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Belief towards caesarean section: A community based study of male partners in Ebonyi State, Nigeria

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Abstract

Introduction: Caesarean section is a surgical procedure used in delivering a baby by incising the abdomen and uterus of the mother. In a typical Nigerian culture, it is seen as a method to deliver a baby when the mother is not strong. Based on this premise, most men show a very negative attitude towards the procedure. This negative attitude may translate to a belief which might not be wholesome.

Objectives: To assess the belief of male partners towards caesarean section.

Methods: A sample of 400 male partners was investigated. The instrument used for data collection was a 22-item valid and reliable ($\alpha = 0.98$) questionnaire developed by the researchers. The questionnaire was administered to the participants on face-to-face approach. Data were analysed using percentages, mean, standard deviation, analysis of variance, *t*-test and multiple regression analysis.

Results: Results data showed that the male partners studied had negative beliefs towards caesarean section. Significant differences existed in the belief of the respondents towards caesarean section as it relates to their age, level of education, occupation, religion and location of residence (p < 0.05). Using a stepwise multiple regression model, all the socio-demographic variables studied played out to be significant (p < 0.05) predictors of belief towards the subject matter.

Conclusion: The male partners have negative belief towards caesarean section and the personal characteristics of the subjects predicted their belief towards the subject matter. The existing phenomenon can be changed through health campaigns and education using healthcare workers and health educators.

Keywords

Belief, cesarean section, male partners

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Introduction

Misconceptions regarding caesarean section (CS) have been reported especially in traditional African settings. These misconceptions have led to an increase in maternal mortality as well as stillbirth when pregnancy is characterized by medical complications. It is still seen by most men as a curse and punishment to the woman and the family. In developing countries like Nigeria, CS is a last resort used for child delivery for pregnant women and it is perceived as a death warrant. CS is a surgical delivery of the fetus through an incision of the abdomen and uterus, that is, laparotomy and hysterotomy. It may be seen as fetus delivery through a surgical incision on the anterior uterine wall. If well planned it

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minimizes the risk of prolapsed, vaginal injury and bleeding. In certain conditions, impulsive CS may lead to complications such as prolonged labour, foetal distress, cord prolapse, uterine rupture, placental problems like placenta praevia, placenta accreta, abnormal presentation like breech or transverse positions, failed instrumental delivery, macrosomia and contracted pelvis.⁵

Delivery through CS is could be a consensus idea in developed countries, probably due to the current safety of the procedure for both the mother and baby. This may be the reason why the CS rate in developed nations is on the increase. For example, Latin America and the Caribbean currently have the highest (40.5%) CS rate, followed by North America (32.3%), Oceania (31.1%), Europe (25%) and Asia (19.2%). Due to the progress in medicine, the procedure has become safer over the years; with many developed nations having rates well over the World Health Organization (WHO) 15% recommendation. Globally, CS rate is estimated at 15%, with an average rate of 3.5% in Africa.⁶ In Nigeria, authors recorded an 11.6% CS rate in the University College Hospital Ibadan between 2000 and 2005.7 National Population Commission (Nigeria) and International Classification of Functioning, Disability and Health (ICF) International⁸ observed that population based CS rate has not increased significantly since 2008 with only 2% of CS delivery which remained unchanged in 2013. Authors⁹ revealed a population-based CS prevalence of 2.1% in Nigeria which is far below the 15% recommended by the WHO. It is regrettable to note that Nigeria is still struggling with the acceptance of issues relating to CS notwithstanding the inherent benefits that could be derived by women that face caesarean delivery.

The yearly maternal mortality rate as a result of unhealthy perceptions about CS continues to increase in rural areas. ¹⁰ For example, WHO statistics revealed that more than half a million women die annually from complications of pregnancy and childbirth and roughly 303,000 women die during and after pregnancy and childbirth. ¹¹ Majority of these deaths occur in low-resource settings like Nigeria. ^{12,13} In 2010, Nigeria contributed to approximately 14% (40,000) of maternal death globally and in 2011, Nigeria's maternal death rate rose to 1000–1500 maternal death per 100,000 births which was adjudged as the highest rate of maternal death globally. ^{14,15} The cause of the increase in maternal mortality could be attributed to the belief men hold about delivery through CS since most of the deaths could have been prevented through an obstetric procedure such as CS. ¹⁶

Belief is the feeling of being sure that something exists or is true. Belief one holds affects one's behaviour and decisions in taking action on health issues. For example, World Health Organization¹⁷ observed that in developing countries most men are still reluctant to accept the efficacy of CS despite its ability to save a life. In most African communities including Nigeria, the decision to seek care is culturally in the hands of the man. ¹⁸ Nigeria's current maternal mortality rate of 630/100,000 live births is indicative that critical

aspects of healthcare delivery continue to fail women.¹⁹ In Uganda, researchers²⁰ observed that CS was regarded as a misfortune or curse and God's punishment to a given individual or family. Authors²¹ in Nigeria noted that some men hold the opinion that caesarean delivery is a punishment for marital infidelity or might be for the financial benefit of the doctor while some believe it is the devil's work. These negative perceptions about CS were identified to exist among rural communities in Southwest Nigeria.²² Researchers^{20,21} had reported the perception of people that CS reduces fertility in women and limits their ability to bear children. Some believe that the procedure is for the rich because of the cost of procuring the procedure. Some also perceive that CS is common among wives of uncircumcized males, whose uncircumcized nature is believed to cause cancer of the reproductive system which leads to CS.^{20,21} These beliefs in developing countries might lead to gross under-utilization of the procedure and could lead to a large burden of obstetric morbidity requiring resolution by CS.

The belief towards CS might be predicted by some demographic variables like age, education, occupation, religion and location of residence of study subjects. For instance, to confirm the above suspicion, in Uganda, it was revealed that 46-year-old men had the wrong belief that CSs are for wives of uncircumcized men and rich civil servants.²² A positive association between belief towards CS and socio-demographic characteristics such as age, education, religion, occupation and location has been reported among southern Asia and sub-Saharan African men.²³ A study in Southwestern Nigeria²⁴ had earlier reported that the educational level of men had no influence on the acceptability of the procedure of CS. Researchers¹⁶ found that men's religious ideologies significantly related to CS refusal in Nigeria. It has been reported that more than 75% of all CS procedures in Nigeria are linked to obstetric emergencies rather than by choice.²⁵

In developed countries, the case of CS is on the increase unlike in developing nations.²⁶ Most men in developing countries often think that the CS procedure signifies reproductive failure. It is usually bad news for them when told that their wives will be delivered through CS. For those that will eventually give their consent, it is done with so much unnecessary delay. This delay occasioned by counselling and consenting to a CS is important in clinical practice in situations like foetal distress and antepartum haemorrhage requiring emergency CS. The aversion to the surgery is often encountered, sometimes responsible for delays in seeking or acquiescing to medical care. This is undesirable, given the attending high level of maternal mortality arising from preventable causes of death in society.^{27–29}

There is a dearth of literature on male partners' belief towards CS in the area under survey. The few available ones focused on female partners and failed to capture male counterparts' views. For instance, a study³⁰ conducted on the perception of CS among pregnant women in a rural missionary hospital did not capture the view of men in this regard. It is

common knowledge that a woman's acceptance of CS may be significantly dependent on the husband's consent as the head of the family. Even with birth plans in place, many Nigerian women opt to deliver with an unskilled birth attendant in a setting other than a hospital.

A study¹ revealed that in Abakaliki, Ebonyi state, women who had CS did not have good reception at home from their relations. It has been observed in many cases where most men abandoned their wives in the hospital just because they delivered through CS. In most cases, on sighting the men in the hospital, the men would claim that they were taxi drivers hired by the family of the woman to facilitate escape. This behaviour oftentimes creates 'bad blood' among families. Therefore, there is a need to study the belief of male partners towards CS in Ebonyi state, Nigeria at least to have baseline data upon which future researchers would take off. Thus, the main purpose of this study was to assess the belief towards CS among male partners in Ebonyi state, Nigeria.

Hypotheses

To establish whether there are differences in the outcome variable (belief towards CS) among male partners studied; the independent variables of age, educational level, occupation, religion and location of residence of participants, five hypotheses were postulated and tested on each of the independent variables.

In 1950, there emerged from the United States Public Health Service a theoretical framework based on social theory to help understand behavioural patterns.³¹ This approach has been frequently applied to study health behaviour, which might include belief towards CS and is known as the Health Belief Model (HBM). From its original conceptualization, variations to the model have proliferated; usually resulting in more detailed models.³² Theories and frameworks have also been derived from the HBM. The most important theoretical approaches used are the Social Learning Theory, 33,34 later renamed as the Social Cognitive Theory, the Theory of Reasoned Action,³⁵ the Theory of Planned Behaviour,³⁶ and more recently, the Interactional Framework.^{37,38} Since belief in any health issue is based on the behaviour of the subject and the social cognition of the importance of the health issue, the HBM fits into the frame of the study.

According to cognitive theories, which the HBM forms part of; the roles of subjective rationales for health-related issues are a function of the subjective values of an outcome and of the subjective expectations that a particular action will achieve that outcome. In its original formulation, the HBM hypothesized that health-related actions depend upon the simultaneous occurrence of three classes of components: (1) the existence of sufficient motivation to make health significant, (2) the belief of a perceived threat to health and (3) the belief that following a particular health recommendation would be beneficial in reducing the perceived threat.^{39–41} The

relationship between these components and behaviour is held to be mediated by demographic factors. The demographic factors may include but are not limited to, age, educational level, occupation, religion and location of residence as was included in this study.

When it was applied, the predictive power of HBM for explaining reproductive and sexual health risks has been inconsistent. The HBM has been criticized because of its inherent conceptual problems. 42–44 Some of the most serious are the failure to consider adequately the bases of variation in an individual's ability both to evaluate the potential consequences of action and to utilize these evaluations, and that the cost-benefit perspectives may be ill-suited for explaining the belief of male partners towards CS.

Methods

Participants and setting

Between June and September 2021, this community-based cross-sectional survey was carried out among 400 male partners of Ebonyi state extraction drawn from two out of three senatorial zones. The sample was calculated using the Yamane⁴⁵ formula for determining sample size as follows:

$$n = \frac{N}{1 + N(e)^2}$$

Where n = sample size

N = number of people in the population = 1,165,032

e = allowable error (%) = 5% = 0.05

Substituting figures in the formula

n = 1,165,032

 $1+1,165,032(0.05)^2$

= 1,165,032

1 + 1,165,032 (0.0025)

= 1,165,032

1 + 2912.58

= 1,165,032

2913.58

n = 399.8627... approximately 400.

To select the sample already determined, the multistage sampling procedure was adopted. In the first stage, the researchers identified already existing three senatorial zones in the state. The second stage involved selecting two zones out of the three zones. The third stage involved the selection of 200 households in each zone sampled in the second stage. In these households, an eligible male couple was purposively sampled and studied. The sample is in line with the rule of thumb^{46,47} which suggests that when the population of a study is up to one million or is in several thousand, a proportion of 1% or less is ideal to be used.

Ethical approval

Ethical approval was waived by the Ebonyi State University Medical School Research Ethics Committee because the study was not conducted in the laboratory using human subjects. Written informed consent was obtained from the participants and the legally authorized representatives of illiterate participants before the initiation of the study.

Inclusion criteria

All male partners who must have had at least one child at the time of the survey were qualified to be included in the study.

Exclusion criteria

Male partners whose wives have not nurtured a pregnancy were excluded from the study.

Research design

The community-based cross-sectional survey used a structured questionnaire developed by the researchers, entitled: Belief towards Caesarean Section Questionnaire (BCSQ) which consisted of 22 items arranged in two sections, A and B. Section A contained five items that elicited information on age, educational level, occupation, religion and location of residence of the research participants. Section B comprised 17 items which gathered data on beliefs towards CS. The research participants were required to indicate on a four-point rating scale of strongly agree, agree, disagree and strongly disagree.

Five experts in Health Education and Nursing Science from two institutions of higher learning in Ebonyi state were used for validating the BCSQ. Thirty male partners in Ebonyi South senatorial zone, not included in the study, were used for the test of reliability. Cronbach's α procedure was used to test the reliability of the instrument and the data yielded a very high coefficient (α =0.98) based on an already suggested judgment.⁴⁴

Variables

Outcome variables

The CS scale comprised 17 items which were scored using a four-point scale (1 = strongly disagree to 4 = strongly agree) with higher scores indicating negative belief or unhealthy belief. For analysis, these items were summed to create a continuous scale which ranged from 1.00 to 4.00.

Explanatory variables

Explanatory variables included five demographic variables including age, educational level, occupation, religion and location of residence of participants.

Procedure

The consent to use the research participants for the research in each senatorial zone included in the study was obtained before data collection. A note with an explanation of the research purpose, method of response and assurance of anonymity was attached to each copy of the BCSQ. Four hundred copies of the BCSQ were administered on the research participants in their respective homes. The researchers and their research assistants stayed with the research participants while they were completing the questionnaire copies. This method was adopted to avoid any possible interaction during the process of responding to the questionnaire. The process of responding and returning copies of the BCSQ by each respondent lasted for about 30 min.

Statistical analysis

The completed copies of the BCSQ were examined for completeness of responses and copies with incomplete responses were discarded. Out of 400 copies of the BCSQ administered, 397 copies representing about 99.3% return rate were used for analysis. Data were analysed using percentages, mean and standard deviation to describe the respondents' demographic characteristics and beliefs towards CS. In describing the belief of the male partners, a mean value of 2.50–4.00 implied negative or unhealthy belief and a mean below 2.50 was adjudged positive belief. Standard deviation checked the variability of the responses. The cut-off point for the study was reached by adding up the scores assigned to the response options and dividing the sum by the number of the response options as follows:

$$\frac{4+3+2+1}{4} = \frac{10}{4} = 2.50$$

t-Test statistic was used to analyse data to ascertain whether any difference existing in the belief of respondents as it relates to the location of residence was significant. On the hand, analysis of variance (ANOVA) was used to establish whether the differences observed in the belief of the participants as it relates to age, educational level, occupation and religion were significant. Post hoc analysis, using the Scheffe method, was run to identify the source(s) of any difference. Furthermore, a regression model was used to check how the respondents' personal variables predicted belief towards CS. An α level of 0.05 was set for the entire test. All data analyses were done with International Business Machine Statistical Package for Social Sciences version 25.0 for windows.

Results

Data in Table 1 show that participants (35.5%) in the age group 31–40 years are more in number than the number in

Table 1. Demographic characteristics of respondents (N=397).

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Variables	Number	Percentage
Age (years)		
20–30	82	20.7
31-40	141	35.5
41–50	97	24.4
51 and above	77	19.4
Total	397	100.0
Educational level		
No formal education	106	26.7
Primary education	98	24.7
Secondary education	131	33.0
Tertiary education	62	15.6
Total	397	100.0
Occupation		
Farmer	110	29.0
Civil servant	99	24.9
Trader	107	27.0
Artisan	76	19.1
Total	397	100.0
Religion		
Christianity	166	41.8
Islam	109	27.5
Tradition	122	30.7
Total	397	100.0
Location of residence		
Urban	178	44.8
Rural	219	55.2
Total	397	100.0

the other age groups. Analysis of the educational level of the respondents indicates that most (33.0%) respondents have attained secondary level of education, most of them; even though less than one-third (29.0%) are farmers; greater (41.8%) numbers are Christians and more than half (55.2%) are rural dwellers.

Results in Table 2 show that all the CS belief statements have above 2.50; the criterion mean set for this study. However, CS is for lazy women (2.72 ± 1.11) , CS is for those women whose husbands are uncircumcized (2.69 ± 1.13) and CS is for those women who cannot fast and pray (2.69 ± 1.06) have the highest mean scores. The overall mean (2.63 ± 0.77) is also above 2.50 indicating that male partners in Ebonyi state have negative beliefs towards CS. The standard deviations show that the responses do not differ so widely.

Data in Table 3 show the summary of the *t*-test and ANOVA analysis on the belief of male partners towards CS as it relates to respondents' demographic characteristics. The data show that significant differences exist in the belief of the respondents towards CS as it relates to all the demographic variables (p < 0.05).

Results in Table 4 show that the multiple regression (*R*) value for age is 0.245 implying a positive relationship and

while the t-value=23.548, the p-value is less than p=0.05 indicating that there is a significant relationship between belief towards CS and the age of the subjects. The value of regression weight β =0.183, which accounts for 18.3% variance in the model indicates a very low predictive value of belief towards CS as it relates to the age of the subjects. The religion of the subjects tends to contribute 35.8% in the model indicating a low predictive index of belief towards CS. The relationship between other indices of characteristics of the participants and belief towards CS is also significant showing that demographic characteristics of the subjects could predict belief towards CS, albeit in varying dimensions.

Discussion

Demographic characteristics of respondents

Results in Table 1 indicated that there were more male partners within the age group 31–40 years, most of the respondents had no formal education, majority were civil servants, there were more Christians compared to other religions, majority of the respondents were rural dwellers. In a typical Nigerian society, the reproductive age for men may normally cluster around 31–40 years when they are very active, therefore, this finding is not out of place. However, most of these men had no formal education. The history of the present-day Ebonyi State, Nigeria, is associated with illiteracy; hence this finding was not amazing but expected to corroborate the findings of a previous study. 14 In addition, the area where the study was conducted is associated with farming contrary to the finding in which most of the men were civil servants showcasing an interesting scenario. There were more Christians than other religious worshippers in the study setting. This was an expected finding based on the current 'born again' movement not only in Ebonyi state but across the globe. That there were more rural dwellers than urban dwellers was an anticipated finding since most people, including men, are attracted to the rural setting contrary to what is obtainable in other states in Nigeria; where most people migrate to urban areas, maybe, because of the presence of modern social amenities that are lacking in the rural setting.

Belief towards CS

Results in Table 2 showed that the male partners studied had unhealthy beliefs towards CS. The reason for this result could be attributed to the fact that in Ebonyi state, women who have had a caesarean did not have good reception at home from their relations. Hence, no man would like their wives to be rejected. This finding tends to lend credence to a previous finding that revealed negative beliefs towards CS among rural communities in Southwest, Nigeria. This finding is echoed in other studies in Ilesha, Nigeria and Uganda whose findings revealed that men perceived CS as a misfortune or curse, God's punishment to a given individual or family.

Table 2. Mean and standard deviation on belief of male partners mean towards caesarean section.

S/N	Belief statements	Mean	SD	Dec.
1.	CS is a curse	2.58	1.16	NB
2.	CS is for the rich people	2.69	1.13	NB
3.	CS is for lazy women	2.72	1.11	NB
4.	CS is for those women whose husbands are uncircumcized	2.69	1.13	NB
5.	CS is for doctors' monetary benefits	2.65	1.12	NB
6.	CS is God's punishment to the woman and the family	2.65	1.09	NB
7.	Women who undergo CS may die	2.65	1.07	NB
8.	CS is being carried out to deny men sex	2.62	1.94	NB
9.	CS is done due to the incompetence of the health workers	2.59	1.03	NB
10.	CS reduces the woman's fertility	2.63	1.03	NB
11.	CS causes bladder problems	2.62	1.05	NB
12.	CS limits the number of children one can have	2.61	1.03	NB
13.	Caesarean delivery leads to family breakups	2.58	1.06	NB
14.	Caesarean delivery is conducted to avoid severe pain and vaginal tears	2.57	1.07	NB
15.	After CS a woman becomes really handicapped	2.58	1.07	NB
16.	CS is for educated women	2.62	1.06	NB
17.	CS is for those women who cannot fast and pray	2.69	1.06	NB
	Overall	2.63	0.77	NB

CS: caesarean section; NB: negative belief.

More so, some people suggest that caesarean delivery reduces the fertility among women and limits their ability to bar children number of children. Some people also adduce that CS is for the rich, especially the civil servants and that caesarean delivery is very common wives of uncircumcized men whose uncircumcized nature is believed to cause cancer in the reproductive system which leads to CS. ^{22,21} These are unhealthy beliefs which are common in developing nations, including Nigeria where Ebonyi state is situated. The beliefs are capable of escalating to gross underutilization of the procedure that could malign the reproductive security of the women.

Differences in belief towards CS

Results in Table 3 revealed that the differences in beliefs towards CS as it relates to socio-demographic variables of age, level of education, occupation, religion and location of residence of participants were significant (p < 0.05). These findings are in agreement with a previous study²³ which reported significant differences in the belief towards CS of study subjects as it relates to the socio-demographics of study subjects in southern Asia and sub-Saharan Africa. These findings are not, however, consistent with a previous study in Southwestern Nigeria²⁴ where the educational level and other personal characteristics of men did not influence the acceptability of the procedure of CS.²⁴ The differences in the findings could be attributed to the difference in the background of the research participants studied. However, the findings are in line with a study¹⁶ which reported that men's religious ideologies were significantly related to CS in Nigeria. Therefore, knowing the spiritual milieu in which these men claim to operate, health workers should organize outreach programs in both rural and urban communities to enlighten men against an unhealthy belief system that could affect them as regards CS and other health matters.

Predictors of belief towards CS

Results in Table 4 examined the socio-demographic characteristics that could predict belief towards CS using stepwise multiple regression. The predictors added to the equation of regression include age, level of education, occupation, religion and location of residence. The results indicated that all the personal characteristics were significant (p < 0.05) predictors of belief towards CS. The implication of these findings points to the need for family and reproductive education programs capable of positively influencing the belief of the male partners towards making healthy decisions towards CS.44 The education given to these men may probably afford them the confidence for making healthy and wise decisions towards CS. Similarly, education might also empower men to reject some sociocultural affinities that influence their belief towards making healthy decisions concerning CS and other reproductive health matters. Programs like integrating spiritual care in the health system using religious health educators and community healthcare workers to provide educative programs to guide the men's activities and perhaps use their influence to bridge the gap between CS and the prevalent socio-cultural norms that are at odds with men's belief towards CS.

The findings reported in this study might not be used in making across-the-board conclusions concerning other groups of men in Nigeria and somewhere else; that may be

Table 3. Summary of t-test and ANOVA analysis on belief of male partners towards caesarean section.

Variables	N	Mean	SD	Obtained value	p Value
Age					
20–30	94	2.38	0.80		
31-40	141	2.62	0.71	F=11.276*	0.000
41–50	97	2.57	0.78		
51 and above	77 ^a	3.04	0.69		
Educational level					
No formal education	129ª	2.84	0.68		
Primary education	115ª	2.65	0.71	F=6.934*	0.000
Secondary education	102ª	2.54	0.82		
Tertiary education	63	2.34	0.87		
Occupation					
Farmer	106ª	2.69	0.71		
Civil servant	115ª	2.08	0.69	F=44.972*	0.000
Trader	111	2.76	0.67		
Artisan	77 ^a	3.19	0.59		
Religion					
Christianity	166ª	2.26	0.77		
Islam	121	2.81	0.71	F=39.482*	0.000
Tradition	122	2.96	0.62		
Location of residence					
Urban	190	2.41	0.82	t = 5.478*	0.000
Rural	219	2.82	0.68		

ANOVA: analysis of variance.

Table 4. Summary of multiple regression analysis of belief of male partners towards caesarean section and demographic characteristics of respondents.

Variables ^{a,b}	R	R ²	β	t Value	p Value
Age	0.245	0.060	0.183	23.548*	0.000
Educational level	0.220	0.048	0.161	34.187*	0.000
Occupation	0.282	0.080	0.205	23.712*	0.000
Religion	0.386	0.149	0.358	22.246*	0.000
Location of residence	0.262	0.069	0.407	16.774*	0.000

^aDemographic characteristics (predictor).

dissimilar to a large degree in every area of life including social and economic situation. The men studied may represent a significant group of the population of Nigeria and the information gathered would help plan potential reproductive and other health-related programs in schools in Nigeria and may be in other nations in sub-Saharan Africa.

A structured questionnaire was used in collecting data for the study. There was no form of control by the researchers over the information supplied by the participants. This lapse natural in survey research may have prejudiced the conclusion of the study to any bearing. The number of participants used in the study could be regarded as a microcosm of the residents, which may have also affected the study's findings. Comparative studies need to be carried out using male partners in other parts of Nigeria.

Conclusion

In the face of the foregoing, it is safe to conclude that in Ebonyi state, male partners have negative beliefs towards CS and age, education, occupation, religion and location of residence were significant predictors of belief towards

^aSources of difference.

^{*}Significant at p < 0.05.

^bDependent variable (belief towards caesarean section).

^{*}Significant at p < 0.05.

the subject matter. The existing trend can be improved if healthcare workers, school teachers, pharmacists and health educators provide health education and proper counselling to men using campaigns and creating awareness on family and reproductive health. More so, it is necessary that reproductive health programs targeting the male population be designed to assist them to make positive decisions in their choice relating to reproductive and other family health matters, including CS.

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Ethical approval

Ethical approval was waived by the Ebonyi State University Medical School Research Ethics Committee because the study was not conducted in the laboratory using human subjects.

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Informed consent

Written informed consent was obtained from the participants and the legally authorized representatives of illiterate participants before the initiation of the study.

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