalloz, Coll. Thèmes et Commentaires.
13. Favre. R. Quelle est la place du consentement dans la pratique française du dépistage de la trisomie 21 par les marqueurs sériques ? *L'observatoire de la génétique*. N° 26, février-mars 2006.  
[www.ircm.qc.ca/bioethique/obsgenetique](http://www.ircm.qc.ca/bioethique/obsgenetique)
14. Hurlimann Th. Programme ministériel d'offre de dépistage de la trisomie 21 au Québec : Quels enjeux ? *L'observatoire de la génétique*. 2008. N° 35 décembre 2007 – mars 2008 1 – 11.  
[www.ircm.qc.ca/bioethique/obsgenetique](http://www.ircm.qc.ca/bioethique/obsgenetique)
15. Geneviève Fraysse. *Du consentement*. Edition du Seuil, Janvier 2007.
16. General Medical Council. *Seeking patient's consent: the ethical considerations*. London. GMC 1999.
17. Moysse D., N. Diedrich. *Vers un droit à l'enfant normal ? L'arrêt Perruche et l'impact de la judiciarisation sur le dépistage prénatal*. Editions érès 2006.

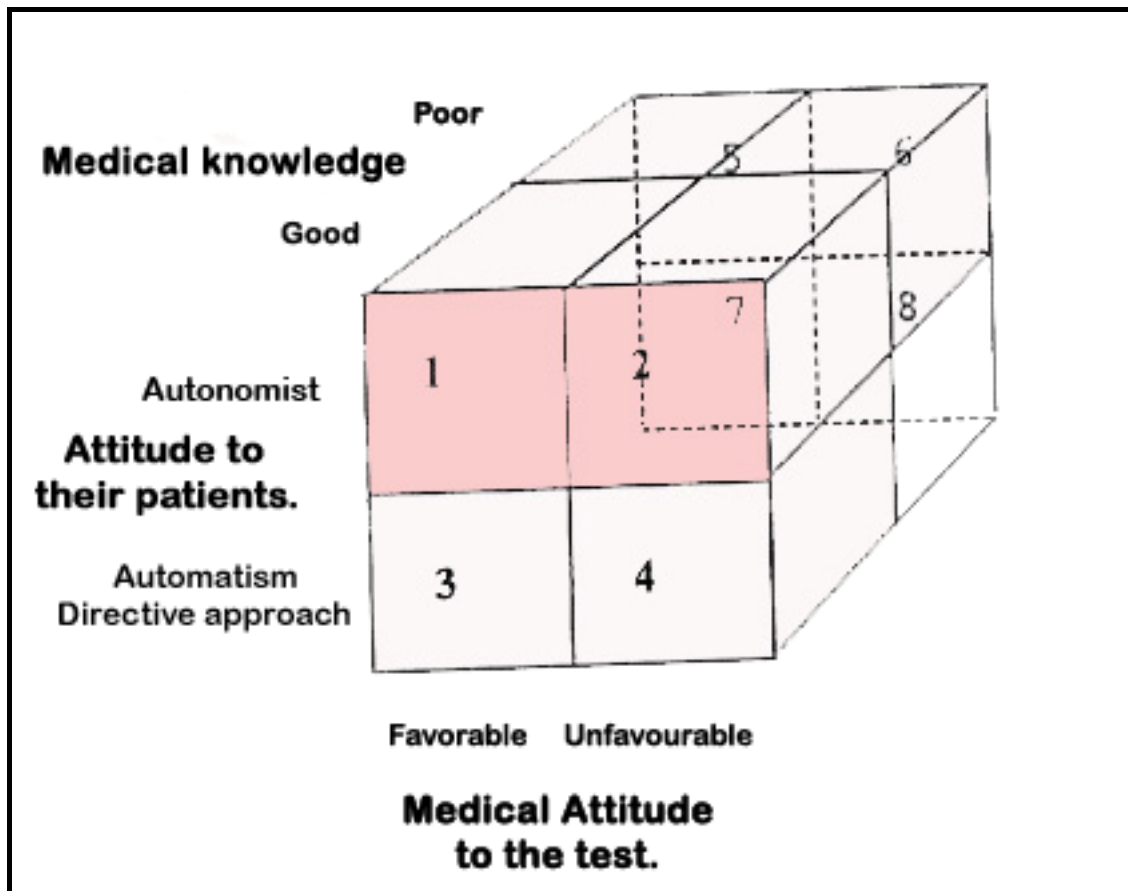
## **Legends.**

**Figure 1:** Classification of the doctors according to their level of knowledge, their attitude to the test and their attitude to their patients.

**Table 1.** Classification of the doctors according to their level of knowledge, their attitude to the test and their attitude to their patients.

**Annexe I.** Questionnaire to the medical correspondents.

Figure 1.



**Table 1.**

Cells	Medical knowledge	Attitude to the test	Position to their patients	Nb.	%
<b>1</b>	+	+	+	82	29.7 %
<b>2</b>	+	-	+	6	2.2 %
3	+	+	-	9	3.3 %
4	+	-	-	1	0.4 %
5	-	+	+	217	46.0 %
6	-	-	+	9	3.3 %
7	-	+	-	37	13.4 %
8	-	-	-	5	1.8 %
Total				276	

# Annexe I.

This questionnaire is strictly anonym.

## Evaluation of the doctor situation.

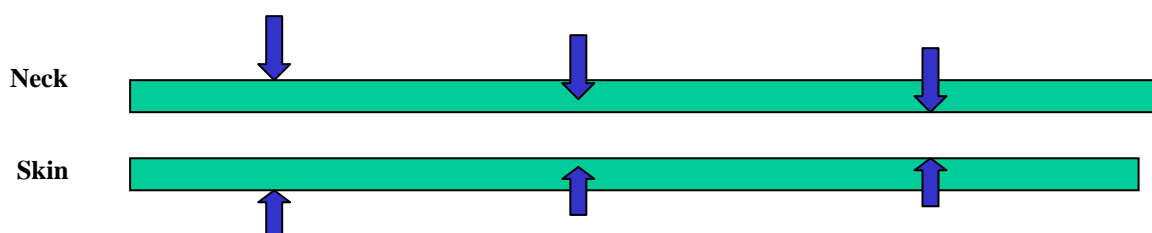
1. What is your age? \_\_\_\_\_ years.
2. What is your sex? Men – Female.
3. What types of practice have you? Hospital – Private practice.
4. If you work in hospital? University hospital – Regional hospital.
5. Are you? General Practitioner – Obstetrician – Midwife.
6. What is the duration of your medical practice? < 5 years, 5 – 10 years, > 10 years
7. What is the location of your practice?  
< 10.000 inhabitants. – 10.000 à 100.000 inhabitants – > 100.000 inhabitants.

## Evaluation of the medical quality score for the interview (IMQS).

8. Do you discuss about the first-trimester ultrasound? Yes – No.
9. What is the duration of the explanation? 5 – 10 – 15 mn – No prior explanation
10. Do you give an information leaflet about the test? Yes - No
11. Is the first-trimester ultrasound obligatory? Yes – No

## Evaluation of the level of medical knowledge.

12. How effective is screening for Down's syndrome by ultrasound scan during the first trimester?  
For 5 % of false positive, the sensitivity of ultrasound alone is :  
\_\_\_\_\_ %. - No response
13. What is the probability of the fœtus having Down's syndrome if the nuchal translucency is thick ?  
\_\_\_\_\_ %. - No response
14. First-trimester ultrasound scan should measure the nuchal translucency (NT) for a height corresponding to the following craniocaudal length (CRL):  
Between 45 – 80 mm - 50 – 90 mm - 60 – 94 mm.
15. What is the optimal position of the calipers for measuring the nuchal translucency?





**16. What measurement of the nuchal translucency (NT) should be retained?**

The smallest - A median – The biggest.

**17. When should we propose a chorionic villous sampling?**

- NT > 2.5 mm for a CRL of 75 mm.
- NT > 2.8 mm for a CRL of 65 mm.
- NT > 3 mm for a CRL of 38 mm.
- No good response.

**18. Why should MoM be used in preference to absolute values for nuchal translucency?**

- MoM allows to obtain a median value.
- MoM reduces the rate of false positive.
- MoM integrates the size of the foetus.
- No idea.

**19. What is the natural fate of foetuses with trisomy 21?**

\_\_\_\_\_ % will spontaneously abort. - No response.

**20. What is the rate of miscarriage following the chorion villous sampling ?**

\_\_\_\_\_ % - No response.

**21. In Down's syndrome screening by first-trimester ultrasound, what is the probability of being considered at low risk?**

\_\_\_\_\_ %. - No response.

**22. Evaluation of the medical opinion of the test.**

**For me, undergoing screening for Trisomy 21 during the first-trimester ultrasound scan at 12 to 13 weeks of pregnancy is:**

- |                  |                            |               |
|------------------|----------------------------|---------------|
| 23. Worrying.    | 1 – 2 – 3 – 4 – 5 – 6 – 7. | Reassuring.   |
| 24. Pointless.   | 1 – 2 – 3 – 4 – 5 – 6 – 7. | Very useful.  |
| 25. A bad thing. | 1 – 2 – 3 – 4 – 5 – 6 – 7. | A good thing. |
| 26. Unpleasant   | 1 – 2 – 3 – 4 – 5 – 6 – 7. | Pleasant      |

27. Which of these responses best applies to you? Tick the correct response.

I think it is a good idea to have a screening test in the first trimester and I am that type of person that prefers to have as many examinations as possible.

I don't think it is a good idea and due to the consequences, I am not convinced that such a test is important.

Other opinion:

## **Evaluation of the doctors' attitude to their patients.**

**28. In your opinion what is the main aim of prenatal diagnosis by ultrasound during the first-trimester?**

1. To allow the patient to have an abortion if an abnormality is found.
2. To optimise perinatal management.
3. To provide the couple with information.

**29. Do you discuss the possibility to observe an increased nuchal translucency (NT > 3mm, for example) prior to the ultrasound examination?**

1. Never
2. Sometimes
3. Always

**30. Do you discuss the signification of a low risk result (NT < 1 mm, for example) before the ultrasound examination ?**

1. Never
2. Sometimes
3. Always

**31. Do you discuss the probability of trisomy 21 if the nuchal translucency is increased (for example, NT > 3 mm) prior to the ultrasound scan?**

1. Never
2. Sometimes
3. Always