Protocol

Identifying predictive factors and developing evidence-based guidelines for promoting respectful maternal and newborn care: a mixed method multiphase study design

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ABSTRACT

Background: Mistreatment of women during pregnancy and childbirth by healthcare workers is a common issue in both private and public sector health facilities in India. Improving the quality of maternity care in these sectors is crucial for promoting institutional births and ensuring positive birth experiences. This study aims to develop guidelines for respectful maternity care (RMC) in India through a multiphase quantitative and qualitative study.
Methods: The study will utilize a mixed methods multiphase design, which involves collecting, analyzing, and integrating both quantitative and qualitative data. This approach follows the principles of pragmatism paradigm, where the integration of different approaches enhances understanding. The quantitative data will be used to expand and explain the qualitative data collected in the first phase. The integration of both types of data will contribute to the development of new RMC guidelines.
Conclusions: This study is the first of its kind in India to develop comprehensive RMC guidelines based on a multiphase study. By exploring the experiences of Indian women regarding disrespect and abuse (D&A) during childbirth and its determinants, the study will provide valuable insights for guideline development. The integration of quantitative and qualitative approaches in the mixed method design will address potential limitations and provide a more comprehensive understanding of the subject.

Keywords: Respectful maternal care, Respectful newborn care, Mixed method study design

INTRODUCTION

Mistreatment of women by healthcare workers during pregnancy and childbirth is commonly reported from both private and public sector health facilities. Efforts to expand institutional births in India would benefit from strengthening the quality of maternity care in both sectors so that evidence-based maternity care is provided, and positive births experiences are ensured. Labor and delivery are sensitive and vulnerable period in a women's life. Pain, insecurity and threat are the cause of vulnerability of women in labour and delivery. Disrespect and abuse

(D&A) is a global phenomenon that affect women's decisions on the type of delivery method, childbirth experience and mental health condition. The World Health Organization (WHO) has issued a statement on disrespect and abuse (D&A) during childbirth, which emphasized the importance of respectful maternal and Newborn care (RMNC) and women's rights during pregnancy and childbirth, and the need for immediate attention to this global phenomenon.[1] Bowser and Hill (2010) presented 7 categories for D&A including physical abuse, discrimination, non-consented clinical care, non-dignified care, non-confidential care, abandonment of care, and detention in health facilities.[2]

D&A during labor and childbirth have increased over the past decade.[3] The review of relevant articles shows that some multifactorial causes including lack of professional support for health care staff, hierarchical work relations, excessive workload, inadequate staff at different levels, and poor infrastructures can contribute to the increased prevalence of D&A.[2,4] Evidence suggests that women may not seek maternity care and may be unwilling tohave normal-vaginal delivery (NVD), if they experience D&A during maternity care.[5,6] D&A can violate human rights and exacerbate women's mental health conditions such as sleep disorders and post-traumatic stress disorder (PTSD).[7] The WHO emphasized the important role of RMNC in statements entitled "RMNC improves lactation" and "recommendations for improving the childbirth experience".[8,9]

Despite the abundance of research on D&A prevalence, few studies have investigated effective measures for reducing and preventing the prevalence of D&A behaviors during labor and birth. The identification f both aggravating and mitigating factors of negative and abusive care provider-patient relationships has been neglected in health systems. Studies have been conducted to assess the role of D&A in childbirth and to assess women's D&A experiences during childbirth.[10-12] No rigorous studies have been conducted to use a standard measurement tool to assess and manage RMC. Mixed methods research can provide the best approach to identify the indicators of D&A while women's experience is explored and considered in developing new guidelines. The mixed method approach supports the integration of different and even contradictory theories, approaches and methods and helps the researchers better understand various concepts. Regarding the importance of labor and birth, and the impact of D&A on women's decisions on the type of birth method, it is necessary to assess the status of D&A and its related factors to improve RMNC behaviors.

Novelty

This study will be the first of its kind, designed to develop RMC guidelines in India based on a quantitative qualitative multiphase study. This study is aimed to develop tool to assess respectful maternal and Newborn care in health care facility. To determine the status of disrespect, abuse, respectful maternal and Newborn care experience by pregnant women in health care facility. To explore the mother's perspectives about determinants of disrespect and abuse during childbirth.

Review of literature

The concept of "safe motherhood" in delivery is limited to physical safety, while delivery has also deep cultural and personal significance for both the women and their family. Thus, the concept of safe motherhood should transcend beyond issues such as prevention from disease or mortality, and other concepts including respecting human rights such as respecting independence, esteem and respect, choices and preferences, as well as solidarity with women should also be considered.[3] Lack of privacy, which includes disregard for visual privacy, lack of confidentiality, insufficient attention to cultural and religious issues in terms of gender differences between parturient women and medical staff, upset about the presence of additional medical staff in the woman's bedside and multiple examinations should be limited. World Health Organization (WHO) has emphasized limitation of vaginal examinations to the degree of necessity or every four hours to diagnose long labour.[1] Every woman is entitled to receiving quality healthcare with characteristics including respect, free of violence and discrimination, with sufficient health information in pregnancy, labour and delivery.[5] Health equity is one of the components of respectful maternal care in which pregnant women should not be discriminated against by race, or cultural or social differences . Inequities are created when barriers prevent individuals and communities from accessing these conditions and reaching their full potential. Health disparities are one way we can measure our progress toward achieving health equity.

The disrespect and abuse (D&A) outcomes are known as public health concerns worldwide.[5] D&A in the delivery room is associated with negative experience of delivery, poor maternal care quality index and a main barrier to achieving maternal health outcomes.[6] In spite of the considerable achievements in maternal and child health, there is still a large number of maternal and neonatal mortality worldwide. It seems that D&A is a key potential obstacle hindering access to delivery facilities and skilled care providers. Goal 3.1 of the sustainable development goals by 2030 developed by United Nations is to ensure healthy lives and promote well-being for all at all ages: reduce the global maternal mortality ratio to less than 70 per 100,1000 live birth.[8-13] In order to achieve this, all stakeholders and relevant institutions should consider respectful pregnancy and delivery care services as a key solution to reducing maternal mortality. However, there is no comprehensive guideline with regards to RMNC. In a study by Down et al to explore the efficacy of respectful maternity care policies for women utilizing delivery services, the evidence with moderate reliability indicated that the interventions such as training change of attitudes and values, launching quality improvement teams,

mentorship program, holding educational workshops in the community, mediation and conflict resolution, and consultation with those suffering from abuse and disrespect, training communication skills, establishing sympathy, support during the delivery, holding educational sessions during pregnancy, and familiarizing women with their rights could enhance positive maternal experiences. Furthermore, respect-associated policies would enhance quality care as well.[14]

A guideline is a written plan which specifies the methods and standards that should be followed in examination or provision of care for a special condition. There is no comprehensive guideline in WHO or provided by other countries for RMC. Determination of RMNC status during delivery in the quantitative phase, interpretation of the perception of women who have given birth about the determining factors and aspects of RMNC in the qualitative phase, and combination of the results of the quantitative and qualitative phases in the combination stage could be useful in providing a guideline for promoting RMNC in maternity wards. The increasing growth of cesarean section rates highlights the urge to develop a supporting guideline to improve the quality of maternity care, reduce D&A during childbirth, and improve women's childbirth experiences. Development of such a guideline would eventually contribute to enhancing the quality of care and reducing D&A in delivery.

Specific objectives

Primary objectives were: to determine the prevalence of disrespect and abuse experienced by pregnant women during child birth in health care facility. To determine the factors affecting disrespect and abuse experienced by pregnant women during child birth in health care facility. To design and validate checklist to assess respectful maternal and Newborn care (RMNC) in labour rooms in tertiary health care facility. Secondary objectives were to determine the agreement for RMC scores and childbirth experience scores among mothers during child birth in health care facility and to explore women's perceptions of various RMC aspects and determinants during childbirth

METHODS

A mixed methods multiphasic design will be used to conduct this study by collecting, analyzing, and integrating the quantitative and qualitative data. Mixed methods are based on the principles of pragmatism paradigm, based on which, the integration of quantitative and qualitative approaches enhances our understanding of an issue or problem. The qualitative data will be expanded and explained based on the collected quantitative data in the first phase, and both the quantitative and qualitative data will be integrated and will be used to develop the new RMC guideline (Figure 1).

Study duration

The study will be undertaken be department of obstetrics and gynecology in collaboration with department of Community and Family medicine over a period of 3 years from September 2023 to December 2026. Phase I: (i.e., the quantitative phase with a cross sectional design) to assess the status of D&A and RMNC during childbirth, their impact on women's experience and (i.e., the qualitative phase with a content analysis method) to explore women's perceptions of RMNC aspects during childbirth.

Study area, design and population

This study will be conducted in in Guntur District, Andhra Pradesh, India. Mixed method study was performed on married women in reproductive age.

Inclusion and exclusion criteria

Women given birth to atleast one biological child in last one year were included. The Women taking antidepressants over the past year. The Women experiencing stressful incidents such as divorce, facing the death of a family member or diagnosis of a family member with an incurable or life-threatening disease within the past 3 months, suffering from a mental disability, being deaf and mentally disabled, still birth and giving birth to a baby with a major anomaly. The woman who are very sick were excluded.

Sample size

Formula used for sample size calculation is

$$n = 4pq(DEFF) / d\,2$$

Where n=sample size, P=prevalence (p), q=complement of prevalence (1-p) and d= absolute precision. Sample size was calculated based on the overall pooled prevalence of disrespectful maternity care 71.3% in India. Level of confidence interval was kept at 95%, i.e., Z = 1.96. Cluster random sampling was used. To overcome the impact of study design on sampling variability, design effect of two is used to estimate the sample size. With absolute precision of 5%, sample size was estimated to be 654. Assuming non-response rate of 15% the final sample size was 750eligible women. Therefore, a sample of 750women will be studied.

Sampling procedure

Multistage Sampling will be adopted. Two of the mandalas from Guntur District will be randomly selected. City/Towns and villages will be enumerated. Rural and urban sample will be typically selected in two stages: the first stage involved random selection of Primary Sampling Units (PSUs), i.e., village in rural and ward in urban. The second stage involved the systematic selection of eligible women within each PSU using the List of eligible women

under anganwadi's retrieved from ICDS Guntur. Village and ward will be considered equivalent to a cluster. A total of 10 villages and 10 wards will be identified in each mandal so a total of 40 cluster. Maximum of 20 eligible women will be studied in each cluster. The process will be repeated until the required sample size is met. Following the completion of the quantitative sampling, the completed RMC questionnaire will be analyzed, extreme case one per cluster will be determined, and interviews will be carried out. In addition, participants with specific differences (in some variables) as well as those for whom unexpected results are found will also be interviewed. The extreme cases on the two sides of the overall RMC score spectrum from phase one (the uppermost and lowermost 10% extreme values) will be selected as the participants in the qualitative phase of the study score. Maximum of 20 in depth interviews of eligible women will be conducted divided equally in urban and rural area.

Procedure

House to house survey will be done in selected village/ward. All the eligible women present will be considered for the study. Investigator introduced herself to the women before the start of the interview and inform them about the research objectives and method, and obtain their written informed consent if willing to participate in the study. The participants will be interviewed to complete the sociodemographic and obstetrics characteristics questionnaire, and the RMC and D&A scales and experience questionnaire (CEQ2).The qualitative data will be audio-recorded during semi-structured in-depth interviews with open-ended questions. During interviews, the researchers will encourage participants to express their views and experiences freely. Prior to the qualitative stage, the interview guide will be developed by designing questions based on the findings of the quantitative study and related factors. To obtain credible data, the research team members will begin the interviews with predesigned questions, analyze responses to each question, and raise in-depth and exploratory questions such as "What do you mean?" "Why?" "Please explain further," and "Please give an example" Semi-structured and in-depths interviews will be conducted in a comfortable place (mother's home or health centre).

Study tool

Questionnaire will be designed via extensive review of literature and piloted. The study tools will be included in the questionnaire. Following the approval of the research project by the Institute Ethics Committee, the researchers will identify eligible women.

The socio-demographic and obstetrics characteristics questionnaire, the RMC and D&A scales, and the CEQ2 will be used to collect the quantitative data. Face-to-face interviews will be conducted to collect the data. The socio-demographic and obstetrics characteristics questionnaire includes questions about age, educational qualifications, occupation, religion, ethnicity, marital status, residential status, family income, living place (city or village), number of pregnancies, number of deliveries and abortions, history of stillbirth and infertility, drug use, history of sexually transmitted diseases, quality of prenatal care, interventions in childbirth (drug, etc.) by the midwife or the gynecologist, patients' freedom and comfort during labor and delivery, length of labor, participation in physiologic childbirth classes, length of stay in the delivery room, number of maternity care providers during the delivery, various delivery complications, delivery time (day or night), previous delivery place, delivery staff (physician, midwife), and gestational age at delivery.

The RMC scale has four domains and 15 items including friendly care (7 items), abuse-free care (3 items), timely care (3 items), and discrimination-free care (2 items). The responses are scored using the following pattern: "totally agree" (score 5), "agree" (score 4), "I do not know or indifference" (score 3), "disagree" (score 2)", and "totally disagree" (score 1). Items with negative meanings are scored using negative digits. This tool will be completed 6–18 h after the childbirth. The validity and reliability of this tool ($\alpha = 0.845$) has been evaluated by Sheferaw (2016).[15] Higher means indicate more positive childbirth experience of RMC.

The D&A scale consists of 7 statements and 23 items including protecting women from physical harm (6 items), protecting their rights for getting information about their condition/informed consent/their preferences (8 items), maintaining their confidentiality and privacy (1 item), maintaining their dignity and respect (2 items), providing them with equitable and discrimination-free care (2 items), taking care of pregnant women (never left without care/ attention) (3 items), and discharging them upon their request (never detaining or confining them against their will) (1 item). The score zero (if the response is no) or one (if the response is yes) is given to each item to measure the frequency of D&A for each item. If any of the items in a statement are positive, then a D&A will be considered for that statement. This scale was designed by Asefa (2015)[16] and approved by Maternal and Child Health Integrated Program (MCHIP).[17]

The Childbirth Experience Questionnaire-2 (CEQ2) developed by Denker et al will be used.[18] It consists of 22 items, which measures women's childbirth experience. This tool will be completed 30-45 days after childbirth. The questionnaire consists of four domains: own capacity (sense of control, personal feeling about childbirth and labor pain), professional support (midwifery information and care), perceived safety (feeling of safety and positive memories from childbirth), and participation (ability to change position, move, and have a say in the choice of pain relief). A 4-point Likert Scale is used to score 19 items, and the other three items are assessed using a visual analogue scale (VAS). The validity and reliability of the tool has been approved by the American Association of Women. The responses are scored using the following

pattern: "totally agree" (score 1), "partly agree" (score 2), "partly disagree" (score 3), and "totally disagree" (score 4). The visual scale values will be converted to scores from 1 to 4: 0-40 (score 1), 41-60 (score 2), 61-80 (score 3), and 80-100 (score 4). Items with negative meanings are scored using negative digits. Higher CEQ2 scores indicate a more positive childbirth experience.

Data analysis

The quantitative data will be analyzed with SPSS-26. The data collected will be analyzed with the assistance of SPSS 26 (IBM Inc., Armonk, NY). Sociodemographic and obstetrics characteristics and RMC and D&A scales will be described by frequency (percent), as well as mean (standard deviation) if the data are normally distributed or median (25 to 75 percentile) if they are not normally distributed. To determine the relationship between RMC and D&A and childbirth experience, bivariate analyses will be conducted, followed by a multivariate analysis to control the effect of confounding variables. To determine the relationship between socio-demographic and obstetrics characteristics with RMC and D&A, bivariate analyses will be performed. Agreement between RMC and D&A will be assessed using kappa. Qualitative data will be analysed using Atlas ti version 22. The audio tapes of the in depth interviews will be transcribed verbatim and then translated into English. Then, the statements will be scanned to identify patterns for RMC and D&A. A conventional qualitative content analysis approach will be adopted to analyze the data. In this approach, the researchers read and interpret all available texts to get a complete understanding of them. Then, the texts are read word-for-word to extract relevant codes. The main advantage of this approach is obtaining direct information from a study without imposing preconceived categories or theories.

Phase 2: Study area: This study will be conducted in a tertiary health care level Guntur District, Andhra Pradesh, India. Study design: Cross sectional study. Study Population: Pregnant women, Doctors in labour room, Nurses in labour room, Supporting Staff in labour room, Birth Companion of the studied women. Inclusion criteria: Pregnant women admitted in the hospital for child birth and Married were included. Exclusion criteria: The Women taking antidepressants over the past year. The Women experiencing stressful incidents such as divorce, facing the death of a family member or diagnosis of a family member with an incurable or life-threatening disease within the past 3 months, suffering from a mental disability, being deaf and mentally disabled, still birth and giving birth to a baby with a major anomaly. The woman who are very sick.

Sample size calculation

Formula used for sample size calculation is:

$$n = 4pq / d^2$$

Where n=sample size, P=prevalence (p), q=complement of prevalence (1-p) and d= absolute precision. Sample size was calculated based on the overall pooled prevalence of disrespectful maternity care 71.3% in India. Level of confidence interval was kept at 95%, i.e., Z=1.96. With absolute precision of 5%, sample size was estimated to be327. Assuming non-response rate of 15% the final sample size will be 375 eligible women. Therefore, a sample of 375 labour will be observed and eligible mothers will be interviewed to validate RMNC checklist. Doctors, nurses, supporting staff and birth companion involved in these 375-labour process of child birth will be interviewed. Sample size will be increased to have Kaiser-Meyer-Olkin Measure of Sampling Adequacy 0.6 to 0.8 to be considered appropriate.

Study tool

Draft Respectful maternal and Newborn care Checklist items will be designed via extensive review of literature and interpreting qualitative and quantative data collected in Phase 1. The integration of the quantitative and qualitative results will aid us to develop a guideline for improving the quality of maternity care provided at maternity wards. However, there will be a systematic review of literature to identify the best practice. The following key terms will be used to search PubMed, Scopus, Embase, Google scholar and Cochrane library. Then, the quality of the obtained data will be evaluated using Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. The evidence and data will be analyzed, to develop the primary version of the guideline.
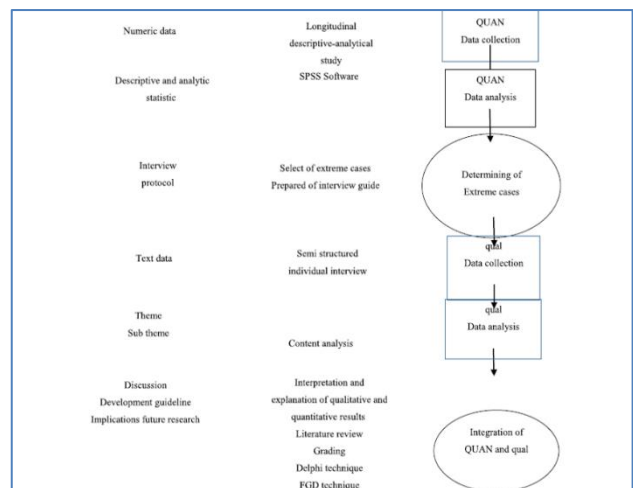

Figure 1: Study diagram.

The respondent experience including eligible mothers, health care workers etc. will be asked to rate s/he RMNC realization on a 5-point Likert scale: Strongly agree, Agree, Neutral, disagree and strongly disagree. The observer Reponses will be asked to rate s/he RMNC realization on a 3-point Likert scale: present, Absent Neutral. The total score will be computed by adding all the

item responses and dividing by the total number of items (items from subscale 1 are reverse coded because they are negatively worded). Higher item scores always indicate greater realization of importance of RMNC.

Step 1: Content validity will be based on the judgment of experts that items and questions in an instrument are essential, relevant, and appropriate to the target culture. Therefore, the purpose of this step is to ensure that the Respectful maternal and Newborn care Checklist is clear and culturally relevant. Both qualitative and quantitative methods will be applied. In the qualitative phase, a panel consisted of 10 specialists of gynaecologists, public health, ANM, Female nursing orderly, midwives etc.and from National Health Program like medical officer, nursing officer, who are in promoting RMNC and evaluated grammar, wording, and scaling of the questionnaire will revise the items in the RMNC tool through the Delphi technique.

In order to determine content validity ratio (CVR), we will choose Lawshe approach. Experts will assess essentiality of each item. They will assess the necessity of the items using a three-point rating scale: (a) not necessary, (b) useful, but not essential, and (c) essential. The CVR for every item will be calculated using formula (N = the total number of experts and n = the number of experts who had chosen the (c) option for each particular item). CVR for the total scale will be calculated. According to the Lawshe table, an acceptable CVR value for 10 experts is 0.6.

Phase 2: Pilot testing will be done on 5 eligible woman. Scale will be further revised for grammar, language as required after pilot testing. After collecting pilot data, responses will be entered into a spreadsheet and cleaning of the data will be done. Maximum and minimum values for the entire dataset will be checked.

Phase 3: The eligible women will be enrolled in the study in the antenatal ward. The researchers will identify eligible women by using the hospital birth statistic system, inform them about the research objectives and method, and obtain their informed consent if willing to participate in the study.

The study data collection will be conducted in the postpartum ward on women who have given birth. Investigator will introduce himself/herself to study participant. Hardcopyof Respectful maternal and Newborn care Checklist with demographic details will be given. Mother, birth companion and health care staff will be interviewed using Respectful maternal and Newborn care Checklist for their respective sub sections. A total of 15-20 min time is expected for answering Respectful maternal and Newborn care Checklist. An independent observer will observe the process of the entire labour to assess Respectful maternal and Newborn care using checklist

Phase 4: Kaiser-Meyer-Olkin Measure of Sampling Adequacy 0.6 to 0.8 will be considered appropriate. Underlying components will be identified using principal components analysis (PCA). The internal consistency of questions loading onto the same factors will be checked by Cronbach's Alpha (CA). Scale will be revised based on information gleaned from the PCA and CA. Considering that even though a question does not adequately load onto a factor, we might retain it if it is important.

Statistical analysis

All the data will be entered into Microsoft Excel 2010. Statistical analysis using descriptive and inferential methods will be performed The data collected were analyzed with the assistance of SPSS 26 and AMOS (IBM Inc., Armonk, NY). Graphs will be produced using EXCEL software after obtaining the relevant information from the SPSS output. Descriptive methods will be used to obtain frequency tables and graphs. Inferential methods will be used for association between selected socio-demographic variables and RMNC. The reliability will be assessed by Cronbach's alpha coefficient. Cronbach's alpha values >0.6, item-total correlation coefficients >0.20, and interitem correlations coefficients <0.80 and higher than zero will be regarded as acceptable. Cronbach's alpha values <0.5 were regarded as unacceptable. An item will be considered for removal if its item-total correlation coefficient is lower than 0.2, provided that its deletion led to an increase of more than 0.1 in Cronbach's alpha coefficient. Exploratory factor analysis (EFA) will be conducted utilizing principal component analysis with varimax rotation. Criteria for retaining factors and items will be having eigenvalues >1 and item loading ≥0.3, respectively. All hypotheses will be tested at the 5% level of significance.

DISCUSSION

As there is no comprehensive guideline in India for RMC, this study is the first of its type designed to develop RMC guideline based on a multiphase study. The present study will provide detailed information on a group of Indian women's experiences of D&A during childbirth and its related factors for the development of the new guideline.[16] The quantitative and qualitative approaches in the mixed method design are integrated to correct possible defects, and provide a better understanding of the subject.[19] The mixed method study will help health professionals understand women's experiences of D&A during childbirth and prevent any potential harm to these women. Developing a guideline that involves evidence based practice principles, women's experiences and maternity staff input can provide a new direction to lead other health care professionals and policymakers with the same characteristics to improve the quality of the care for women across the country.

Future plans based on the study outcome

The RMC guideline obtained from this research can be employed for management, policymaking, educational, and research purposes, and be effective in enhancing the

quality of services provided to pregnant mothers. Considering the increasing rate of C-section in our country, it is expected that with implementing of guideline, women would have greater tendency to undergo natural delivery. Implementation of the guideline will help gain awareness about the benefits and obstacles of executing this guideline across the Indian population. A large scaletraining initiative to orient all maternity care personnel to the principles of respectful maternity care

Limitations and strengths

One of the main strength of this study is that in addition to applying quantitative and qualitative results, the opinions of a specialist panel will be used which increases the generalizability of the results to the entire country. Regarding the limitations, some of the recommendations of the study will be based on the cultural context and conditions of the local population studied.

CONCLUSION

The study aims to address the mistreatment of women during pregnancy and childbirth by developing RMC guidelines in India. The mixed methods approach will combine quantitative and qualitative data to improve understanding and inform the development of the guidelines. This study has the potential to enhance the quality of maternity care and ensure positive birth experiences for women in India.

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