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Pregnancy, oral health and dental education: an overview on the northeast of Italy

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Abstract

Objectives: To evaluate the level of knowledge of pregnant women and puerpers about oral health and prevention during and after gestation.

Methods: One hundred women aged 18-49 years (mean age 33±6 years) were included in this cross-sectional study. An anonymous questionnaire with 24 items related to oral health has been administered during or just after pregnancy. Firstly, answers have been analyzed on the full population and then subdividing the sample on the base of age ranges (G1: 18-25 years, G2: 26-35 years and G3: >35 years) and number of pregnancies (FP: first pregnancy; SP: second or more pregnancies). Parametric tests have been chosen for the statistical analysis; in particular, Anova test for independent samples was used to evaluate differences of baseline demographic characteristics among subgroups G1, G2, G3 while chi-square test was used for FP and SP subgroups. Anova test was also used to intercept differences on answers given to the questionnaire among G1, G2 and G3 group; for FP and SP group was used t-test.

Results: Level of information and knowledge of the full sample was medium-low and no significant differences have been observed between groups regarding

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Giuseppe Ricci: Department of Medicine, Surgery and Health Sciences, University of Trieste, Trieste, Italy; Institute for Maternal and Child Health, IRCCS "Burlo Garofolo", Trieste, Italy awareness of the own level of the oral hygiene and knowledge of oral care.

Conclusions: Results of this survey underline the high necessity of educational programs regarding oral care in pregnant and puerpers women. A strict collaboration between medical figures (dentist, oral hygienist, gynecologist and obstetric) is strongly encouraged to spread the concept of prevention.

Keywords: education; oral health; oral hygiene; pregnancy; prevention.

Introduction

Pregnancy is a unique moment for a woman. The physical and psychological modifications correlated to gestation may affects many behaviors of woman's day life and can lead to underestimate or consider as secondary some aspects such as oral health [1].

Furthermore, oral cavity may be involved in paraphysiologic or pathologic changes due to the direct hormonal action of estrogens and progesterone on periodontal tissues, bacterial metabolism and immune response [2, 3]. Caries, enamel erosion, gingivitis and periodontitis are the most common pregnancy-related oral manifestation [1].

During pregnancy, an increased incidence of dental caries is strictly correlated to an augmented consumption of carbohydrates, variations in composition of saliva, frequent episodes of vomiting or gastro-esophageal reflux. These phenomena provoke a reduction of oral pH that creates an ideal environment for cariogenic bacteria if associated to a poor oral hygiene [4].

Risk factors of enamel erosion are similar to those of dental caries. Erosive lesions are more extended if tooth brushing is performed immediately after vomiting with an incorrect technique.

The incidence of gingivitis is very high considering that 35–100% of pregnant women develops gum inflammation even in absence of dental plaque; if correlated to a good level of oral hygiene, this condition is reversible and it resolves after childbirth [5]. The relation between periodontitis

and adverse pregnancy outcomes has been largely discussed [6, 7].

Several researches showed that in pregnant patients affected by periodontitis the diffusion in the bloodstream of periodontal bacteria [8] and products of inflammation (i.e., prostaglandin E2 [PGE2], tumor necrosis factor- α [TNF- α], interleukin [IL]-1, IL-6) may trigger an inflammatory reaction in the maternal-fetal unit [9, 10].

Some authors underlined that many of the risk factors for adverse outcomes of pregnancy are the same involved in periodontitis (smoke and stress are the most important for both situations), so other etiological factors have to be researched to identify a possible cause-effect relationship [11].

To avoid the development or worsening of these oral-related manifestations, the primary prevention should be the first step in the treatment of pregnant women [1]. However, at our knowledge, in the Northeast Italy there are not available informative programs or public trainings that deal this topic. Actually, the information regarding the impact of oral health on pregnancy progress, are given from the dentist or dental hygienist to the patient, individually. This is the reason why few data are available about the level of awareness in pregnant and puerpers women community.

Based on the above considerations, the aim of this study was to perform a survey on the degree of knowledge regarding oral health and its correlations with pregnancy in a sample of these category of patients.

Materials and methods

Design, participants and procedures

This cross-sectional study was conducted during 2015 at the Institute for Maternal and Child Health, IRCCS "Burlo Garofolo" located in Trieste, Italy. The research has been conducted for thesis purposes and has been approved by the General Direction of the institute. No formal ethics approval was required because of the observational nature of the research.

In 2015 Trieste had 1.342 newborns. 22.4% of these had a foreign mother. A remnant of about 1,000 patients represented the mean population of Italian newborns in the year.

A calculation of the sample size has been made considering a confidence level of 95% so that a group of 100 patients represented the final study population. Pregnant or puerpers women who came at the public hospital for routine obstetrics visits were consecutively recruited. An informed written consent was obtained from each patient to use data for the research that was conducted in agreement with the guidelines of the Helsinki Declaration as revised in 1975 and amended in October 2003.

The participants received an anonymous questionnaire and 100% of them has been correctly compiled and returned. The

document included a first part for collection of socio-demographic variables (age, educational degree, number of pregnancies, and period of gestation) and 24 multiple-choice questions belonging to six categories: personal oral hygiene habits, general knowledge about oral hygiene, knowledge about relationships between pregnancy and oral health, knowledge about development of oral pathologies associated to pregnancy, information about the child oral health and prevention, type of information received from health-care staff during pregnancy regarding oral health.

Items were randomly ordered to avoid suggesting or influencing the answers; the mean time of compilation was about 10 min.

Statistical analysis

SPSS software for MAC OS X (SPSS Inc., Chicago, IL, USA) was used to perform the data analysis. After testing the normality of the data using a Shapiro-Wilk test and the equality of variance among the datasets using a Levene test, parametric tests were chosen. The whole sample was firstly divided into subgroups based on age ranges (G1: 18–25 years; G2: 26–35 years and G3: >35 years) and then into subgroups based on the number of pregnancies (FP: first pregnancy; SP: second or more pregnancies). The difference of baseline demographic characteristics among subgroups G1, G2 and G3 have been tested using the ANOVA test for independent samples except for the variable "age" that was analyzed with the chi-square test. The difference of baseline demographic characteristics among subgroups FP and SP have been tested using the chi-square test except for the variable "age" that was analyzed with the *t*-test for independent samples.

Then, the ANOVA test for independent samples was used to intercept the differences of answers among G1, G2 and G3 groups with regard to oral habits and theoretical knowledge on oral hygiene.

Finally, the t-test for independent champions was used to intercept the difference of answers between P1 and P2 groups with regard to oral habits and theoretical knowledge on oral hygiene.

Results

One hundred percent of patients completed the question-naire (total=100 patients). The age of the participants ranged from 18 to 49 years, with a mean age of 33 years (SD \pm 6). Forty-six percent of the women declared to have a degree, 40% an high school certificate, 14% a secondary school certificate or less. Twenty participants were puerpers, 80 were pregnant and more than half of these were at their first pregnancy (59%). Tables 1, 2 show the descriptive statistics of the sample with regards to subgroups divided for age (G1, G2 and G3) and number of pregnancies (FP and SP), respectively.

Considering that the mean age of the first pregnancy for Italian mothers in the county of Trieste is about 33 years, the choice of the above mentioned age categories cut point has been made different experiences both from the

Table 1: Description of participants with regard to subgroups based on age range (G1: 18-25 years; G2: 26-35 years and G3: >35 years).

	Total (n=100)	G1 (n=10)	G2 (n=54)	G3 (n=36)	p-Value
Age, years, mean (SD)	33 (6)	22 (2.5)	31 (2.5)	39 (3)	0.049
Secondary school certificate or less, n (%)	14 (14)	3 (30)	7 (13)	4 (11.1)	ns
High school certificate, n (%)	40 (40)	7 (70)	14 (25.9)	19 (52.8)	0.034
Degree certificate, n (%)	46 (46)	0 (0)	32 (59.3)	14 (38.9)	0.036
Puerpers, n (%)	20 (20)	4 (40)	10 (18.5)	6 (16.6)	0.041
First pregnancy, n (%)	59 (59)	10 (100)	35 (64)	14 (38.9)	0.033
Second (or more) pregnancy, n (%)	41 (41)	0 (0)	19 (36)	22 (61.1)	0.041
1st Trimester, n (%)	2 (2)	0 (0)	2 (3.7)	0 (0)	ns
2nd Trimester, n (%)	14 (14)	2 (20)	6 (11.1)	6 (16.6)	ns
3rd trimester, n (%)	64 (64)	4 (40)	36 (66.7)	24 (66.7)	0.026

ns, not significant.

Table 2: Description of participants with regard to subgroups based on number of pregnancies.

	Total (n=100)	FP (n=59)	SP (n=41)	p- Value
Age, years, mean (SD)	33 (6)	31.2 (5.8)	35.3 (4.3)	ns
Secondary school cer- tificate or less, n (%)	14 (14)	9 (15.2)	5 (12.1)	ns
High school certifi- cate, n (%)	40 (40)	22 (37)	18 (44)	ns
Degree certificate, n (%)	46 (46)	28 (47.4)	18 (43.9)	ns
Puerpers, n (%)	20 (20)	15 (25.4)	5 (12.2)	0.037
1st Trimester, n (%)	2 (2)	0 (0)	2 (4.8)	ns
2nd Trimester, n (%)	14 (14)	8 (13.5)	6 (14.6)	ns
3rd trimester, n (%)	64 (64)	36 (61)	28 (68.3)	ns

FP, first pregnancy; SP, second or more pregnancies. ns, not significant.

obstetrics (O) and dental (D) aspect i.e., over 35 years of age a higher combined (O+D) experience is expected, while from 18 to 25 years a lesser one is expected from both points of view. Then, this stratification highlights if a particular slice of the patients has specific needing in terms of knowledge of oral health-related issues and would benefit of targeted programs of health promotion.

Answers to the questionnaire for the whole population and subgroups about habits and theoretical knowledge on oral health are reported in Tables 3, 4, respectively.

Discussion

An adequate level of oral hygiene is always desirable for maintenance of oral cavity health; this is even more important when physiological homeostasis of the mouth goes through important changes such as in pregnancy. Literature has extensively illustrated changes which occur during different phases of gestation [12, 13]. Moreover, several studies investigated consciousness of gynaecologists about the importance of maintenance oral health in pregnancy. In their study, Hashim and Akbar found that 95.4% of gynaecologists interviewed were confident with the association between oral health and pregnancy [14]; nevertheless they did not provide information to pregnant women and puerpers about oral health and benefits from fluoride assumption [15]. This finding is strengthen by the answers given to two questions about fluoride included in the questionnaire administered in this study; it emerged that only 12% of them had received suggestions regarding the necessity or not to assume fluoride during pregnancy and the same percentage of women had been informed about fluoride administration to the baby. It is known that fluoride assumption during pregnancy has an effect on amelogenesis of deciduous teeth to prevent risk of caries [16]. Nevertheless, Italian guidelines for antenatal oral health care state that fluoride administration during pregnancy is no more justified to enhance, in perspective, oral health of the unborn baby. Also the latest SINU (Società Italiana di Nutrizione Umana-Italian Society of Human Nutrition) recommendations assert that there is no needing for increasing of fluoride needs during pregnancy or breastfeeding [17].

Previous studies correlated the educational level of population to periodontal status care, in particular Yalcin et al., in their study, gave oral hygiene instructions to the entire population enlisted for the research; plaque index, gingival index and probing depth scores increased during first, second and third trimesters and when the clinical parameters and demographic variables were compared, only educational level and periodontal care seemed to be statistically significant (p < 0.05) [18]. In the present study socio-cultural level has been evaluated only through the schooling of the mothers. This choice was made because of

Table 3: Items and answers to the multiple-choice questionnaire in total population and subgroups about habits (G1: 18-25 years; G2: 26-35 years and G3: >35 years).

Question							Answe	er, n (%)
	Total (n=100)	G1 (n=10)	G2 (n=54)	G3 (n=36)	p- Value	FP (n=61)	SP (n=38)	p- Value
Daily oral hygiene habits								
What do you use for daily oral hygiene?								
- Toothbrush	98 (98)	9 (90)	53 (98.1)	36 (100)	0.017	59 (96.7)	39 (100)	0.042
 Interdental floss 	48 (48)	2 (20)	27 (50)	19 (52.7)	0.003	21 (34.4)	27 (71)	ns
- Mouthrinse	54 (54)	4 (40)	29 (53.7)	21 (52.3)	0.009	30 (49.1)	24 (63.1)	ns
 Other (interdental brush) 	4 (4)	0 (0)	2 (3.7)	2 (5.5)	ns	1 (1.6)	3 (7.8)	ns
How many times dental floss should be used daily?								
- 1 time/week	7 (7)	0 (0)	5 (9.2)	2 (5.5)	ns	3 (4.9)	4 (10.5)	ns
- It is not necessary	2 (2)	1 (10)	0 (0)	1 (2.7)	ns	2 (3.2)	0 (0)	ns
- At least 1 time/day	81 (81)	6 (60)	43 (79.6)	32 (88.8)	0.036	49 (80.3)	32 (84.2)	ns
- Only when I have something between the teeth	8 (8)	1 (10)	6 (11.1)	1 (2.7)	0.049	3 (4.9)	5 (13.1)	ns
How often do you usually perform dental routine visit	s?							
- 1 time/year	35 (35)	3 (30)	19 (35.1)	13 (36.1)	0.021	19 (31.1)	16 (42.1)	ns
- When I need dental treatment	35 (35)	5 (50)	20 (37)	10 (27.8)	0.038	24 (39.3)	11 (28.9)	0.037
- Every 3-6 months	28 (28)	1 (10)	15 (27.8)	12 (33.3)	0.001	17 (27.8)	11 (28.9)	ns
– Never	1 (1)	1 (10)	0 (0)	0 (0)	_	1 (1.6)	0 (0)	_
How many times toothbrush should be used daily?	. ,	` ′	` '	, ,		, ,	, ,	
- Only 1 time	0 (0)	0 (0)	0 (0)	0 (0)	_	0 (0)	0 (0)	_
- At least 2 times	97 (97)	9 (90)	54 (100)	34 (94.4)	0.001	59 (96.7)	38 (100)	ns
 Sometimes 	3 (3)	1 (10)	0 (0)	2 (5.6)	ns	2 (3.2)	1 (2.6)	ns
What is the most important moment for toothbrushin			* * *	, ,		` ,	. ,	
- In the morning	10 (10)	4 (40)	6 (11.1)	0 (0)	Ns	8 (13.1)	2 (5.2)	0.024
– After lunch	7 (7)	0 (0)	3 (5.5)	4 (11.1)	Ns	3 (4.9)	4 (10.5)	ns
- Before to go bed	77 (77)	5 (50)	41 (75.9)	31 (86.1)	0.041	45 (73.7)	32 (84.2)	ns
How do you usually clean your mouth after an episod		- ()	, ,	(,		, ,	(,	
I don't clean it	10 (10)	2 (20)	4 (7.4)	4 (11.1)	ns	6 (9.8)	4 (10.5)	ns
 Brushing teeth 	34 (34)	2 (20)	19 (35.1)	13 (36.1)	0.013	20 (32.7)	14 (36.8)	ns
 With water and/or sodium bicarbonate 	53 (53)	5 (50)	29 (53.7)	19 (52.8)	0.021	31 (50.8)	22 (57.8)	0.05
Possible pathologies	()	2 (2 1)	_, (,,,,	-, (,-,-,		- ()	(5,15)	
Do you see blood when you brush your teeth?								
- Often	19 (19)	3 (30)	6 (11.1)	10 (27.8)	ns	13 (21.3)	6 (15.7)	ns
– Never	4 (4)	1 (10)	2 (3.7)	1 (2.8)	ns	3 (4.9)	1 (2.6)	ns
- Sometimes	77 (77)	6 (60)	46 (85.1)	25 (69.4)	0.002	44 (72.1)	33 (86.8)	ns
What manifestation do you see in your mouth during	, ,		10 (0312)	25 (6)11)	0.002	(/ = /	33 (00.0)	
- Gingivitis	29 (29)	4 (40)	18 (33.3)	7 (19.4)	0.046	23 (37.7)	6 (15.7)	0.039
- Increase of saliva	3 (3)	0 (0)	2 (3.7)	1 (2.8)	ns	1 (1.6)	2 (5.2)	ns
- Epulis	2 (2)	0 (0)	1 (1.8)	1 (2.8)	ns	2 (3.2)	0 (0)	ns
- Change of taste	11 (11)	2 (20)	5 (9.3)	4 (11.1)	ns	6 (9.8)	5 (13.1)	ns
- Anyone	29 (29)	4 (40)	15 (27.8)	10 (27.8)	ns	14 (22.9)	15 (39.4)	ns

Values are given as n (%). FP, first pregnancy; SP, second or more pregnancies; ns, not significant.

the moment in which the questionnaires have been delivered. In fact, to avoid incomplete responses, due to the limited time the patients spent in the waiting room, a restricted list of questions has been selected. Results showed that the socio-cultural level was medium-high; in fact 46% had a degree and 40% a high school certificate.

Literature widely reported the importance of correct oral hygiene behaviour in preventing caries and/or periodontal problems in fact dentists and oral hygienists focus

their attention on provide patients an appropriate motivation using strict motivational strategies [19, 20]. In the present study, an analysis regarding oral hygiene habits, and also knowledge about possible pathologies or physiological modifications that may occur during pregnancy, has been made. Answers related to daily oral hygiene habits showed that almost all women (98%) uses toothbrush daily, but this percentage decreased considerably for the daily use of interdental floss (48%) or other oral

Table 4: Items and answers to the multiple-choice questionnaire in total population and subgroups about theoretical knowledge (G1: 18-25 years; G2: 26-35 years and G3: >35 years).

Question (correct/best answer)						Answe		
	Total (n=100)	G1 (n=10)	G2 (n=54)	G3 (n=36)	P- Value	FP (n=61)	SP (n=38)	p- Value
General knowledge about oral hygiene								
What is dental plaque? (A soft deposit)	28 (28)	4 (40)	15 (27.7)	9 (25)	ns	23 (37.7)	5 (13.1)	0.008
What does plaque cause? (Inflammation, halitosis, dyschromia)	28 (28)	5 (50)	16 (29.6)	7 (19.4)	0.046	19 (31.1)	9 (23.6)	0.031
What do bleeding gums mean? (Inflammation)	96 (96)	9 (90)	53 (98.1)	34 (94.4)	0.019	58 (95)	38 (100)	0.029
What is the cause of dental decay? (Bacterial activity)	63 (63)	8 (80)	37 (68.5)	18 (50)	0.038	42 (68.8)	21 (55.2)	0.021
How can you avoid tooth decay? (Brushing correctly 2 times a day and reducing sugar intake)	75 (75)	5 (50)	43 (79.6)	27 (75)	0.027	45 (73.7)	30 (78.9)	ns
Knowledge about pregnancy and oral hygiene								
Is it important to maintain great oral hygiene during pregnancy? (Surely)	96 (96)	8 (80)	53 (98.1)	35 (97.2)	0.037	58 (95)	38 (100)	0.049
Mother's periodontal disease may contribute to premature birth (True)	15 (15)	3 (30)	6 (11.1)	6 (16.7)	ns	9 (14.7)	6 (15.7)	Ns
Should you increase the number of dental visits during pregnancy? (Yes)	61 (61)	7 (70)	36 (66.7)	18 (50)	0.022	37 (60.6)	24 (63.1)	0.046
Is it possible to perform dental treatment during preg- nancy? (Yes, the best moment is the second trimester)	39 (39)	4 (40)	25 (46.3)	10 (27.8)	0.028	26 (42.6)	13 (34.2)	0.009
Can bacterial pass from mother's oral cavity to fetus? (Yes)	32 (32)	4 (40)	17 (31.4)	11 (30.5)	0.041	21 (34.4)	11 (26.3)	0.007
Information about the baby								
Is the number of deciduous and permanent teeth the same? (No)	84 (84)	8 (80)	48 (88.8)	28 (77.7)	0.012	50 (81.9)	34 (89.4)	0.044
When does the first deciduous tooth appear? (Around 6 months of age)	71 (71)	7 (70)	38 (70.3)	26 (72.2)	0.038	42 (68.8)	29 (76.3)	ns
When would you bring your baby at the dentist? (When all deciduous teeth appear)	41 (41)	5 (50)	23 (42.5)	13 (36.1)	0.050	30 (49.1)	11 (29.9)	0.010
If the baby receive fluoride systemically, he does not need fluoride topically (True)	76 (76)	9 (90)	35 (64.8)	32 (88.8)	0.032	44 (72.1)	32 (84.2)	ns
Information received from health care staff								
Have you ever received the suggestion to assume fluoride during pregnancy? (Yes)	12 (12)	1 (10)	7 (12.9)	4 (11.1)	ns	7 (11.4)	5 (13.1)	ns
Have you ever received the correct information about fluoride administration at the baby? (Yes, in detail)	12 (12)	0 (0)	6 (11.1)	6 (18.1)	ns	2 (3.2)	10 (26.3)	0.042

Values are given as n (%). FP, first pregnancy; SP, second or more pregnancies; ns, not significant.

hygiene devices such as interdental brush (4%). This finding agrees with the results obtained by Murphey [21]. Author reported that flossing is less common than tooth brushing among pregnant women, and this was associated with underestimation of the set of problems associated with gum bleeding. Conversely, when it was asked how many times dental floss should be use daily, 81% of interviewed women answered "at least one time per day", demonstrating that the theoretic knowledge about the proper manner to maintain good oral hygiene is not inadequate.

Poor oral care and periodontal disease are associated with preterm birth [22] and perinatal problems [23-25] but when pregnant women were asked about pregnancy and oral health, it emerged that their knowledge of the relevance of oral health was inadequate; in fact, although 96% of the sample was aware of the importance of maintain a great oral hygiene during pregnancy, 61% of patients thought that increasing number of dental visits during pregnancy could be useful, and only 15% of patients knew that periodontal disease may contribute to premature birth. Unfortunately, not only population is scarcely informed about therapies that may be performed during pregnancy, but also dentists and gynaecologists have no sufficient knowledge of guidelines concerning dental treatment during gestation [26]. An Australian study analysed dentist's knowledge about oral care during pregnancy; 185 dentists have been enrolled in this survey, 99% of them agreed about the importance of dental visit during pregnancy but only 20% agreed about that there is a good understanding of this topic among health professionals [27]. Furthermore, it emerged that dentists have an inadequate knowledge of the association between periodontal disease and birth outcomes [27]. To the question "Is it possible to perform dental treatment during pregnancy?", only 41% of the sample gave the correct answer (which was "Yes, best the second trimester"). This finding reveals the poor knowledge about dental treatments during gestation period. A study performed among dental residents in Nigeria about the knowledge on safety of dental treatments during pregnancy (in particular endodontic therapies) showed that the cohort of dentists considered was aware of the importance not to defer dental treatments till after delivery in case of pain and infections. However, there was still lack of knowledge of the correct positioning of pregnant patients on the chair and on the best timing of treatment [28].

Based on the guidelines supported by the American Dental Association, pregnant women are encouraged to continue dental visits during pregnancy, and if the last control dates back to more than 6 months, or if any oral or dental problem arises, a dental visit is strongly recommended [29].

Among the sample considered in this study, 35% of women declared to perform at least one dental visit per year, 35% went to the dentist when they retained to need dental treatment, 28% every 3–6 months and, only 1% of women affirmed that they did not usually go to the dentist for routine controls.

There are some limitations in this survey, such as the absence of an objective evidence of the oral status and the choice of a restricted list of questions due to the limited compilation times in the waiting room. However, results represent an important basis to justify the use of public resources in the treatment of this vulnerable population.

Conclusions

In conclusion, among this group of pregnant and puerpers patients, knowledge about the relation between pregnancy and oral health is medium-low without significant differences between the study groups.

Since a large number of women still underestimate this correlation and its impact on the pregnancy course, this highlights a lack of primary prevention on oral health during all the period of gestation.

Information programmes about oral health during pregnancy should be encouraged and improved in the northeast Italy community. In perspective, the second step of this community study will be that of creating a clinical flow for these special needs group of patients. This should include the possibility of an initial dental assessment for all

pregnant women with the aim of informing future mothers on the relations between pregnancy and oral health (primary prevention) and of intercepting and treating mothers with therapy needing (secondary and tertiary prevention).

Future objectives include the promotion of prevention campaigns for women in fertile age, institution of community courses for oral health education and a more strict collaboration between medical figures (gynecologists, obstetricians, dentists and dental hygienists).

Let women understand that the maintenance of proper oral health it is not only an advantage for themselves but also for the unborn child may strength the motivation of future mothers in preserving a good oral health.

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Ethical approval: The research has been conducted for thesis purposes and has been approved by the General Direction of the Institute (Institute for Maternal and Child Health, IRCCS "Burlo Garofolo" located in Trieste, Italy). The study has followed the guidelines of the Helsinki Declaration of 1975, as revised in 1983. No formal ethics approval was required because of the observational nature of the research.

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