

Addressing the inequalities in maternal and child healthcare utilization

Edited by

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Addressing the inequalities in maternal and child healthcare utilization

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WOmen's Action for Mums and Bubs (WOMB) Trial Protocol: A Non-randomized Stepped Wedge Implementation Trial of Participatory Women's Groups to Improve the Health of Aboriginal and Torres Strait Islander Mothers and Children in Australia

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Introduction: In Australia, there have been improvements in Aboriginal and Torres Strait Islander maternal health, however inequities remain. There is increasing international evidence illustrating the effectiveness of Participatory Women's Groups (PWGs) in improving Maternal and Child Health (MCH) outcomes. Using a non-randomized, cluster stepped-wedge implementation of a complex intervention with mixed methods evaluation, this study aims to test the effectiveness of PWGs in improving MCH within Indigenous primary care settings in Australia and how they operate in various contexts.

Methods: This study takes place in ten primary health care services across Australia and involves the recruitment of existing PWGs or the setting up of new PWGs. Services are paired based on geography for practical reasons and two services commence the PWG intervention at three monthly intervals, with the initial four services being those with existing women's groups. Implementation of the PWGs as an intervention involves training local facilitators of PWG groups, supported engagement with local MCH data through workshops, PWGs identifying and prioritizing issues and strengths and co-implementing solutions with health services. Outcomes are measured with yearly MCH audits, a cost-effectiveness study, and process evaluation of community participation and empowerment.

Discussion: This study is the first to formally implement and quantitatively, yet with contextual awareness, measure the effect of applying a community participation intervention to improve the quality of Aboriginal and Torres Strait Islander MCH in Australia. Findings from this work, including detailed theory-producing qualitative analysis, will produce new knowledge of how to facilitate improved quality of MCH care in Indigenous PHC settings and how to best engage community in driving health care improvements.

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INTRODUCTION

The health, social and economic outcomes for Aboriginal and Torres Strait Islander Australians continue to be substantially worse than for other Australians (1–3). In Australia, improving the quality and consistency of PHC provided to Aboriginal peoples and Torres Strait Islanders is an essential part of the Australian Government's Close the Gap program (4). Maternal and child health (MCH) is consistently named a priority area by Aboriginal and Torres Strait Islander peoples, policy makers health service providers, and researchers (5, 6). Although Aboriginal and Torres Strait Islander infant mortality rates and the proportion of low birth weight babies born are falling, they remain almost double those of non-Indigenous infants (1).

Internationally, primary health care (PHC) is recognized as critical to addressing inequities in health status (2, 3). While Indigenous PHC services [both Aboriginal Community Controlled Health Services (ACCHS) and government services] provide PHC for Indigenous people, the quality of care and health outcomes can vary significantly between services (3, 7).

Continuous Quality Improvement (CQI) aims to facilitate ongoing improvement in the quality of PHC by using objective information to analyze and improve systems, processes and outcomes (8). A CQI strategy based on audit and feedback cycles of “plan, do, study, act” provides a theoretical, coherent and practical way for PHC services to identify, address and overcome barriers to quality care (9, 10). Modern CQI approaches incorporating service user participation, engagement, shared-decision making and tailoring to context address both scientific and humanistic values (10). Such approaches may also offer the potential to enhance MCH through the improvements in quality made in the PHC setting. International empirical evidence

suggests that an integrated approach that includes community women as active participants (11) working alongside service providers can improve both the quality and outcomes of MCH care in a relatively short time period (11–13). Furthermore, CQI fits with the principles and values of Aboriginal and Torres Strait Islander people (expressed in national statements on research and cultural respect) (14, 15). Despite the demonstrated benefits of community participation (16), very few quality improvement interventions in Aboriginal and Torres Strait Islander PHC have focused on factors beyond service provision as part of their implementation. None have explicitly tested community participation aimed at enhancing community decision-making and co-production in health care and health service design. Similarly, in evaluating quality improvement interventions, the cost effectiveness of community participation in light of MCH improvements in service provision and health outcomes has not been assessed. Hence, there is a need to add to the evidence in this area.

There is persuasive international research illustrating the effectiveness of participatory women's groups (PWGs) in improving MCH outcomes such as neonatal and maternal mortality rates via improved quality of care, women's empowerment, and new learning (11, 16–18). There is considerable evidence internationally (19, 20) and in Australian Aboriginal and Torres Strait Islander settings (21) that empowerment of women is achieved through participation in such women's groups. Empowerment means healing from past wounds, developing strength and skills to live life in a positive way, to have good relationships with others and to work together to make communities a better place (22). A systematic review with meta-synthesis found that participatory interventions using women's groups are effective in improving neonatal and maternal survival (23). This led to the identification of PWGs, coupled with health systems strengthening and community action, as highly effective strategies for improving MCH that are low-cost, sustainable, and scalable.

Morrison et al. (20) have named four mechanisms to explain the positive impact of women's groups on health outcomes in a study of maternal and newborn health in Nepal. The groups: (a) learn about health; (b) develop confidence; (c)

Abbreviations: ACCHS, Aboriginal Community Controlled Health Services; CCA, Cost-Consequence Analysis; CEA, Cost-Effectiveness Analysis; CQI, Continuous Quality Improvement; CRE-IQI, Centre for Research Excellence in Integrated Quality Improvement; EES, Emotional Empowerment Scale; FWB, Family Wellbeing Program; GEM, Global Empowerment Measure; ICER, Incremental Cost-Effectiveness Ratio; MCH, Maternal and Child Health; MCH QCI, Maternal and Child Health Quality of Care Index; PWG, Participatory Women's Groups; RSF, Remote Service Futures.

disseminate information in their communities; and (d) build community capacity for action (20). Based on this evidence, we hypothesize that improvements in MCH related to participation in PWGs may be mediated through measurable changes in empowerment.

The study discussed above took place in Nepal, with contextual factors including a weak health system funded through significant contributions from external development partners who are influential in decision-making. In addition, similar to most low-resource settings, the PHC system is dependent on extensive contributions from female community health volunteers (over 50,000 in Nepal). External agents call on these women volunteers to assist in conducting MCH interventions (24). By comparison, the Australian public health system is relatively strong and does not rely on volunteers to provide PHC services. Interventions are usually provided by health professionals, many of whom are unfamiliar with working collaboratively with women's groups. Yet, we know that working partnerships in Indigenous health are fundamental (25); PHC staff and managers need to be supported to understand the importance of community participation in co-producing responsive MCH services that aim to improve patient outcomes.

There are compelling examples of Aboriginal and Torres Strait Islander community responses to health and well-being needs that arise spontaneously within communities. The overarching example is the Aboriginal community controlled health movement as the expression of Indigenous cultural values within a predominantly western health sector (26). On a smaller scale, the Strong Women, Strong Babies, Strong Culture program in the Northern Territories employed older community women to work individually with pregnant women to improve health behavior and health care access. A small, but significant increase in birthweight over an 8 year period was demonstrated through this program (27). The Aboriginal-developed Family Wellbeing Program (FWB) is another empowerment-based participatory approach, designed to support the capacity for individuals, organizations and communities to gain control over their lives to improve wellbeing and quality of life (21, 28–30). FWB has been successfully applied by our team to MCH care, organizational change and team strengthening (amongst others). Reported benefits of FWB include greater understanding and mutual respect between health staff, an enhanced capacity to work with others toward common goals, and improved access to health services and high quality service delivery (31, 32).

This study examines whether PWGs, as an intervention, improve the quality of Indigenous MCH care. More specifically, it will determine the effectiveness of PWGs in improving quality of care and intermediate health and well-being outcomes in MCH; the cost-effectiveness of PWGs for improving quality of MCH care; the degree to which the PWGs are associated with a change in empowerment measured using the global empowerment measure (GEM) scores for women involved (22); and the processes through which PWGs exert effects in various contexts.

RESEARCH QUESTION AND OBJECTIVES

Do participatory women's groups (PWGs), as an intervention, improve the quality of maternal and child health (MCH) care in Australian Indigenous primary health care (PHC) services?

The objectives are to determine:

- 1) The effectiveness of PWGs in improving quality of care and intermediate outcomes in MCH;
- 2) The cost-effectiveness of PWGs for improving quality of MCH care;
- 3) The degree to which the PWGs are associated with a change in global empowerment measure (GEM) scores for participating women; and
- 4) How and why PWGs exert their effects in various contexts.

METHODS AND ANALYSIS

Design

A stepped wedge cluster implementation (non-randomized) of a complex intervention was chosen for ethical and logistical reasons. It allows all participating PHC services to receive the PWG intervention in sequential order, where evidence of effectiveness can be assessed with pre- and post-intervention observations from each service (33). This design has an advantage in improving power with smaller numbers of services where intra-cluster correlation is high (optimizing feasibility). By allowing services to act as their own historical controls it also accounts for underlying differences between clusters that may confound results in the more traditional parallel cluster designs. Through the collection of routinely recorded MCH audit data, the study assesses the effectiveness of a complex intervention involving PWGs addressing issues in MCH care to improve outcomes amongst Indigenous mothers and babies. To complement the design, qualitative research with PHC services and PWGs will explore contextual barriers and enablers to successful implementation of the PWG in various settings throughout Australia.

Recognizing that patients, clinicians and policy makers need real world evidence to make informed decisions about their healthcare, the study represents a range of typical Indigenous PHC settings, using realistically attainable intervention approaches under real-world conditions, and reporting relevant outcomes to all stakeholders (34).

To test the effectiveness of the PWG intervention, this design is blended with our commitment to a participatory approach informed by Indigenous ways of being, knowing and doing and an all-teach and all-learn philosophy. This is done in part through optimizing the flexibility to respond to the rich and varying needs and contexts of individual health services and communities, whilst maintaining the integrity and consistency of the intervention. One example of this is that initial meetings with participating services determined that there are two groups of services, four services with existing functional women's groups and active auditing (early services) and six services who do not yet have a functional women's group

and/or have auditing delays (later services). Recognition of these differences, and a rejection of the concept of randomization as disempowering by participating services and partners has led to a revision of the design in terms of randomization of the order of intervention, as described below. Furthermore, service representatives and PWG facilitators are all involved in collaborative planning and training meetings, steering group meetings, and team communication strategies throughout the life of the study. This study protocol was developed as required by the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (**Supplementary Material 1**).

Study Setting

This study is conducted in partnership with ten *primarily Indigenous* PHC services in Queensland, New South Wales, Northern Territory and Western Australia. *Primarily Indigenous* refers to services that are an Aboriginal Community Controlled Health Service or government service funded primarily to service Aboriginal or Torres Strait Islander people. Participating services represent a range of jurisdictions, service size, remoteness, governance models and CQI tools.

Study Participants

The target population to whom our findings apply is primarily Indigenous PHC services and women and children who access Indigenous PHC services. Thus, PHC services are eligible to participate if they fulfil the following inclusion criteria: (a) are a primarily Indigenous PHC service (b) are engaged in some auditing of MCH service provision using a recognized and evidence-based audit tool (35, 36); (c) have a formal or informal community women's group associated with the service or a desire to establish one; (d) are willing to support at least one staff member to attend facilitator training; and (e) have agreement from CEO, Chair and key clinical staff to participate and share aggregated service level data during the study.

The PWG Complex Intervention

PWG facilitators are recruited via the PHC service. The PHC services nominate two women leaders, ideally Aboriginal or Torres Strait Islander, to work as PWG facilitators. It is important to have at least two PWG facilitators trained in order to provide support and improve sustainability of the local PWG (for example, should one facilitator resign their position, or leave the area).

PWG membership eligibility extends to all female community members who have an interest in MCH and may include but is not limited to the following:

- Pregnant women
- Mothers
- Women who may be pregnant but not yet aware
- Elders who are not health professionals.

An existing or new community women's health and wellbeing group forms the foundation of the complex intervention. Establishment of a new PWG or refreshing the membership of an existing group (if needed) will be led by the PHC service and may involve community consultation, engaging with existing

community groups and other community organizations. PWG facilitators attend a training program during the set-up phase of the study. The purpose of this training is to build relationships and communication strategies between PWG facilitators and investigators; to share learning about facilitating the PWG; to become familiar with MCH audit data; and engage in a cyclical process of planning and implementation of changes to improve MCH called the Remote Service Futures (RSF) framework.

The RSF framework guides the PWG intervention planning and implementation process (37). The RSF uses a semi-structured approach to identifying needs, planning interventions, and implementation by community people in partnership with health professionals with monitoring via a series of workshops (38). This approach has recently been tested in Australian rural communities in improving oral health care, and found to be feasible when used with skilled facilitation (38–40). **Table 1** outlines the RSF framework activities important in the PWG intervention.

Following training, the facilitators return to their communities and consolidate or establish their PWG. The facilitators work collaboratively with PWG members on MCH improvements using the RSF framework. It is important for PWGs to link with existing community initiatives (for example, Health Action Teams, Domestic Violence support groups, breastfeeding peer-counselors). The role of women in these groups is to: share local knowledge and community perspectives, focus on building community expectations, encourage community ownership of services, engage in activism

TABLE 1 | RSF framework activities important in PWG intervention.

Phase 1: Planning workshops	Phase 2: Implementation workshops
Identification of PWG members	Workshop 1: Monitoring implementation of planned MCH improvements
Workshop 1: Sharing knowledge: What are some things that PWG members know about that affect the health of mums and bubs? What are the strengths and limitations of the maternal and child health (MCH) support services for this community?	Workshop 2: monitoring implementation of planned change
Workshop 2: Sharing knowledge of what is happening in the care and health of mothers and babies in the community—through national and local data, health service information, and other information regarding social issues (family support, access to adequate child care or housing, family issues).	Workshop 3: monitoring implementation of planned change
Workshop 3: Women share ideas on what might lead to MCH improvement. What can be done in the community to improve the health/care of Mums and Bubs? Share knowledge of what other Aboriginal and Torres Strait Islander communities have done in other relevant area.	Workshop 4: monitoring implementation of planned change
Workshop 4: Developing a community MCH improvement plan with prioritized items	Ongoing PWG activity as desired by community Ongoing implementation. Translation of outcomes

for high quality care, and plan and develop initiatives to improve MCH. MCH nursing and/or medical staff may also be included to build their own capacity to respond to community perspectives.

During the intervention, each PWG decides the exact timing and interval of the four planning workshops. These may be at approximately monthly intervals (completed in the first six months of the intervention, with the flexibility to accommodate significant community events). There is an ongoing relationship between the investigators and the PWGs so that technical support, for example, extra data, assistance in using audit data, or information about implementation of changes, can be provided if necessary. The type or frequency of technical support is recorded for each PWG and form part of the process evaluation of the PWG. PWG facilitators and members are informed that the MCH improvement plan needs to be cost neutral and within the remit of the health service and PWG/community to implement within a 12-month period. Three initiatives from the community MCH quality improvement plan will be prioritized for implementation, and these will be implemented and monitored through a series of four workshops over 8 months at intervals to suit the services (at approximately bimonthly intervals). Annual meetings will bring facilitators together to disseminate their experiences, share learning and enhance the knowledge base for groups to respond to local needs, issues and priorities. Strategies considered and implemented by groups will differ according to prioritized goals and what is contextually appropriate and might involve health service or community level initiatives. Examples from previous PWG interventions include patient-held records, service report cards, breastfeeding support groups and community education programs.

As part of the intervention, services are provided with AU\$5,000 per year to support the study at their facility as they wish (for example, part compensation for staff time, producing health promotion resources in response to PWG group input). In addition, PWG facilitators receive a small amount of reimbursement (0.1 Full Time Equivalent) during the intervention period to directly off-set time and contributions to the facilitation of the PWGs. Both of these are factored into the cost effectiveness analysis.

Outcomes

The primary outcome measure is a change in the MCH Quality of Care Index (QCI) from aggregated de-identified health service audit data. The MCH QCI provides an indicator for overall adherence to delivering recommended services based on evidence based clinical best practice guidelines in the delivery of care. The MCH-QCI (%) is calculated from audit data as (total number of services provided)/(total number of recommended services) * 100 (Table 2) (41). Baseline audit data is collected from services at yearly intervals (over ~1 week at the end of each year) for the 5-year duration of the study. Given the stepped wedge start-time of the intervention, each service will have at least one set of pre-intervention audit data (some up to three) and at least two sets of post-intervention audit data (some up to four; Figure 1). Patients attending the services whose charts may be audited are women with an infant aged between 2 and 14 months at the time of audit, resident in the community for at

TABLE 2 | Indicators included in MCH quality of care index.

Maternal Health QCI30 Clinical Indicators	Laboratory investigations: urinalysis (three time points), blood group, antibodies, full blood examination, rubella, Hepatitis B, syphilis serology, HIV, morphology US Physical examination: weight (two time points), body mass index; blood pressure (three time points); fundal height (two time points), fetal heart rate (two time points) History of risk factors: cigarette use, alcohol use, illicit drug use (each at two time points) Antenatal discussions: antenatal education, healthy living (nutrition, exercise, oral health, breastfeeding), psychosocial situation (domestic environment, family support, financial and housing)
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least 6 months of the pregnancy and using the PHC service as her usual source of care.

Secondary outcomes: Secondary outcomes will include: (i) percentage of pregnant women having their first antenatal visit before 13 weeks gestation; and (ii) mean birthweight.

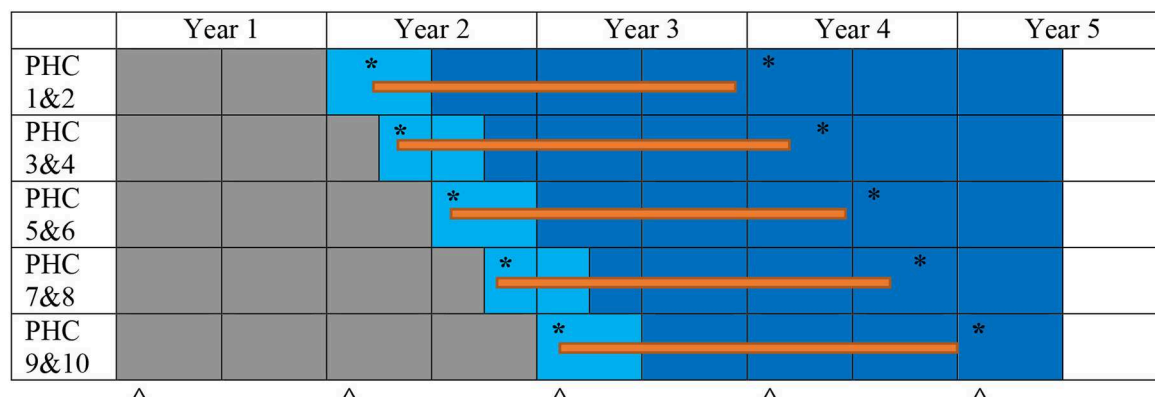
Process measures include changes in empowerment for PWG members [measured using the validated Growth and Empowerment Measure (GEM)] (22), alongside a theory-generating process evaluation using qualitative methodology informed by Indigenist and critical theory of the implementation and experience of the intervention (42, 43).

A cost-consequence analysis (CCA) and cost-effectiveness analysis (CEA) will be undertaken from the health system perspective. The outcomes for the CCA will be all primary and secondary outcomes for the study. The outcome for the CEA will be a 100 g increase in mean birthweight (as the main direct health outcome measure).

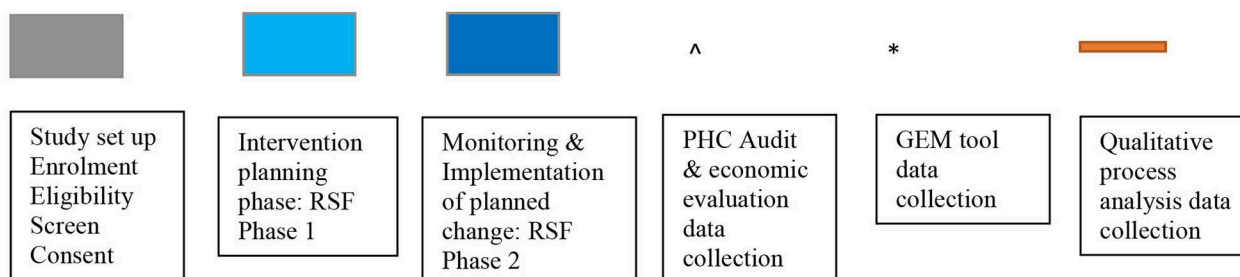
Participant Timeline

The non-randomized cluster stepped-wedge design involves staged implementation of the intervention with two services commencing the intervention planning period at three monthly intervals (Figure 1). Initially, the study was planned to be randomized in terms of the timing of commencement of the intervention, but it became apparent that some of the services were ready much earlier than their allotted start date, based on the pre-existence of a functional women's group. We considered stratified randomization, but ultimately came to the conclusion (with our service partners) that imposing a randomized order on a complex intervention with a presumed theoretical basis of empowerment was likely to be counterproductive in terms of relationship building/engagement with community members and was unpopular with staff at participating services. Thus, randomization of start order was abandoned, and time of commencement will be adjusted for statistically as part of the analysis.

The first phase of the study is the start-up phase and involves study set up, engagement of stakeholders, recruitment of services, recruitment of PWG facilitators, training and formation of PWGs. At the first service engagement meeting in late 2018, services were paired in terms of timing of the intervention for practical reasons based on geographic proximity, to improve feasibility of support (both from the project team and from



Key



Note: PHCs 1-4 are the early ready services, and PHCs 5-10 are the later ready services

FIGURE 1 | Stepped wedge design and participant timeline.

facilitators at the partner site). The four “early ready” services will embark on the complex intervention first, at three month intervals. The remaining six services have agreed an order of implementation based on perceived readiness (**Figure 1**). On commencing the intervention, there is a 6-month intervention planning phase comprising the RSF Phase 1 planning workshops and between two and three years for the implementation of MCH improvement plans and monitoring implementation of planned changes (RSF Phase 2) depending on the time of entry.

Sample Size

The study is conducted with ten services that have self-nominated and been engaged with MCH audits. The number of maternal records examined in a service at a single audit cycle ranges from <5 to >100, but is usually ~20. Actual mean of the MCH-QCI from 43 services previously involved with One21seventy MCH audits is 65.97% with standard deviation (SD) of 13.58% and a change of 5% is likely to be clinically significant. A stepped-wedge design with five steps, ten clusters and intraclass co-efficient of 0.15 and an average cluster size of 20 has a design effect of 0.40 (with only two baseline and one subsequent audit) (44). Using

our expected sample size of 200 audit records from 10 services and a design effect of 0.4 with $\alpha = 0.05$, an SD of 13.58, 99% power is achieved for detecting a 5% change in our primary outcome. This is a conservative estimate. This sample size also gives a statistically significant result if mean birthweight is 100 g higher after the intervention than in the pre-intervention state (e.g., 3.3 kg v 3.2 kg). For the proportion of pregnant women with their first antenatal visit prior to 13 weeks gestation, this study will produce a statistically significant result if the odds of a pregnant woman attending in the first trimester are 1.5 times higher in the PWG group than in the pre-intervention group.

Recruitment

Recruitment to this study is at three levels: PHC service recruitment, PWG facilitators and recruitment of individuals into the PWG.

PHC Services

An information sheet about the study and an invitation for services to self-nominate has been circulated through peak bodies, state health partners, investigators’ networks. Follow up

by meetings to provide further information and check eligibility has occurred with interested services. Attention has been paid to maximize variability amongst services as well as enabling services to make an informed choice about participation, considering all factors. Maximizing variability assists in determining how the intervention might be transferable to different settings. Service consent to participate involves meetings with the PHC service staff to discuss the study and written consent from an Aboriginal Community Controlled Health service Board or CEO to participate.

PWG Facilitators

Individuals are invited to participate as PWG Facilitators via the PHC health service. Members of the investigation team discuss the study with nominated PWG facilitators and seek written consent.

PWG Members

Individuals are invited to participate in the study via the PHC service and PWG facilitators. The PHC service determines the appropriate approach to recruitment depending on the context but includes activities: local advertisement, community meetings, via other local community groups and stakeholders. Interested individuals are provided information about the study and assessed for eligibility. Verbal and written consent to participate is obtained by the PWG facilitators. Within existing PWG groups, individuals who choose not to be part of the study will continue to participate in group activities outside of the MCH planning and implementation process.

PHC service and PWG retention are promoted by inviting PHC representatives and PWG facilitators to be members of the project steering committee. Regular email updates and newsletters are available to PHC service staff and PWG facilitators. In addition, a closed facebook group will be established so that they can share information and progress with each other. PWG participant retention is promoted by flexibility to the needs of the group when organizing planning and evaluation meetings; sharing newsletters and other study communications where appropriate; providing reminders of upcoming meetings and regular feedback on topics discussed.

Given the thorough processes that the services and investigator team undergo once services are involved it is unlikely that a service would withdraw. However, there is a plan in place if a service can no longer participate involving maximizing possible data collection for that service and adjusting the analysis accordingly. There may be changes in personnel at the PHC service and amongst the PWG facilitators. Comprehensive refresher training is available in any aspect of the study should PHC staff or PWG facilitators require this, managed within the pragmatic nature of the trial. Participants in the PWG may withdraw from the study for any reason at any time. If they choose to withdraw this will not affect their relationship with the PHC service or the investigator team. If they withdraw from the study they can request that data is returned or destroyed.

Allocation

Two health services each commence the intervention at 3-monthly steps, and as discussed above, randomizing the order of intervention implementation was abandoned for ethical and theoretical reasons. This is now a non-randomized trial, still with a stepped wedge design and cluster intervention. Although not universally accepted, there are precedents for this design in the literature (45) including suggestions for analysis to compensate for the lack of randomization (46). The team's belief is that in a design with three month steps, and an expected time frame of 12 months for maximal effect the detrimental effects of this in terms of potential allocation bias are likely to be outweighed by relational benefits in terms of control and implementation. Services act as their own controls, thus no blinding at service level is either feasible or necessary. Analysis adjusts for the time of commencement of the intervention.

Data Collection, Management and Analysis Primary and Secondary Outcomes

Cross-sectional data for the primary and secondary outcome measures are collected from services by service staff using the One21Seventy MCH audit tool (35) (from which the MCH-QCI can be obtained) based on evidence-based best practice guidelines about quality MCH care. Processes for conducting these audits and ensuring data quality are well described (3, 7, 41, 47). The MCH-QCI is calculated at the beginning of the study and on an annual basis using existing mechanisms and supports that are part of the inclusion criteria. At least five sets of audit data will be available for each service. This is adequate time to demonstrate significant impacts on quality of care and possibly some health outcomes such as birthweight. Patients attending the services whose charts may be audited are women with an infant aged between 2 and 14 months, resident in the community for at least 6 months of the pregnancy and using the PHC service as her usual source of care.

Data, from which the primary and secondary outcome measures (MCH-QCI) will be drawn, is the property of the PHC service and the service forwards de-identified data to the research team for analysis. This data is in electronic form using a template designed by the research team. This template includes the name and a full description of the variable. Members of the investigator team including the statistician are responsible for checking the templates sent by PHC services and responding to any data queries.

The unit of analysis for the primary outcome is the health service. For the primary analyses (for both primary and secondary outcomes), it is likely that the PWG will have an effect on outcomes after 12 months from the start of the intervention at each step. The outcomes will be analyzed using linear mixed effects models. The models will have a random effect for community, and fixed effects for the effects of time. Estimates of the effect of PWGs will be reported along with 95% confidence intervals. Secondary analyses may adjust for rurality, service size, number of audit cycles and governance structure (ACCHS or government service), and various sensitivity analyses may be undertaken. Statistical significance is set at $p < 0.05$ level to test the hypothesis that there was a significant change in each of

the outcome measures from baseline score. Imputation analysis is used to account for the effect of missing data.

Process Measures Evaluation

PWG facilitators keep a journal to capture evidence about the process of implementation, such as the number of women attending the meeting and their timing, areas of discussion, key learnings, other community members and organizations involved. In addition, regular communication with project managers and through the closed facebook group will allow the facilitators to discuss any issues and gain support from others.

Empowerment of women who are members and facilitators of the PWGs in each community is measured at the onset of the process (at the start of the intervention planning phase in each service), and at the end of the intervention period. This is done through the administration of the GEM, both the Emotional Empowerment Scale (EES) and the 12 Scenarios to measure the empowerment process (22). In addition, satisfaction with the PWG process, implementation and experience of the intervention and outcomes are evaluated using semi-structured interviews at the completion of the study. Participants include PWG participants and facilitators, along with some health care providers and community women who have not been involved in the women's groups. Around 10 interviews will be performed for each participating community.

GEM tool data is collected in hard copy, entered electronically by a member of the investigator team and original data kept in a locked cabinet at the sponsor organization. Data entered is cross checked by another investigator to increase the accuracy of data entry and coding. Digitally recorded qualitative interview data is transcribed as word documents. The team has developed a protocol to manage the de-identification and cross checking of qualitative data with respondents. This includes the creation of a flow chart for qualitative data management, standardization of file naming conventions, agreed de-identification processes and cross checking with other members of the investigator team.

The process evaluation strategy is based on robust strategies for evaluating complex interventions, aiming to develop a programme theory for the intervention (48). For process evaluation measurement using the GEM tool, pre and post GEM scores are analyzed using bivariate descriptive statistics. Qualitative evaluation of the process and outcomes using detailed interviews and observation via facilitator journals will uncover how participatory groups and individuals are able to produce and sustain change in MCH care, neglected in previous studies of women's group interventions. Qualitative data (journals and interviews) are transcribed in full. Transcripts are entered into NVivo and abductive coding (49) will first group the findings and do a line by line coding under each question and then inductively identify themes from the data using constant comparison. Analysis of the qualitative data is led by Aboriginal and Torres Strait Islander investigators. The combined findings will be used to generate an explanatory theory about how and why the intervention works (or otherwise) in a variety of contexts. In doing this we will integrate qualitative themes derived from trial data with Aboriginal and Torres Strait Islander knowledge frameworks and concepts (50).

Economic Evaluation

A cost-consequence analysis (CCA) and cost-effectiveness analysis (CEA) will be undertaken from the health funders perspective. Costs for the CCA and the CEA will be obtained from the trial data, and include all training (including annual meetings), staff time and resource use costs to the health system for a hypothetical nation-wide roll-out of the program. The outcomes for the CCA will be all primary and secondary outcomes for the study. The outcome for the CEA will be change in mean birthweight (as the main direct health outcome measure). The analysis will identify the incremental cost-effectiveness ratio (ICER) of a nationwide roll-out of the WOMB intervention compared to standard care. A budget impact analysis, that captures the impacts of the intervention on expenditure of the Federal and state governments, and individuals over a 5 year time frame, will also be undertaken.

Data management procedures for the economic analysis will follow the same process as primary and secondary outcome data and will be cross checked in consultation with health economists on the investigator team.

Implications and Significance

Despite growing international evidence, this study is the first to formally implement and assess in a cluster stepped-wedge design using quantitative outcome measures related to health care delivery, empowerment and health outcomes, the effect of applying a community participation intervention (PWG) to improve the quality of Indigenous MCH care in Australia. It brings together best practice in participatory approaches to strengthening health care with the expertise and reach of an experienced research collaboration to allow community members and health care providers to engage with MCH data from their community and implement changes to improve quality of care. Importantly (and often missing from previous research), the evaluation involves a cost-effectiveness analysis and a strong qualitative evaluation to learn how and why various components of the intervention exert any effects in various contexts. The economic evaluation also provides decision makers with evidence regarding the likely costs or cost-savings associated with wider roll-out of the intervention being tested.

Study outcomes will include: (i) refinement of a novel and scalable methodology with significant potential to engage community members and health care providers in MCH service improvement; (ii) development of a programme theory about mechanisms whereby PWGs exert their outcomes; (iii) direct transfer of findings to other Indigenous PHC services and to state and federal policy makers through well-established networks of knowledge exchange and partnership. Through this work the authors anticipate new knowledge of how best to facilitate improved quality of MCH care in Indigenous PHC settings and how to engage community members in driving health care improvements—this, in turn, will contribute to better intermediate health outcomes for women and babies and thus health outcomes for Indigenous Australians.

Ethics and Dissemination

Ethical Approval

Ethical approval has been obtained through the Human Research Committee of the Northern Territory Department of Health and Menzies School of Health Research (ethics approval number is HREC 2018-3076); and James Cook University Human Research Ethics Committee (H7441). Additional ethical approval was obtained from the Western Australian Aboriginal Health Ethics Council (890) and the Aboriginal Health and Medical Research Centre Ethics Committee (1439/18). All eligible participants are required to provide signed informed consent before taking part in the study.

Data Management

All study related information is stored securely at the sponsor organization. All participant information is stored in a locked cabinet at the sponsor organization. All data sets are allocated an identification number to maintain participant confidentiality. Only study team members who are involved in data analysis have access to data.

Raw data are kept in a locked cupboard in the Principal Investigator's Office, and electronic data are stored on a password-protected computer. After the study finishes, electronic data will be transferred to a CD-ROM and also stored in a secure database repository and password protected. Electronic data on any other computers will be deleted. Raw data will be retained for at least 5 and 15 years respectively in accordance with NHMRC and the Australian Code for the Responsible Conduct of Research guidelines (51).

Participating services are involved in all decisions about data usage. No reference will be made in oral or written reports which could identify participants or the services without their written consent. None of these data, collected as part of this research, will be re-used without explicit permission. Raw data will be transferred to investigators involved in data analysis in other universities in accordance with protocols to safeguard data integrity.

Governance

The Steering Committee of the Centre for Research Excellence in Integrated Quality Improvement (CRE-IQI) is the overarching collaborative structure within which WOMB sits and consists of a broader network of Indigenous primary health care stakeholders. The CRE-IQI Steering Committee provides advice where required on the implementation of the actions devised by the PWGs, including the measurement of intermediate health outcomes and identify opportunities for broader roll-out and scale-up of study learnings.

The WOMB Steering Committee is responsible for monitoring conduct of the implementation, data collection and reporting. Committee membership comprises investigators, participant PHC services, facilitators of the PWGs and other members to be determined by the group. This group comprises members from the sponsoring organization and has no competing interests. It also assists in facilitation between the PWGs and their respective PHCs to implement action for mums and bubs; review and endorse interim reports; devise a knowledge transfer plan in phase 1 of the study; and assists with knowledge transfer activities throughout the life of the study.

Any protocol modification will be documented with appropriate justification and approved by the investigator team and steering committee. The final version will be presented to the relevant Ethics Committees, if required.

As the potential for harm based on this trial of women's group activity is extremely low, no formal stopping guidelines have been proposed. Ongoing process evaluation will ensure that any unanticipated unhelpful outcomes are identified and can be addressed.

Dissemination and Data Sharing

This study will be conducted in partnership with the PWG in each community, thus, overall results will be available for the PWG through existing auditing systems in the PHC services and a face-to-face visit to each service to present and discuss their own results overall. Interim progress reports will be made available to the steering committee of the CRE-IQI and study steering committee. The de-identified results of the research overall, across the ten services, will be made available to participating services through webinars, videos, and a face-to-face meeting.

This study will generate evidence about the effectiveness and cost effectiveness of community participation that is translatable to PHC settings in other Indigenous communities. Dissemination of findings to other Indigenous PHC services and to state and federal policy makers will occur through well-established networks of knowledge exchange and partnership; particularly through the networks of the CRE-IQI and through policy briefs and academic publication.

Trial Status and Protocol Version

Recruitment underway: Began April 2018 (services) and October 2018 (facilitators) and expect completion of recruitment approximately March 2020.

April 2018 Original Version 1

May 2018 Version 1.1	Primary reason for amendment – Ethical review process NT Health Ethics committee requested amendments to inclusion criteria to include women who are pregnant. Ethics committee review requested clarification on risk mitigation processes for participants
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May 2019 Version 1.2	Primary reason for amendment- Modification of trial design from randomized to non-randomized. Statements were added and modified to improve clarity of trial design, participant inclusion and exclusion criteria and statistical methods.
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DATA AVAILABILITY STATEMENT

The datasets generated for this study are available on request to the corresponding author.

AUTHOR CONTRIBUTIONS

SL, CF-B, JT, YC-J, RB, JE, MP, VM, EC, RE, AE, MZ, KC, RP, MR-M, and JK initiated the study design, contributed to the development of the study, and application for funding.

EC, HF, MZ, and AE provided expertise in trial design and biostatistics. AE is conducting the primary statistical analysis. EC and HF are conducting the economic analysis. KC led the development of the protocol. All authors contributed to refinement of the study protocol and approved the final manuscript.

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not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpubh.2020.00073/full#supplementary-material>

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Cost-Effectiveness of Vitamin D Supplementation in Pregnant Woman and Young Children in Preventing Rickets: A Modeling Study

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Background: Literature on the cost of management of rickets and cost-effectiveness of vitamin D supplementation in preventing rickets is lacking.

Methods: This study considered the cost-effectiveness of providing free vitamin D supplementation to pregnant women and children <4 years of age with varying degrees of skin pigmentation to prevent rickets in children. Estimates for the prevalence of rickets were calculated using all cases of rickets diagnosed in Central Manchester, UK and census data from the region. Cost of management of rickets were calculated using National Health Service, UK tariffs. The efficacy of vitamin D supplementation was based on a similar programme implemented in Birmingham. Quality of life was assessed using utility estimates derived from a systematic literature review. In this analysis the intervention was considered cost-effective if the incremental cost-effectiveness ratio (ICER) is below the National Institute for Health and Care Excellence, UK cost-effectiveness threshold of £20,000 per Quality-adjusted life year (QALY).

Results: Fifty-seven patients (26 dark, 29 medium and 2 light skin tones) were managed for rickets and associated complications over 4-years. Rickets has an estimated annual incidence of 29.75 per 100,000 children <4 years of age. In the dark skin tone population vitamin D supplementation proved to be cost saving. In a medium skin tone population and light skin tone populations the ICER was £19,295 per QALY and £404,047 per QALY, respectively.

Conclusion: Our study demonstrates that a vitamin D supplementation to prevent rickets is cost effective in dark and medium skin tone populations.

Keywords: rickets, prevention, cost-effectiveness, incremental cost-effectiveness ratio, quality adjusted life years, decision tree model

Research in Context

Evidence Before This Study

Literature on the cost of management of rickets and cost-effectiveness of Vitamin D supplementation in preventing rickets is lacking in the UK and worldwide. Global consensus guidelines on Vitamin D rickets noted the lack of data to provide guidance on cost-effectiveness of supplementation (1).

Added Value of This Study

This study investigated the cost-effectiveness of an intervention where vitamin D supplements would be provided free of charge to pregnant women and children under 4 years of age in order to prevent rickets. Skin pigmentation is a risk factor for the development of vitamin D deficiency rickets (1) and hence this analysis assesses the intervention's cost-effectiveness in the general population and at-risk subgroups consisting of participants with varying degrees of skin pigmentation. Results from this study shows that the intervention is estimated to be clinically beneficial and cost-saving in participants with medium and dark-skin tone, respectively.

Implications of All the Available Evidence

There is evidence to support population-based vitamin D supplementation of pregnant women and children under 4 years of age as it reduces incidence of rickets (2). In this study we present evidence of cost-effectiveness of vitamin D supplementation in pregnant women and children <4 years of age with varying degrees of skin pigmentation in UK. Health care policymakers can use this evidence in implementing population-based interventions to reduce the prevalence of rickets and its complications in at-risk populations.

INTRODUCTION

Vitamin D is a fat-soluble nutrient required for calcium and phosphorus homeostasis and for skeletal mineralization. Vitamin D deficiency as reflected by serum 25-hydroxy vitamin D (25OHD) concentration of <30 nmol/l is associated with musculoskeletal and non-musculoskeletal manifestations (3). Musculoskeletal outcomes of vitamin D deficiency includes rickets and osteomalacia in children, osteomalacia in adults, reduced muscle strength and increased risk of falls (3). Non-musculoskeletal manifestations of vitamin D deficiency include increased risk of cancers, cardiovascular diseases, auto-immune diseases, all-cause mortality, infectious diseases, and age-related macular degeneration (1, 3).

The prevalence of vitamin D deficiency in the general population in England and Wales is 23% (3). Endogenous synthesis of Vitamin D occurs when ultraviolet-B radiation penetrates into the epidermis. Skin pigmentation interferes with sub-cutaneous vitamin D synthesis; as a result, deficiency prevalence is as high as 80% in population with darker skin tones and therefore they are at a higher risk of developing skeletal and extra-skeletal manifestation of Vitamin D deficiency than people with a lighter skin tone (3, 4). In addition deficiency has also been reported in vegans and vegetarians residing in UK (5).

Vitamin D supplementation, is known to be effective in preventing skeletal manifestations of vitamin D deficiency such as rickets and its associated complications (2). While there is

uncertainty about vitamin D deficiency preventing extra-skeletal manifestations, the recent individual patient metanalyses by Martineau and colleagues showed that it was effective in reducing risk of respiratory tract infections, especially in those who are vitamin D deficient (6).

Rickets results in bone pain, impaired growth, dental enamel hypoplasia and skeletal deformities including abnormally shaped skull, bowed legs, knocked knees, chest deformities and swelling of ends of the long bones. In severe cases, deficiency can cause hypocalcaemic seizures and life-threatening dilated cardiomyopathies (3, 7). Rickets and vitamin D deficiency can result in considerable costs to the National Health Service (NHS) especially when compared with the cost of vitamin D supplements, though there is a lack of evidence on this in the UK and worldwide (3). Rickets and vitamin D deficiency are also associated with the possibility of lifetime complications which if unaddressed can result in significant disutility (3).

Currently, the NHS operates the "Healthy Start" scheme for low-income households where multivitamin supplements, including 10 µg (400 IU) of vitamin D, are provided free of charge to pregnant woman and children under 4 years of age, with other families advised to buy the recommended supplements (8). However, uptake of Healthy Start vitamins is very low and cases of rickets are continued to be reported in the UK (9, 10).

Historically a table spoon of cod liver oil (5 ml containing 400 IU of vitamin D) was found to be effective in prevention rickets in children (11, 12). Following extensive review of literature and expert opinion, global consensus guidance recommends 400 IU of vitamin D as an effective dose in preventing rickets (1). In UK, the current DOH recommends 7.0 and 8.5 µg of vitamin D per day and in addition pregnant and breastfeeding women should receive 10.0 µg of vitamin D per day to ensure that the mother does not suffer from vitamin D deficiency thus avoiding neonatal hypovitaminosis (1, 3). To the best of our knowledge the cost-effectiveness of this public health recommendation has not been evaluated. Thus, the purpose of this study was to determine if Healthy Start vitamin D supplementation of all pregnant women and children under 4 years of age or only those with a darker skin tone who are at a higher risk of developing vitamin D deficiency associated rickets would be cost-effective in preventing rickets in children.

METHODS

Study Perspective

Analysis was conducted from a NHS and personal social services (PSS) perspective, following the National Institute's for Health and Care Excellence (NICE) reference case and was focussed on the population of Central Manchester, UK (13). The objective was to ascertain the cost-effectiveness of vitamin D supplementation in pregnant women and in children <4 years of age in preventing rickets in children in the following skin tone subgroups: light, medium, and dark.

Target Population

Skin pigmentation is a risk factor for rickets and therefore separate analyses were conducted for population subgroups

consisting of pregnant women and children <4 years of age with light, medium and dark skin tones. Skin tone assignments were based on rickets patients' ethnicity. Patients of Afro-Caribbean origin were considered to have dark skin tone; those from South Asian and Middle Eastern origin medium skin tone and those of European origin light skin tone. After analyzing the observational dataset, it was found that 95% of the rickets cases (95% CI 0.86–0.98) had onset before the age of 48 months. For this reason, children under 4 years of age were considered to be the primary target population, which is in line with the existing recommendations. Skin tone specific and overall prevalence of rickets in the target area were estimated using this observational dataset and census data (14).

Analytical Methods and Conceptual Model

A decision tree model (Figure 1) was developed in Microsoft Excel (© Microsoft Corporation). In addition to rickets, vitamin D deficiency is associated with other health outcomes, prevalence of which would change if prevalence of vitamin D deficiency changed (15). To account for this, the model included increases in mortality and disutility associated with vitamin D deficiency (3). They were chosen because evidence did not allow the quantification of causal links for more specific conditions, assuming an increased all-cause mortality summarized the effects of fatal outcomes, e.g., cancer; and non-fatal outcomes were summarized by assuming a disutility.

Vitamin D supplementation during pregnancy decreases the risks of infant vitamin D deficiency rickets (3). The model accounts for this as the observational dataset accounts for infant rickets cases related to their mother's vitamin D deficiency and cases developed post-birth; also intervention effect estimates capture the effect of vitamin D supplementation pre and post birth. Infant formula is enriched with vitamin D and formula fed infants should not be supplemented. The model accounts for this in the same manner as to prenatal supplementation.

Time Horizon

In the base-case, the time horizon is 4 years, the period over which vitamin D supplements would be provided free of charge. After this period supplementation and vitamin D deficiency rates, would eventually return to baseline with no differences in costs or utilities between the study groups expected during this time. Due to the limited data on lifelong complications, the base-case analysis assumes no incidence of lifelong complications, the impact of these assumptions is investigated in the scenario analysis where the time horizon is increased to lifetime in accordance with the NICE reference case.

Health Outcomes

Following the NICE reference case an attempt was made to measure health outcomes using quality-adjusted life years (QALYs) (13). To do this utility and disutility estimates were required for the health states included in the model, again according to the NICE reference case these utilities should be measured using a preference based instrument. However, no preference-based instrument is validated for use in early childhood and estimates of HRQoL in the included health states

are unknown. Thus, counterfactual utility estimates were derived from age adjusted population baseline and disutility estimates.

Baseline utility was estimated using an UK algorithm for EQ-5D-3L:

$$U_{\text{BASELINE}} = 0.950857 - 0.000259 * \text{age}^{2+} 0.021213 * \text{gender}$$

Where gender = 1 for males and 0 for females (16, 17).

Two systematic literature searches were conducted to identify evidence on HRQoL in rickets and vitamin D deficiency. Expert knowledge suggested non-existing evidence on HRQoL in life-long complications and scoping searches were not promising. As a result, systematic literature search to inform this parameter, which is only used in scenario analysis, when the time horizon extends to lifetime, was not conducted and the analysis relied on expert estimate.

Rickets and vitamin D deficiency related HRQoL targeted searches are reported in the Supplementary Appendix. The former resulted in identification of a single study, the latter two studies, one of which was excluded due to population differences (18–20).

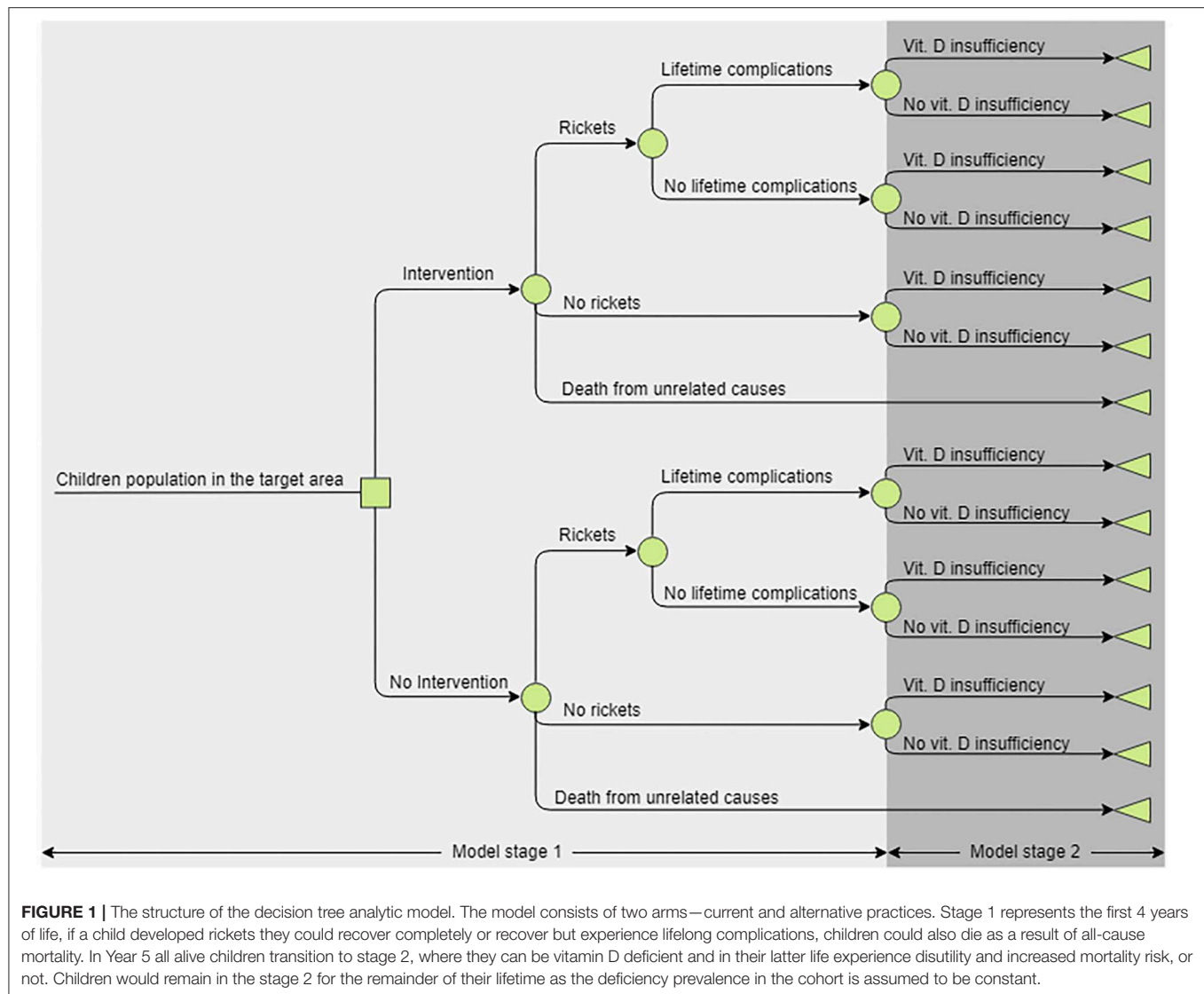
The study for HRQoL in rickets was assessed to have a high risk of bias, and hence was later replaced by a higher quality study (Table S1) published after the systematic literature search, identified by experts in the field (21). This study reported utility values derived from proxy valuations using a preference-based HRQoL tool: Child Health Utility 9 Dimension (CHU9D) questionnaire, preference-weighted by the general population in the UK (22). There was no information on the duration of rickets-related disutility, hence expert estimates were used.

The study on vitamin D deficiency-related HRQoL was assessed as being at low risk of bias. HRQoL in this study was measured using EQ-5D-5L and converted to utility values using a US valuation study (23). As the conversion method recommended by the Decision Support Unit (research body commissioned by NICE to provide methodological support) required the scores from the individual dimensions of the EQ-5D-5L to convert to the 3D version, which were not published, proportionate disutility, with reference to the baseline was estimated on the EQ-5D-5L scale and then assumed generalizable to the EQ-3D-3L scale (24). This disutility is only considered in the scenario analysis, when the time horizon extends to lifetime, as it only affects the population above 67 years (SD not reported). The additive method was used to estimate disutility in subjects experiencing lifetime complications and vitamin D deficiency (25).

Utility estimates used in analysis are reported in the Table 1. It should be acknowledged that the methods used for utility estimation comes with considerable limitations. However, they are believed to be the best considering the level of available evidence. All utility estimates were tested in the threshold analyses to assess the impact they may have on the decision.

Transition Probabilities Between Health States

The estimation of intervention effectiveness was based on two papers reporting the intervention implemented in Birmingham



and the baseline rickets incidence rates in the target area, acquired after analysis of the observational dataset (2, 26). It was assumed that the effectiveness of vitamin D supplementation in reducing the incidence of rickets would be equivalent to that reported in Birmingham and this effect would be achieved by increasing supplement uptake rates in pregnant woman and children under 4 years of age, figures presented in **Table 2** (2, 26).

Scenario analysis where the time horizon is increased to lifetime required additional parameters associated with considerable uncertainty. There was no evidence on the frequency of life-long complications, included in this analysis hence expert estimates were used. The assumed mean is 10% (assumed SD 10% of the mean value) for all the population subgroups. In the PSA this parameter was assigned a beta distribution with parameters $a = 8999.99$ and $b = 81000$.

Vitamin D deficiency in people aged 77 years or greater, ($SD = 8.84$) is associated with increased mortality risk (3). To account to this, in the presented scenario analysis it was assumed that by the

time the population reaches this age, vitamin D deficiency rates have reached the population baseline. Estimates of population vitamin D deficiency baseline was derived by pooling data from UK national surveys reported in SCAN report (**Table S2**) (3, 27, 28). The vitamin D deficiency-related mortality risk increase was estimated using figures acquired from Cochrane meta-analysis, RR for mortality = 1.05 (SE = 0.02); for patients aged 77 years or greater (3, 29). In the PSA the RR for mortality was assigned a Log-normal distribution with parameters $a = 1.05$, $b = 0.02$ and patient age was assigned a normal distribution with parameters $a = 76.92$, $b = 8.84$.

Calculation of Resource Use and Costs

The model considered the following costs: rickets treatment, intervention, management of vitamin D deficiency and lifetime complications.

All cases of rickets diagnosed in Greater Manchester were identified and confirmed based on abnormal biochemistry (low

TABLE 1 | Utility estimates used in the decision analytic model.

Type of the parameter	Value	Evidence source
Rickets		
Utility		
Mean (SD)	0.621 (0.18)	(21)
Assumed distribution	Beta (30.64; 18.70)	
Time in the state		
Mean (SD)	2 yr. (0.2)	Assumed SD; expert opinion
Assumed distribution	Gamma (100; 0.02)	
Vitamin D insufficiency		
Disutility		
Mean (SD)	0.2% (0.001)	(19)
Assumed distribution	Beta (958479.4; 478281120.8)	
Age at which disutility onsets		
Mean (SD)	67.04 yr. (6.70)	Assumed SD (19)
Assumed distribution	Normal (67.04; 6.70)	
Rickets related lifetime complications		
Disutility		
Mean (SD)	5% (0.005)	Expert opinion
Assumed distribution	Beta (38000; 722000)	
Duration	Lifetime	Expert opinion

TABLE 2 | Estimated intervention effect on rickets and Healthy start supplement uptake.

Parameter	Value	References
Estimated risk change of having rickets (OR) [*]		(2)
Mean value (SD)	0.41 (0.34)	
Assigned distribution	Log-normal (0.41; 0.34)	
Baseline supplementation prevalence		(26)
Woman	41.00%	
Assigned distribution	Beta (6446.00; 9278.00)	
Children	9.64%	
Assigned distribution	Beta (4104.00; 42656.00)	
Change in the numbers of distributed supplements (%)		(26)
Woman supplements [#]		
Mean value (SD)	17 (0.17)	
Assigned distribution	Beta (2871.95; 14022.00)	
Children supplements [#]		
Mean value (SD)	20 (0.20)	
Assigned distribution	Beta (1999.97; 8000.00)	

^{*}OR – odds ratio, calculated from the reported figures.

[#]SD was not reported; hence it is assumed to be 10% of the reported mean.

25OHD of <30nmol/l, high alkaline phosphatase and elevated parathyroid hormone) and confirmed radiological changes of rickets. Rickets treatment costs, till radiological signs of healing of rickets and normalization of biochemistry, were calculated from an observational dataset, using NHS tariffs 2016-2017 to derive unit prices (Table S3) (30). As these costs differed between population subgroups, group specific mean values were used.

TABLE 3 | Prices of the vitamin D supplements (source: "Healthy Start", 2018).

Type of the supplement	Price per pack (£)	Days sufficient	Price per year/ pregnancy (£)
Woman's Healthy start supplement	0.74	56	3.57
Children's Healthy start supplement	1.52	56	9.90

To account to the skewed data, a SD of 10% of the mean was assumed.

Intervention associated costs include costs of supplement acquisition (Table 3) and costs of intervention administration. It is assumed that administration costs also include the costs of a promotion campaign which was part of the campaign implemented in Birmingham and contributed, to an unknown extent, toward achieving the clinical effect (2, 26). The total price of the supplements per single patient is calculated as the price of supplements for children for the 4 year duration of the intervention and the price of supplements for pregnant woman for the duration of pregnancy.

To take into account the different ways in which the proposed program can be implemented, threshold analyses were conducted to inform an economically justifiable budget to cover costs of the promotion campaign, distribution of supplements and overheads. In the base case this is assumed to be £10,000 per year for the Central Manchester region.

In the scenario analysis where lifetime complications were assumed, costs of managing these and vitamin D deficiency-associated disutility are included. As there was no information identified, expert estimates were used (Table S3).

Uncertainty Handling

Various uncertainties surrounding the decision problem were assessed following recommendations by Claxton (Supplementary Appendix), the results of these analyses are presented in the following sections (31).

Role of the Funding Source

Thornton & Ross Pharmaceuticals, UK provided financial support only for collecting data on cost of management of rickets. No specific funding was used for data analysis, interpretation of results and writing of this manuscript.

RESULTS

Observational Dataset Analysis

Demographic characteristics of children under 4 years of age in Central Manchester area are presented in Table S4 and for those with rickets in Table 4. Risk of rickets estimates based on diagnosis between Jan 2009 to Dec 2013 are presented in Table 5 (annual risk and incidence rate) and Table S5 (4-year risk). Analysis of this dataset revealed considerable differences in risks of rickets estimates and rickets management costs, between population subgroups Table 6 and Table S3. Children with dark skin tones were found to be the most at risk and their treatment

TABLE 4 | Demographic characteristics of the incidence population (observational dataset).

Parameter	
Age at first admission (months)	
Mean (SD)	21.16 (22.42)
Sex <i>n</i> (%)	
Male	36 (63.16)
Female	21 (36.84)
Skin tone; <i>n</i> (%)	
Light	2 (3.51)
Medium	29 (50.88)
Dark	26 (45.61)

No missing observations.

TABLE 5 | Estimated annual risks of having rickets and rickets incidence rates by skin tone (observational dataset).

	General population	Children with medium and dark skin tones	Children with light skin	Children with medium skin tone	Children with dark skin tone
<i>n/N*</i>	9.33/36,413	9.00/19,069	0.33/17,344	4.83/14,117	4.17/4,952
Per 100,000 children	25.63	47.19	1.92	34.23	84.14

*Calculated as average number of cases per year by number at risk which, was acquired from census data (14).

TABLE 6 | Rickets management costs by population subgroup (observational dataset; 2016–2017 year price equivalent).

Population subgroup	Mean (£)	Observed SD
Children with light skin	1,750	48
Children with medium skin tone	2,385	3,759
Children with dark skin tone	7,305	16,208

costs were also the highest (£7,305 per patient), as they were more likely to suffer from rickets and vitamin D deficiency-associated complications such as hypocalcaemic seizures and dilated cardiomyopathy.

Base-Case Analysis

Deterministic base-case results are presented in **Table 7** and suggest that intervention is cost saving while producing health benefits for children with a dark skin tone, cost-effective in children with a medium skin tone but not cost-effective in children with light skin tone. Probabilistic base-case analysis results are presented in **Table 8** and the cost effectiveness plane is presented in **Figure 2** (13).

TABLE 7 | Base case analysis results (deterministic analysis).

Description	Results		Incremental		ICER (£)
	Costs (£)	QALYs	Costs (£)	QALYs	
Dark skin tone					
Comparator	21.46	3.334151			
Intervention	19.74	3.335339	−1.68	0.001188	Dominant
Medium skin tone					
Comparator	2.85	3.333224			
Intervention	12.14	3.333706	9.30	0.000482	19,295
Light skin tone					
Comparator	0.12	3.335305	-	-	-
Intervention	10.99	3.335332	10.91	0.000027	404,074

Uncertainty Handling

Univariate sensitivity analysis, where single parameters were changed between the lower and upper limits of their 95% confidence interval to test how this variation might influence the incremental cost-effectiveness ratio (ICER) value was undertaken. As shown in **Figures 3A–E**, the risk of having rickets could influence the adoption decision (i.e., whether the intervention was cost-effective) only in the medium skin tone subgroup. Other parameters were tested but did not alter the adoption decision in any population group.

Parameters elicited from experts, or where risk of bias was assessed to be high were tested in a threshold analysis (**Table 9**). In this analysis parameters were manipulated to identify the values at which the adoption decision changed. As in the previous analysis's adoption decision was the most certain for groups consisting of children with light and dark skin tones. In the medium skin tone group relatively insignificant changes in some of the parameter values (e.g., rickets duration, intervention costs without supplements, and change in supplementation rates) brought ICER values above the lower threshold value of £20,000. However, parameter values at which ICER exceeded the upper threshold value of 30,000 can be considered highly unlikely.

Structural uncertainty around life-long complications was assessed in scenario analysis, where the modeled time horizon was extended to lifetime. The results presented in **Table 10** show that the ICERs are reduced compared to the base case model with a 4-year time horizon but not to a point at which the intervention became cost-effective in a light skin tone population.

DISCUSSION

To the best of our knowledge, this analysis is the first cost-effectiveness study of a vitamin D supplementation-based rickets prevention programme in pregnant women and children <4 years of age to prevent rickets in children. An analysis conducted by York Health Economics Consortium concerning vitamin D was a cost-consequence analysis and is of limited comparability (32). The study conducted in Birmingham investigated the

TABLE 8 | Base case analysis results (probabilistic analysis).

Description	Mean results		ICER (£)			Probability cost effective	
	Costs (£)	QALYs	Mean value	95% confidence interval		$\lambda = \text{£}20,000$ per QALY	$\lambda = \text{£}30,000$ per QALY
				Lower bound	Upper bound		
Dark skin tone							
Comparator	£21.46	3.334138					
Intervention	£20.23	3.335279	Dominant	Dominant	Dominant	0.99	0.99
Medium skin tone							
Comparator	2.84	3.333228					
Intervention	12.17	3.333689	20,222	20,038	20,405	0.52	0.58
Light skin tone							
Comparator	0.12	3.335298					
Intervention	10.99	3.335323	423,340	417,256	£429,425	0.00	0.00

Probabilistic analysis results are generated by assigning standard mathematical distributions reflecting model parameter uncertainty (presented throughout the text and in the Appendix) and then randomly drawing a sufficiently large sample (in this case 10,000 draws) of model outputs, which is then analyzed using standard statistical techniques (mean, interquartile range), ICER confidence intervals acquired using Jackknife method (Simulation Modeling and Analysis, 2000).

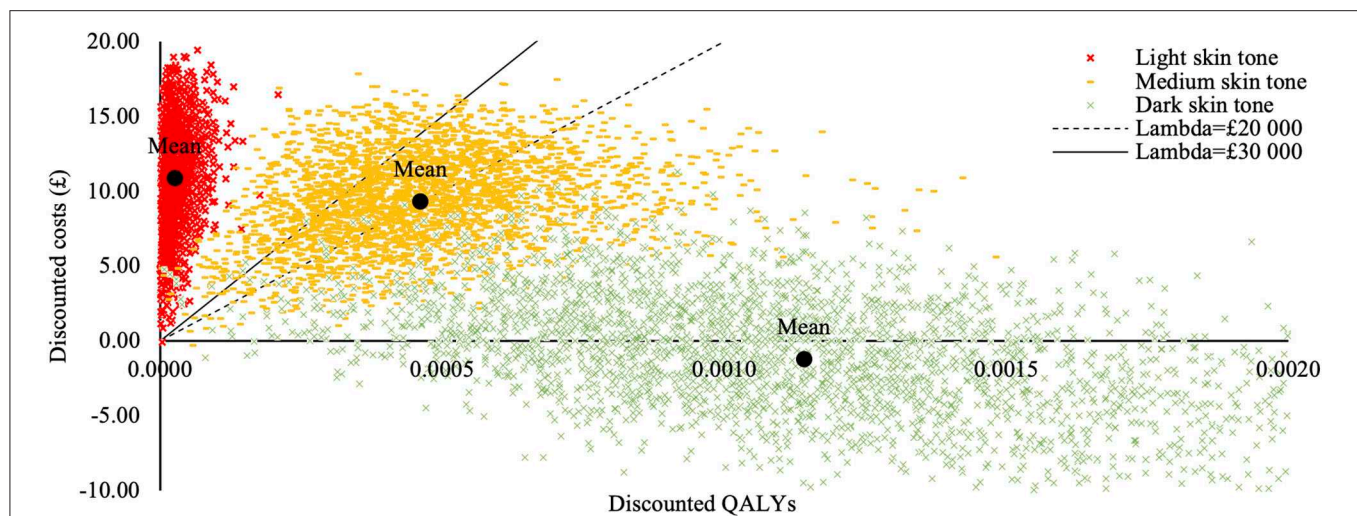


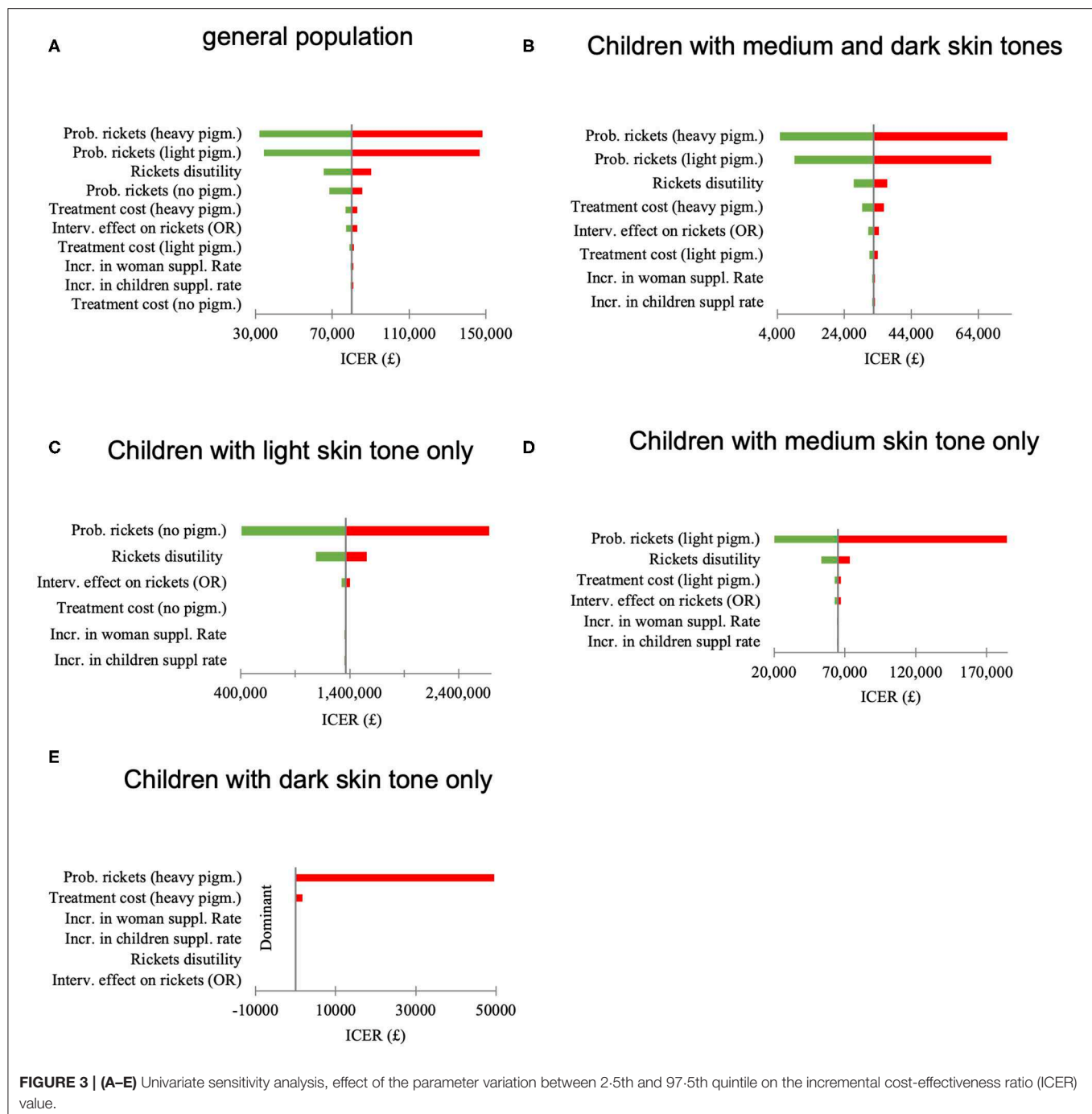
FIGURE 2 | Cost-effectiveness acceptability plane for the homogenous population subgroups (base-case analysis). Cost effectiveness acceptability plane was generated in the probabilistic sensitivity analysis and illustrates differences in costs and treatment outcomes between current and alternative practices, taking parameter uncertainty into account. Each dot represents a random probabilistic estimate of the incremental costs and quality adjusted life years (QALYs). Cost-effectiveness probabilities presented in the base case analysis are calculated as a proportion of these samples below the threshold values. The mean price per QALY value for the subgroup consisting of children with dark skin tone is below the “x” axis meaning the intervention is cheaper than the current practice; the price per QALY estimates for the subgroup consisting of children with medium skin tone are scattered in the upper quadrant around the threshold lines, illustrating uncertainty of intervention’s cost-effectiveness. The price per QALY estimates for the subgroup consisting of children with light skin tones are concentrated along the “y” axis, well above budget threshold lines, illustrating minimal health gains and considerably higher costs.

clinical impact of supplementation rather than cost-effectiveness (2, 26).

Our study shows that such a programme dominated standard care (increasing health outcomes while reducing costs) in participants who have a dark skin tone but is not cost-effective in participants whose skin tone is light. In participants with a medium skin tone the deterministic ICER is £19,295 per QALY; PSA: £20,222 per QALY crossing the willingness to pay threshold adopted by NICE of £20,000 per QALY but still below the upper value of £30,000 per QALY.

In our analysis the annual rickets incidence in general population was found to be 26 cases per 100,000 children under 4 years of age, significantly lower than that reported in Birmingham (120 cases per 100,000 children under 5 years of age) (2). We believe that the difference is due to geographical, socio-economic or methodological differences between the two studies and that our results are applicable to locations where the annual incidence rate of rickets is similar or higher.

Univariate sensitivity analyses showed that rickets prevalence was the main driver of cost-effectiveness. Baseline rickets



prevalence is the highest in dark skin tone participants and lowest in light skin tone participants as evidence from our and other studies suggests (3). Our results extend this evidence and suggest a relationship exists between skin pigmentation levels and the cost effectiveness of a vitamin D supplementation programme to prevent rickets in children.

Another univariate sensitivity analysis was conducted to address uncertainty around baseline HRQoL estimate (0.9607) which was varied between the quartiles for the difference between

HRQoL for children in perfect health (1.000) and children with rickets (0.621) (Table S6). The decision remained unchanged for participants with dark and participants with a light skin tone. However, for participants with a medium skin tone the decision would change between the 25th quartile (0.905) ICER = £23,192 and the 50th quartile (0.811) ICER = £34,701 if threshold of £30,000 per QALY is assumed and between the 100th (1.000) and 75th (0.905) quartiles if threshold of £20,000 per QALY is assumed.

TABLE 9 | Parameter threshold analysis to determine decision changing values for most uncertain parameters.

Value at which ICER is equal or exceeds threshold value							
Description	Base case value	Light skin tone		Medium skin tone		Dark skin tone	
		ICER = 404,074		ICER = £19,295		Intervention dominates	
Lambda (£)		20,000	30,000	20,000	30,000	20,000	30,000
Rickets duration (yr.)	2	40.45	26.96	1.93	1.28	<0	<0
Intervention costs (excl. supplements, £/yr.)	10,000	<0	<0	13,526	63,877	275,731	399,832
Intervention OR for rickets incidence	0.410	<0.001	<0.001	0.427	0.597	0.822	0.866
Increase in woman supplementation rates (%)	17	<0	<0	20	54	>100	>100
Increase in children supplementation rates	20.0	<0	<0	21	33	79	>100

Results of the threshold analysis testing baseline QoL presented in Supplementary Appendix.

TABLE 10 | Scenario analysis assuming lifelong complications.

	Deterministic ICER (£)	
	Base case value	Scenario estimate
Children with light skin tone	404,074	351,613
Children with medium skin tone	19,295	16,996
Children with dark skin tone	Intervention dominates	Intervention dominates

The base case analysis results were estimated assuming a four-year time horizon and zero probability of lifetime complications. It is known that rickets is associated with significant effects on health in the short-term. It is also believed that rickets in some cases has longer-term (lifetime) effects on health. When these are included (scenario analysis) the level of uncertainty in the results increases significantly because parameters associated with longer-term complications are based on expert opinion. If lifetime complications do exist at the levels our experts believe, and if other health benefits to pregnant women and children are also taken into consideration (33–35), then the ICER will be lower than estimated in the base case analysis, thereby increasing the cost-effectiveness of the intervention.

In summary, our study demonstrates that population-based Healthy Start Vitamin D Supplementation Programme in pregnant women and children under 4 years of age aimed to lower rickets incidence rates in children is clinically effective and cost-saving in participants with a dark skin tone, cost effective in participants with a medium skin tone (assuming threshold of £30,000 per QALY) but not cost-effective in participants with a light skin tone. We believe that results of this study will help to guide policy makers in allocating resources and implementing vitamin D supplementation programmes to prevent rickets in children.

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DATA AVAILABILITY STATEMENT

All datasets presented in this study are included in the article/**Supplementary Material**.

ETHICS STATEMENT

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. Written informed consent from the participants' legal guardian/next of kin was not required to participate in this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

VF, ZM, and RP: study design and manuscript preparation. VF, FJ, ZM, and RP: study investigator. FJ, AD, IZ, and RP: collection and assembly of data. VF, AR, and MS: data analysis. All authors: data interpretation, manuscript review and revisions, and final approval of manuscript.

FUNDING

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SUPPLEMENTARY MATERIAL

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It's the Destination *and* the Journey—A Mapping of the Challenges in Transport and Referral for Maternal and Newborn Health in Pandemics and Beyond

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INTRODUCTION

There has been an abundance of work in the last few years highlighting the importance of high-quality health systems as foundational to achieving better health outcomes (1). Quality provision of care is particularly critical for women and newborn during the perinatal and the immediate postpartum period (2). Transport issues are generally considered as important for access to care, but the quality of these transport and referral systems is equally essential. Recent systematic reviews related to the provision of intrapartum and postnatal care found that women were unlikely to accept referral if they had negative perceptions of the health facility (3) and were generally unsatisfied with delays in referral processes (4). Other studies have noted poor capacity at referring facilities (5), as well as challenges with coordination, communication, documentation, and adherence to referral protocols, especially for newborns (6).

The World Health Organization standards for quality of maternal and newborns care and for care of small and sick newborns include that women and newborns must be assessed and treated with available resources or appropriately referred, without delay at any time. Functional referral systems are thus integral at each stage: initial transport to the facilities, referral between facilities, and transportation whenever follow-up is required (7, 8). The COVID-19 pandemic has stretched the limits of health systems, including transport and referral pathways (9); the question of how women and their newborns reach these facilities becomes ever more urgent in this current pandemic.

WHAT IS REFERRAL WITHOUT A SYSTEM? JUST A RECOMMENDATION

Every health facility cannot not be equipped to deal with maternal and neonatal emergencies. Many countries have established regionalization of obstetric care, focusing on a few tertiary hospitals able to care for obstetric and perinatal emergencies, using a network of primary and secondary facilities to assess, stabilize, and refer (10). Referral systems call on inter-sector approaches that involve transportation, communication, and finance sectors and a coordinated response from the referring facilities and the receiving ones (11). This requires on going national or regional assessments of population needs and health system capabilities and coordinated communication.

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Seamless communication requires adequate staffing at the referring and receiving facilities, with clear roles before, during, and after transport (7, 8). Within both referring and receiving facilities, it may not be clear whose responsibility is it to assist or coordinate the process, and choices may be made *ad hoc* rather than through a centralized system. In a study surveying decision-makers in Argentina, 75% stated that issues with coordination between facilities was a key barrier to timely referrals (12). A study in the Netherlands identified a desire for providers at the referring facilities to be more familiar with the services and competencies at the receiving facilities (6). In both high- and low-income settings, poor coordination between facilities leads to lost time, unnecessary visits to multiple sites, and additional costs. Receiving facilities must be notified of incoming patients in order to prepare equipment, medication, and staff. In low-resource settings, reliable technological systems, such as functional landlines or sufficient mobile airtime, may be barriers to such care, but high-resource settings often have inequitable distribution of facilities and resources such that some receiving facilities are overwhelmed and others are inaccessible due to location or cost (13). A maternal and newborns mortality reduction project in Zambia and Uganda selected ambulance coordination as a key intervention to improve health outcomes (14), aiming to reduce the burden on individuals to implement and improvise. A study in a large Canadian city found unnecessary delays in neonatal transport related to a lack of immediate vehicle, blood, or bed availability. Further unpublished reports have noted a lack of precision on the timing of incoming critically ill patients to tertiary facilities, and in countries without universal health coverage such as the United States, there are many documented challenges related to insurance policies, from the necessity of traveling further to reach facilities within an insurance network to unexpected costs from emergency ambulance transport by road and by air (15).

Strengthening referral systems is not inexpensive (11, 16, 17). Beyond the purchasing or leasing of vehicles and petrol and maintaining a functional fleet, the training, certification, and supervision of drivers are also necessary for safe and stable transportation (13). Appropriate transport goes beyond sufficient number of vehicles and drivers. Oftentimes, ambulances are not fully equipped with proper stabilization medications or oxygen and incubators. A study at one tertiary facility in Nigeria found that <10% of critically-ill neonates had been transported in vehicles with oxygen or resuscitation equipment (13). Throughout the world, many patients travel to facilities in private vehicles; even in ambulances, medical providers do not always travel with the patient during referral. Other studies have found that many women and newborns are not stabilized prior to transport; many are discharged or referred with no follow-up plan (16). A mixed-methods study related to surgical capacity in Uganda reported on the common occurrence of women in obstructed labor receiving medication, but not being directed or escorted to a particular facility and left to coordinate their own transport (18). A report from Mexico documented cases of critically ill newborns transported without medical personnel present (19). Even in places where transport to a facility is free for patients, it is rare that transport is provided after discharge,

for either returning home or for follow-up visits. The cost of returning to the facility has been found as a barrier to care in both high- and low-income settings (4, 20).

Multiple Delays

The traditional framework of the three-delay model (delay in deciding to seek care, delay in reaching a health facility, and delay getting appropriate treatment) can also be applied to challenges specific to transport (21). We carried out a mapping exercise of the necessary aspects of a functional transport and referral system across each type of delay (**Table 1**). To reduce the first delay, there must be recognition of symptoms and knowledge of how to initiate rapid and safe transport. To reduce the second delay, vehicles must be dispatched and ambulances or other systems of transport must be deployed. The local geography, epidemiology, and political conditions must be understood in order to select appropriate methods of rapid and safe transport. In referring between facilities, coordination should be facilitated, understandable, and seamless. Equipment and staff for stabilization, triage, and treatment must be available at the referring and receiving facilities. To reduce the third delay, the facility level must meet the minimum standards to assess, treat, or refer the patient. Where post-discharge follow-up is needed, plans must be in place to assist families in returning for care. At every stage, families should be treated with respect, with clear communication and proper consent procedures, and as much involvement as possible.

In most countries, obstetric and newborns transport is still largely the responsibility of the woman and her family. Women may already face limited decision-making power or control of funds for care-seeking and transport, and this may be exacerbated further during acute medical emergencies, when there are unexpected additional costs or uncertain insurance coverage. Even where referral is initiated by a health facility, many women and their families are responsible for getting themselves to tertiary facilities, even when the condition is time-critical. As many as 60–80% of obstetric patients in one study in Ghana arrived in the referral hospital by taxi or taken by family or friends (22). Families coordinating their own referrals may face challenges with language and literacy, including the reasons and the level of urgency. Women and their families may not know where to go; they may not have the funds to pay for transportation or the time to arrange the safest or lowest cost options, especially if they or their newborns are in critical condition (6, 7, 13, 16).

There have been reports of health workers and hospital staff arranging and paying for referral, volunteering time to coordinate transport, or offering their existing personal phone and professional networks (23, 24). Thus, the system relies on health workers to go beyond their job duties, adding to both their burden and that of patients.

Respectful Care and Transport

Women and newborns deserve respectful care during each step on their journey to receive health services: during travel, upon arrival, and in the case of being referred to other facilities. Safe, reliable transport is as important as other healthcare needs (25).

TABLE 1 | Facets and functions of the transport and referral system in maternal and newborn care (potentially exacerbated by the COVID-19 pandemic).

Function	Requirements	Exacerbation due to COVID-19
Recognition of symptoms	<ul style="list-style-type: none"> Knowledgeable woman or family member, or health worker visit Antenatal assessment with appropriate skill and technology 	<ul style="list-style-type: none"> Health workers may be unable to visit houses because of travel restrictions and infection-prevention measures Women may have had fewer antenatal care visits and be less prepared
Initiate transport	<ul style="list-style-type: none"> Knowledge of whom to contact for information and care Phone number or SMS to call for help Free hotline or airtime 	<ul style="list-style-type: none"> Fear of travel and infection Unclear regulations about the definition of “essential” or “exempted” health care Unclear knowledge of what constituted an “essential” health intervention Informal payments by staff may not be available during times of economic hardship of staff
Dispatch center	<ul style="list-style-type: none"> Proficiency in multiple languages Ability to send ambulance or health care worker to home or referring health center 	<ul style="list-style-type: none"> Fewer staff available Center overwhelmed with COVID-19 cases
Ambulances	<ul style="list-style-type: none"> Vehicle must be maintained and available All costs must be covered (including fuel) Woman/newborn must be stabilized Ambulances must be sanitized frequently Boats, helicopters, or other modes of transport may be required where there are no passable roads 	<ul style="list-style-type: none"> Fewer drivers available Drivers must be protected from COVID-19 exposure (space and personal protective equipment, PPE) Restrictions on travel because of lockdowns Ambulances may be repurposed for COVID-19 patient transport Ambulances need more decontamination Increased risk of COVID-19 exposure due to ineffective infection control Oxygen may be less available because of need for COVID-19 patients Staff may be redeployed for COVID-19 patients Families may not be allowed to accompany woman/newborn
Basic level facilities	<ul style="list-style-type: none"> Rapid assessment and management Equitable triage based on severity Providers and medications must be available Ability for further transport/refer to other facilities Ability to stabilize pre-transport Must coordinate referral with dispatcher and receiving facility Detailed record keeping 	<ul style="list-style-type: none"> Fewer staff available Delays may occur if entry only permitted after COVID-19 screening Triage more complex with COVID-19 patients Oxygen and ventilators may be prioritized for COVID-19 More crowding and fewer beds available Food may not be served due to COVID-19 concerns Increased risk of COVID-19 exposure if no running water or ineffective infection control Potential shortages of medications due to supply chain disruption
Emergency-level facilities	<ul style="list-style-type: none"> Effective handover to receiving facility Equitable triage based on severity Assessment and management Detailed record keeping Registration for inpatient admittance Sufficient space, technology, and skill for critical care Private, hygienic spaces for postoperative recovery Proper consent for procedures Waiting room availability for families or support persons Civil registration information for newborns (birth and death certificates) 	<ul style="list-style-type: none"> Fewer clinical and administrative staff available Delays may occur if entry only permitted after COVID-19 screening Triage more complex with COVID-19 patients Oxygen and ventilators may be prioritized for COVID-19 More crowding and fewer beds available Food may not be served due to COVID-19 concerns Increased risk of COVID-19 exposure if no running water or ineffective infection control Potential shortages of medications due to supply chain disruption Reliance on technology is inequitable in poor facilities
Neonatal intensive care	<ul style="list-style-type: none"> Competent staff Appropriate pediatric equipment Facilitation of breast milk/human milk feeding Facilitation of skin-to-skin care when possible Family access to newborn Rooming-in whenever possible 	<ul style="list-style-type: none"> Fewer staff available Equipment may be delayed due to supply chain issues Limited oxygen availability because of COVID-19 prioritization Newborns may be kept separate from parents due to COVID-19 concerns Limited access of family members to neonatal intensive care unit (NICU) Space may have been repurposed for COVID-19 patients

(Continued)

TABLE 1 | Continued

Function	Requirements	Exacerbation due to COVID-19
Post discharge follow-up	<ul style="list-style-type: none"> • Information about how/who to follow-up, by phone or in person • Knowledge about danger signs • Transport should be provided free 	<ul style="list-style-type: none"> • Fewer staff available • Limited ability for in-person follow-up • Families may be discouraged from seeking postnatal care • Fear of exposure of newborn to pathogens
Respectful family communication and involvement	<ul style="list-style-type: none"> • Health facility must be a welcoming and supportive environment • Health workers should be trained, supported, and respected themselves • Families must be given transparent information and involved in decision-making • Translators and interpreters should be available • All women should be respected regardless of socioeconomic status, ethnicity or race or origin, age, preexisting conditions or disability, etc. 	<ul style="list-style-type: none"> • Family members may not be able to be present • Communication technology may not be equitably distributed • Fewer translators available • PPE hinders facial expressions, eye contact, lip reading • Few social workers available • Health care workers are overstressed • Guidelines may be changing rapidly • COVID-19 patients may be stigmatized

Even when transport is provided, there may be little or no assistance provided to facilitate the transfer and limited emotional or psychosocial support in a stressful time. In many cases, family members are unable to travel with the woman or newborns; at times, the woman or the newborns may not be stabilized before travel or accompanied by a health care professional, jeopardizing their health on the journey and leaving a vulnerable patient alone (13, 16). While rare, there have been reports of newborns separated from their parents in order to receive medical care at a different setting, thus leaving the newborns alone at a critical time for survival and limiting the parents' ability to consent for their child's care (19).

The impact of mistreatment during transport and referral for critical mothers and newborns, while unknown, is likely to be detrimental given the documented negative health effects of mistreatment during childbirth on maternal and newborns health (26). The receipt of poor quality care or poor treatment at previous health facility visits, including lack of assistance with transport, may deter care utilization, especially where the direct and indirect costs of care-seeking may be high. Women and families have been found to bypass the nearest options for perceived better quality care elsewhere, potentially leading to longer journeys, higher risk, and more delays (11). Families may completely avoid care-seeking (or delay until the health condition is more severe) due to stigma or fear of mistreatment upon arrival, as many women are blamed for arriving at facilities "late" and with complications, and some are even fined (25). Under-resourced and overcrowded facilities are more likely to treat women poorly or deny care, including turning people away, neglecting them once they arrive, or demanding payments before providing services or discharging (27, 28). Avoidance or denial of care may be affecting the most vulnerable, further increasing inequity in access to safe and respectful care.

Finally, the lack of a transport system to morgues or funeral sites leaves some families without a respectful option after the death of a family member (including stillbirths and newborns) at a facility or in transit (29).

THE DOUBLE BURDEN DURING POPULATION EMERGENCIES AND CRISES

This already challenging situation of maternal and neonatal transport is exacerbated by population emergencies, such as the one posed by the COVID-19 pandemic.

The COVID-19 pandemic has impacted health systems in low- and high-resourced settings alike, including the different aspects of transport and referral systems. As part of our mapping exercise, we delineated the various facets of a transport and referral system and how the COVID-19 pandemic is exacerbating or may exacerbate each step along the transport and referral pathway (Table 1).

Successful referral systems for obstetric and perinatal emergencies during population emergencies and crises require multiple contingencies along the pathway. Any weakness in the process can result in increased delays or failure to reach a facility, potentially leading to excess deaths. Existing barriers will only be exacerbated during emergencies, both in acute events and protracted ones. In some cases, travel has become unsafe due to fear of contagion (30) or impossible because of restrictions, which may result in fewer ambulances for obstetric and neonatal emergencies, fewer available drivers or mechanics, fewer options for public transport, and delays such as police roadblocks and reduced circulation for public and private transport. A recent WHO survey of health system disruption resulting from COVID-19 indicated that a wide range of health services, including those for obstetric and neonatal emergencies, have been negatively impacted by the pandemic (9).

Dedicated transport vehicles are often needed during infectious disease outbreaks (31, 32), but in weak health systems, this will come at the expense of primary care and essential services. Medical transport of women and newborns needs to be prioritized in population emergencies, and to the greatest extent possible, provided for free and with ensured safe passage (33). The importance of well-functioning dispatch services with active collaboration between referral levels and across sectors, formalized communication strategies, and transport arrangements becomes paramount. While the unique

epidemiologic situation in each setting will determine the specific policies, agreed-upon, adaptable protocols for referring and receiving facilities that respond to global standards for quality care are needed. This includes supervision and accountability for performance and additional support during crises.

BUILDING BETTER TRANSPORT SYSTEMS

A stronger transport system will result from an integrated and inter-sectoral approach. To strengthen systems, governments and health programs need to monitor the process by performing audits, collecting utilization and performance data, and being responsive to the needs of women and their families, as well as health workers and other support staff. More work is needed to continue improving and measuring effective referral and transportation interventions, policies, and strategies (4, 11). The COVID-19 pandemic has shed light on the existing weaknesses

in transport and referral systems and calls on the global maternal and perinatal health community to advocate and ensure that transport methods are safe, available, and effective.

AUTHOR CONTRIBUTIONS

This article was first conceived by VB and ES. ES wrote the first draft of the manuscript. All authors contributed equally to the final write-up. All authors approved the final version of the manuscript.

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Influence of Conditional Cash Transfers on the Uptake of Maternal and Child Health Services in Nigeria: Insights From a Mixed-Methods Study

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Background: Increasing access to maternal and child health (MCH) services is crucial to achieving universal health coverage (UHC) among pregnant women and children under-five (CU5). The Nigerian government between 2012 and 2015 implemented an innovative MCH programme to reduce maternal and CU5 mortality by reducing financial barriers of access to essential health services. The study explores how the implementation of a financial incentive through conditional cash transfer (CCT) influenced the uptake of MCH services in the programme.

Methods: The study used a descriptive exploratory approach in Anambra state, southeast Nigeria. Data was collected through qualitative [in-depth interviews (IDIs), focus group discussions (FGDs)] and quantitative (service utilization data pre- and post-programme) methods. Twenty-six IDIs were conducted with respondents who were purposively selected to include frontline health workers ($n = 13$), National and State policymakers and programme managers ($n = 13$). A total of sixteen FGDs were conducted with service users and their family members, village health workers, and ward development committee members from four rural communities. We drew majorly upon Skinner's reinforcement theory which focuses on human behavior in our interpretation of the influence of CCT in the uptake of MCH services. Manual content analysis was used in data analysis to pull together core themes running through the entire data set.

Results: The CCTs contributed to increasing facility attendance and utilization of MCH services by reducing the financial barrier to accessing healthcare among pregnant women. However, there were unintended consequences of CCT which included a reduction in birth spacing intervals, and a reduction of trust in the health system when the CCT was suddenly withdrawn by the government.

Conclusion: CCT improved the utilization of MCH, but the sudden withdrawal of the CCT led to the opposite effect because people were discouraged due to lack

of trust in government to keep using the MCH services. Understanding the intended and unintended outcomes of CCT will help to build sustainable structures in policy designs to mitigate sudden programme withdrawal and its subsequent effects on target beneficiaries and the health system at large.

Keywords: conditional cash transfer, maternal and child health, Nigeria, financial incentives, unintended consequences, utilization

INTRODUCTION

Globally there has been an increasing effort to improve Maternal and Child Health (MCH), yet maternal mortality is still relatively high particularly in Sub-Saharan Africa (SSA). The vast majority of these preventable deaths (94%) occurred in low-resource settings (1).

In Nigeria, maternal mortality fell from 576/100,000 and under-five mortality of 128/1,000 live births in 2013 (2) to 512/100,000 and 132/1,000 live births in 2018, respectively (2). However, the use of ante-natal care (ANC) in Nigeria rose from 61% in 2013 to 67% in 2018, and skilled birth attendants from 38 to 43.3%, respectively (2). Furthermore, there are inequities in the utilization of MCH services, which have persisted over the years in Nigeria. The Nigerian Demography Health Survey found that women in urban communities are much more likely to receive ANC from a skilled provider compared to women in rural communities; 84 vs. 56%, respectively (2). Similarly, among children under-five (CU5) 157/1,000 live births occur in rural communities and 92/1,000 live births in urban communities (2).

Several economic, socio-cultural behavioral, and health system factors contribute to low levels and inequities in the utilization of MCH services. These include high direct and indirect costs of healthcare-seeking; the opportunity cost of being away from work or income-generating activities (3, 4); lack of transportation fare; and inaccessibility of health facilities due to high cost, attitude of health workers (5); asymmetry of information etc. (3). Also, the most common method of paying for health care in Nigeria is through out-of-pocket payments as over 69% of total health expenditure is incurred by households out-of-pocket at health facilities (6). Hence, low-income people are unable to afford health services (7) and geographical isolation of hard-to-reach communities from health facilities limits access to services; and to trained health workers (8, 9).

In order to improve service utilization and reduce inequities in access to health services financial incentives such as conditional cash transfers (CCTs) have been increasingly utilized among the important tools to encourage behaviors or actions to a desired one, such as providing and utilizing maternal and child health services (10). Financial incentives operate by providing an immediate reward for a behavior that will lead to long term health

improvements (11). The incentives also influence health system actors on the demand side (to access the right services at the right time) and on the supply side (to provide the right services, of high quality, to all those who need them) (12).

Financial incentives particularly the CCTs are increasingly becoming popular in African countries including Nigeria which aid in improving health services (13–15), other sectors (16, 17) and poverty alleviation (18). The incentives also improve employee's performance (10), optimize the behavior of healthcare providers and their clients for maternal and neonatal health (12).

CCT in healthcare programmes functions by providing financial incentives to its users (specific population) to promote health-seeking behavior and create a positive impact on their health (11). CCTs have been suggested to potentially tackle financial barriers and motivational barriers to care-seeking and service utilization among beneficiaries (19, 20). CCTs seems to be particularly beneficial to poorer households, on the condition that those households will meet certain criteria such as periodic growth monitoring, up-to-date vaccinations, focused ANC, facility delivery, etc. to a health facility (18, 21, 22). While acknowledging the positive outcome of CCTs on health, of which has been the focus of most studies in recent times, scholars have called for greater attention to studying unintended consequences and moral concerns related to CCTs arising in a variety of local contexts (11, 23–25). The designs of CCT can be broadly similar but the specific designs are very different with regards to incentive size, time, duration etc. and these factors can make a difference (26).

In Nigeria, CCT was implemented within a special MCH intervention programme, called the Subsidy Reinvestment and Empowerment Programme (SURE-P) Maternal and Child Programme (SURE-P/ MCH) between 2012 and 2015 to improve uptake of MCH service in rural communities (27). Although a study has been published about CCTs in SURE-P/MCH (28), our paper provides in-depth exploration of how CCT worked, and the intended and unintended consequences of CCT implementation. This study therefore, aims to provide an insight into how CCT influenced MCH service uptake among pregnant women in rural Nigeria.

DESCRIPTION OF SURE-P PROGRAMME IN NIGERIA

In recognition of the poor MCH indices, the Nigerian Government between 2012 and 2015, implemented a Subsidy Reinvestment and Empowerment Programme (SURE-P), to invest profits from fuel revenues into a social protection

Abbreviations: CCT, conditional cash transfer; MCH, maternal and child health; CU5, children under-five; SURE-P, Subsidy Reinvestment and Empowerment Programme; SURE-P/MCH Subsidy Reinvestment and Empowerment Programme, Maternal and Child health; CHEW, Community health extension worker; PHC, Primary health centre; VHW, village health worker; WDC, ward development committee; ANC, ante-natal care; HMIS, health management information system.

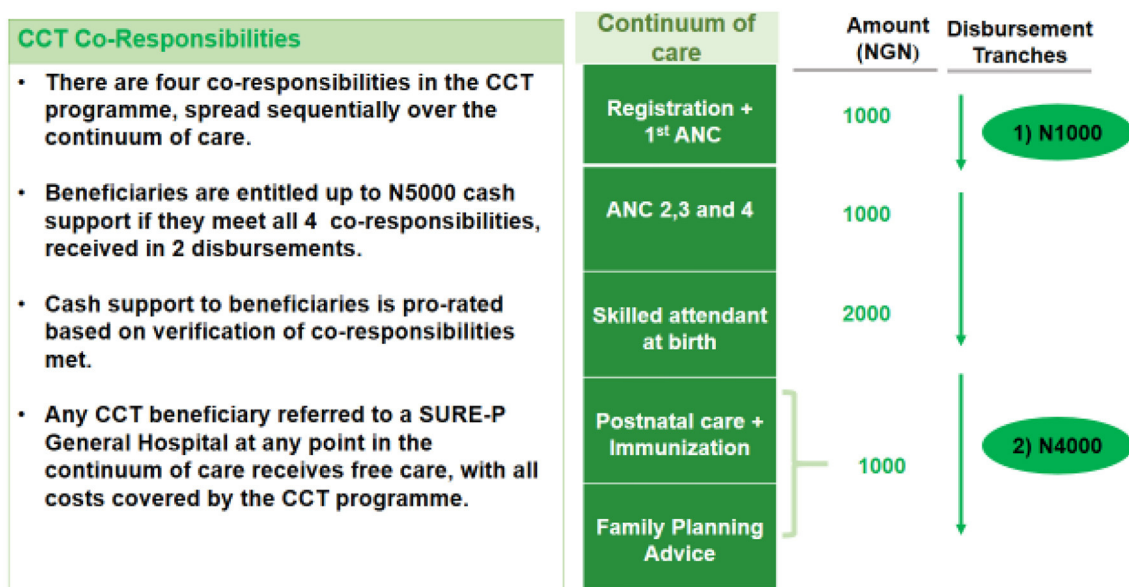


FIGURE 1 | Method of CCT payment. Source: MCH Programme Implementation Unit (PIU). The SURE-P MCH Conditional Cash Transfer Programme is designed to encourage women to register and complete the continuum of care for MCH services. By the end of 2013, ~14,500 women had enrolled for the CCT Pilot Programme in eight states and the Federal Capital Territory (FCT).

fund for vulnerable populations (27). The SURE-P had a mother and child health (MCH) component (SURE-P/MCH) aimed at improving the lives of mothers and their infants. The SURE-P/MCH programme comprised both supply and demand components. The supply-side component aimed to broaden access to quality maternity services and improve MCH outcomes through providing resources: recruiting and training PHC workers [2,000 midwives, 10,000 community health extension workers (CHEWs)], infrastructural development, and the increasing availability of supplies and medicines. The demand component aimed to increase the utilization of health services during pregnancy and at birth using a conditional cash transfer (CCT) programme as a resource. Its target was to incentivize pregnant women to prioritize access and utilization of facility-based MCH services in rural communities by paying the women a stipend of 5,000 naira (about US\$30) through the Continuum of pregnancy (Figure 1). All pregnant women in the community were eligible to participate in the programme irrespective of social-economic status because the CCT was not based on poverty reduction unlike other social security programmes but to support women in rural areas who are susceptible to financial hardship when accessing care. The programme was carried out in three clusters in each state, but, CCT was done only in one cluster in the nine States as a pilot intervention of which Anambra was among (28).

METHODS

Study Area

This study was undertaken in Anambra State, southeast Nigeria. Anambra state was chosen as a case study for in-depth

understanding of the inquiry into the CCT component of SURE-P/MCH programme. The state has a population of about 4.1 million and has a mix of urban and rural areas. MCH services are primarily provided from the Primary Health Centres (PHCs), each of which covers a given catchment population. In the context of the SURE-P/MCH programme, four PHCs are linked to a named general hospital for referral of Emergency Obstetric Complications (EOCs), and this is referred to as a cluster (4 PHCs +1 General hospital). Four PHC implemented the CCT programme in the State. However, there are some trained (maternity homes) and untrained (TBAs, Patent medicine Vendors) services who also offer unmonitored MCH provision.

The CCT intervention was originally designed to be administered using the above design as outlined in Figure 1. In practice, during implementation, beneficiaries only received money after their attendance of each service has been logged and verified, sometimes the length of this verification process meant that they were paid lump sums at the end of the delivery (28).

Study Design

This was a 5-year multi-phased mixed-methods retrospective study in which various components of the intervention were evaluated to provide a conceptual information on the process (including barriers and enablers) that underlie the effect of CCTs on the uptake of health services. Qualitative data collection and secondary quantitative analysis of routinely collected administrative and CCT data were used to enable adequate triangulation and an in-depth and rich description of findings. CCT is a fairly new initiative in the country at the time and was initiated as a pilot intervention (28). The full methodology protocol is explained in detail elsewhere (29). This paper focuses

one component (CCT intervention) of the wider study which was carried out in four (4) out of the 12 PHCs that implemented the programme.

Qualitative data [document reviews, in-depth interviews (IDIs) and focus group discussions] and quantitative methods [service utilization data from the Health Information Management System (HMIS)] were collected to cover pre-, during and post-SURE P/MCH programme. All the data collection tools/guides (Additional file 1) were developed by the researchers for the purpose of the study. Document reviews of relevant contextual literature were carried out. A logic map (30), of the expected process of programme interventions and how these could lead to outcomes was also developed. In-depth interviews of relevant stakeholders on both demand and supply-side were conducted to explore various dimensions of the CCT component of this programme and stakeholders' experiences in implementing CCT in the selected health facilities.

Sampling and Data Collection

The SURE-P/MCH intervention was carried out in three health facility clusters, all three had the MCH interventions and only one had an additional CCT intervention. For this study, we purposively selected the SURE-P/MCH + CCT cluster within the larger project which is the focus of our study.

The respondents were purposively recruited from these facilities to include the facility managers ($n = 4$) and other health workers (Midwives and CHEWs) ($n = 9$). On the demand side, we also conducted four FGDs (6-8 participants per group) with service users (pregnant women who had received/were receiving maternal care services at the time of the study), and four FGDs with Village Health Workers (VHWs) (4-6 participants per group). The VHWs who were members of the communities were responsible for identifying pregnant women in their community and encouraging them to attend and use health care facilities. VHWs also assisted the women in registering for antenatal care (ANC) and enrolment into the CCT registers. We also had four FGDs with the family members of service users (6-8 participants per group), and four FGDs with the ward development committee (WDC) members (5-10 participants per group), who are community representatives that oversee the functioning of the facilities. National and State-level policymakers and programme managers ($n = 13$), who were either involved in the design or administration of the CCT intervention were also interviewed. These groups of respondents were interviewed by experienced researchers about their experiences of the CCT intervention from their various perspectives. Each interview was audio recorded, and handwritten notes were taken. Interviews and discussion were conducted at places convenient for the respondents/participants including health facilities, offices, village halls, and houses. Each interview lasted for an average of 60 min. Prior to commencement of the data collection a relationship was established with some of the respondents during the research project planning meetings and mobilization phase of data collection.

The quality of data collection was ensured at different steps of the process (piloting and post-piloting revision of tools, collection, transcription, translation, anonymization,

digitization/entry into software, coding, and analysis). Mechanisms for quality assurance used included appropriate training (e.g., of transcribers of key concepts/terms used), multiple researchers working on the same data (e.g., coding by at least two researchers), continuous peer-review and peer-support within and between the different partner teams.

Secondary data on facility attendance and utilization from 2012 to 2017 were also collected from the facility Health Management Information System (HMIS) using a standardized pro forma developed for the study. Data was collected from registers stored in the facilities, and from monthly utilization data summaries sent to the local government authorities. The indicators collected include attendance for ANC, facility delivery, child immunization, post-natal care, and family Planning.

Data Analysis

Underpinning Theoretical Framework

To understand how CCT influences utilization of MCH services we drew majorly upon Skinner's (1957) reinforcement theory which focuses on human behavior in our interpretation of the influence of CCT in the uptake of MCH. According to the theory, behavior is a "function of its consequences," which implies that desirable behavior can be increased through the positive reinforcement technique or rewards. The reinforcers could be financial or non-financial (31, 32). The theory proposes that someone's behavior could be influenced by using reinforcement, punishment, and extinction. The key concept of the theory is "reinforcement," "punishment," and "extinction." Skinner, stated that rewards used to reinforce the desired behavior, punishments are used to avert undesirable behavior while extinction means to terminate a learned behavior. Skinner classified reinforcement into positive and negative reinforcement. The positive reinforcement occurs when the consequence resulting in the behavior one is trying to produce increases the probability that the desired behavior will continue. On the other hand, negative reinforcement is when a negative consequence is withheld if undesired behavior is demonstrated, which will increase the likelihood that the behavior you are seeking out for will continue. Punishment occurs when you enforce a negative consequence to decrease undesirable behavior. While negative reinforcement involves withholding a negative consequence to encourage desirable behavior, punishment is imposing a negative consequence to discourage unwanted behavior. The third concept; extinction trick up Operant Conditioning's sleeve which tries to attempt to terminate a learned behavior by withdrawing the positive reinforcement that stimulated the desired behavior. In this paper, the theory has utility in explaining the use of CCT as a financial reinforcement that stimulates pregnant women's decision to register for and utilize MCH services as well as deliver in health facilities. The extinction concept explains the sudden withdrawal of CCT leading to a reduction in attendance and utilization of MCH services among pregnant women. The desired learned behavior for MCH uptake among pregnant women in the implementing facilities was extinguished although not completely. Similarly, Motivation Crowding Theory reflects on the impact/effect of withdrawal of the monetary incentives in community perceptions of society and

motivation. It suggests that discounting monetary incentives of a programme lead to a reduction in intrinsic motivation and, consequently decrease zeal/effort to engage in a task or role (33).

Qualitative Data

The study used manual content analysis approach. Audio files were first transcribed in the language of the interview, and then translated to English language, where necessary. Initially two FGD and IDI transcripts with rich information were selected for thorough study and coding. Key themes relating to CCT and its influence on utilization of MCH services were generated and then formed the initial coding scheme. The scheme was then tested on four new transcripts (two FGD and IDI each) and refined into a final coding scheme which was then applied to all the transcripts. After which, related codes were grouped into four broad themes, which were used in interpreting and reporting the findings. The themes identified were: process of payment of CCT; facility attendance and utilization of MCH services; unintended consequences of the provision of CCT and; sustainability of CCT as a strategy for uptake of MCH services.

Quantitative Data

The secondary analysis of MCH facility data monthly HMIS data on key MCH indicators were analyzed using SPSS. All were measured as counts per facility across the SURE-P/CCT cluster: (1) total antenatal clinic (ANC) visits (the total number of women that month who visited the PHC for any ANC meeting); (2) total postnatal clinic (PNC) visits, (the total number of women that month who visited the PHC for any PNC meeting) and; (3) number of deliveries taken by a skill birth attendant. Frequencies and simple bar-chart were used for representing the results.

RESULTS

Based on our analysis of the data, four interrelated broad themes were identified: the process of payment of CCT and its influence on utilization of MCH services; facility attendance and utilization of maternal and child health services; unintended consequences of the provision of CCT and; sustainability of CCT as a strategy for uptake of MCH services. These are presented next.

Process of Payment of CCT and Its Influence on the Utilization of MCH Services

The payment process of the CCT prompted some pregnant women to comply with facility attendance and complete various stages of the utilization of MCH services to ensure they received the complete payment. This resulted in increased uptake of MCH services (**Figure 1**). The CCT given to the pregnant women who completed ANC visits, delivered at the facility and PNC visits was made available to the women through different processes, either as a one-off payment or four installment payments. However, CCT facilities paid the eligible women using various mechanisms that were not standardized. A respondent from a CCT facility explained how the payment was made:

“For the installment mode of payment, women who registered were given one thousand-naira, completion of 4 antenatal visits made the women entitled to two thousand naira, delivery at the facility attracted another payment of one thousand naira while an additional one thousand naira was given for immunizing the child making it a total of five thousand naira. The payment was not made monthly” (Health worker).

The SURE-P/MCH staff involved in making payments to pregnant women visited the facilities a minimum of twice per year. The visits of the women were documented and the facility would inform the women the day of payment from SURE-P/MCH staff so they will come with their registration cards to the facility for payments. The card will serve as proof of attendance to them in completing the different steps of the process and they will be paid accordingly for one to four visits.

According to the health workers, paying a pregnant woman who had registered and completed her antenatal visits a sum of 3,000 naira motivated the women to utilize the facility and ensured that they fulfilled every requirement that will enable them to collect the complete money.

Pregnant women who registered and completed their antenatal visits but did not deliver at the facility were only paid for what they were due for. This made other women strive to complete the whole process in that way more people came to the facility and continued to attend. From another CCT facility, in the words of one of our respondents:

“The women know that they won’t be paid completely if they don’t have a complete visit; they made every effort to see to it that they had a complete visit for their antenatal and delivery so they could receive their complete money” (WDC).

When the village health workers were asked if the women who did not receive complete CCT were offended or upset, they stated that *“the person would not like it, but she will understand that the mistake was hers. Some of them understood that it was their fault, some were given 3000N and they understood that the reason was that they didn’t complete” (VHW)*. Interestingly, women failing to achieve the desired behavior promoted by the CCT seemed to be blamed for this while contextual social and institutional barriers [facility security (reference our paper), cost, unplanned contingencies intrinsic in delivery] were somehow taken for granted in these perceptions.

On a practical level the installment payment (when paid on time) made to the pregnant women was a source of financial help to them to solve the problem transportation to the facility and this motivated them to attend and complete their antenatal visits as stated by family members of the facility users at a CCT implemented facility. *“It helped women very well. It helped them to continue their antenatal. It equally helped a woman whose husband is not financially buoyant. The woman will use that money for transportation....”*

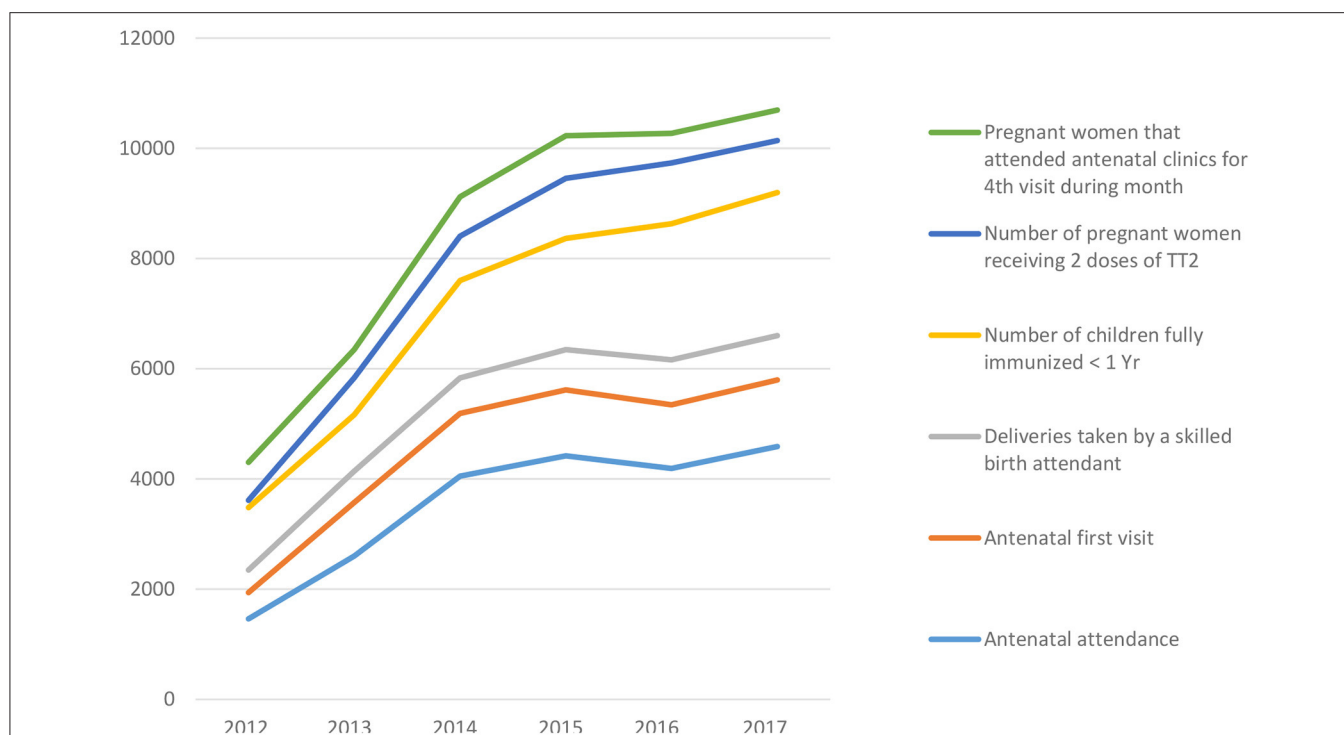


FIGURE 2 | Trend of MCH service uptake pre, during and post-SURE P/MCH intervention among pregnant women between 2012 and 2017 in Anambra state, Nigeria.

Facility Attendance and Utilization of Maternal and Child Health Services

Findings from our quantitative data showed a trend of rising utilization of MCH services from 2012 to 2015 in the CCT cluster (Figure 2). There was a steady rise in trend across all the 6 MCH indicators: antenatal attendance, antenatal first visit, antenatal 4th visit, delivery by a skilled birth attendant, pregnant women receiving 2nd dose of tetanus toxoid and the number of children fully immunized at <1 year of age.

The findings from qualitative study shows that providing pregnant women with CCT motivated them to attend health facilities with the resultant improved utilization of MCH services (antenatal, delivery, postnatal, and immunization). A health worker from one of the CCT facilities alluded to the fact that there was marked increase in the utilization of facilities, she said “that going back to the records before SURE-P, the most they had was about 2 deliveries monthly and majority of the time there was no delivery but during SURE-P/CCT, monthly neonatal deliveries rose to 12/ month.”

A midwife from another CCT facility also buttressed the increase in the number of facility deliveries; “And when they brought the CCT, we started having many clients. Before we left, our average monthly delivery rose to thirty. So, the CCT attracted them to come.” A village health worker described it as overcrowding of the facility, and she stated that it was because of the CCT. Other cadres of health workers interviewed in CCT facilities corroborated with the previous workers and their statement was as follows; “The SURE-P people tried and

with that CCT it made the pregnant mothers be coming here” (Facility Manager).

CCT motivated some pregnant women to use the facility to the extent that women who would not normally access care at the facility because they do not attach importance to the use of healthcare institutions for pregnancy and delivery started using the facility. Although some other services such as free drugs, delivery, treatment and mama kits accessibility motivated them.

“There were some women that were used to delivering at home, but because of the CCT, some of them came to the health center for delivery. But if they were not given that CCT, they would deliver at home to avoid paying hospital bills. “The money they received through the programme motivated them to come to the facility and again they had better access to treatments and other drugs needed for antenatal and delivery. This brought about the progress of the health center as more people started to utilize their services” (VHW).

Family members of service users and service users also added to the evidence that there was increased utilization of the health facility during the SURE-P/MCH programme, indigenes and non-indigenes alike accessed the facility because of CCT and they were happy with the programme. In their own words, “the money given to pregnant women helped to draw many women to the hospital,” “it was during that time (SURE-P /CCT) that many people started coming. If you come here at that time, you will see a lot of pregnant women.”

Unintended Consequences of the Provision of CCT

Healthcare staff mentioned that some of the women seem to perceive the CCT as an opportunity to collect money from the government and it seem that some were willing to get pregnant in quick succession so as to collect the CCT yet again from the government. The health workers had to counsel them again on the importance of child spacing.

“Before long, you will see the person again. We also advise them to watch how they give birth so that they will be able to give birth to the number of children they can raise and not be carried away by free things”. Some of the women interviewed were asking if SURE-P was coming back so they could go and get pregnant again” (VHW).

The money was not always used to pay for direct maternal and child health commodities. For example, some women started businesses with the money while others used it to solve other personal problems. In the words of a village health worker in one of the CCT facilities,

“The money that they received was seriously empowerment to them. I have seen a woman who came here and collected hers, since she collected it completely at once she used it to start selling something immediately, which she is now using to feed the child. There is another woman who collected hers and used it to buy pesticides for her crops. From there, she empowered herself”. Also, a family member of service users said that “the money-motivated them (Services user) to keep coming to this health center. Even if you are a millionaire no money is small money. At times, if you are given ₦1,000.00 you can use it to solve a big problem” (VHW).

Sustainability of CCT as a Strategy for Uptake of MCH Services

The decline in uptake of MCH services following withdrawal of the programme is shown in data utilization patterns (**Figure 2**) where there was an obvious decline across all the MCH service indicators as presented by a dip on the line graph in 2016 immediately after the programme was terminated.

In the word of a village health worker, *“That is not true there is a significant difference in the number of people that are utilizing it now and those that were utilizing it then. If 100 people were visiting the facility during SURE-P, now there are just 20 persons that are utilizing. Do you not see that the difference is much?”*, Family members of service users in another CCT facility confirmed the statement of the health worker. *They said that during SURE-P the facilities were usually overcrowded but now post sure the place had become empty with very scanty attendance.”*

The group of women who would not ordinarily use the facility that did because of the CCT also stopped coming. *“After the SURE-P MCH programme, some people were still coming but people that were not used to coming stopped coming” (VHW).* Another health worker said she noticed that since SURE-P stopped people no longer came to the facility as before. And one of them gave the reason being that it was because CCT was stopped. *“When you tell them to come now, they will tell you they won’t that they don’t give money anymore (referring to the CCT*

payment)” (VHW). Some clients who were coming from other villages that were not walking distances to the facility also stopped attending because they could not afford the transportation fare and had no hope of collecting CCT.

The withdrawal of the conditional cash transfer and the SURE-P/MCG programme also led some to distrust in the health system and subsequent reduction in utilization of MCH services. Consequently, some women began to visit other service providers, including TBAs. In the word of a WDC member, *“The problem of inconsistencies in government policy is discouraging to some people. I once met a woman whom I talked to about coming to the health center and she reminded me that her daughter gave birth and was then not among those that were paid because the programme has seized to operate. She said I should leave her alone those things about government are not trustworthy” (WDC).*

However, despite the withdrawal of the programme and its financial incentives, some service users still have confidence in health system and maintained unwavering trust in health providers due to their satisfaction and the level of interpersonal trust previously built on the health providers.

DISCUSSION

This study highlights three key issues the positive effect of CCT; the unintended consequences of CCT; and the sustainability of CCT in MCH services uptake. The positive effects relate to how CCT improved uptake of MCH services directly as a motivating factor and indirectly due to the method of payment of CCT. The unintended consequences of CCT relate to the effect of CCT that although was beneficial to the recipient but not a goal for implementing CCT, and thirdly, the failure of the programme to sustain its goal in the long term.

Our study revealed that implementing CCT contributed to increased uptake and utilization of MCH services in the study facilities. This could be attributed to the anticipated reinforcer/reward (CCT) as Skinner postulated in his reinforcement theory which states that behavior is a function of its consequences, on which our study hinged on (32). The implication is that CCT was a good motivating factor for some women. It undoubtedly took care of some financial barriers which are a major reason for poor health-seeking behavior especially among rural residents in SSA (34–36) as well as the opportunity cost of being away from income-generating activities during a healthcare-seeking time (3, 37). Since the incentive was paid post-behavior, those motivated by the CCT had to have some prior resources that allowed them to perform the desired behavior (e.g., pay for transport) before collecting the money weeks or months later.

More so, our findings are suggestive of temporary reduction of home and traditional birth deliveries in the study communities since pregnant women who would ordinarily not use health facilities started doing so. This finding conforms to the assertion that cash incentives can be useful in promoting positive health-seeking behaviors among women in rural communities (38). Our finding is in consistence with a systematic review on

the impact of CCT on Maternal and Newborn Health in Kenya, Malawi, India, Nepal, Uruguay, Cambodia, and South Africa which showed a significant increase in the utilization of different MCH service (prenatal monitoring, ANC, facility deliveries and, immunization) (22, 28, 39) among the target population. A similar study in Nigeria corroborated with our study showing a significant increase in more women attending four or more ANC visits, facility birth, and receiving two or more tetanus toxoid doses during pregnancy (28, 40). In the context of other healthcare preventive and curative services, CCT had been previously reported to improve: HIV testing, care, and prevention (13, 41); completion of tuberculosis treatment regimens (42, 43); adherence to the hepatitis B vaccine (44) and; nutritional uptake (45).

The payment process of CCT instilled the desired behavior among pregnant women who were determined to complete different stages of the conditions attached to payment of the monetary incentives. This suggests that women's continual efforts to meet the condition for CCT were stimulated leading to improved MCH uptake which would have been lower if the payment was one-off. Our finding has important public health implications in regions where uptake of MCH services is low.

We found that the CCT which was intended to motivate women to use health facility resulted in a reduction in birth spacing intervals. The women receiving CCT saw it as an opportunity to get money from the government, so, many of them were getting pregnant quickly to benefit from the financial incentive. The long term effect of such programme could be outrageous increase in population particularly among CU5. Our finding is in line with other studies that show that conditionality attached to the CCT undermined the programme's objective. For instance, a financial incentive programme intended to increase demand for public maternity services was observed to increase pregnancy rates (18, 46). Another study reported in Brazil, where CCT was designed to improve children's nutrition outcomes, but, led to some parents under-investing in their children's health, which resulted to reduction in their weight due to the erroneous parents perception that CCT and other programme's benefits would be discontinued if the children grow well (47). Additionally, we found that CCT was a financial aid for establishing petty businesses and solving personal problems outside what it was intended for. Our study agrees with previous studies which averred that CCT was used in addressing poverty as beneficiaries indicated that they utilized the money in establishing businesses (40, 48). This is not a surprise as 40.1% of the total population of Nigeria were categorized as being poor and has actual per capita expenditure less than N137,430(\$381) per year (49).

As evident in our study implementing CCT as a behavioral change tool for MCH uptake was not a sustainable strategy as some women were demotivated from using health facilities following its withdrawal, thus decline in MCH services attendance. It was envisaged that with CCT, overtime, the women would come to understand the importance of accessing health care during pregnancy and delivery given that they were taught all the time and they confessed to their observed reduction in maternal and child mortality. Despite that, as soon as the

programme ended and over time they realized the money was not going to be paid anymore, most of them withdrew from utilizing MCH services in the facility. The majority of village health workers observed a reduction in the number of clients. This was demonstrated in the dip curve as shown in figure although the curve did eventually continue declining afterward probably due to other MCH programmes (e.g., Saving One Million Lives) that commenced soon after SURE-P/MCH programme was withdrawn by the new federal government. This is suggestive that for CCT programmes to be sustained and possibly scaled-up, it is largely dependent on political will and support. This is evident in the literature (11, 23, 26) suggesting that the use of financial incentives to advance a population's health-seeking behavior, at times, do not last long because it does not impact intrinsic motivation and there the life span seem dependent on political support available to them (10). The inability of financial incentives to sustain long-term health improvements have been often reported (10) and the authors equally noted that the sustainability of financial incentives programmes is dependent on efforts of policy champions in donor and governmental organizations to ensure political and financial support and on whether it is subject to specific political interests, and recognizing this has proven helpful for programmes in other LMIC countries such as Kenya and Uganda.

It is important that policymakers and government should reflect on and build-in a sustainable structure in policy designs to mitigate sudden programme withdrawal and its subsequent effects on service users and the health system at large. Exploring other forms of incentives which could provide long-term benefits to beneficiaries while also putting into consideration measures to avert or control negative unintended consequences of such a sustainable strategy.

Strengths and Limitations of the Study

A major strength of this study is that it explored the views of different actors, who were either directly or indirectly involved with the planning and/or implementation of the programme. The cross-cutting response supplied by the respondents provided an in-depth overview of how CCT influenced MCH uptake in Anambra State. More so, using mixed methods; qualitative and quantitative (pre and post service utilization data) contributed largely to the richness of the study because it enabled complementarities and validation findings through triangulation.

Our study has some limitations. First, results of our sample may not be generalizable to others states/Nigeria, since we collected data from just 1 state out of 9 states that implemented SURE-P/MCH+CCT. However, principles highlighted in this study may be transferable to similar contexts. Secondly, we did not explore the influence of supply side factors on the MCH uptake, which may have also contributed to increased uptake of MCH services in the study communities. Furthermore, although ANC, health facility delivery and PNC utilization increased during the programme implementation, it remains unknown whether CCT has a significant effect on pregnancy outcomes, which this study did not measure, this highlight an area for further study.

CONCLUSION

In this study, it has been established that CCT incentivized pregnant women leading to increased uptake of ANC, facility delivery, and PNC which had helped in improving temporary access to these MCH services as more women were able to use health facilities better than before the programme in Anambra State, Nigeria. Ultimately, in combination with other measures, it removed financial barriers to accessing MCH services. The programme equally had some unintended outcomes which include assisting beneficiaries financially in setting-up businesses to advance their standard of living; reduction in childbirth spacing and trust in the health system. However, withdrawal of the CCT led to a decline in uptake of MCH services in the study facilities. CCT as a social intervention for the uptake of MCH services is a sustainable strategy. The findings will be useful to policymakers and the government in designing and implementing health programmes to enhance access to health services.

DATA AVAILABILITY STATEMENT

The datasets presented in this study can be found in online repositories. The names of the repository/repositories and accession number(s) can be found below: University of Leeds SAN (Storage Area Network) repository, http://library.leeds.ac.uk/info/422/policies/189/university_of_leeds_research_data_management_policy/1.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Ethical approvals were obtained from the Faculty of

Medicine and Health at the University of Leeds, United Kingdom (ref: SoMREC/14/097), and the Health Research Ethics Committee of the University of Nigeria Teaching Hospital, Ituku-Ozalla, Enugu (Ref: NHREC/05/02/20088-FWA00002458-IRB00002323). The patients/participants provided their written informed consent to participate in this study.

CONSENT FOR PUBLICATION

Informed consent for publishing anonymised data was obtained from all study participants prior to the interviews.

AUTHOR CONTRIBUTIONS

AM, TE, OO, BU, and TM conceptualized the study. UE, CO, PO, UA, and EE participated in data collection and involved in data analysis. UE, CO, PO, UA, EE, and BE prepared the first draft of the manuscript. All authors reviewed and approved the final version of the manuscript.

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Extending Postpartum Medicaid Beyond 60 Days Improves Care Access and Uncovers Unmet Needs in a Texas Medicaid Health Maintenance Organization

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Under longstanding federal law, pregnancy-related Medicaid coverage is only guaranteed through 60-days postpartum, at which point many women become uninsured. Barriers to care, including lack of insurance, contribute to maternal mortality and morbidity. Leveraging the Families First Coronavirus Response Act, a federal law requiring that states provide continuous coverage to Medicaid enrollees during the COVID-19 pandemic as a condition of receiving enhanced federal financial support, we examine whether postpartum women seek additional care, and what types of care they use, with extended coverage. We analyze claims from the Parkland Community Health Plan (a Texas Medicaid Health Maintenance Organization) before and after implementation of the pandemic-related Medicaid extension. We find that after implementation of the coverage extension, women used twice as many postpartum services, 2× to 10× as many preventive, contraceptive, and mental/behavioral health services, and 37% fewer services related to short interval pregnancies within the first-year postpartum. Our findings provide timely insights for state legislators, Medicaid agencies, and members of Congress working to improve maternal health outcomes. We add empirical evidence to support broad extension of Medicaid coverage throughout the first-year postpartum.

Keywords: postpartum coverage, Medicaid extension, health services utilization, maternal health, rapid repeat pregnancy

INTRODUCTION

Under longstanding federal law, individuals eligible for Medicaid on the basis of pregnancy are only guaranteed 60 days of postpartum coverage (1). After this arbitrary cliff, many women become uninsured (2, 3). Women's health experts, including the American College of Obstetricians and Gynecologists (ACOG) (4), maintain that inadequate access to health insurance during the full year postpartum contributes to preventable maternal mortality and morbidity.

Some state legislatures and Medicaid programs across the country are considering extending the postpartum coverage period beyond 60 days to improve maternal health outcomes. Most states opted to pursue iterations of this policy via Section 1115 waiver authority. Then, in March of

2021, the American Rescue Plan Act (ARPA) created a new, streamlined pathway for states to extend postpartum coverage via a Medicaid state plan amendment (SPA) (5). Weeks later, the Biden administration issued its first approval of a Section 1115 waiver from the state of Illinois to extend coverage (6).

Since the passage of ARPA and the approval of the Illinois waiver, state activity to adopt this policy has increased (7). As a result of this momentum, the United States Congress is considering building on the ARPA SPA by requiring states to extend coverage for pregnant women who rely on Medicaid for pregnancy-related care to 12 months after the end of pregnancy as part of the Build Back Better agenda (8). Questions remain, however, regarding whether individuals will utilize additional health care services and experience improved outcomes with extended postpartum coverage.

A provision in the Families First Coronavirus Response Act (FFCRA) of 2020 provides a unique opportunity to study the potential impact of extending the Medicaid postpartum coverage period. By requiring that state Medicaid programs provide continuous coverage to enrollees through the end of the COVID-19 public health emergency (PHE), the FFCRA functionally extends coverage for pregnant women beyond 60 days postpartum (9, 10).

While decades of health services research demonstrate that broadening access to health insurance, including through Medicaid, improves insurance coverage and maternal health outcomes, no study has used claims data to examine the impact of the FFCRA's continuous coverage provision on postpartum utilization in real time (11–13). Thus, the objectives of this study were to determine whether postpartum women use additional health care services with extended Medicaid coverage, what types of services they use, and what diagnoses are associated with their postpartum health services utilization. These findings are timely and help inform the ongoing debates in state legislatures and Congress about the benefits of extending postpartum coverage under Medicaid.

METHODS

We conducted a retrospective cohort study of postpartum women using Medicaid claims data from the Parkland Community Health Plan (PCHP). Of note, pharmacy claims were not included in these analyses. We analyzed all singleton deliveries between 06/01/2019 and 12/31/2020 among women aged 14–48 years old. Two postpartum cohorts were identified: a Pre-FFCRA cohort of women who delivered before 01/17/2020 and were, therefore, not impacted by the coverage extension, and a Post-FFCRA cohort of women who delivered on or after 01/17/2020 and were eligible for the coverage extension (which went into effect 03/18/2020). Women covered by Traditional Medicaid, the Children's Health Insurance Program (CHIP) unborn child option, and those with invalid eligibility records were excluded (see **Supplementary Figure 1**). A cohort of Medicaid-insured children age 2–17 was identified as an external comparison group to control for secular trends and pandemic-related effects on utilization.

In a secondary analysis, the Pre-FFCRA cohort was further divided into women who experienced a coverage termination at 60 days postpartum (i.e., without subsequent coverage) and women who remained eligible for Medicaid after 60 days postpartum under a different eligibility category (i.e., with subsequent coverage) to further characterize the impact of extended postpartum coverage pre-pandemic. Eligibility categories for subsequent Medicaid coverage included pregnancy-related Medicaid (for new pregnancies), Temporary Assistance for Needy Families (TANF), and Medicaid for children under age 19 for the teenage mothers.

Primary outcomes were health services utilization, including postpartum and all-cause outpatient services, mental/behavioral health (MBH) and substance use disorder (SUD) services, preventive and problem-related services, and emergency department (ED) and inpatient services (14). All COVID-related diagnoses were removed from the analyses to avoid any skewness of Post-FFCRA data due to COVID-related utilization. Outcomes were measured in the first-year postpartum across the following time intervals: 7–90-days; 91–182-days (i.e., 3–6-months); and 183–365-days (i.e., 6–12-months). The 90-days cutoff was used to reflect that, under federal law, pregnancy-related Medicaid eligibility continues through the end of the month in which the 60-days postpartum period ends (1). Coverage for pregnant women, therefore, might continue for up to 90-days postpartum when the end of the 60-days postpartum coverage period overlaps with the beginning of a calendar month. We, therefore, used the 90-days upper-bound cutoff for all women (rather than actual end-of-coverage date) as a stringent benchmark and to facilitate comparison with the Post-FFCRA cohort. Sensitivity analyses using actual end-of-coverage date yielded similar findings (data not shown). Utilization was calculated for each cohort either by dividing the number of members with a specific type of claim by the cohort size (percent cohort) or by dividing the number of claims of a specific type by the cohort size (visit rates per 100 members).

The primary analysis was to measure between-cohort differences in health services utilization, comparing Pre-FFCRA vs. Post-FFCRA cohorts. Adjusted analyses were not performed because baseline characteristics were comparable between cohorts. For outpatient services claims, primary diagnoses were identified and categorized as postpartum, general exam, pregnancy-related, or contraceptive services. Furthermore, diagnoses and places of service were used to categorize claims as MBH/SUD, preventive, problem-related, or acute care (ED and inpatient) services.

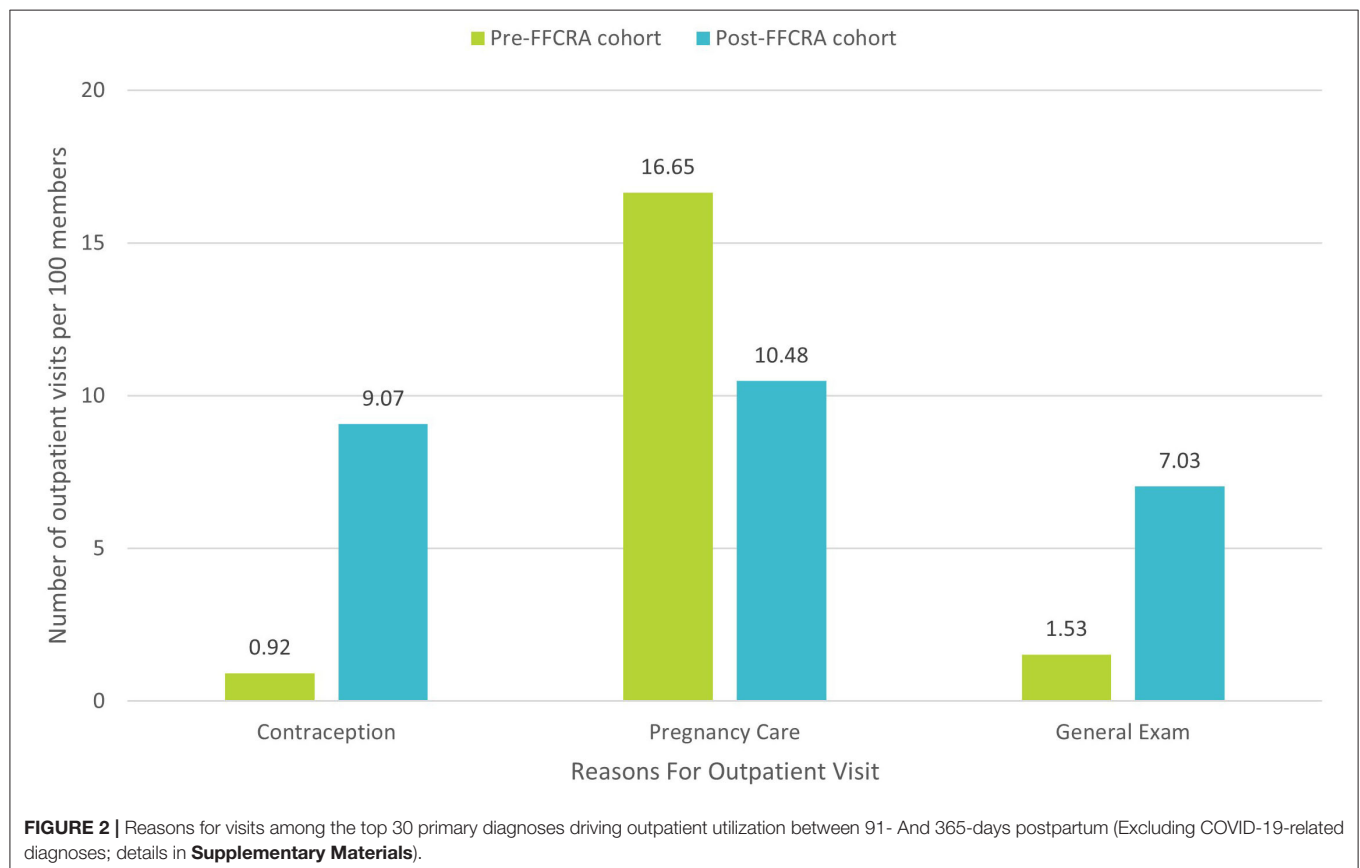
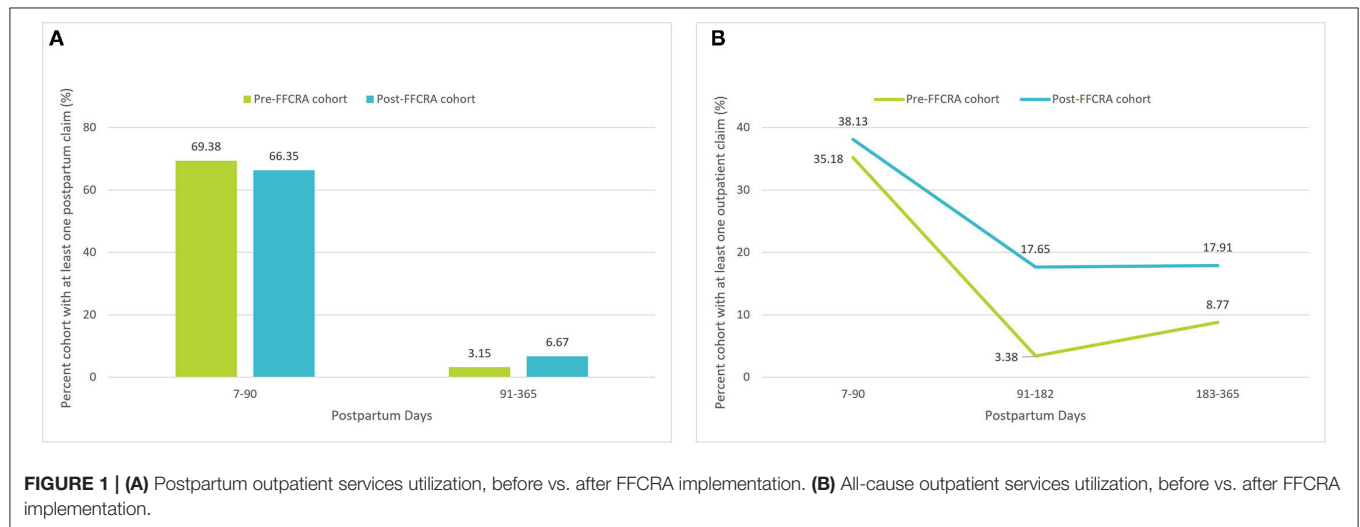
The secondary analysis was a three-way comparison of health services utilization among Pre-FFCRA women without subsequent coverage vs. Pre-FFCRA women with subsequent coverage vs. Post-FFCRA women. Results of the secondary analysis are reported in the **Supplementary Materials**, along with additional methodologic details, including a cohort creation diagram, variables definitions, and a comparison of baseline cohort characteristics.

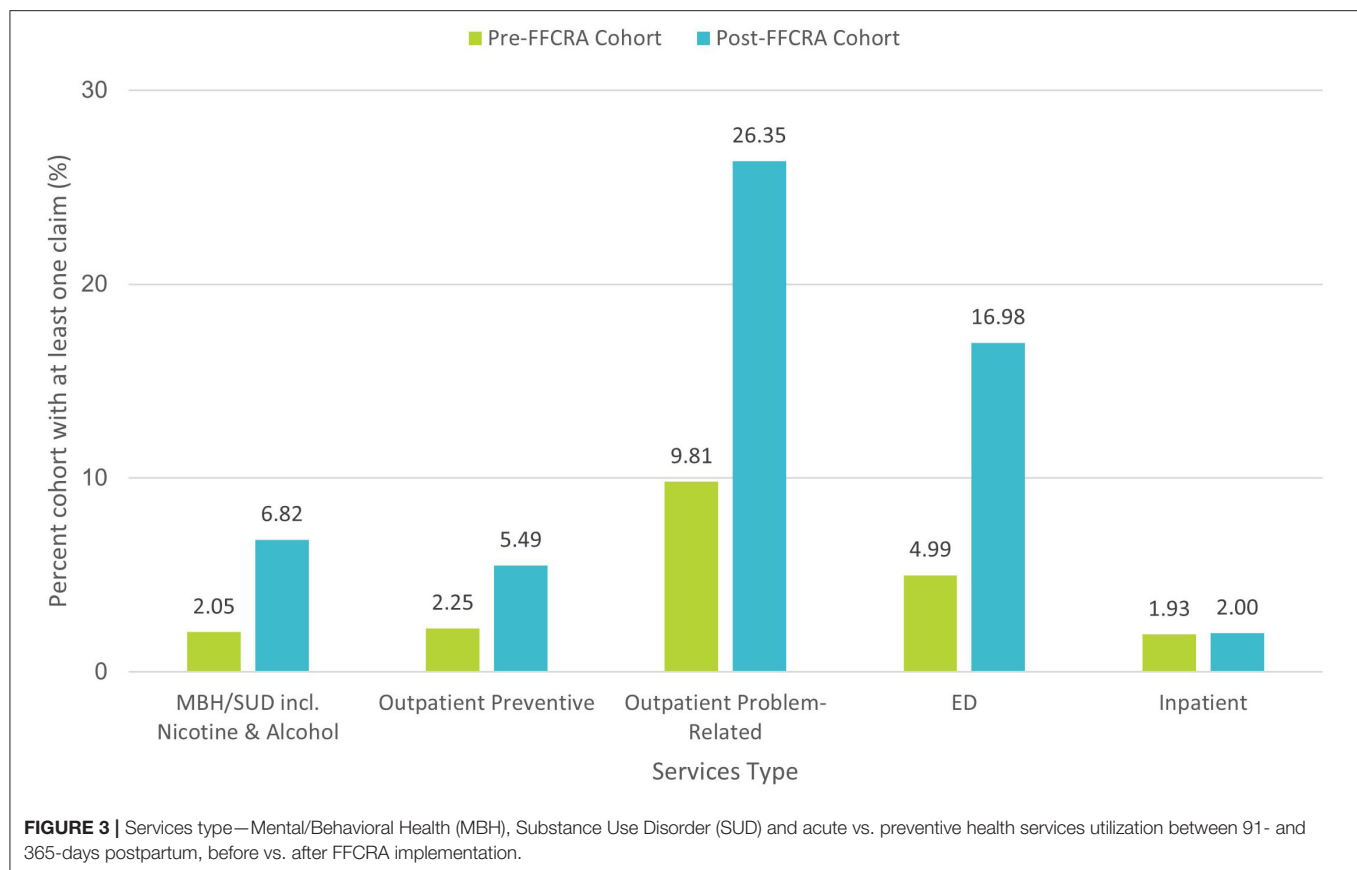
RESULTS

Included in the analysis were 3,465 Pre-FFCRA and 5,411 Post-FFCRA deliveries. Socio-demographic characteristics were comparable between cohorts (**Supplementary Table 1**).

Postpartum and Outpatient Services Utilization

Figure 1A depicts changes in postpartum services utilization (as defined by HEDIS criteria) and **Figure 1B** depicts trends in overall outpatient services utilization, comparing Post-FFCRA vs. Pre-FFCRA cohorts. Within 90 days of delivery, postpartum





services utilization was comparable Post-FFCRA vs. Pre-FFCRA (**Figure 1A**). After 90 days postpartum, however, Post-FFCRA utilization was 2-fold higher than Pre-FFCRA utilization (6.7 vs. 3.2%, respectively; **Figure 1A**). The same patterns were observed when examining all outpatient services utilization. Although overall outpatient services utilization decreased after 90-days postpartum, Post-FFCRA utilization was 2–5-fold higher than Pre-FFCRA utilization through the end of the first-year postpartum, with 17.7% of Post-FFCRA women receiving outpatient care between 91- and 182-days and 17.9% between 183- and 365-days postpartum, vs. 3.4 and 8.8% for Pre-FFCRA women, respectively. Further analyses revealed that, in the Pre-FFCRA cohort, all outpatient utilization after 90-days postpartum occurred among women with subsequent coverage while no utilization was recorded after 90-days postpartum for women without subsequent coverage (See Methods and **Supplementary Figure 3** for details).

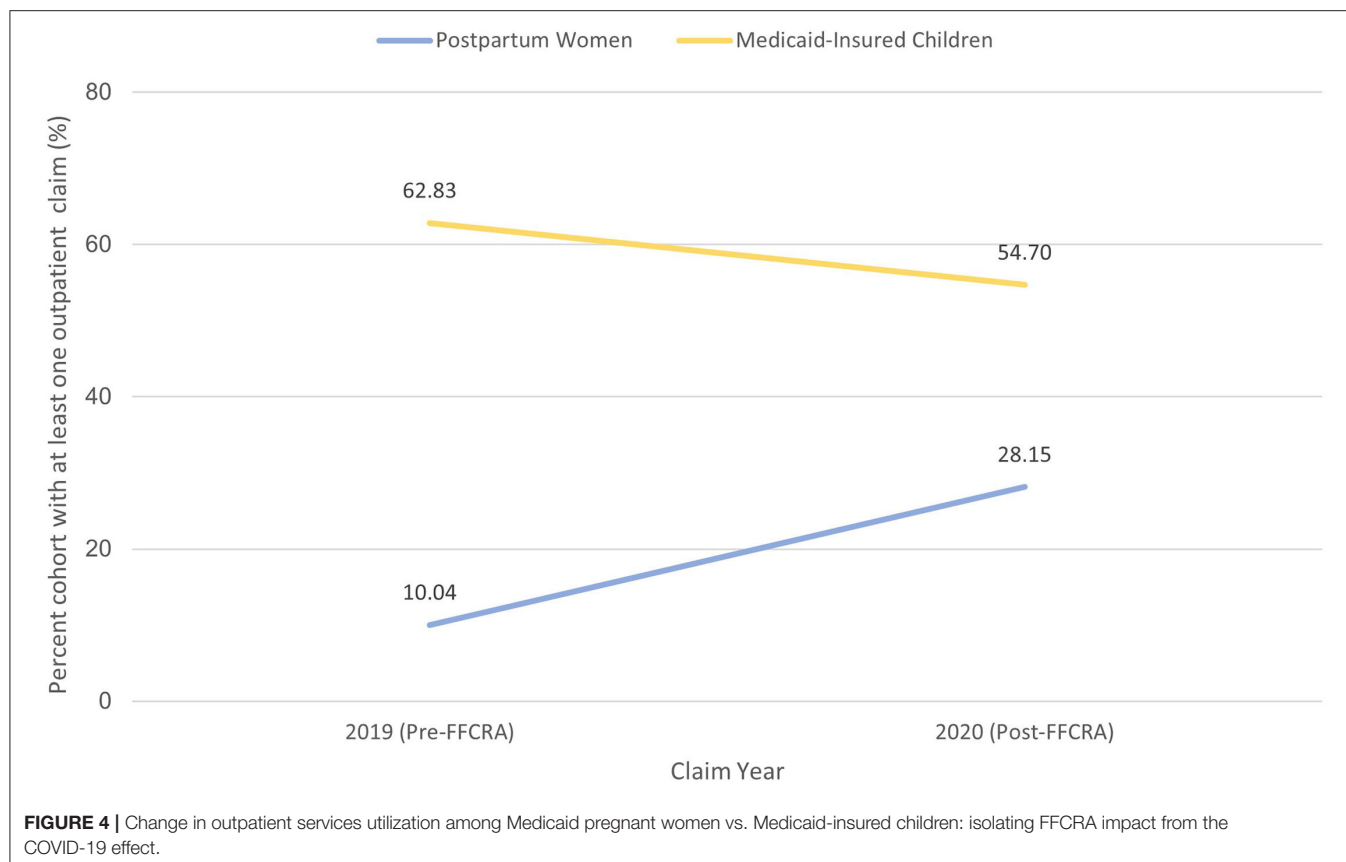
Reasons for and Types of Services Utilization

In further analysis of the reasons for services utilization, Post-FFCRA women used 10× as many contraceptive services and 37% fewer services for subsequent pregnancies within the first-year postpartum (37.1% relative drop and 6.2% absolute drop in pregnancy-related services; **Figure 2**), suggesting that increased access to contraceptive services associated with postpartum

Medicaid extension might contribute to decreasing the incidence of short interval pregnancies, a known risk factor for poor maternal and infant health outcomes. Moreover, Post-FFCRA MBH/SUD services utilization was 3× the Pre-FFCRA rate (6.8 vs. 2.1%, respectively; **Figure 3**), thus uncovering crucial unmet needs for MBH/SUD services when women lose Medicaid coverage at 60-days postpartum (see detailed description of MBH/SUD definition in **Supplementary Table 2**). Additionally, outpatient utilization for preventive and problem-related services more than doubled Post-FFCRA vs. Pre-FFCRA (5.5 vs. 2.3%, and 26.4 vs. 9.8%, respectively; **Figure 3**). Although Post-FFCRA ED visits increased 3-fold, inpatient admissions remained unchanged (**Figure 3**), suggesting that ED visits might have been driven by ambulatory-care-sensitive or lower acuity conditions.

Analysis of COVID-19 Pandemic Effects

To separate the impact of the FFCRA coverage extension from the concomitant effects of COVID-19 related disruptions on health services utilization, we compared Pre- and Post-FFCRA changes in outpatient services utilization among postpartum women vs. Medicaid-enrolled children age 2–17 (less likely to be impacted by FFCRA). Following FFCRA implementation, while outpatient utilization between 91- and 365-days postpartum almost tripled among postpartum women, overall outpatient utilization decreased by 13% among Medicaid-enrolled children (Postpartum women: Pre-FFCRA 10.0%, Post-FFCRA 28.2%



vs. Children: Pre-FFCRA 62.8%, Post-FFCRA 54.7%; **Figure 4**). Opposite trends in outpatient services utilization among postpartum women vs. Medicaid-insured children suggest that the observed increase in utilization among postpartum women is not the sole consequence of pandemic disruptions or secular trends, and most likely the result of the FFCRA's continuous coverage requirement. These results are further supported by the finding that outpatient utilization between 90 days and 6 months postpartum were comparable between Post-FFCRA women and Pre-FFCRA women with subsequent coverage, while no utilization was observed among Pre-FFCRA women without subsequent coverage (**Supplementary Figure 3**).

DISCUSSION

Our analysis demonstrates that the FFCRA's continuous coverage requirement is associated with a sustained increase in preventive services utilization throughout the first-year postpartum. Other benefits include increased utilization of contraceptive services, decreased incidence of short interval pregnancies, and increased utilization of MBH/SUD services.

These findings are timely, as multiple state legislatures and Medicaid programs consider the necessity for and parameters of extending postpartum coverage beyond 60 days (10). The ongoing debate largely centers on the optimal duration of

coverage (e.g., 6- vs. 12-months) and the breadth of services (e.g., full scope vs. limited to certain conditions) that should be provided (15). Our analysis informs the debate with empirical data supporting a broad extension of Medicaid services through the first-year postpartum, in alignment with the recommendations of ACOG and other clinician organizations as well as dozens of maternal mortality review committees (4). State-level proposals that fall short of these recommendations may fail to meet the health care needs of women in the first-year postpartum, as demonstrated by our analysis showing that about 1 in 5 women (17.9%) still seek outpatient services after 6 months postpartum as illustrated in **Supplementary Figure 3**. One potential consequence of unmet preventive/problem-related care—as a result of premature postpartum coverage disruptions—is an increase in uncompensated care delivered in the ED or inpatient setting. This reactive approach to care has suboptimal efficiency, incurs high societal costs, and creates a financial liability for safety net systems. Moreover, the Post-FFCRA increase in contraception utilization suggests that there may be limitations to limited-benefit Medicaid family planning programs. While some states may provide auto-enrollment into such programs at 60 days postpartum, women may not be aware of the program or the services provided, or may be hesitant to use the coverage since it is not comprehensive and may require them to change providers. Extending postpartum coverage beyond the duration of the PHE may be particularly beneficial for women

living in states that have not adopted Medicaid expansion as they rely heavily on limited-benefit programs for access to health care beyond 60 days (16).

Our analysis has some limitations. First, our data is limited to a single Medicaid health plan in Texas and, though robust, is not nationally representative. Second, the observed Post-FFCRA decrease in pregnancy-related services utilization in our study could be partially explained by the well-documented decline in the nation's fertility rate associated with the COVID-19 pandemic (17). The 6% absolute decline in our study, however, is larger than the 4% decline reported in the general population by Hamilton et al. (17), suggesting that at least part of the change we report is non-pandemic-related. Third, we were unable to accurately assess the impact of the FFCRA's coverage extension across racial/ethnic groups due to incomplete documentation of race and ethnicity in Medicaid data. Fourth, we were unable to fully assess health services utilization for the Pre-FFCRA cohort due to lack of access to utilization data once Medicaid coverage was terminated after 60 days postpartum. The subgroup of women for whom data is available, including Pre-FFCRA women with subsequent coverage or women with Traditional Medicaid are not a suitable comparator for the Post-FFCRA cohort given that they meet various eligibility criteria to maintain their coverage. Overall utilization observed among Pre-FFCRA women without subsequent coverage after 60-days postpartum might be underestimated as it does not account for uncompensated or self-paid care for which data is not typically available in Medicaid claims. It remains, however, that utilization patterns in the Post-FFCRA cohort can be reasonably assumed to represent the needs of the Pre-FFCRA cohort. Lastly, we could not assess maternal and infant mortality in either cohort in the absence of vital statistics data and as this analysis was beyond the scope of this manuscript.

Future studies should be undertaken to: assess the impact of the FFCRA coverage extension across a diverse group of Medicaid health plans nationwide; carefully evaluate the impact of extended coverage on maternal and child health outcomes,

including an assessment of racial/ethnic disparities; assess the impact of extending postpartum Medicaid coverage beyond the COVID-19 PHE (as states implement Section 1115 waivers and the new SPA to extend postpartum coverage); and explore the indirect effects of extended postpartum coverage on the health care safety net.

DATA AVAILABILITY STATEMENT

The data analyzed in this study is subject to the following licenses/restrictions: The datasets presented and analyzed in this study are not publicly available. This is private Medicaid and CHIP claims data for Parkland Community Health Plan members. Requests to access these datasets should be directed to GK, graham.keeve@phhs.org.

AUTHOR CONTRIBUTIONS

YP and VC contributed to conception and design of the study. XW performed the statistical analysis. YP, XW, and EE wrote the first draft of the manuscript. EE and GK contributed to the policy interpretation of analysis. All authors contributed to critical revision of the manuscript for important intellectual content and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpubh.2022.841832/full#supplementary-material>

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Fertility Intention and Related Factors for Having a Second or Third Child Among Childbearing Couples in Shanghai, China

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Background and Purpose: As the global fertility rate declines, China has issued two and three-child policies in the past 10 years. Therefore, this study serves to evaluate fertility intention rates and related factors in couples intending to have a second child and third child.

Methods: A cross-sectional survey was conducted in mainland China from July to August 2021. Couples with one or two children were invited to participate in our study in order to collect information about more than one child fertility intention and the possibly related factors. Odds ratios (ORs) and their corresponding 95% confidence intervals (CIs) were calculated and adjusted for potential confounding factors.

Results: Data was collected from a total of 1,026 couples. Among couples with one child, 130 (16.2%) couples had the intention to have a second child. Additionally, only 9.4% of couples with two children desired to have third child. The study revealed large differences in socioeconomic and personal factors between the two groups. For couples with intentions for a second-child, a female age >35 years (adjusted odds ratio, aOR 1.92), a first child's age range from 3 to 6 (aOR 3.12), annual child spending as a percentage of household income >30% (aOR 2.62), and children's educational barriers (aOR 1.55) were associated with lack of intent to have a second child. Similarly, among couples with two children, parents with family financial constraints (aOR 6.18) and children's educational barriers (aOR 4.93) are more likely to have lack of intent to have a third child. Here, we report that government policies encouraging fertility (aOR 0.04) can effectively promote couples to pursue a second or third child.

Conclusion: Overall, couples with one or two children in Shanghai had a low intention to give birth to a second or third child. In order to increase the birth rates, it is necessary to implement policies to reduce the burden of raising children and provide relief to parent's pressure of rearing a child with increased free time.

Keywords: fertility intention, second child, third child, childbearing age, influencing factors

INTRODUCTION

Fertility has always been a key issue of national concern. The decline in fertility is becoming an inevitable trend in most countries around the world, especially in developed countries (1, 2). Low fertility rates are influenced by a range factor including medical infertility and lack of fertility intention (3). Couples with physical infertility may seek medical support (4). While often perceived as simply a behavioral choice, fertility intention needs to be clearly investigated regarding influencing factors such as sociodemographic and economic characteristics (5).

In the late 1970s, the one-child policy, which was also called “family planning,” was implemented to relieve the population pressure and support China in leaving severe poverty (6). During this policy, each couple was allowed to bear only one child. Now, several decades later, China has become one of the “low-fertility-rate countries” (7) and has had to meet new challenges which are aftereffects of the policy such as accelerated population aging, skewed sex ratio, and decline in the working-age population, all of which may hinder economic development (8).

Since 21st century, China has gradually changed its fertility policy, from a selective two-child policy to a comprehensive two-child policy. Nevertheless, according to the China Health Statistics Yearbook, the total annual births number in China has not shown an obvious growth trend (9) (**Figure 1**). On August 20, 2021, the Chinese government amended the Family Planning Law to allow a couple in China to have three children.

Recently, research on fertility intention has become the focus of fertility level because of the essential role of couples' behavior in the mediation of fertility outcomes (10). Although there are discrepancies between fertility intention and behavior at the individual level, on a population-level, fertility intention is correlated with having a child (11). Fertility intention is regarded to predict fertility behavior and it is affected by government policy as well as individual, social, economic, and cultural factors (12, 13). In China, previous studies have shown that the prevalence of the fertility intention was 39.4% for a second child in 2017, and 12.2% for a third child in 2021 among the general population (14, 15). According to this year's National Bureau of Statistics, 43% of the births in 2021 were second births. Therefore, it is imperative to evaluate the fertility intention for a second or third child and related factors. To date, few studies have been conducted to evaluate fertility intention in parous couples (16). Most studies of fertility intentions involve all couples of childbearing age. Here, we investigate the intention to have a second/third child among couples who already have one/two children to remove confounding factors and clearly understand mechanisms.

Considering remediating the current situation of low birth rates, efforts should be made to address associated factors in target families with one or two children. This study is designed to evaluate the factors influencing parous women's choice of have one more child. Thus, this research serves to provide information on the uptake of the universal multiple birth policy on individual, social, and economic levels so that a higher fertility rate may be achieved.

METHODS

Study Design and Participants

We conducted a cross-sectional survey in Shanghai from July to August 2021. The study population was based on the female fertility prospective cohort established between 2013 and 2017 at one of the pre-pregnancy centers in Shanghai, which contains information on basic sociodemographics and reproductive intentions (17). Couples with one or two children were invited to participate in our study to share information about their “second/third births intentions” and likely related factors.

The inclusion criteria of our study were as follows: females aged between 20 and 45 years old, married with one or two living children, no history of severe physical or mental diseases, and voluntary participation in the study. The private information of patients has been strictly protected and data has been anonymized. Patients had the right to refuse or quit the study at any point effective immediately.

Definition of Fertility Intention

Fertility intention refers to people's desire to have children and pursuit of childbirth (18), which is impacted by the expectation of the number, timing, gender, and quality of the children. Fertility intention, which was the dependent variable and primary outcome, was measured by one question: “Do you intend to have another child?” with the response options being: “do not intend, intend, and uncertain” accordingly.

Procedures

An in-person questionnaire and conversation were carried out to collect information from each participant. The questionnaire included the following components: sociodemographic characteristics of the women and their husbands (age, BMI, birthplace, education level, household annual income, family type, number of children, history of disorders, and pregnancy history, etc.), information of the first and second children in the family (age, gender, and economic investment, etc.), whether or not to have one more child and the reason related to it (whether to have second child for family with one child; whether to have third child for family with two child), ideal number of children (How many children do you think is appropriate in the family), and the factors which may influence the decision of having another child (economic status, working conditions, government policy, childcare, and challenges with access to children's education). The contents of the questionnaire were appropriately revised after review and pretest by professors in Gynecology (ZJ). Finally, the validity and reliability of questionnaire is established.

To ensure a high quality of data collection, the questionnaire was filled out by the investigator during the interview according to standard protocol. If participants did not answer any questions because they were unwilling to respond, it was treated that as missing information.

Couples with one child were divided into three groups: with second-child intention (those with fertility intent), without second-child intention (those who wanted no more children), and undecided (those who have not decided whether or not to

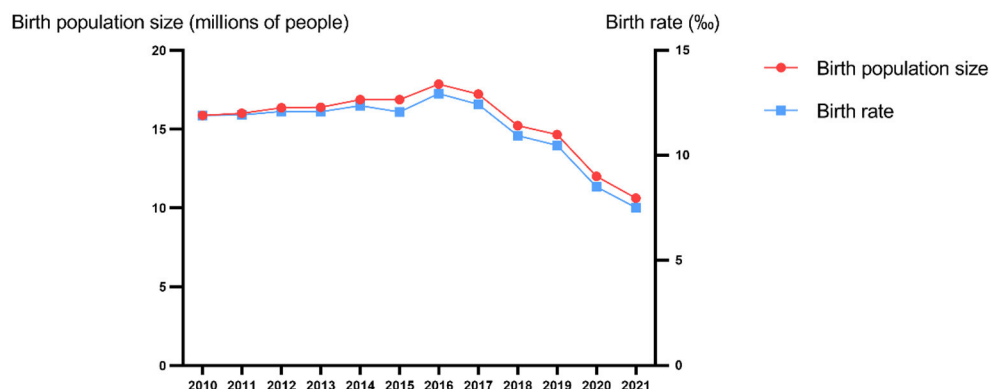


FIGURE 1 | The Birth Population Size and Birth Rate in China.

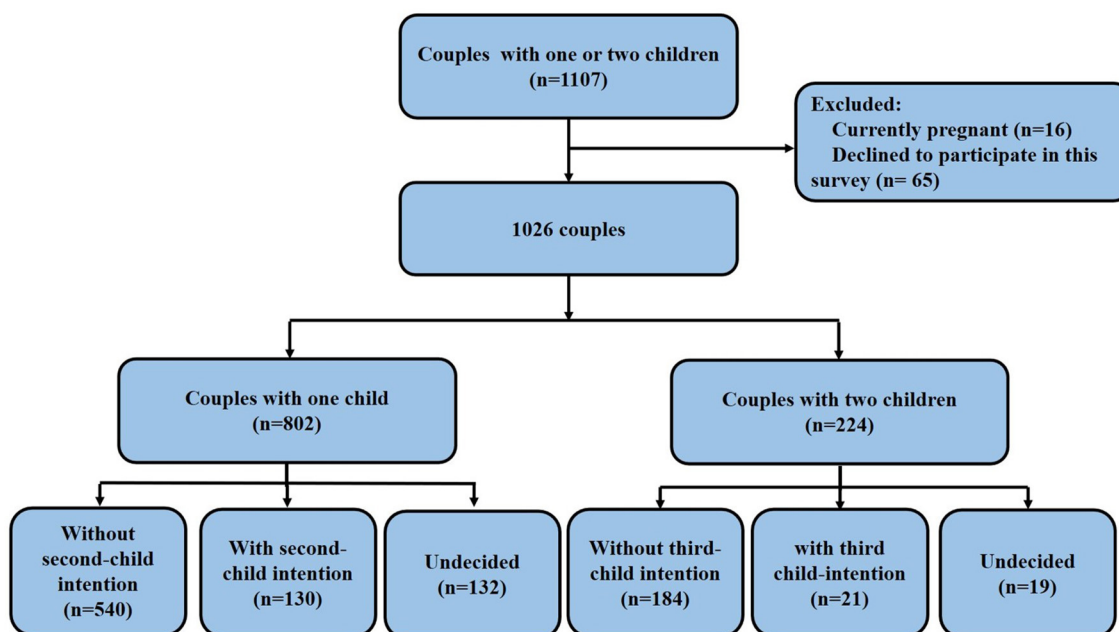


FIGURE 2 | Flow chart.

have a second child). Accordingly, couples with two children were divided into three groups in the same way.

Statistical Analysis

All of the data were analyzed using SPSS (Version 26.0, IBM, Corp, Armonk, NY, USA). Between the groups with and without second/third child intention, a chi-squared test was used to compare the differences in basic characteristics. A binary logistic regression with “intention for a second child” and “intention for a third child” as the dependent variable and demographic factors as explanatory variable was conducted to test the associations between the intention for a second or third child and demographic factors of the couples or their children. Univariable

conditional logistic regression analysis was also used to calculate crude odds ratios (ORs) and their 95% confidence intervals (CIs). According to the univariate analysis results, the covariables with $P < 0.1$ were included in the multivariate logistic regression model. Multivariate logistic regression analysis was performed to explore the potential factors and corresponding ORs. Statistical significance was indicated by p -value < 0.05 .

RESULTS

Basic Characteristics

Shown in **Figure 2**, a total of 1,107 women were recruited for the study and agreed to participate to the questionnaire in person.

TABLE 1 | Sociodemographic characteristics of study participants.

	ALL couples with one child		Have no second- child intention		Have second- child intention		Undecide		P ^c	ALL couples with second child		Have no third-child intention		Have third-child intention		Undecide		P ^c
	N = 802 ^a		N = 540		N = 130		N = 132			N = 224 ^a		N = 184		N = 21		N = 19		
	n	%	n	%	n	%	n	%		n	%	n	%	n	%	n	%	
Age , years , women																		
<35	432	53.87	267	49.44	85	65.38	80	60.61	0.001	76	34.08	62	33.88	8	38.10	6	31.58	0.814
≥35	370	46.13	273	50.56	45	34.62	52	39.39		147	65.92	121	66.12	13	61.90	13	68.42	
Age , years , men																		
<35	304	41.30	186	37.27	53	47.75	65	51.59	<0.001	63	29.72	53	30.99	5	22.73	5	26.32	0.686
≥35	432	58.70	313	62.73	58	52.25	61	48.41		149	70.28	118	69.01	17	77.27	14	73.68	
BMI^b,women																		
<18.5	117	16.57	70	14.77	23	19.01	24	21.62	0.264	23	11.17	19	11.45	2	8.70	2	11.76	0.994
18.5-23.9	528	74.79	363	76.58	90	74.38	75	67.57		155	75.24	124	74.70	18	78.26	13	76.47	
≥24	61	8.64	41	8.65	8	6.61	12	10.81		28	13.59	23	13.86	3	13.04	2	11.76	
BMI^b,men																		
<18.5	16	2.36	11	2.42	3	2.56	2	1.87	0.619	2	0.98	2	1.22	0	0.00	0	0.00	0.700
18.5-23.9	417	61.41	272	59.78	79	67.52	66	61.68		128	62.75	106	64.63	12	52.17	10	58.82	
≥24	246	36.23	172	37.80	35	29.91	39	36.45		74	36.27	56	34.15	11	47.83	7	41.18	
Education attainment, women																		
High school or low	42	5.61	23	4.61	11	9.02	8	6.30	0.395	21	9.91	14	8.14	4	18.18	3	16.67	0.366
Junior college or university	609	81.42	413	82.77	94	77.05	102	80.31		169	79.72	138	80.23	17	77.27	14	77.78	
Graduate or above	97	12.97	63	12.63	17	13.93	17	13.39		22	10.38	20	11.63	1	4.55	1	5.56	
Education attainment, men																		
High school or low	40	5.37	21	4.22	13	10.74	6	4.76	0.028	20	9.43	12	6.98	4	18.18	4	22.22	0.088
Junior college or university	609	81.74	415	83.33	88	72.73	106	84.13		158	74.53	132	76.74	16	72.73	10	55.56	
Graduate or above	96	12.89	62	12.45	20	16.53	14	11.11		34	16.04	28	16.28	2	9.09	4	22.22	
Birthplace, women																		
Shanghai	288	39.78	213	43.92	34	28.57	41	34.17	0.004	63	30.43	51	30.18	8	40.00	4	22.22	0.486
Other place	436	60.22	272	56.08	85	71.43	79	65.83		144	69.57	118	69.82	12	60.00	14	77.78	
Birthplace, men																		
Shanghai	334	46.84	246	51.36	45	38.79	43	36.44	0.002	62	30.54	48	29.27	8	38.10	6	33.33	0.685
Other place	379	53.16	233	48.64	71	61.21	75	63.56		141	69.46	116	70.73	13	61.90	12	66.67	
Annual household incomes (RMB)																		
<200,000	46	5.84	34	6.44	7	5.47	5	3.79	0.288	18	8.18	18	10.00	0	0.00	0	0.00	0.002

(Continued)

TABLE 1 | Continued

	ALL couples with one child		Have no second-child intention		Have second-child intention		Undecided		P ^c	ALL couples with second child		Have no third-child intention		Have third-child intention		Undecided		P ^c
	N = 802 ^a		N = 540		N = 130		N = 132			N = 224 ^a		N = 184		N = 21		N = 19		
	n	%	n	%	n	%	n	%		n	%	n	%	n	%	n	%	
200,000–300,000	109	13.83	64	12.12	22	17.19	23	17.42		34	15.45	32	17.78	1	4.76	1	5.26	
300,000–400,000	212	26.90	144	27.27	36	28.13	32	24.24		56	25.45	47	26.11	1	4.76	8	42.11	
400,000–500,000	354	44.92	242	45.83	48	37.50	64	48.48		77	35.00	57	31.67	11	52.38	9	47.37	
>500,000	67	8.50	44	8.33	15	11.72	8	6.06		35	15.91	26	14.44	8	38.10	1	5.26	
Parent's family situation																		
Both only child	389	48.50	271	50.19	54	41.54	64	48.48	0.237	59	25.99	46	25.00	7	29.17	6	31.58	0.844
Both non-only child	204	25.44	139	25.74	32	24.62	33	25.00		56	24.67	48	26.09	4	16.67	4	21.05	
One of only child	209	26.06	130	24.07	44	33.85	35	26.52		112	49.34	90	48.91	13	54.17	9	47.37	
First child's age, years																		
≤2	157	19.58	90	16.67	32	24.62	35	26.52	0.013	8	3.52	7	3.80	1	4.17	0	0.00	0.746
3–6	621	77.43	436	80.74	91	70.00	94	71.21		106	46.70	88	47.83	11	45.83	7	36.84	
≥7	24	2.99	14	2.59	7	5.38	3	2.27		113	49.78	89	48.37	12	50.00	12	63.16	
Second child's age, years																		
≤2	/		/		/		/		/	94	38.37	77	41.85	12	28.57	5	26.32	0.006
3–6										150	61.22	107	58.15	30	71.43	13	68.42	
≥7										1	0.41	0	0.00	0	0.00	1	5.26	
Previous history of gynecological diseases																		
No	672	83.79	469	86.85	107	82.31	96	72.73	<0.001	198	88.79	158	87.78	23	95.83	17	89.47	0.499
Yes	130	16.21	71	13.15	23	17.69	36	27.27		25	11.21	22	12.22	1	4.17	2	10.53	
Previous history of gynecological surgery																		
No	735	92.57	490	92.11	116	89.23	129	97.73	0.025	214	95.96	172	95.56	24	100.00	18	94.74	0.56
Yes	59	7.43	42	7.89	14	10.77	3	2.27		9	4.04	8	4.44	0	0.00	1	5.26	
The item parents pay most for first child																		
Education	538	67.08	373	69.07	85	65.38	80	60.61	0.161	197	87.95	162	88.04	19	90.48	16	84.21	0.828
Others	264	32.92	167	30.93	45	34.62	52	39.39		27	12.05	22	11.96	2	9.52	3	15.79	
The item parents pay most for second child																		
Education	/		/		/		/		/	79	35.27	61	33.15	9	42.86	9	47.37	0.348
Others										145	64.73	123	66.85	12	57.14	10	52.63	
Annual first child expense^d																		
<70,000	579	72.56	370	68.90	105	81.40	104	78.79	0.001	104	46.85	87	47.80	8	38.10	9	47.37	0.002
70,000–100,000	148	18.55	118	21.97	15	11.63	15	11.36		68	30.63	62	34.07	2	9.52	4	21.05	
100,000–140,000	38	4.76	32	5.96	3	2.33	3	2.27		24	10.81	17	9.34	3	14.29	4	21.05	
>140,000	33	4.14	17	3.17	6	4.65	10	7.58		26	11.71	16	8.79	8	38.10	2	10.53	

(Continued)

TABLE 1 | Continued

	ALL couples with one child		Have no second-child intention		Have second-child intention		Undecided		P ^c	ALL couples with second child		Have no third-child intention		Have third-child intention		Undecided		P ^c
	N = 802 ^a		N = 540		N = 130		N = 132			N = 224 ^a		N = 184		N = 21		N = 19		
	n	%	n	%	n	%	n	%		n	%	n	%	n	%	n	%	
Annual second child expense																		
<70,000	/		/		/		/		/	197	88.74	165	90.66	16	76.19	16	84.21	0.134
70,000–100,000										17	7.66	13	7.14	2	9.52	2	10.53	
100,000–140,000										3	1.35	2	1.10	1	4.76	0	0.00	
>140,000										5	2.25	2	1.10	2	9.52	1	5.26	
Factors affecting the fertility intention																		
Family financial constraints^e																		
No	381	47.74	286	53.36	63	48.46	32	24.24	<0.001	76	33.93	57	30.98	15	71.43	4	21.05	<0.001
Yes	417	52.26	250	46.64	67	51.54	100	75.76		148	66.07	127	69.02	6	28.57	15	78.95	
Working conditions^f																		
No	719	90.10	487	90.86	110	84.62	122	92.42	0.063	197	87.95	162	88.04	17	80.95	18	94.74	0.407
Yes	79	9.90	49	9.14	20	15.38	10	7.58		27	12.05	22	11.96	4	19.05	1	5.26	
Fertility-encouraged government policy^g																		
No	655	82.08	448	83.58	97	74.62	110	83.33	0.053	149	66.52	135	73.37	2	9.52	12	63.16	<0.001
Yes	143	17.92	88	16.42	33	25.38	22	16.67		75	33.48	49	26.63	19	90.48	7	36.84	
Childcare barriers^h																		
No	89	11.15	65	12.13	18	13.85	6	4.55	0.026	30	13.39	26	14.13	3	14.29	1	5.26	0.553
Yes	709	88.85	471	87.87	112	86.15	126	95.45		194	86.61	158	85.87	18	85.71	18	94.74	
Children's educational barriersⁱ																		
No	279	34.96	172	32.09	60	46.15	47	35.61	0.010	100	44.64	77	41.85	15	71.43	8	42.11	0.035
Yes	519	65.04	364	67.91	70	53.85	85	64.39		124	55.36	107	58.15	6	28.57	11	57.89	

^aThe sum does not necessarily equal the sample size for all variables because of missing data.^bBMI is defined as Body mass index. Body mass index is defined as weight in kilograms divided by the square of height in meters.^cPearson's χ^2 test.^dAnnual first child expense: the total annual investment in children's life, education, etc.^eFamily financial constraints: the shortage of money in raising more children.^fWorking conditions: no extra time to raise more children due to work.^gFertility-encouraged government policy: A policy to encourage childbirth by providing maternity subsidies and maternity leave.^hChildcare barriers: the shortage of time or labour in raising more children.ⁱChildren's educational barriers: the stress of meet the educational needs of children.

Then, 65 (5.8%) couples subsequently declined to participate in the survey and 16 (1.4%) couples were pregnant. As a result, 1,026 couples were enrolled in the study, including 802 (78.2%) couples with one child and 224 (21.8%) couples with two children.

Table 1 shows the sociodemographic characteristics of all participants. In the second-child intention group, the mean age [\pm standard deviation (SD)] was 34.91 (\pm 3.40) for the women and 36.68 (\pm 3.86) for the men. Furthermore, for couples in the third-child intention group, the female and male mean age [\pm (SD)] was 36.87 (\pm 4.15) and 38.66 (\pm 5.02). For most couples, their family's annual income was between 300,000 to 500,000 yuan. Couples with one child mostly came from only-child families, while families where only one parent was from an only child family accounted for most of the couples with two children.

Intention to Have a Second or Third Child

As shown in **Table 2**, among couples with one child, 130 (16.2%) couples had the intention to have a second child, while 540 (67.3%) couples had no intention of having another child, and another 132 (16.4%) couples had not yet decided. The majority of couples with two children (82.4%) showed no desire to have third child and only 9.4% of couples expressed the intention to have a third child. Overall, participants indicated that the ideal number of children was 1.72 ± 0.52 . Furthermore, the ideal number of children among couples with one child was 1.61 ± 0.52 . In contrast, the ideal number of children for couples with two kids was 2.06 ± 0.34 .

Factors Influencing Fertility Intention

The crude odds ratios (cORs) and adjusted odds ratios (aORs) of factors associated with second-child intention are shown in **Table 3**. A female age >35 years [aOR 1.92 (1.27–2.91)] and annual child-related spending as a percentage of household income $>30\%$ [aOR 2.62 (1.05–6.53)] were associated with a lack of intent to have a second child. For couples with one child, education accounted for 67.1% of the total annual investment in that child. Families with two children spent 87% of child-related expenses on the first child's education. In the second child, the proportion of investment in education dropped to 35.3%. Educational barriers prevent parents from having a second child, regardless of being a one- or two-child families [one-child family: aOR 1.55(1.03–2.33); two-child family: aOR 4.93(1.34–18.14)]. Couples with a child aged 3 to 6 [aOR 3.12(1.19–8.17)] were less likely to have a second child. Moreover, the fertility-encouraged government policy [aOR 0.61(0.38–0.98)] makes it easier for couples to have a second child.

However, for families with two children, the age of the both of the two children and the financial investment in the second child have no effect on the intent to have the third child (**Table 4**). Among couples with two children, parents with family financial constraints [aOR 6.18(1.80–21.22)] are more likely lack intent to have a third child. Therefore, the government policy encouraging fertility may make people more willing to have a third child [aOR 0.03(0.01–0.17)].

TABLE 2 | The overall intention for the number of children among study participants.

	<i>n</i>	%
The number of ideal children among all couples (<i>n</i> = 1,026)		
1	326	31.77
2	667	65.01
3	32	3.12
≥4	1	0.10
Mean ± SD	1.72 ± 0.52	
The number of ideal children among couples with one child (<i>n</i> = 802)		
1	322	40.15
2	468	58.35
3	12	1.50
≥4	0	0.00
Mean ± SD	1.61 ± 0.52	
The number of ideal children among couples with two children (<i>n</i> = 224)		
1	4	1.79
2	199	88.84
3	20	8.93
≥4	1	0.45
Mean ± SD	2.06 ± 0.34	
Intention for a second child		
No	540	67.33
Yes	130	16.21
Undecided	132	16.46
Intention for a third child		
No	184	82.14
Yes	21	9.38
Undecided	19	8.48

DISCUSSION

In the context of an overall low fertility rate, the intention rates investigated here for second and third births were 16.2% and 9.4% in Shanghai, respectively. This finding is lower than that of Jue Liu who found the second-child intent rate was 39.4% in central and eastern China after the universal two-child policy (15). Likewise, the third-child intention rate in our survey was also lower than the data obtained nationwide by another scholar in 2021 which was 12.2% (14). Unlike previous studies (10), here, we conducted a cross-sectional survey among couples with one child for second-child intention and couples with two children for third-child intention, controls for confounding factors and provides more detail and therefore accuracy (19, 20). In addition, we found that the baseline age of the participants in this study was older than that of the previous two studies. We believe that this is related to the social culture of late marriage and late childbearing of Women in Shanghai, which is based on the rapid economic development of Shanghai (9). It can be observed that differences in race, region, and social culture lead to differences in fertility intention. A study from Bangladesh suggested that the willingness of local women to have a second child was 71.2%, and the willingness to have a third child was 55% (21). In Iran,

TABLE 3 | Factors associated with second-child intention.

	Have no second-child intention <i>N</i> = 540	Have second-child intention <i>N</i> = 130	Unadjusted OR (95% CI) No second-child intention vs. have second-child intention	<i>P</i>	Adjusted OR (95% CI) No second-child intention vs. have second-child intention	<i>P</i>
Age, years, women						
<35	267	85	Ref	0.002	Ref	0.002
≥35	273	45	1.86 (1.27–2.77)		1.92 (1.27–2.91)	
First child's age, years						
≤2	84	30	1.41 (0.52–3.80)	0.023	1.97 (0.70–5.52)	0.017
3–6	371	90	2.40 (0.94–6.10)		3.12 (1.19–8.17)	
≥7	56	7	Ref		Ref	
The percentage of child-related expense (%)^a						
<10	370	105	Ref	0.054	Ref	0.117
10–30	118	15	1.47 (0.91–2.37)		1.26 (0.77–2.07)	
≥30	32	3	2.86 (1.17–6.95)		2.62 (1.05–6.53)	
Fertility-encouraged government policy						
No	448	97	Ref	0.053	Ref	0.039
Yes	88	33	0.58 (0.37–0.91)		0.61 (0.38–0.98)	
Children's educational barriers						
No	172	60	Ref	0.003	Ref	0.038
Yes	364	70	1.81 (1.23–2.68)		1.55 (1.03–2.33)	

^a The percentage of child expense (%) = 100% × Annual child-related expense/Annual household income.

The sum does not necessarily equal the sample size for all variables because of missing data.

Pearson's χ^2 test.

a country also with a low fertility rate, 43% of families in the city of Tehran who already had a one child have a second child (22). In most developed countries, according to the National Survey of Family Growth (NSFG), about 12.8% of families were unwilling to have any children in 2017, and this trend increases each year (1).

Couples' age was one of the most important associated factors with the second-child intention. We found that women who were 35 and older were less likely to want to have a second child. Perhaps people realize that being an older woman can lead to infertility and more pregnancy complications (18). A large number of studies have confirmed that before the age of 35 is the optimal reproductive age for women, which is consistent with our results (23). However, this pattern was not reflected in the third-child intention population: women with two children were not influenced by their age in their intent to have a third child. A possible explanation is that the baseline age of women who wish to have a third child is older (mean age: 36.87), and women older than 35 account for 65.8% of the total "third child intent" population. In addition, older women are less likely to have children (12, 13). Most women are facing infertility troubles caused by advanced age, rather than other factors affecting their desire to have a third child.

Most studies have shown that the high cost of education can be a deterrent to fertility (15). Although most of the children attend tuition-free schools in Shanghai, many parents take additional

tutoring or extracurricular education, which increases the cost. This study also confirms that the family financial burden of education in Shanghai is significantly negatively correlated with fertility willingness.

Children dependency ratio is the population of children aged 0–14 divided by the working population aged 15–64. According to the *China Statistical Yearbook-2021*, Shanghai has the highest per capita disposable income in China (72,232 RMB), while its children dependency ratios were the lowest in the country. The children dependency ratio of 13.25 in Shanghai is almost half of the national average of 26.24. The decline in the number of children a family needs to support leads families to pursue meritocratic individual education, where the cost of educating a single child is relatively high. Existing data confirms this; the per capita expenditure on education and culture of Shanghai residents ranks first in China (as shown in **Supplementary Table 2**). When the number of children in a family increase, the financial investment in education of the whole family will increase greatly without culturally changing the previous education model. This increased burden of education discourages couples from having a second or third child.

In another survey (13, 24), a family's socioeconomic status was found to be associated with raising a third child. Our findings confirm these results. In our study, family financial constraints have a negative effect on the third-child intention. Greater economic resources mean that families can afford the high costs

TABLE 4 | Factors associated with third-child intention.

Have no third-child intention N = 184		Have third-child intention N = 21	Unadjusted OR (95% CI) No third-child intention vs. have third-child intention	P	Adjusted OR (95% CI) No third-child intention vs. have third-child intention	P
Age, years, women						
<35	62	8	Ref	0.700	Ref	0.713
≥35	121	13	1.20 (0.47–3.05)		1.24 (0.39–3.98)	
First child's age, years						
≤2	7	1	0.99 (0.41–2.40)	0.992	0.86 (0.21–3.46)	0.837
3–6	88	11	0.87 (0.10–7.71)		0.62 (0.05–8.63)	
≥7	89	12	Ref		Ref	
The percentage of children expense (%)^a						
<10	24	5	Ref	0.067	Ref	0.080
10–30	63	11	1.19 (0.38–3.89)		0.54 (0.12–2.53)	
≥30	93	5	3.88 (1.04–14.48)		4.34 (0.64–17.54)	
Family financial constraints						
No	57	15	Ref	<0.001	Ref	0.004
Yes	127	6	5.57 (2.06–15.10)		6.18 (1.80–21.22)	
Fertility-encouraged government policy						
No	135	2	Ref	<0.001	Ref	<0.001
Yes	49	19	0.04 (0.01–0.17)		0.04 (0.01–0.19)	
Children's educational barriers						
No	162	19	Ref	0.014	Ref	0.016
Yes	22	2	3.47 (1.29–9.36)		4.93 (1.34–18.14)	

^aThe percentage of children expense (%) = 100% × Annual two children expense/Annual household income.

The sum does not necessarily equal the sample size for all variables because of missing data.

Pearson's χ^2 test.

of raising and educating children. This is also in accordance with additional observations in this study, such as couples whose annual child-related spending was >30% of annual were less likely to have a third child.

Furthermore, our results showed that couples had lower intentions to have a second child when the first child was 3–6 years old. A possible explanation for this might be that Chinese law requires children to start school after the age of 6, which provides couples more time and energy to consider raising another child. Consistent with the present results, previous studies have demonstrated that more disposable time increases a woman's desire to have children (13).

The decline in fertility and changes in population structure can facilitate the adjustment of national fertility policies (25). The new policies not only provide support and resources for couples, but also provide financial help in terms of medical insurance (26). On August 20, 2021, the implementation of China's three-child policy legally stipulates that couples can have three children and enjoy these supporting measures (27). For couples who wish to have third child, maternity leave, maternity benefits, and maternity insurance provide the free time and financial support which according to this study are key to choosing to have another child. Therefore, these factors may explain the relatively positive correlation between government policy encouraging fertility and greater fertility intention.

The fertility intention metric includes the ideal number of children, gender, and time to have children. In the absence of coercive birth restrictions, the number of children people have depended largely on how many they want. Some scholars have found that although China's population policy is gradually opening up, the ideal number of children has been declining in recent years, and economic development and the improvement of education level may likely contribute to a continuous decline in the ideal number of children (28). A couple's ideal number of children is affected by factors such as population policy, economic factors, and children's education, leading to a large gap between the ideal and reality. The gap is more pronounced among families with one child, rather than two. Most families with one child have an ideal number of two children, but economic, educational and other factors prevent them from pursuing a second child. The ideal number of children for families with a second child is close to 2, which is exactly what they expect. Therefore, in order to increase the levels of fertility intention, and thus increase the fertility level and birth rate, We must urge the government to introduce policies, such as providing maternity subsidies, or reducing the burden of children's education.

There are some limitations to our study. First, as this is a single-center study in Shanghai, the sample size is relatively small. Although our sample size still meets the basic statistical

requirements and can detect a moderate effect size as significant, these results may not be applicable to other regions. In addition, the target population of this survey is people of childbearing age who have lived in Shanghai for a long time. In Shanghai, there are more people with higher education levels, higher incomes, and advanced ages, which has certain deviations from the national average. People in Shanghai cannot represent women in all regions of China. Future research may focus on people from different regions of China and different economic and cultural backgrounds. In addition, this cross-sectional study can accommodate the multiple child-bearing intentions of couples of childbearing age in Shanghai, providing valuable data for policy departments, but cannot determine causal relationships from these associations.

CONCLUSION

In conclusion, couples with one or two children in Shanghai have low intentions to give birth to a second or third child. Their decision is probably influenced by female age, age of the first child, family economic conditions, children's education expenses, and national fertility policies. It is necessary to take measures to reduce the financial burden of raising children and increase free time for couples to provide relief from parents' pressure of rearing a child. Governments and societies need increase efforts to support the intention to have a second or third child and thus increase the national fertility rate.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

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ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Institutional Review Board of the International Peace Maternity and Children's Health Hospital. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

JZ was conceived of the study and participated in its design, as well as supervised the study, and critically revised the manuscript. CZ performed the investigation and wrote the manuscript. LY and YW contributed to collection. YZ and SJ participated in statistical analysis. All authors read and approved the final version of the manuscript.

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SUPPLEMENTARY MATERIAL

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Proportion and associated factors of respectful maternity care during childbirth in North Showa zone public health institutions, North Showa, Ethiopia: An institutional-based cross-sectional study

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Background: Respectful maternity care is one of the key strategies to increase access to use skilled maternity care services. However, limited studies are done about the extent of respectful maternity care during labor and delivery in Ethiopia, particularly in the study area.

Objective: This study aimed to determine the proportion and identify the associated factors of respectful maternity care during childbirth among women who gave birth in North Showa zone public health institutions, North Showa zone, Ethiopia, 2020.

Methods: An institutional-based cross-sectional study was conducted among women who got birth in North Showa public health institution from October 20 to November 20, 2020. A systematic random sampling technique was used to select study participants. Logistic regression with adjusted odds ratio and 95% uncertainty interval was used to declare statistically significant variables based on $p < 0.05$ in the multivariable logistic regression model.

Result: The overall proportion of respectful maternity care during childbirth was 48.6 % (95% CI: 44.6–52.3%). Urban residence AOR = 2.6 (95% CI: 1.8, 3.6), being multiparous AOR = 1.6 (95% CI: 1.1, 2.3), having planned pregnancy AOR = 2.4 (95% CI: 1.3, 4.3) and giving birth in health center AOR = 1.6 (95% CI: 1.2, 2.8) were statistically significant factors with respectful maternity care during labor and delivery.

Conclusions: The proportion of respectful maternity care during childbirth is low. Being from an urban community, being multiparous, having planned pregnancy, and giving birth in a health center were factors that could increase the likelihood of women getting respectful maternity care during

childbirth. Based on the identified factors strategies need to be designed and implemented to enhance the level of respectful maternity care.

KEYWORDS

childbirth, Ethiopia, labor and delivery, respectful maternity care, proportion

Background

Respectful maternity care (RMC) is an approach centered on an individual, based on principles of ethics and respect for human rights, and promotes practices that recognize women's preferences and women's and newborns' needs (1). Non-respectful maternity care during childbirth is a violation of a universal human right that is due to every childbearing woman in every health system, is common throughout the world, and can occur at the level of interaction between the woman and provider leading to low intake of maternity service (2).

In 2013 about 289,000 women died, worldwide, due to complications in pregnancy and childbirth (3). The most important intervention in reducing maternal morbidity and mortality is using skilled assistance during pregnancy and childbirth. Improving the quality of care provided, especially elements of respectful maternity care is an important strategy to increase the use of facility-based childbirth in low-income (4, 5).

Childbirth is a special moment for parents, families, and communities but can also be a time of intense vulnerability for women to be exposed to disrespectful and abusive behavior while at the health facilities. If mothers do not receive what they perceive as compassionate and respectful maternity care during facility-based childbirth their intention to use facility-based maternity services will be reduced (6).

A woman's experience of care in childbirth is an important determinant of her future decisions related to seeking health care from health facilities. Women's negative encounters with health workers during delivery could result in regret to use maternity health care services (7). However, many women across the world experience disrespectful, abusive, or neglectful treatment during childbirth in health institutions (8). Improving respectful maternity care is a critical strategy to increase facility-based childbirth and ensure effective implementation of women's rights and women-centered approaches in maternal health services.

There are factors associated with the level of respectful maternity care identified by previous studies such as sociodemographic variables, mode of delivery, and complications during labor and delivery (9, 10). This study intended to identify significant factors that can be associated with the provision of respectful maternity care agreeing to the nature of the community in the study area.

Ethiopian federal ministry of health in its Health Sector Transformation Plan (HSTP) has planned to increase the

level of deliveries attended by skilled birth attendants. To achieve this plan, the Ministry has identified caring, respectful, and compassionate health professionals as one of the four transformation agendas. Lack of respect for patients and their families is a common complaint and having RMC health professionals is a critical requirement to ensure equity and achieve high-quality health services on its HSTP.

Despite the problem, little research has been conducted in Ethiopia, particularly in the study area about the proportion of respectful maternity care and its associated factors. The current study is therefore aimed to determine the magnitude and factors associated with respectful maternity care during childbirth in north Showa zone public health institutions, North Showa, Ethiopia, 2020.

Methods and materials

Study design and period

An institution-based cross-sectional study was conducted from October 20 to November 20, 2020.

Source and study population

Source of population

The source populations for the study were all women who gave birth at public health institutions in the North Shewa zone.

Study population

All women who gave birth at the selected health institutions in the North Shewa zone during the data collection period.

Sample size determination

The sample size is calculated using Epi Info Stat Calc version 7.2.1 population survey by taking assumptions of population size >10,000, 95% confidence interval, the proportion of compassionate and respectful maternity care (35.8%) from the previous study (11), confidence limit (margin of error) 5%, and by adding 10% non-response rate. The final sample size was calculated to be.

$$n = \frac{(z\alpha/2)^2(p(1-p)d^2 = (1.96)^2(0.358)(1-0.358)}{(0.05)^2} = 353 \quad (1)$$

Where: - $z\alpha/2$ is z value for 95% confidence level

d is margin of error and

p is proportion

by adding non-response rate 10% with 2 design effect
 $(353 + 35) \times 2 =$ our final sample size was 776.

Sampling technique and procedure

There are 10 public hospitals and 90 health centers in the North Showa zone; from those public health institutions, we selected 5 hospitals and 45 health centers randomly. The total sample sizes were allocated proportionally to each of the selected hospitals and health centers by reviewing the number of deliveries attended during the preceding month before data collection. Finally, the determined samples were selected by a systematic random sampling technique.

Inclusion and exclusion criteria

Inclusion criteria

All women who gave birth at selected health institutions in the North Shewa zone during the data collection period.

Exclusion criteria

Women who are unable to communicate effectively due to serious illness were supposed to be excluded from the study.

Data collection tools procedures

Data were collected using a structured and semi-structured interviewer-administered questionnaire having two parts. The first part contained baseline data regarding the Socio-demographic ideas of respectful maternity care. The remaining part of the questionnaire composes of obstetrics-related questions. The questionnaires were developed in English by reviewing various literature and translated into the local language Amharic then retranslated back to English to check the consistency. Pretest was conducted at public health institutions in the East Gojjam zone and necessary corrections to the tool were employed accordingly. Data collection was done by 35 trained midwives and supervised by 5 BSc Midwives.

Operational definitions

- **Respectful maternity care:-** Women were considered to have received respectful maternity care during labor and childbirth if they answered yes to all of those questions assessing RMC or verification criteria used for assessing the four categories (friendly care, abuse free care, timely care, and discrimination-free care) of RMC during labor and childbirth (10, 12, 13).

Statistical analysis

All collected questionnaires were rechecked for completeness and coded. Then these data were entered and cleaned using Epi Info 7 software and exported to SPSS version 21 for analysis. Bivariable logistic regression was employed to identify an association, and a multivariable logistic regression model was used to identify the effect of independent variables on the outcome variable.

Variables having $P < 0.25$ in the Bivariable analysis were fitted into the multivariable logistic regression model. Ninety-five percent confidence interval of odds ratio computed and variable having $P < 0.05$ in the multivariable logistic regression analysis considered as determinant factors for respectful maternity care. Before the actual logistic regression analysis, the necessary assumption of the logistic regression model was checked by using the Hosmer-Lemeshow test of goodness of fit which has a chi-square distribution.

Results

Socio-demographic characteristics of the participants

A total of 776 post-partum women were interviewed in this study, and all of the participants completed the questionnaire making the response rate 100%. The mean age of participants was 27.65 ± 5.2 , and it ranged from 16 to 45 years. The participants' average family income was 6476.1 and the minimum and maximum family income were 200 and 80,000 ETB, respectively). Among respondents; 634 (81.7%), 731 (94.2%), 722 (93%), and 479 (61.7%), of the participants, were orthodox, married, Amhara, and lived in urban (Table 1).

Obstetrics/health care service-related characteristics

over half, 508 (65.5) of the respondents were multiparous, and 678 (87.4%) and 720 (92.8%) of the participants had planned and wanted pregnancy, respectively. Among the women who

TABLE 1 Socio-demographic characteristics of women who gave birth in North Showa zone public health institutions, North Showa zone, Ethiopia, 2020 (N = 776).

Characteristics	Frequency	Percent (%)
Age in years		
15–19	22	2.8
20–24	184	23.7
25–29	316	40.7
30–34	169	21.8
> 35	85	11.0
Religion		
Orthodox	634	81.7
Muslim	108	13.9
Protestant	32	4.1
Catholic	2	0.3
Marital status		
Single	31	4.0
Married	731	94.2
Divorced	8	1.0
Separated	6	0.8
Educational status		
Can't read and write	178	22.8
Can read and write	98	12.6
Primary school	138	17.8
Secondary school	157	20.2
Diploma and above	295	26.4
Husband educational status		
Can't read and write	140	18.0
Can read and write	124	16.0
Primary school	129	16.6
Secondary school	148	19.1
Diploma and above	235	30.3
Ethnicity		
Amhara	722	93.0
Oromo	48	6.2
Tigre	6	0.8
Residence		
Urban	479	61.7
Rural	297	38.7
Occupation		
Housewife	391	50.4
Private employer	66	8.5
Government employee	157	22.6
Merchant	73	9.4
Student	25	3.2
Daily labor	16	2.1
Farmer	30	3.9
Husband occupational status		
Farmer	288	37.1
Government employee	216	27.8
Merchant	160	20.6

TABLE 1 Continued

Characteristics	Frequency	Percent (%)
Private employer	52	6.7
Student	8	1.0
Daily labor	28	3.6
Other *	24	3.1

*Includes driver (18), jobseeker (3), tailor (3).

had ANC follow-up (715); 425 (45.5%) of them had ANC follow-up about four and above. Among women who had ANC follow-up (715), the majority 84.6 % (605) had ANC follow-up at the health center the others 19.4% (139) and 12.4 % (890) had ANC follow up at the government hospital and private health institution, respectively. The majority, 684 (88.1) of the participant's labor was established spontaneously, and the majority 502 (64.2%) of women's duration of labor was <12 h. On the other hand, three fourth of the participants stayed for more than 12 h in the HF. Nearly half and three fourth of the health care providers were females and midwives by profession. 422 (54.4%), 733 (94.5%), 613 (79.0%), and 423 (54.5%) of the respondents were delivered at night time, the neonate was alive, had no complications during labor & delivery, and had delivered in the health center, respectively (Table 2).

The proportion of respectful maternity care (RMC) during childbirth

Of all the respondents, 377 (48.6%) of the participants have received respectful maternity care during childbirth. The rest 399 (51.4%) women have not received maternity care during childbirth respectfully.

Factors associated with respectful maternity care (RMC) during childbirth

In this study binary Logistic regression was performed to assess the association of each independent variable with the outcome variable (RMC). The variables that showed a significant level ($p < 0.25$) were added to the multivariate regression model. The model contained seven (7) independent variables; namely residence, parity, planned pregnancy, the status of ANC follows up, duration of stay in the health facility, complications during labor and delivery, and place of delivery were the associated variables in bivariate Logistic regression. The researchers identified four variables that were significantly associated with RMC.

The result of this study revealed that those respondents who were from urban were 2.6 times more likely to receive respectful

TABLE 2 The Obstetric/health care service-related characteristics among women who gave birth in north Showa zone public health institutions, North Showa zone, Ethiopia, 2020 (*N* = 776).

Characteristics	Frequency	Percent (%)
Parity		
Primi parous	268	34.5
Multiparous	508	65.5
Planed pregnancy		
Yes	678	87.4
No	98	12.6
Have ANC follow up		
Yes	714	92.0
No	62	8.0
Labor start		
Spontaneous	684	88.1
Induced	68	8.8
C/s	24	3.1
Mode of delivery		
SVD	569	73.3
Instrumental	59	7.6
C/S	148	19.1
Time in labor		
<12 h	502	64.7
>12 h	274	35.3
Time stays in a health facility		
<12 h	249	32.1
12–24 h	291	37.5
>24 h	236	30.4
Sex of health provider attending labor		
Female	357	46
Male	419	54.
The profession of health provider		
Midwifery	574	74
Nurse	5	0.6
General practitioner	1	0.1
Intern	29	3.7
ISO	94	12.1
Gynecology	73	9.4
Time of delivery		
Day	354	45.6
Night	422	54.4
Neonate alive		
Yes	733	94.5
No	43	5.5
Any complication during L&D		
Yes	163	21.0
No	613	79.0
Place of delivery		
Health center	423	54.5
Hospital	353	45.5

maternity care (RMC) than those who were from rural, [AOR = 2.6 (95% CI: 1.8, 3.6)]. Those women who were multiparous also received respectful maternity care 1.6 times higher than those who were primiparous women, [AOR = 1.6 (95% CI: 1.1, 2.3)]. Similarly, those participants who had planned pregnancy had over two times the odds to receive RMC than those who were unplanned pregnancy, [AOR = 2.4 (95% CI: 1.3, 4.3)].

Respondents who were delivered at the health center were 1.6 times more likely to receive respectful service than those mothers delivered at the hospital, [AOR = 1.6 (95% CI: 1.1, 2.3)].

On the other hand, the other three (3) independent variables such as status of ANC follow-up, duration of stay in the health facility, and Complications during labor& delivery were not showed significant association with our dependent variables (Table 3).

Discussion

This study assessed the proportion and associated factors of respectful maternity care during labor and delivery among women who gave birth in north Showa zone public health institutions, North Showa zone, Ethiopia. And the result showed that the proportion of respectful maternity care was 48.6%. This result was lower compared to the study conducted in Bahir Dar (57%) (10) and in referral hospitals of Northwest Amhara (56.3%) (9). The possible reason for this difference might be because those covered a limited area that had a limited number of health institutions.

On the other hand, this finding was higher compared to the results of the study done in Addis Ababa (21.4%) (12), Oromia (35.8%), India (28.7%) (14), Iran (24.3%) (15). The reason for this discrepancy might be some of those studies were focused on a single city and most of them included hospitals nearly equal to or over the number of selected health centers that had relatively more case flows that resulted to have more disrespectful care.

Regarding factors associated with respectful maternity care during childbirth, women who reside in urban were 2.6 times more likely to receive maternity care during labor and delivery respectfully than women who come from rural. These findings were supported by the study conducted in Bahir Dar (10). This could be explained by, even though rural women are vital, they had relatively compromised awareness, involvement, and capabilities for decision making which make them passive and non-empowered for the care they received.

Being multiparous had a positive association with respectful maternity care. Multiparous women were 1.6 times more likely to have respectful maternity care than primiparous. This result is in line with the study done in India (14). This might be due to the reason that multiparous women had the experience of giving birth and they knew what would have been expected from them and health care providers to have harmonious interaction for receiving the care respectfully.

TABLE 3 Bivariate and multivariate logistic regression analysis of RMC among women who gave birth in north Showa zone public health institutions, North Showa zone, Ethiopia, 2020 (N = 776).

Variables	RMC		COR (95% CI)		AOR (95%CI)	
	Yes	No				
Residence						
Urban	276 (57.6)	203 (42.4)		2.6 (1.9, 3.5)		2.6 (1.8, 3.6)*
Rural	101 (34)	196 (66)		1		1
Parity						
Primi parous	115 (42.9)	153 (57.1)		1		1
Multiparous	262 (51.5)	246 (48.4)		1.4 (1.05, 1.9)		1.6 (1.1, 2.3)*
Planned pregnancy						
Yes	352 (52)	326 (48)		3.1 (1.9, 5.0)		2.4 (1.3, 4.3)*
No	25 (25.5)	73 (74.5)		1		1
ANC follow up						
Yes	367 (50.8)	352 (49.2)		1		1.2 (0.6, 2.5)
No	15 (24.1)	47 (75.9)		3.2 (1.7, 5.8)		1
Stay in a health facility						
<12 h	115 (46.2)	134 (53.8)		1.2 (0.8, 1.7)		1.0 (0.7, 1.6)
12–24 h	166 (57)	125 (42)		1.9 (1.3, 2.7)		1.5 (1.0, 2.2)
>24 h	96 (40.7)	140 (59.3)		1		1
No						
Complications during labor & delivery						
Yes	68 (41.7)	95 (58.2)		1		1
No	309 (50.4)	304 (49.5)		1.4 (1.01, 2.01)		1.1 (0.7, 1.7)
Place of delivery						
Health center	240 (56.7)	183 (43.7)		2.0 (1.5, 2.7)		1.6 (1.1, 2.3)*
Hospital	137 (38.8)	225 (61.2)		1		1

Note that * are variables showed significant association with $p \leq 0.05$.

This study also revealed that women who had planned pregnancy had over two times more chances to receive respectful maternity care. A similar finding was reported from studies done in the Oromia region (11). This might be because having a planned or timed pregnancy could inspire the women to use other maternity health care services starting from antenatal care, this might increase women's positive cooperation with the health care provider to have respectful maternity care during childbirth.

The result of the current study showed that the odds of having respectful maternity care were 1.6 times higher among women who gave birth in a health center than in a hospital. There are studies explored in line with this association, studies done in Oromia (11). The possible explanation might be due to health centers having relatively lower case flow than hospitals, this may be good for health care providers not to be bored and disrespect the laboring women.

Overall, the practice of respectful maternity care during labor and delivery in public health institutions in the North Showa Zone was low; on the other hand, the proportion of disrespectful and abusive care among study participants was

51.4% which is higher compared to previous findings. Strategies must be designed to provide respectful maternity care for all laboring women, such as providing training for health care workers about the importance of RMC, creating a comfortable and attractive working environment for a health worker to build a harmonious interaction with women, and employing sufficient professionals on health institutions are the least of interventions to increase the proportion of the women who received respectful maternity care (RMC) during labor and delivery.

Conclusions

The results of this study show that the proportion of respectful maternity care during labor and delivery in public health institutions in the North Showa Zone was 48.6%. On the other hand, 51.4% of the study participants faced disrespectful and abusive care.

Factors such as; urban residence, being multiparous, having planned pregnancy, and giving birth in a health center were positively associated with respectful maternity care during

childbirth. Based on factors associated with RMC, specific strategies and interventions should be designed to increase the magnitude of respectful maternity care during childbirth.

Strength and limitation of the study

- A causal relationship cannot be established due to the cross-sectional nature of the study.
- Representative sample taken among women giving birth in North Showa Zone public health institutions.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by Debre Berhan University, College of Health Science Research Committee. The patients/participants provided their written informed consent to participate in this study.

Author contributions

NA and AM designed the study, participated in the data collection, performed analysis and interpretation

of data, and drafted the paper and the manuscript. GT and YA designed, approved the proposal with some revisions, participated in data analysis, and revised subsequent drafts of the paper and the manuscript. All authors contributed to the article and approved the submitted version.

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Conflict of interest

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Challenges in postnatal care provision in Ethiopia

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Background: Most maternal deaths occur during the first 48 h after delivery; thus, a critical time for monitoring possible complications arising from the delivery. Quality postnatal care can contribute to a decrease in maternal mortality and morbidity rates. Despite the importance of postnatal care, it is generally a neglected aspect of maternal and child health services in most developing countries, including Ethiopia.

Objectives: The objective of the study was to describe the challenges experienced by postnatal care providers and coordinators in providing postnatal care in the Ethiopian context.

Methods: A quantitative cross-sectional descriptive study was conducted and data were gathered from 422 postnatal care providers and coordinators during November 2018. A simple random sampling technique was used to select the respondents and the data were gathered through a self-administered questionnaire. The data were cleaned, coded and entered into the Statistical Package for Social Sciences (SPSS) version 21 for analysis. Open-ended questions for qualitative enhancement were open-coded and thematically analyzed.

Results: The findings revealed a lack of physical resources; infrastructure problems; cultural concerns; inadequate capacity building; inaccessibility of health services; unavailability of guidelines; a lack of communication with healthcare users and poor monitoring and evaluation as challenges.

Conclusion: To improve postnatal care in Ethiopia and, ultimately, mother and child health, the challenges experienced by postnatal care providers and coordinators have to be dealt with. A strategic action plan with the active involvement of all stakeholders must be developed and implemented to deal with the challenges and improve postnatal care.

KEYWORDS

postnatal care, challenges in postnatal care, Ethiopia, maternal and child health, quality postnatal care

Introduction and background

Despite the goals set by the United Nations (UN) to reduce maternal mortality by three-quarters from 1990–2015, and the sustainable development goals to reduce maternal mortality in Ethiopia to 199 per 100,000 live births, the rates are still unacceptably high (1, 2). In Ethiopia the maternal mortality rate remained stagnant over the past 18 years with an average of between 412 and 871 per 100,000 live births (3).

The postnatal period is an area of concern, since more than 60% of maternal deaths occur during this period and about 45% of them die within 1 day of delivery. The risk of maternal death is the highest close to birth, especially within the first 24 h and then gradually decreases over the subsequent days and weeks. It is estimated that 65% of maternal deaths occur within 1 week of delivery and nearly 80% within 2 weeks of delivery (4–6).

Postnatal care is among the major recommended interventions that can reduce maternal deaths globally, because during this period health professionals can diagnose postpartum problems and potential complications to ensure prompt treatment or interventions (6). Maternal morbidity and mortality can be prevented or reduced significantly if women their families and the community recognize the danger signs and promptly seek healthcare services during the postpartum period (7).

Scientific evidence indicates that the provision and utilization of postnatal care services in many African countries is challenged by factors such as (1) the 40-day period after childbirth that allows mothers and babies to be only indoors for the first month; (2) misconceptions about the importance of postnatal care; (3) the lack of awareness of postnatal care and its benefits; (4) the cost of health services; (5) transport costs; (6) accessibility and the (7) distances to health facilities (8–12). It has also been reported that the attitudes of healthcare providers are a barrier to the utilization of postnatal care in many countries (13, 14).

Despite the existence of evidence on the importance and advantages associated with optimal utilization of postnatal care from different sources, the uptake of these services is still very low and varies across regions and countries (11, 15). In low-income countries, like Ethiopia, the utilization of postnatal care is as low as 19% (3). Hence, the objective of this study was to identify the challenges of postnatal care service provision in Ethiopia to recommend interventions for improvement.

Methods

Study setting and period

The study was conducted in Oromia regional state in Ethiopia during the month of November 2018. Administratively, Oromia is divided into 18 zones that are divided into 309 districts (councils), 44 town administrations and 6,881 *kebeles* (subdivisions) (16).

Study design

A quantitative cross-sectional descriptive study was conducted to identify challenges pertaining to postnatal care service delivery in Ethiopia. Data were gathered from a

stratified random sample of a population of 2,925 postnatal care providers (2,865) and 60 coordinators at various health facilities, departments, health centers and hospitals and from district and regional health departments.

Sample size

A total sample of 422 respondents was determined, using the single population proportion formula $n = Z (\alpha/2)^2 P (1-P)/d^2$
 $n = 1.96^2 1 (1-0.5)/0.05^2$
 $n = 384$

The assumptions under this formula were:

- n = sample size
- $Z (\alpha/2)$ = the value of normal distribution, representing a confidence level of 95% with a value of 1.96.
- P = Proportion of the case
- d = Margin of error—considering a non-response rate of 10%, the final sample size was 422. The first assumption was that no studies were conducted on the specific topic and the prevalence is considered to be 50% at 95% confidence interval, with a margin of error (confidence limit) of 5%. The other assumption was that there might be a 10% non-response rate.

Data collection instrument

A self-developed questionnaire based on a thorough literature review was pre-tested and used for data gathering. Open-ended questions were included for qualitative enhancement to allow for personal opinions and views.

Data collection

The data collectors received a 3-day training course before the data collection process commenced. The data collectors and researchers distributed an information letter as well as the voluntary consent form among all selected respondents at the health facilities and postnatal care departments. After reading and understanding the information sheet, the volunteers signed the consent form, indicating their willingness to participate. This was followed by questionnaires administration to every consenting participant, requesting them to complete the questionnaire in private in their own time and return the completed questionnaire within 2 days.

Data quality management

To enhance the validity and reliability of the instrument, a pre-test was conducted among 5% (21 pre-test respondents) of the sample size that had similar characteristics as the

study participants but were selected from health facilities and departments located outside the study areas. Data were gathered by ten purposively selected data collectors.

Data analysis

Data were cleaned, coded and captured from the 422 questionnaires into the Statistical Package for Social Sciences (SPSS) software programme (version 21) for analysis. The findings were summarized and presented in tables and pie-charts, using frequencies and percentages. The responses to open-ended questions were open-coded and thematically analyzed. Although the quantitative data obtained provided valuable insights into the challenges experienced, the narrative data that was thematically analyzed provided rich data to allow for a more comprehensive description of the study findings.

TABLE 1 Socio-demographic characteristics of respondents ($N = 422$).

Variable	Category	Frequency	Percent
Age	Younger than 30	115	27.3
	30–39	142	33.6
	40–49	122	28.9
	50–59	39	9.2
	60 and older	4	0.9
Gender	Male	174	41.2
	Female	248	58.8
Educational level	Master's	34	8.1
	Bachelor's	263	62.3
	Diploma	125	29.6
Work experience in years	1–10 years	234	55.5
	11–20 years	151	35.8
	21–30 years	37	8.8

Ethical considerations

Ethical approval was obtained from the Research Ethics Committee of the Department of Health Studies, University of South Africa (UNISA) to conduct the study. Permission letters to support the study and gain access into the field were received from the respective administrative offices of Oromia Regional State Health Bureau, from each health facility such as health centers, hospitals, district and regional health departments before involving the participants in the study. The participants received an information letter about the research, the objectives of the research and their right not to participate, not to answer a question or to withdraw from the study at any time during data collection without any negative consequences for them.

Results

Socio-demographic characteristics

Four hundred and twenty-two respondents agreed to participate and provided completed questionnaires for analysis.

Hundred and forty-two ($f = 33.6\%$) respondents were between 30 and 39 years old, 122 ($f = 28.9\%$) were between 40 and 49 years and 115 ($f = 27.3\%$) were younger than 30 years (refer to Table 1).

More than half of the respondents were females (58.8%) similar to the female/male ratio of the health care providers offering postnatal care in Ethiopia (17).

Two hundred and sixty-three ($f = 62.3\%$) were in possession of a bachelor's degree, and 125 ($f = 29.6\%$) had a diploma in a healthcare-related field. The evidence indicated that the nurses, midwives and other healthcare providers with advanced qualifications have more advanced knowledge and skills to offer standardized and quality postnatal care (18, 19); therefore, the Ethiopian health system is very privileged (refer Table 1).

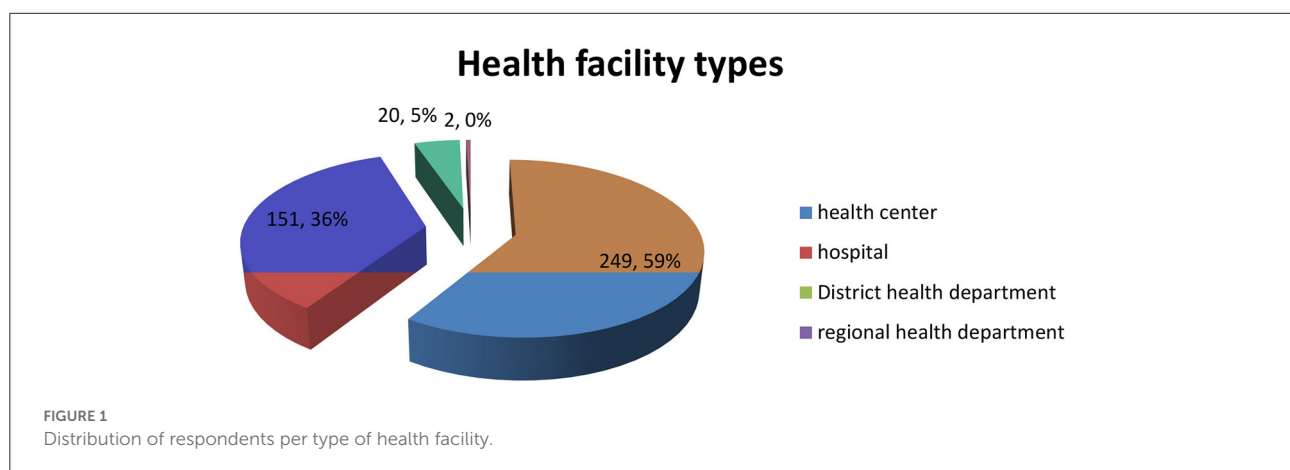


TABLE 2 Postnatal care practices in Ethiopia (N = 422).

Variable	Category	Frequency (F)	Percent (%)
Availability of separate postnatal unit	Yes	238	56.4
	No	184	43.6
Orientation in postnatal care	Yes	273	64.7%
	No	149	35.3
Competency of the postnatal care providers	Yes	279	66.1
	No	143	33.9
Continuing professional education	Yes	262	62.1
	No	160	37.9
Accessibility to guidelines	Yes	318	75.4
	No	104	24.6
Utilization of guidelines	Yes	311	73.7
	No	111	26.3

Slightly more than half of the respondents (55.5%) had work experience of 10 years or less, with only 35.8% who had between 11 and 20 years of experience in their current position (refer to Table 1). The Ethiopian healthcare workers seemed to have adequate experience to contribute to effective and standard postnatal care provision, as indicated in the literature (20).

As indicated in Figure 1, many respondents (59.0%) were working at health centers, 151 (f = 36%) were working in district hospitals, and 20 (5%) were working at the district health department. Only two (0.5%) were working at the regional health department.

Physical resources

Quality, evidence-based and standardized postnatal care can be provided if guidelines are available and used (21). **Guidelines on postnatal** service delivery need to be assessable to all service providers. A matter of concern is that 24.6% (n = 104) of respondents do not have immediate access to guidelines related to postnatal care (refer to Table 2). **Inaccessible guidelines** can compromise the postnatal care rendered and lead to differences in the quality of services offered to mothers and their babies (6).

Respondents to the open-ended questions confirmed the need for assessable guidelines:

“Though there are many challenges on postnatal care services, the shortage of guidelines is a serious challenge which compromises the quality of postnatal care provided to mothers and newborns.”

“All health facilities rendering postnatal care must use the recommended guidelines to improve the quality of postnatal care.”

Alarming was that, despite the benefits of using the guidelines, 26.3% (n = 111) of the respondents do not use the guidelines related to postnatal care (refer Table 2), possibly with a further negative impact on postnatal service delivery.

The respondents identified (44. 1%) an inadequate budget allocation for postnatal care services, possibly with a negative impact on the quality of postnatal care.

The provision of quality postnatal care can only be achieved when the health facilities are provided with the necessary equipment and supplies (22). However, a participant emphasized the following in the open-ended questions:

“Health facilities do not provide quality postnatal care as they lack the necessary equipment needed for postnatal care services.”

“Postnatal care in Ethiopia is exposed to the shortage of equipment such as diagnostic equipment and essential drugs.”

Infrastructure

In order to render quality postnatal care, a specific room or area designated for postnatal care service delivery is needed to ensure that health care providers provide quality postnatal care to postnatal mothers (23). It is therefore of cause for concern that 43.6% of the respondents indicated that there is not a separate room for postnatal care provision (refer Table 2). This finding is very different from a study conducted in Kenya where 78.82% of respondents reported that postnatal mothers were being nursed in units specially designated for them (23).

Mothers who need to travel long distances to use a service need waiting homes where they can stay from the late gestational age to encourage pregnant mothers and their families to use postnatal care services not only in Ethiopia, but also in other African countries (24). The lack of such a facility was elaborated on:

“The health facilities lack functional maternal waiting homes where mothers rest before and after delivery.”

Inadequate bed capacity and rooms available after birth possibly leads to the women being discharged 6h after giving birth (23, 25). Consistently, the participants mentioned the following:

“Some mothers are discharged early as there are no adequate rooms and beds in the health facilities.”

Sometimes the lack of bed capacity resulted in mothers and children sleeping on the floor (14, 26), constituting a real

risk to their health. This statement is supported by one of the participants:

“There are occasions where women sleep on the floor as a result of lack of adequate bed (s) in some health facilities.”

It is essential that there is electricity and clean running water at every health facility if quality health care is to be rendered (26). However, in the Ethiopian context, the participants indicated the following:

“Many of the health facilities in rural areas use lamps during the night-time to provide skilled delivery and postnatal care services which compromise the quality of services offered to mothers.”

“In some health facilities, there is no water supply.”

Inaccessible health services

The accessibility of the health service is one of the factors that determine its utilization, since maternal interest alone may not ensure the utilization of the services (27). Similarly, participants in the current study shared the following in this regard:

“In Ethiopia, though there are improvements in accessibility of the maternal health care including postnatal care, still many women in rural areas do not have access that must be improved.”

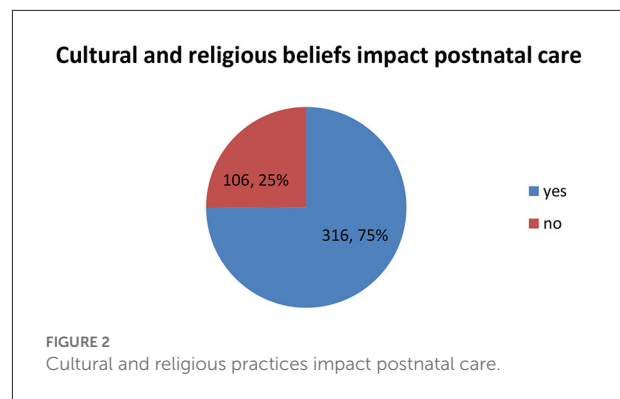
Inadequate or inappropriate transport and the unavailability of ambulance services make it difficult for women to reach (28) the health facilities which compromises the utilization of postnatal care. The participants referred to this concern by responding as follows:

“Though there are improvements in transportation services in Ethiopia still it is a challenge for postnatal care services as many women from rural areas do not have transportation access and are forced to walk on foot for more than 2 h when they seek health services.”

Road inaccessibility is one of the challenges related to transportation services when offering postnatal services (29, 30), which negatively impact on postnatal care in Ethiopia and other countries. The participants mentioned the following in this regard:

“The unavailability of roads and bad terrain in Ethiopia is a barrier for many women residing in rural areas of Ethiopia that need to be addressed if postnatal care is to be improved.”

The distance to health facilities is challenging as women residing in remote areas have difficulty in utilizing maternal



health services, including postnatal care (31). This is also confirmed by narrative data:

“Long-distance to the health facility is a barrier for postnatal care utilisation as many women may not seek health care when the health facility is far.”

Cultural concerns

Cultural practices have an impact on the health of mothers and babies during the postnatal period (32); therefore, such practices must be identified and attended to when offering the service. In this study 75% ($n = 316$) of respondents were of the opinion that the cultural practices in the community have an impact on both the provision and reception of postnatal care (refer to Figure 2).

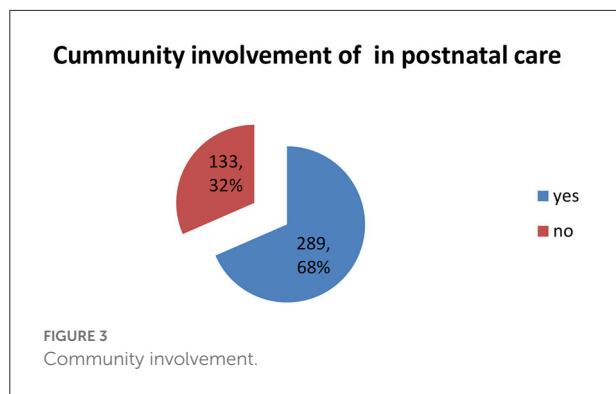
Some participants' emphasized the impact of culture:

“There is no preparation of porridge in the health facilities even the coffee ceremony is not commonly practiced. However, women in Ethiopia like to have those cultural ceremonies.”

The 40-day period after childbirth that allows mothers and babies to be indoors for the first month, has a negative impact on the utilization of postnatal care. In some cultures the postnatal mother wants to attend to cultural practices in their homes (8), as indicated by some participants:

“Some postnatal women want to remain at home during the postnatal period to practice their beloved culture.”

Despite the fact that health service programmes run successfully when community members are involved, as described by Babalola, Van Lith, Mallalieu, Packman, Myers, Ahanda, et al. (33), 32.0% ($n = 133$) of respondents did not involve community leaders in planning and providing postnatal care services (refer to Figure 3).



Lack of communication

Professional orientation before offering a service is essential to ensure quality care (23); thus, orientation given by experienced postnatal care providers or unit coordinators will make a significant contribution to quality postnatal care. However, in the Ethiopian context only 64.7% ($n = 273$) of respondents indicated that they have received orientation on postnatal care.

Effective telephone communication between the postnatal mother or her family to notify midwives, health extension workers or other health professionals when in need of postnatal care can increase the utilization of postnatal services (34). Participants in this study reported the following in this regard:

“Many women and their families in Ethiopia do not know whom to call and where to go when they need postnatal care or develop any health problem.”

Inadequate capacity building

Incompetent postnatal care providers pose a challenge for postnatal service delivery, as competency is a pre-requisite for standardized quality postnatal care (21, 35). The study findings, however, revealed that 33.9% ($n = 143$) of postnatal care providers indicated that they **lack the competency** to provide quality postnatal care (refer to Table 2).

The Ethiopian Federal Ministry of Health (FMOH) recommends continuing professional development to ensure that healthcare providers possess the competencies required to practice safely, effectively and to provide quality healthcare services. However, this study revealed that only 62.1% ($n = 262$) participated in continuous professional education to ensure competency while working in the postnatal care unit (refer Table 2).

Postnatal care providers need to participate in continuing professional development to update their knowledge and skills for providing quality and standardized postnatal care (36). Participants confirmed this requirement and reported as follows:

“Postnatal care providers should attend continuing professional development frequently to update their skills if postnatal care services are to be improved.”

“Postnatal care providers who have no continuing professional development have difficulty in rendering quality services.”

Poor monitoring and evaluation

Effective postnatal care monitoring and evaluation mechanisms are of great importance to the assessment of the quality of postnatal care offered to mothers and their babies; responses to the interventions provided to mothers and babies, and whether the postnatal care services led to the objectives being achieved (37). Postnatal services need to be monitored and evaluated at all levels where postnatal service provision and coordination is carried out, as indicated by participants in the current study:

“In most of the health facilities, monitoring, and evaluation of postnatal care services are poor. However, as it is an integral component of the postnatal services it needs to be improved in Ethiopia.”

“There should be strong monitoring and evaluation if postnatal care is to be improved.”

Discussion

The challenges identified by respondents in the Ethiopian context that can influence the provision and utilization of postnatal care were similar to the challenges identified in other studies (11, 38). Postnatal service delivery will not improve in the absence of research into human resources, physical resources, financial resources and equipment and supplies (22, 23).

Challenges pertaining to the lack of physical resources due to an inadequate budget namely, electricity constrains, limited water supply, inadequate equipment and supplies and limited bed capacity and rooms available after birth are posing a challenge to postnatal care in various regions of the world (14, 22, 24, 26).

Challenges pertaining to the infrastructure of healthcare facilities and accessibility of these facilities in terms of poor road infrastructure and transport challenges are documented challenges in developing countries (28–31), despite being a requirement for postnatal care improvement (23, 36).

Findings from this study indicated the inaccessibility of health services as a challenge for quality postnatal care. Similar evidence is documented in literature studies (39, 40).

Quality, evidence-based and standardized postnatal care can only be provided if guidelines are made available and used by all healthcare workers. To prevent unorganized and fragmented

postnatal care being provided to postnatal mothers and their newborns (34).

Effective telephone communication between the healthcare providers and the community (23, 34) and a quality monitoring and evaluation system are essential components of quality postnatal care delivery.

From the literature, it is evident that numerous attempts were made to improve postnatal care and postnatal care service delivery. Despite all the efforts made, it remains a challenge as utilization remains low. An action plan involving all stakeholders in the development thereof (mothers, healthcare professionals, policy-makers) is needed to facilitate the implementation of strategies and guidelines. This will encourage ownership of the action plan, including providing guidance on who needs to take responsibility for which actions within a very specific timeline. In this way progress can be monitored and accessed and a plan can be adopted or adapted to suit changing healthcare environments and context.

Conclusion

The study revealed there is a lack of physical resources, infrastructure problems, cultural concerns, inadequate capacity building, inaccessibility of health services, unavailability of guidelines, a lack of communication with healthcare users and poor monitoring and evaluation as challenges which negatively impact on the provision and utilization of postnatal care services similar to other African countries. Healthcare professionals in the African context need to take responsibility and provide a realistic solution in the form of action plans to facilitate the process, ultimately improving maternal and newborn health. As part of the action plans, maternal dignity, respect and satisfaction can get due attention to ensure that the service is utilized in future.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

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Ethics statement

The studies involving human participants were reviewed and approved by University of South Africa (UNISA). The patients/participants provided their written informed consent to participate in this study.

Author contributions

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Contextualizing a framework for improving postnatal care in Ethiopia

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Background: Postnatal care is among the major recommended interventions to reduce maternal deaths. To improve the low postnatal care utilization in Ethiopia, the framework developed for this purpose in Kenya was contextualized and adapted for implementation in the Ethiopian context.

Objectives: The objectives of this article are to share the process followed to contextualize Chelagat's framework for improving postnatal care, for the implementation in Ethiopia as well as the finalized contextualized framework.

Methods: A quantitative descriptive research design was adapted. A self-administered questionnaire was used to gather data during November 2018 from 422 postnatal care providers and coordinators, using stratified random sampling. The AGREE II was utilized to assess adaptability and applicability and an open-ended question allowed to assess the challenges and opportunities for utilizing the framework. The data were analyzed using SPSS computer software, Version 23.

Results: The findings revealed that the framework from Chelagat was adaptable to use for the improvement of postnatal care in the Ethiopian context. The results from the analysis of the data using AGREE II indicated an average domain score of 92%, for contextualization possibility.

Conclusion: The framework originally developed by Chelagat was contextualized and refined to be implemented in Ethiopia to improve postnatal care.

KEYWORDS

contextualizing a framework, postnatal care, improving postnatal care, maternal health, quality postnatal care

Background

Despite the goals set by the United Nations (UN) to reduce maternal mortality to <70 per 100,000 live births, the rates in Sub-Saharan Africa are unacceptably high (1, 2, 40). The maternal mortality rate in Ethiopia remained stagnant over the past years as it averaged between 412 and 871 per 100,000 live births (1). Most maternal deaths occur during the first 48 h after delivery, despite this time, being critical for monitoring the complications arising from the delivery (3) and thus preventing the maternal mortality.

More or less 65% of maternal deaths occur within 1 week of delivery and nearly 80% of maternal deaths occur within 2 weeks of delivery, (6, 7) thus during the most critical first few days after birth (3, 8). The vast majority of maternal deaths, within the first 48 h after delivery are preventable, providing the delivery of optimal postnatal care (4, 5). The maternal morbidity is associated with missed opportunities for preventive measures such as early diagnosis and treatment (8).

Timely quality postnatal care during the first hours and days after birth is essential for improving maternal and newborn health (8–10). Despite accessible postnatal care being positively associated with improve maternal and neonatal mortality and morbidity rates (11, 12), only 17% of women in Ethiopia receive postnatal care during this crucial time (3).

Despite the many advantages of postnatal care, it remains a neglected part of maternal and child health service in most developing countries (13, 14) including Ethiopia. Most mothers do not receive postnatal services from competent health professionals (15, 16).

Quality postnatal care should be a comprehensive or integrated package that covers a range of aspects that affect both the mother and baby. Postnatal services should (1) provide the support for the mother and her family in the transition to a new family, (2) contribute to the prevention of health problems in mother and baby, (3) ensure the early diagnosis of possible complications, (4) provide the treatment for complications that occur in mothers and infants, (5) refer the mother or infant for specialist care when necessary, (6) provide health education on baby care, maternal nutrition, and contraception, (7) support and promote breastfeeding, (8) provide contraception service, and (9) provide an immunization service for the infant (8, 17).

Kenya and Ethiopia are Sub-Saharan countries experiencing similar challenges pertaining to postnatal care. In Sub-Saharan countries including Kenya and Ethiopia, the inaccessibility of health services, misconception about postnatal care as well as diverse culture and norms are some of the challenges contributing to low postnatal care utilization (19, 20). To assess the possibility for adapting or contextualizing a framework developed for the Kenyan context in Ethiopia, broad similarities and differences were worth taking note of.

Postnatal care utilization

Postnatal care coverage in Ethiopia is extremely low with only 19% women receiving care, thus 81% of women not receiving postnatal care (3). Furthermore, 95% of those who did receive care, did not receive care within 2 days after delivery as is recommended (3, 8). In Kenya, 53% of women receive postnatal care (18), which is more than double compared with that of Ethiopian women. As both countries share similar socio-demographic and socioeconomic characteristics, similar challenges pertaining to accessing and utilizing postnatal care

are experienced; amongst others are (1) the recognized 40-day period of rest and staying indoors (19, 20), (2) cultural misconceptions of postnatal care, (3) lack of awareness of the advantages of postnatal care, (4) limited financial resources and transport costs, (5) accessibility challenges, and (6) the long distances to health facilities (21–23).

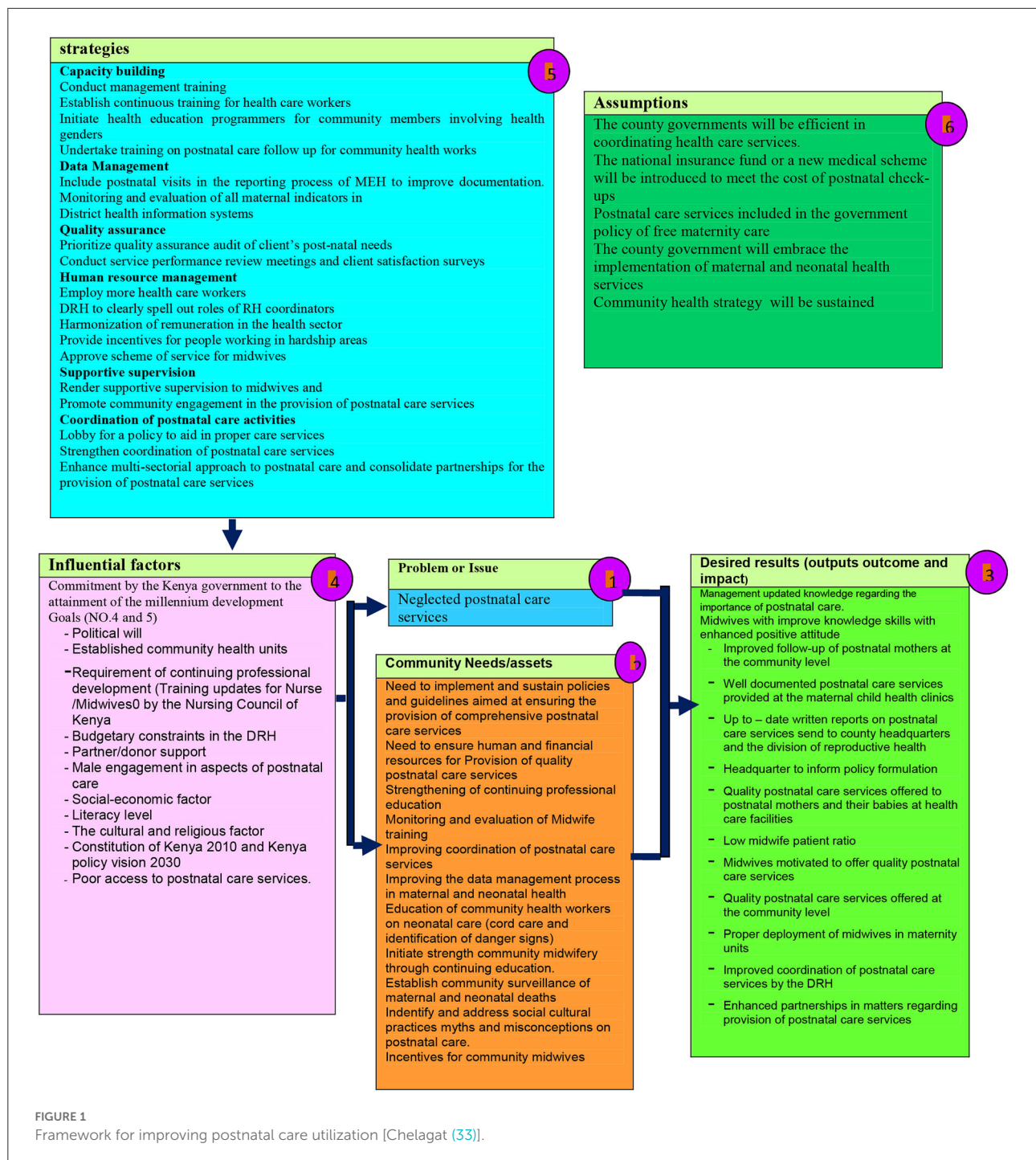
Challenging to postnatal care delivery in both countries is the reported negative attitudes of health care providers (24, 25), hindering postnatal care utilization. Despite the efforts made in Ethiopia to decrease the maternal mortality by increasing maternal health care utilization (including postnatal care) through different strategies, such as health sector reforms, increasing the number of trained health professionals, and health facilities, there was neither a significant reduction in maternal mortality nor an increase in postnatal care utilization (3).

Chelagat's framework

In 2015, Chelagat developed a framework that was validated and recommended for implementation in Kenya, as well as in other countries with similar context, for improving postnatal care. Implementation of this framework can ultimately improve maternal and neonatal outcomes in countries with similar challenges.

Chelagat's framework, underpinned by the Systems Model, was developed and guided by the Theory of Change Logic Model (Figure 1). This framework presents a picture of how a certain effort or initiative to improve postnatal care is supposed to work. It explains why the strategies identified in the framework are a good solution to the experienced challenge (26). The framework is a systematic and visual way of understanding the relationship among the resources required to operate postnatal care services, the activities to be undertaken, and the results that the framework hopes to achieve (27).

In Chelagat's framework, neglected postnatal care in Kenya was identified as the main problem to be addressed (Figure 1, number 1). This problem is in accordance with the problem identified in Ethiopia (Figure 1). The assumptions for implementing the framework (Figure 1, number 6) relate to the expectations or predictions behind how certain factors could affect strategies addressing neglected postnatal care. The identified strategies to improve postnatal care in Kenya, as indicated in the framework (Figure 1, number 5), were expected to be similar to those that might improve postnatal care in Ethiopia. The framework also includes the intended results or outcomes (Figure 1, number 3) and the influential factors (Figure 1, number 4) for both problem and implementation of the framework (26–28).



Methods

Study design

A quantitative descriptive cross-sectional study design was employed to assess, adapt, and contextualize the framework developed for the Kenyan context for the possible implementation in Ethiopia.

Population

The study was conducted in Oromia regional state, purposively selected as it is geographically large in comparison with other regions and nearly one-third of the Ethiopian population live in the Oromia region (3).

The stakeholders (national and provincial reproductive health coordinators as well as all midwives and nurses allocated

to midwifery units in all hospitals in Kenya) participating and contributing to the development of Chelagat's framework, were similar to the stakeholders involved in postnatal care in Ethiopia. Therefore, the postnatal care service providers, namely, midwives, nurses, and health officers at health facilities, as well as the district, regional, and national reproductive health coordinators in the Ethiopian health system assisted in adapting and contextualizing the framework.

Sample size and sampling procedure

The postnatal care providers and coordinators working at the 80 health centers, 25 hospitals, the district and regional postnatal care coordinators in the district health departments, as well as the regional health department, formed the population. The identified populations are key to postnatal care in the Ethiopian health system. The total number of participants comprised of 422 participants (294 nurses, 74 midwives, 46 health officers, 6 district postnatal care coordinators, and 2 regional postnatal care coordinators). The study respondents were selected by using stratified simple random sampling as there was a sampling frame prepared by the researcher based on the existing lists of postnatal care providers and coordinators at each health facility or health department.

The total sample size was determined, using the single population proportion formula as described by Kothari (29):

$$n = Z(\alpha/2)^2 * P(1 - P) / d^2$$

$$n = (1.96)^2 * 1(1 - 0.5) / (0.05)^2$$

$$n = 384$$

The assumptions under this formula were as follows:

$$n = \text{sample size;}$$

$$Z(\alpha/2) = \text{the value of normal distribution representing a confidence level of 95\%. Its value is 1.96;}$$

$$P = \text{proportion of the case;}$$

$$d = \text{margin of error.}$$

Considering a non-response rate of 10%, the final sample size was 422.

The sampling frames were the lists of individuals from which the researcher selected the sample, namely, the lists of postnatal care providers and postnatal care coordinators.

Research instrument

A questionnaire was used to collect data from each participant to assess applicability, for the adaptation and

contextualization of the framework in the Ethiopian context. Ten trained field workers were purposively selected from university graduate nurses to gather the data. Before commencement of the actual data collection, a pilot study was conducted with 5% (21) of the participants who were outside the study area but who were postnatal care providers and coordinators (30).

The AGREE II, a standardized and tested questionnaire (30, 31), was used for data collection. Additional questions, guided by standardized WHO guidelines, were added to the AGREE II to assess baseline information on postnatal care services in Ethiopia as to compare the data, with that available from Kenya. The data from the questionnaires were analyzed with the assistance of a statistician. The Statistical Package for Social Scientists (SPSS) computer program, Version 21 was used to process and analyze the data. Descriptive statistics, using frequencies and percentages for categorical data were used, and the results for this study were presented in text form, in tables, and in pie charts.

For guideline or framework adaptability assessment, AGREE is a commonly used instrument. The instrument allows for assessing methodological rigor and transparency in which a guideline or framework is developed. The original AGREE instrument has been refined, which has resulted in the new AGREE II version and a new user's manual which was published in 2013 (31). AGREE II includes 23 appraisal criteria (items) organized within six domains and two overall assessments as follows: (1) Overall framework quality; (2) Recommendation for use. The six domains are (1) overall aim of the guideline, (2) stakeholder involvement, (3) rigor of development, (4) clarity of presentation, (5) applicability, and (6) editorial independence.

Each domain in AGREE II assesses, by means of a Likert scale, a unique dimension of the developed framework quality. The participants were allowed to provide individual opinions on what they believe would improve the quality of the guidelines or framework to be contextualized in the space that was provided additional to the AGREE II tool.

Data gathering process

Ten data collectors (6 males and 4 females) from a university college of medicine and health sciences were purposively selected for assisting with data collection. They were chosen based on their experience as fieldworkers. They shared with all eligible respondents an information and recruitment letter and provided a consent form to complete, if volunteering to participate. The data collectors distributed the questionnaires to all consenting participants, requesting them to complete it in private and return the completed questionnaire within 2 days.

Data analysis

The data analysis was done, using statistical procedures as well as open coding for the open-ended questions. Quantitative data were analyzed, summarized, and presented in tables and pie charts using frequencies and percentages (32), applying the principles suggested by AGREE II (2013:10). The analysis of the questionnaire, thus, was based on the following six domains indicated in AGREE II: (1) Scope and Purpose; (2) Stakeholder Involvement; (3) Rigor of Development; (4) Clarity of Presentation; (5) Applicability, and (6) Editorial Independence.

As recommended in AGREE II, each of the AGREE II items and the two global rating items were rated on a 7-point scale that ranged from 1 to 7 (1–strongly disagree to 7–strongly agree). The AGREE II User's Manual section was used to rate each domain. Accordingly, the AGREE II was used to calculate the domain scores by summing up all the scores of the individual items in a domain and scaling the total as a percentage of the maximum possible score for that domain calculated as follows:

Maximum possible score = 7 (strongly agree) × number of items × 422 (appraisers).

Minimum possible score = 1 (strongly disagree) × number of items × 422 (appraisers).

As recommended in AGREE II, the scaled domain for the contextualization possibility of the framework was assessed using the formula (31):

$$\text{The scaled domain} = \frac{\text{Obtained score} - \text{Minimum possible score}}{\text{Maximum possible score} - \text{Minimum possible score}}$$

An inductive thematic analysis was employed for the narrative data from open-ended questions. Themes and categories were identified after the data were read and coded so that similar ideas were grouped as themes that were underpinned by categories.

Ethical consideration

Ethical approval to conduct the study was obtained from the ethics committee from the custodian university (HSHDC/452/2015). Permission and support to conduct the study and gain access into the field were obtained from the respective administrative offices of Oromia Regional State Health Bureau, each health facility, including health centers, hospitals, district, and regional health departments as well as from each individual respondent who volunteered to participate.

TABLE 1 Sociodemographic characteristics of respondents.

Variables	Category	Frequency (F)	Percent (f)
Age	Younger than 30 years	115	27.3
	30–39 years	142	33.6
	40–49 years	122	28.9
	50–59 years	39	9.2
	60 years and older	4	0.9
Gender	Male	174	41.2
	Female	248	58.8
Educational level	Master's	34	8.1
	Bachelor's	263	62.3
	Diploma	125	29.6
Work experience in years	1–10 years	234	55.5
	11–20 years	151	35.8
	21–30 years	37	8.8

Results and discussion

Biographical data (N = 422)

All 422 respondents volunteered to participate and completed the questionnaires. Table 1 presents the sociodemographic characteristics of the respondents. Among the respondents, 27.3% were younger than 30 years of age, 0.9% were older than 60 years of age, and 33.6% were between 30–39 years of age (Table 1). This indicated nearly all respondents from all professions, who were within the productive age group that positively influences postnatal care services as supported by Dlamini (9).

A total of 58.8% of the respondents in this study were females and 41.2% were males (Table 1), similar to in Kenya where 88.5% of the postnatal care providers were females (33, 34).

Many respondents were in possession of bachelor's degrees (62.3%) or diplomas (29.6%) in a health care-related profession. The Ethiopian health care system is very fortunate to have more degree-holding nurses than Kenya, where only 1.96% of nurses were degree holders (33). Nurses, midwives, and other health care providers with advanced qualifications have more advanced knowledge and skills to offer standardized and quality postnatal care to mothers and newborns (35, 36), and therefore the Ethiopian health system is privileged. Only a small number (8.1%) were in possession of master's degree in a health care-related profession. This is of concern as those with postgraduate qualifications can conduct research, change policies, and influence decisions made by policy makers (36).

Two hundred and thirty-four (55.5%) of the respondents had work experience of 10 years or less, 35.8% had 11–20 years of experience and 8.8% over 21 years of experience in postnatal care service delivery, thus they have adequate and relevant clinical

experience in postnatal care services to contribute to effective and standard postnatal care provision (37). The mean duration of work experiences among postnatal care providers in Ethiopia is similar to that reported in Kenya, where it was 11.22 years (33).

Adaptation possibility assessment for Chelagat's framework in the Ethiopian context (application of agree II)

The possibility to adapt the Chelagat framework in Ethiopian context was described according to the findings received from each specific domain of the AGREE II tool. The AGREE II tool has six domains on which the possibility of adapting is described.

Domain 1: Scope and purpose of the framework

Domain 1 is concerned with (1) the overall aim of determining the framework's possibility to be contextualized, (2) the specific health problem (the neglected postnatal care) to be addressed, and (3) the target population, to whom the framework is meant to apply, is to be assessed. This domain deals with the potential health impact of the contextualized framework on postnatal mothers, families, the community, and the health system.

The assessment was based on whether the overall objective of the framework, namely, the expected improvement in postnatal care as a result of the implementation of the contextualized framework, can be achieved in Ethiopia. It also considered whether the health question, the problem (neglected postnatal care, as identified in Kenya), is relevant within the Ethiopian context as well as whether the framework clearly described the target population to whom the contextualized framework will apply.

Moreover, AGREE II does not stipulate minimum domain scores or patterns of scores across domains to differentiate between high-quality and poor-quality guidelines. However, it recommends that decisions should be made by the user and guided by the context in which AGREE II is being used (31). Therefore, a domain score of 75% or more was considered for all domains to indicate a high-quality framework recommended for use in the Ethiopian context.

For domain 1, the average scaled score of the assessment was 93.4%. With this average score of 93.4%, the participants, therefore, believed that the objectives of the framework and the problem that needs to be solved in Ethiopia were similar to the problem in Kenya (neglected postnatal care), indicating that the implementation of this framework can improve postnatal care within the Ethiopian context (Table 2).

Domain 2: Stakeholder involvement

The second domain focused on the extent to which Chelagat's framework was developed by the appropriate and similar stakeholders to that of Ethiopia and whether it addressed the views of all the intended users. The assessment was made using seven items, namely, (1) whether the relevant group of experts participated in the development of the framework, (2) whether the views and preferences of the target population were taken into consideration, (3) if the factors that affect postnatal care utilization were included, (4) if the strategies for improving postnatal care were included, (5) whether the role of the community in improving postnatal care was considered, (6) if the outcome on postnatal care, if implemented, were indicated, and (7) whether the target users of the framework were clearly defined.

The average scaled score of the assessment was 90% (Table 2). The participants, with an average score of 90%, found the framework to have been clearly described and the relevant group of experts participated in the development. This finding is an indication that the implementation of this framework could therefore be adapted for the Ethiopian context.

Domain 3: Rigor of development

Domain 3 assessed issues related to the process used to gather and synthesize the evidence, the methods to formulate the recommendations, and updating them. The specific assessment was made on whether the developed framework (1) used systematic methods, (2) followed clear criteria for selecting evidence, (3) described the strengths and limitations of the body of evidence clearly, (4) described the methods used for formulating the recommendations clearly, (5) considered the health benefits, (6) considered the health side effects in making the recommendations, (7) considered the health risks in formulating the framework, (8) considered the link between the recommendations and the supporting evidence, (9) explicitly involved postnatal care experts for improvements of postnatal care, and (10) provided a procedure for updating the guideline.

An average scaled score of the assessment of domain 3, was 92% (Table 2), thus indicating that the framework was developed according to all 10 aspects listed above. This result indicated that the scientific rigor of the framework developed by Chelagat was of high quality which, in turn, indicated that all aspects were included during the development and therefore relevant for implementation in the Ethiopian context.

Domain 4: Clarity of the framework

Domain 4 is concerned with the language, structure, and format of the developed Chelagat framework. When a framework is developed for improvement in a health-related field, the framework developers expect that it should provide a

TABLE 2 Domain scores ($n = 422$).

Domain	Profession and number of appraisers	Total number of items	Minimum possible score	Maximum possible score	Obtained score	The scaled domain score
The scope and purpose	422	3	1,266	8,862	8,864	93,4
Stakeholder involvement	422	7	2,954	20,678	18,899	90
Rigor of development	422	10	4,220	29,540	27,605	92
Clarity of the framework	422	3	1,266	8,862	8,339	93
Applicability of the framework	422	4	1,688	11,816	11,120	93
Editorial independency	422	1	422	2,954	2,769	94
Implementation of the framework will improve the provision of postnatal care in the Ethiopian context	422	1	422	2,954	2,748	92

concrete and precise description of—in this study’s context—the strategy, how the strategy will be implemented, and what segment of the population should be involved, as informed by the body of evidence. It is important to note that, in some instances, the evidence may not always be clear and there may be uncertainty about the best care option(s) or strategies.

When such doubts exist, the framework developers are expected to make evidence clear to enhance the implementation of the framework (31). For the implementation of the framework, postnatal care providers and coordinators should be able to easily find the most relevant recommendations and evidence in the framework. The clarity of the framework developed by Chelagat to improve postnatal care in Kenya was assessed in this study focusing on whether the framework (1) is specific and unambiguous, (2) the different options for the provision of postnatal care are presented in the recommendations, and (3) used key recommendations that are easily identifiable.

The average scaled score of the assessment of domain 4 was 93% (Table 2), thus indicating that the framework was developed according to all three aspects listed above, thus relevant and implementable in Ethiopia.

Domain 5: Applicability of the framework

Domain 5 of the assessment was concerned with the likely barriers and facilitators to the implementation, strategies to improve uptake, and resource implications of applying the developed framework. The applicability of the framework developed by Chelagat for the improvement of postnatal care in Kenya was assessed in this study specifically focusing on the (1) description of the facilitators and barriers to the application of the framework, (2) provision of advice or tools on how the framework is put into practice, (3) consideration of the potential resources identified in applying the recommendations,

and (4) presentation of monitoring and auditing criteria for the implementation of the framework into practice.

The average scaled domain score of domain 5 was 93% (Table 2), thus indicating that the framework was developed according to all aspects listed above. The results from this domain indicate that Chelagat’s framework is highly applicable and can easily be implemented to improve postnatal care within the Ethiopian context (Table 2).

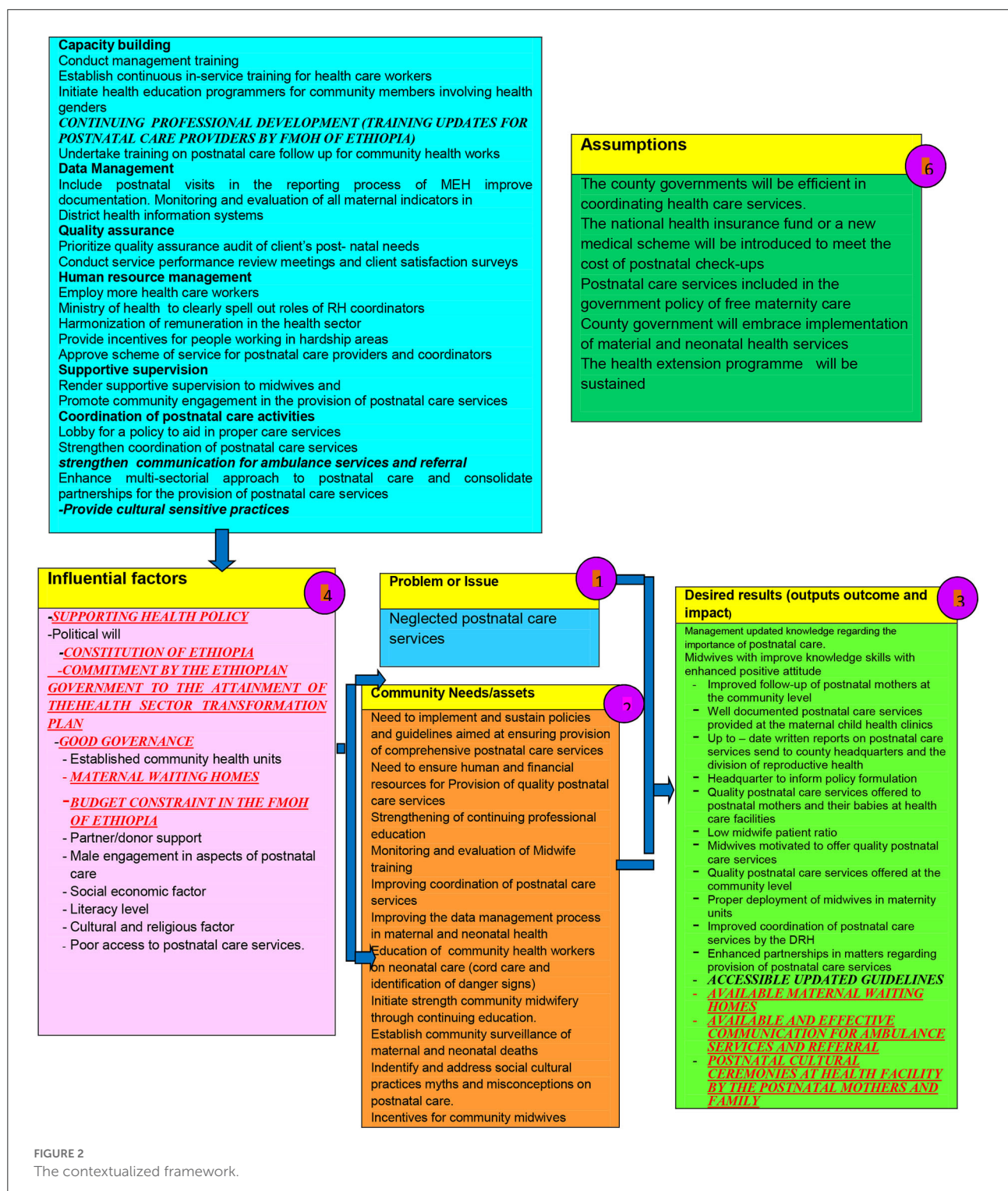
Domain 6: Editorial independence

Domain 6 of the assessment for the adaptation and contextualization possibility of the framework was concerned with the formulation of recommendations not being unduly biased with competing interests. The assessment considered whether there were competing interests among experts participating in the development of Chelagat’s framework. The average scaled score of domain 6 was 94% (Table 2).

This is an indication that the experts who were involved in the development of Chelagat’s framework independently participated in the study and contributed their professional expertise to the development thereof, thus adaptable for implementation in Ethiopia.

Overall assessment of the framework for implementation

The section in the AGREE II, addressed the overall assessment, thus the rating of the overall quality of the framework. It assessed whether the framework developed by Chelagat for the improvement of postnatal care in Kenya could be recommended for use in Ethiopian practice to facilitate improvement of postnatal care (31).



The expectation is that a standardized framework must be based on the scientific evidence and reliable information; it must follow an unbiased process in development, and primarily target the health needs of the public including that of postnatal mothers (38).

The average scaled score of the assessment on this domain was 92% (Table 2). This domain assessed the postnatal care providers' and coordinators' recommendations on the implementation of the framework developed by Chelagat for the improvement of postnatal care within the

Kenyan context. The average domain score of 92% was indicative that the framework developed by Chelagat is recommended to be adapted to improve postnatal care in the Ethiopian context.

The contextualized framework

To contextualize the framework found to be adaptable for the Ethiopian context, the ADAPTE—an international collaboration of guideline developers, researchers, and clinicians who aim to promote the development and use of clinical practice guidelines through the adaptation of existing guidelines—as described by Harrison, Legare, Graham and Fervers (39), was utilized. Factors specific to Ethiopia, such as the health policy, cultural issues, health system, maternal health care utilization, the budget for health care, and available human resources, were taken into consideration in contextualizing the framework for the Ethiopian context. There was no significant difference in the related factors between Kenya and Ethiopia, however, the few aspects specific to Ethiopia, identified by the literature review and the data gathered from respondents, were included as context points in the contextualized framework.

The context points that were identified by the participants and the available literature are indicated in red, bold, underlined, and caps in the contextualized framework. Therefore, as illustrated in Figure 2, the original framework remained as developed and designed by Chelagat (33), and the context points were included to indicate an added information for the contextualized framework for the Ethiopian context.

The following adaptations were included: (1) *Strategies* continuing professional development (training updates for postnatal care providers by FMOH of Ethiopia); (2) *Influential factors* supporting health policy, Constitution of Ethiopia, commitment by the Ethiopian government to the attainment of the health sector transformation plan, good governance, improved maternal waiting homes and budget constraint in the FMOH of Ethiopia; and (3) *Outputs* that include accessible updated guidelines, available maternal waiting homes, available and effective communication with ambulance services, as well as available postnatal cultural ceremonies at a health facility. These adaptations were identified from respondents' recommendations, as well as from the available literature.

Limitations

There might have been differences in views and opinions among postnatal care providers in unselected health

facilities due to possible differences in access to resources for postnatal care.

Conclusion

The framework developed by Chelagat (2015) to improve postnatal care in Kenya was found suitable for adaptation in the Ethiopian context. With the support of all stakeholders, the framework was adapted to be context specific, thus successfully contextualized for utilization in Ethiopia. Due to the active involvement of all stakeholders during the process, this contextualized framework is owned by postnatal care providers in Ethiopia, positively impacting on the possible success of implementation. However, any framework will only be effective, provided that the methods and strategies used in the framework are shared among the relevant stakeholders responsible for the implementation.

Researchers and policy makers need to utilize all avenues to adapt and contextualize existing frameworks for possible implementation in different contexts.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The study involving human participants were reviewed and approved by the IRB (Ethics Committee) of the University of South Africa. The participants provided their written informed consent to participate in this study.

Author contributions

Both authors equally contributed to the conceptualization, design, acquisition of data, analysis, interpretation of the data, and drafting of the manuscript. Both authors contributed to the article and approved the submitted version.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Maternal and dietary behavior-related factors associated with preterm birth in Southeastern Terai, Nepal: A cross sectional study

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Background: Preterm birth (PTB) is a global issue although its burden is higher in low- and middle-income countries. This study examined the risk factors of PTB in Southeastern Terai, Nepal.

Methods: In this community-based cross-sectional study, a total of 305 mothers having children under the age of 6 months were selected using systematic random sampling. Data were collected by structured interviewer-administered questionnaires and maternal antenatal cards from study participants for some clinical information. Predictors of PTB were identified using multi-level logistic regression analysis at a P -value < 0.05 .

Results: Of the total 305 mother-live-born baby pairs, 13.77% (42/305) had preterm childbirth. Maternal socio-demographic factors such as mothers from Dalit caste/ethnicity [adjusted odds ratio (AOR) = 12.16, 95% CI = 2.2–64.61] and Aadibasi/Janajati caste/ethnicity (AOR = 3.83, 95% CI = 1.01–14.65), family income in the first tercile (AOR = 6.82, 95% CI = 1.65–28.08), than their counterparts, were significantly positively associated with PTB. Likewise, other maternal and dietary factors, such as birth order first-second (AOR = 9.56, 95% CI = 1.74–52.53), and birth spacing ≤ 2 years (AOR = 5.16, 95% CI = 1.62–16.42), mothers who did not consume additional meal (AOR = 9.53, 95% CI = 2.13–42.55), milk and milk products (AOR = 6.44, 95% CI = 1.56–26.51) during pregnancy, having < 4 antenatal (ANC) visits (AOR = 4.29, 95% CI = 1.25–14.67), did not have intake of recommended amount of iron and folic acid tablets (IFA) (< 180 tablets) (AOR = 3.46, 95% CI = 1.03–11.58), and not having adequate rest and sleep (AOR = 4.83, 95% CI = 1.01–23.30) during pregnancy had higher odds of having PTB than their counterparts.

Conclusion: Some socio-demographic, maternal, and dietary behavior-related factors were independently associated with PTB. These factors should be considered while designing targeted health interventions in Nepal. In addition, we recommend specific measures such as promoting pregnant women to use available antenatal care and counseling services offered to them, as well as having an adequate diet to a level that meets their daily requirements.

KEYWORDS

antenatal care, cross-sectional study, dietary behavior, obstetric history, preterm birth, deprived group, Nepal

Introduction

Preterm birth (PTB) refers to a live birth that occurs before 37 completed weeks of gestation (1). Depending upon the gestational age, the preterm has been categorized as extremely preterm (<28 weeks), very preterm (28 to 32 weeks), and moderate to late preterm (32 to 37 weeks) (1, 2). Of approximately 15 million PTB occurring annually worldwide, 1 million of them die as a result of preterm-related complications before the child reaches the age of 5 years. A majority of such events occur in low- and middle-income countries, especially Southeast Asia and sub-Saharan Africa (3). More efforts are therefore necessary for low- and middle-income countries to achieve the United Nations Sustainable Development Goal 3 target 3.2 which aims to end all preventable deaths of newborns and children aged under 5 years of age by 2030 (3–5). Nepal remained with the 20th highest rate of PTB in the world in 2010 (6), and prematurity has often been reported as one of the major causes of neonatal deaths in Nepal (7–9).

PTB has numerous short- and long-term impacts on children. Children with PTB have a lower chance of survival; they are more likely to contract respiratory and other common childhood infections (6, 10–12), and they have long-term neurodevelopmental impairment that leads to poor learning abilities, cognition, behavior, and reduced physical and mental ability; as well as several non-communicable health problems such as hypertension, cardiovascular and cerebrovascular diseases; type 2 diabetes; chronic kidney disease; asthma; and pulmonary abnormalities (11–13). In addition, PTB is associated with increased hospitalization rates and healthcare costs, leading to a burden on the healthcare system and economy (14–16).

Several prior scientific reports have explored a wide range of maternal socio-demographic characteristics such as younger (<20 years) or advanced maternal age (>35 years) (17–20), none or lower educational level (20–22), rural residents (20), none or suboptimal utilization of antenatal care services (17, 20, 23, 24), existing or previous maternal obstetrical and medical conditions such as the history of previous

PTB, adverse birth outcomes and abortions, pregnancy-induced hypertension, preeclampsia, antepartum hemorrhage, premature membrane rupture, multiple pregnancies, short (≤ 2 years) birth spacing (20, 22–24), infectious diseases, and anemia occurring during pregnancy (24) were independently positively associated with PTB.

In Nepal, few hospitals and community-based studies have reported on the status of PTB in recent decades (25–28). In addition, little is known about the risk factors of PTB in Nepal (26, 28). A recent study from Nepal mainly examined the sociodemographic, maternal, and obstetrical factors associated with the outcome of interest (26), while another previous study reported that young maternal age (≤ 18 years) increased the risk of PTB (28). This study was designed and performed to fill the literature gap and explore some additional factors associated with PTB in Nepal. In addition, we believe that the findings of this local area research might provide evidence to modify some of the modifiable associated factors of PTB, guide with better counseling pregnant women, and help local area strategy formulation to reduce long-standing problem of PTB.

Materials and methods

Study design, area, and subjects

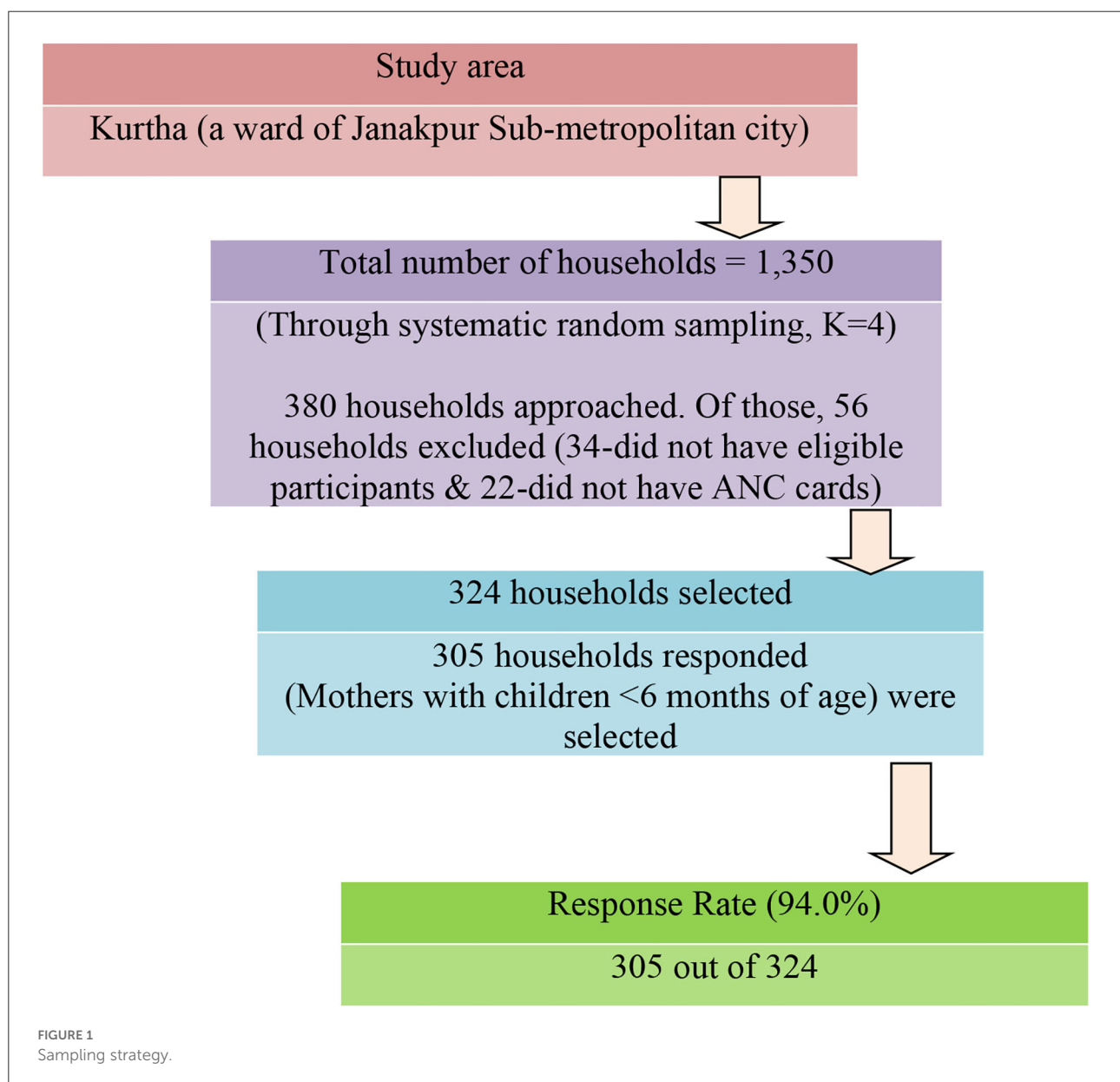
A community-based cross-sectional study was carried out in Kurtha of Janakpur sub-metropolitan city in the Dhanusa district of Southeastern Terai, Nepal. The study area consisted of several clusters located in a semi-urban area within a 3-km distance from the Janakpur sub-metropolitan city. The study area is located in the southern plains of Madhesh province, Nepal. The Madhesh province consists of eight districts, including Dhanusha. Most people in the study area are similar to people residing in the same province in terms of language, culture, and literacy status (29).

According to the 2011 census, the study area included 1,350 households with a population of approximately 7,815 individuals. The total number of women of reproductive

age (15–49 years) was 1,820 (30). The sampling frame was generated through the list of households with a list of women obtained from the record of the Sub-metropolitan city. A total of 305 households from the study area were selected using systematic random sampling. The sampling interval ($K = 4$) was determined by dividing the total number of households by the sample size. The first household selection followed a simple random sampling technique. Mothers with children <6 months of age in the selected households constituted the study participants. If a mother with a child <6 months of age was not found in the selected household, the subsequent households were recruited until the eligible participant requirement was met. Of a total of 380 households visited, 56 households did not

meet the selection criteria (34 households did not have study participants, and 22 did not have ANC cards with them). Finally, we got responses from 305 households out of 324, giving rise to a response rate of 94% (Figure 1). Random selection (lottery method) was used in case of more than one study subject was available in the selected household.

A sample of 305 study subjects was estimated using the formula, $n = Z^2pq/d^2$ (31), where, $Z = 1.96$, p = proportion of gestational age <37 weeks in Nepal = 17.2% (32), $q = (1-p) = (100-17.2) = 82.8\%$, and d = desirable error 0.05 (5% margin of error). Thus, we found $n = 219$ study subjects. Considering the design effect of 1.25 and the non-response rate of 10%, we required 302 study subjects.



Finally, we enrolled a total of 305 study participants in this study.

Data collection

Data were collected between 1 July 2019 and 20 August 2019. Face-to-face interviews were conducted by 10 medical undergraduate students after they participated in a 5-day data collection training. Data were collected using a structured questionnaire adapted from the Nepal Demographic and Health Survey (NDHS) 2016 (33). The outcome variable of the study was PTB. It was defined as the birth of a baby at fewer than 37 weeks gestational age or fewer than 259 days since the first day of the women's last menstrual period (LMP) (1). Gestational age was recorded from the antenatal card (community midwives maintain such records in rural Nepal) which was obtained directly from the study participants during data collection. The major independent variables of interest were nature of the diet, consumption of additional meals (including one more meal apart from the regular diet/meal by pregnant women.), consumption of green leafy vegetables, consumption of fruits and juice, consumption of milk and milk products, consumption of meat and meat products, consumption of tobacco, consumption of alcohol, antenatal care, place for antenatal care (ANC), Tetanus-Diphtheria (TD) vaccination, number of iron tablets consumed, rest and sleep during pregnancy (operationally defined as whether or not the pregnant women were taking 2 h of rest during day time for current pregnancy), birth order, birth spacing, place of delivery, mode of delivery, sex of the child, birth weight. Maternal age was categorized as <20 years, 20–30 years, and > 30 years. Ethnicity was based on the caste system in Nepal and was divided into three major groups based on available literature and similarities between the caste/ethnic groups as Dalit, Aadibasi/Janajati, and the upper caste group (34). Maternal education was recorded as primary education (1–5 years of schooling), secondary education (6–10 years of schooling), and higher secondary education and above (more than 10 years of schooling). The maternal occupation was coded as non-working (household work), business/service, and agriculture/daily wage labor.

Statistical analysis

Data were entered into Epi Data Entry 3.1 (EpiData Association, Odense, Denmark), checked for accuracy, edited as required, and then transferred to SPSS for Windows Version 27.0 (SPSS Inc., Chicago, USA) for analysis. A chi-squared test for independence was undertaken to test the associations between PTB and selected individual socio-demographic, dietary, and maternal care-related variables. The effect of

each possible predictor variable on PTB was estimated using univariate analysis (crude analysis).

We used regression diagnostic procedures to check evidence of multicollinearity or overly influential outliers in the models. However, we did not detect any multicollinearity or overly influential outliers in the models. All variables considered to be important ($p < 0.10$) were incorporated into the multi-level logistic regression analysis by backward elimination methods. Variables entered in level-I were: socio-economic variables (caste/ethnicity, family income); level-II were: socio-economic variables and food consumption behavior (caste/ethnicity, family income, consumption of additional meal, consumption of green leafy vegetables, consumption of milk and milk products); level-III were: socio-economic variables, food consumption behavior and ante-natal factors (caste/ethnicity, family income, consumption of additional meal, consumption of green leafy vegetables, consumption of milk and milk products, antenatal care, number iron tablets consumed, rest during pregnancy, birth order, and birth spacing), and level-IV were: socio-economic variables, food consumption behavior and antenatal factors and birth outcomes (caste/ethnicity, family income, consumption of additional meal, consumption of green leafy vegetables, consumption of milk and milk products, antenatal care, number iron tablets consumed, rest during pregnancy, birth order, and birth spacing, sex of child, and birth weight). Results that were significant in the final model were reported as adjusted odds ratios (AORs) with 95% confidence intervals (CI). All tests were two-tailed and p -values of < 0.05 were considered statistically significant.

Ethics

The study protocol was approved by the Research Ethics Committee of Janaki Medical College, Janakpur, Nepal (approval number: 11-077-078). Detailed information about the study was given to subjects before their enrollment in the study and a written informed consent was obtained thereafter. Participants' privacy, confidentiality, and anonymity were maintained in the study and personal identifiers were removed before starting data analysis.

Results

Personal characteristics and dietary behavior of study subjects

Tables 1, 2 show the socio-demographic characteristics of the study subjects and their dietary behavior during pregnancy. Of a total of 305 study participants, 13.77% (42/305) had preterm childbirth. The univariate analysis showed a significantly higher proportion of women who were from the Dalit caste/ethnicity

TABLE 1 Socio-demographic characteristics of study subjects.

Characteristics	Total N (%)	Preterm N (%)	Full-term N (%)	P-value
Age group (in years)				
<20 years	26 (8.5)	5 (19.2)	21 (80.8)	0.508
20-30 years	245 (80.3)	34 (13.9)	211 (86.1)	
>30 years	34 (11.1)	3 (8.8)	31 (91.2)	
Caste/ethnicity				
Dalit	65 (21.3)	17 (26.2)	48 (73.8)	0.003
Aadibasi/Janajati	112 (36.7)	9 (8.0)	103 (92.0)	
Upper caste	128 (42.0)	16 (12.5)	112 (87.5)	
Religion				
Hindu	298 (97.7)	41 (13.8)	257 (86.2)	0.968
Others	7 (2.3)	1 (14.3)	6 (85.7)	
Education of subjects				
Primary	86 (28.2)	15 (17.4)	71 (82.6)	0.401
Secondary	149 (48.8)	20 (13.4)	129 (86.6)	
Higher secondary	70 (23.0)	7 (10.0)	63 (90.0)	
Education of husband				
Primary	74 (24.3)	14 (18.9)	60 (81.1)	0.277
Secondary	137 (44.9)	15 (10.9)	122 (89.1)	
Higher secondary	94 (30.8)	13 (13.8)	81 (86.2)	
Occupation of subjects				
Housework	250 (82.0)	32 (12.8)	218 (87.2)	0.301
Service/business	49 (16.0)	8 (16.3)	41 (83.7)	
Agriculture/ labor	6 (2.0)	2 (33.3)	4 (66.7)	
Occupation of husband				
Abroad	62 (20.3)	6 (9.7)	56 (90.3)	0.497
Service/business	85 (27.9)	141 (6.5)	71 (83.5)	
Agriculture/ labor	158 (51.8)	22 (13.9)	136 (86.1)	
Type of family				
Joint/extended	108 (35.4)	29 (14.7)	168 (85.3)	0.515
Nuclear	197 (64.6)	13 (12.0)	95 (88.0)	
Family income				
1st tercile	120 (39.3)	24 (20.0)	96 (80.0)	0.039
2nd tercile	102 (33.4)	10 (9.8)	92 (90.2)	
3rd tercile	83 (27.3)	8 (9.6)	75 (90.4)	

(26.2%), followed by the upper caste group (12.5%) who gave birth to more preterm babies than the Aadibasi/Janajati caste/ethnicity (8.0%) ($p = 0.003$). Similarly, those subjects who were in the first tercile of the family income group (20.0%) were found to have a significantly higher proportion of preterm birth than the second and third tercile family income groups (9.8 and 9.6%, respectively, $p = 0.039$) (Table 1). Out of eight variables related to dietary behavior during pregnancy examined, only two variables were found to be statistically significant to have a higher proportion of PTB. Pregnant women who did not consume the additional meals during pregnancy had more PTB (32.5%) compared with those who consumed additional meals (10.9%), while those who did not consume

green leafy vegetables gave birth to more preterm babies (32.3%) than those who consumed them (8.8%) ($p = <0.0001$) (Table 2).

Maternal care and newborn characteristics

Table 3 presents the results of univariate analysis on the effect of antenatal, natal, postnatal, newborn characteristics and obstetric history of pregnant women associated with PTB. Those who received <4 ANC visits (41.7%), did not consume

TABLE 2 Dietary behavior during pregnancy among study subjects.

	Total N (%)	Preterm N (%)	Full-term N (%)	P-value
Nature of diet				
Vegetarian	79 (25.9)	15 (19.0)	64 (81.0)	0.118
Non-vegetarian	226 (74.1)	27 (11.9)	199 (88.1)	
Consumption of additional meal				
No	40 (13.1)	13 (32.5)	27 (67.5)	<0.0001
Yes	265 (86.9)	29 (10.9)	236 (89.1)	
Consumption of green leafy vegetables				
No	65 (21.3)	21 (32.3)	44 (67.7)	<0.0001
Yes	240 (78.7)	21 (8.8)	219 (91.3)	
Consumption of fruits and juice				
No	183 (60.0)	28 (15.3)	155 (84.7)	0.342
Yes	122 (40.0)	14 (11.5)	108 (88.5)	
Consumption of milk and milk products				
No	204 (66.9)	33 (16.2)	171 (83.8)	0.083
Yes	101 (33.1)	9 (8.9)	92 (91.1)	
Consumption of meat and meat products*				
No	152 (49.8)	21 (13.8)	131 (86.2)	0.214
Yes	74 (24.2)	6 (8.1)	68 (91.9)	
Consumption of tobacco				
Yes	7 (2.3)	1 (14.3)	6 (85.7)	0.968
No	298 (97.7)	41 (13.8)	257 (86.2)	
Consumption of alcohol				
Yes	17 (5.6)	3 (17.6)	14 (82.4)	0.633
No	288 (94.4)	39 (13.5)	249 (86.5)	

*n = 226.

recommended iron (<180 iron tablets) during pregnancy (22.4%), did not have adequate rest and sleep had a significantly higher rate of preterm birth (50.0%) ($p = <0.0001$) than their counterparts. In addition, our study also found that birth order first-second (16.8%) compared to third or more (8.7%) ($p = 0.045$) and birth spacing ≤ 2 years (24.3%) compared to more than 2 years (11.8%) ($p = 0.025$) had significantly higher rates of PTB. Likewise, mothers who gave birth to LBW babies (28.6%) were found to have significantly higher rates of PTB than normal (11.6%) ($p = 0.006$).

Maternal characteristics, dietary behavior, antenatal care, and obstetric history associated with PTB

Table 4 shows the results of multi-level logistic regression analysis for PTB among study subjects. Maternal characteristics such as caste/ethnicity, family income, birth order, and birth spacing, dietary behavior such as consumption of additional meals, consumption of milk or milk products

during pregnancy, components of antenatal care practices-ANC visits, consumption of a recommended amount of IFA (≥ 180 tablets), and rest and sleep were significantly associated with preterm birth in the final adjusted model.

Mothers from Dalit caste/ethnicity (AOR = 12.16, 95% CI = 2.28–64.61) and Aadibasi/Janajati caste/ethnicity (AOR = 3.83, 95% CI = 1.01–14.65) compared to upper caste group, family income in the first tercile (AOR = 6.82, 95% CI = 1.65–28.080) than those in third tercile were more likely to give preterm birth. Likewise, birth order first-second (AOR = 9.56, 95% CI = 1.74–52.53) than third or more, and birth spacing ≤ 2 years (AOR = 5.16, 95% CI = 1.62–16.42) were at greater risk of PTB. Mothers who did not consumed additional meal (AOR = 9.53, 95% CI = 2.13–42.55), milk and milk products (AOR = 6.44, 95% CI = 1.56–26.51) during pregnancy, having <4 times ANC visits (AOR = 4.29, 95% CI = 1.25–14.67), not having the recommended amount of IFA intake (<180 tablets) (AOR = 3.46, 95% CI = 1.03–11.58), and not having adequate rest and sleep (AOR = 4.83, 95% CI = 1.01–23.30) during pregnancy had higher odds of having PTB than their counterparts.

TABLE 3 Antenatal, natal and postnatal care characteristics, maternal obstetric history, and newborn characteristics associated with PTB.

Characteristics	Total N (%)	Preterm N (%)	Full-term N (%)	P-value
Antenatal care				
<4 times	36 (11.8)	15 (41.7)	21 (58.3)	<0.0001
≥4 times	269 (88.2)	27 (10.0)	242 (90.0)	
Place for ANC				
Primary health care center	57 (18.7)	11 (19.3)	46 (80.7)	0.395
Government hospital	123 (40.3)	16 (13.0)	107 (87.0)	
Private hospital	125 (41.0)	15 (12.0)	110 (88.0)	
TD vaccinated				
No	2 (0.7)	1 (50.0)	1 (50.0)	0.136
Yes	303 (99.3)	41 (13.5)	262 (86.5)	
Number of iron tablets consumed				
<180 tablets	143 (46.9)	32 (22.4)	111 (77.6)	<0.0001
≥180 tablets	162 (53.1)	10 (6.2)	152 (93.8)	
Adequate rest and sleep during pregnancy				
No	18 (5.9)	9 (50.0)	9 (50.0)	<0.0001
Yes	287 (94.1)	33 (11.5)	254 (88.5)	
Birth order				
First-second	190 (62.3)	32 (16.8)	158 (83.2)	0.045
Third-more	115 (37.7)	10 (8.7)	105 (91.3)	
Birth spacing (<i>n</i> = 189)				
≤2 years	70 (23.0)	17 (24.3)	53 (75.7)	0.025
More than 2 years	119 (39.0)	14 (11.8)	105 (88.2)	
Place of childbirth				
Home	11 (3.6)	2 (18.2)	9 (81.8)	0.665
Health facility	294 (96.4)	40 (13.6)	254 (86.4)	
Mode of childbirth (<i>n</i> = 258)				
Normal	156 (51.1)	20 (12.8)	136 (87.2)	0.870
Cesarean section (C/S)	8 (2.6)	1 (12.5)	7 (87.5)	
Vacuum delivery	141 (46.2)	21 (14.9)	120 (85.1)	
Sex of child				
Male	164 (53.8)	28 (17.1)	136 (82.9)	0.071
Female	141 (46.2)	14 (9.9)	127 (90.1)	
Birth weight (<i>n</i> = 294)				
Low weight (<2,500 grams)	35 (11.9)	10 (28.6)	25 (71.4)	0.006
Normal weight (≥2,500 grams)	259 (88.1)	30 (11.6)	229 (88.4)	

Discussion

In this community-based cross-sectional study, of total of 305 mother-live-born baby pairs of <6 months, we found that 13.77% (42/305) had preterm childbirth. Some sociodemographic factors such as mothers from Dalit and Aadibasi/Janajati caste/ethnicity, family income in the first tercile, and maternal factors such as first-second birth spacing ≤2 years, having <4 antenatal (ANC) visits, not having the recommended amount of IFA intake (<180 tablets), not having

adequate rest and sleep during pregnancy, had higher odds of having PTB. In addition, we found some maternal dietary behavior-related factors such as mothers who did not consume additional meals, milk and milk products during pregnancy, were positively associated with PTB.

PTB is disproportionately concentrated in low-income countries in Asia and Africa. It has been estimated that about 11 million (85%) PTB occurred in Asia and Africa compared to around 0.5 million PTB in Europe and North America together (excluding Mexico) in the year 2005 (35). There are

TABLE 4 Factors associated with pre-term delivery by multilevel logistic regression analysis.

Characteristics	COR (95%CI)	AOR (95%CI)			
		Model-I	Model-II	Model-III	Model-IV
Caste/ethnicity					
Dalit	2.47 (1.15–5.31)	4.05 (1.68–9.74)	–	14.52 (2.78–75.76)	12.16 (2.28–64.61)
Aadibasi/janajati	0.61 (0.25–1.44)	2.47 (1.15–5.31)	–	3.94 (1.02–15.15)	3.83 (1.01–14.65)
Upper caste group	Reference	Reference	–	Reference	Reference
Family income					
1 st tercile	2.34 (1.00–5.91)	–	–	6.95 (1.67–28.93)	6.82 (1.65–28.08)
2 nd tercile	1.01 (0.38–2.71)	–	–	2.29 (0.52–10.07)	2.25 (0.51–9.88)
3 rd tercile	Reference	–	–	Reference	Reference
Consumption of additional meal					
No	3.91 (1.82–8.42)	–	–	9.07 (2.10–39.18)	9.53 (2.13–42.55)
Yes	Reference	–	–	Reference	Reference
Consumption of green leafy vegetables					
No	4.97 (2.50–9.88)	–	5.80 (2.84–11.84)	–	–
Yes	Reference	–	Reference	–	–
Consumption of milk and milk products					
No	1.97 (0.90–4.30)	–	2.63 (1.15–6.04)	6.38 (1.56–26.07)	6.44 (1.56–26.51)
Yes	Reference	–	Reference	Reference	Reference
Antenatal care					
Less than 4 times	6.40 (2.95–13.86)	–	–	4.83 (1.43–16.23)	4.29 (1.25–14.67)
More than 4 times	Reference	–	–	Reference	Reference
Number iron tablets consumed					
<180 tablets	4.38 (2.06–9.28)	–	–	3.35 (1.00–11.28)	3.46 (1.03–11.58)
≥ 180 tablets	Reference	–	–	Reference	Reference
Rest during Pregnancy					
No	7.69 (2.85–20.76)	–	–	5.08 (1.05–24.40)	4.83 (1.01–23.30)
Yes	Reference	–	–	Reference	Reference
Birth order					
First-second	2.12 (1.01– 4.51)	–	–	9.29 (1.69–50.91)	9.56 (1.74–52.53)
Third-more	Reference	–	–	Reference	Reference
Birth spacing					
≤2	2.40 (1.10–5.25)	–	–	5.41 (1.71–17.11)	5.16 (1.62–16.42)
More than two	Reference	–	–	Reference	Reference
Sex of child					
Male	1.86 (0.94–3.70)	–	–	–	–
Female	Reference	–	–	–	–
Birth weight					
Low weight	3.05 (1.33–6.97)	–	–	–	–
Normal weight	Reference	–	–	–	–

AOR, adjusted odds ratio; COR, crude odds ratio; CI, confidence interval; All variables considered to be important ($p < 0.10$) in univariate analysis were entered into the multi-level logistic regression analysis.

different factors that are associated with PTB in published literature, such as the sociodemographic, geographic, pre-existing, and existing medical and obstetrical conditions and other attributes of the subjects (17, 20, 24). The proportion of PTB in our study (13.77%), however, is comparable to

previous studies from low-and-middle income countries being conducted in Tanzania (17), and Kenya (18), while it is lower than that of the reports from Bangladesh (22.3%) (21). Studies being conducted in different geographical settings of Nepal reported PTB ranged from 9.8 to 21.2% between 2014 and

2020 (25, 26, 36) suggesting a continued burden of PBT in Nepal.

In this study, we observed some sociodemographic factors such as mothers who were from Dalit, and Aadibasi/Janajati caste/ethnicity and family income in the first tercile were more likely to have PTB. The caste-based system and lower family economy of Nepal have an inverse relation to health and well-being including maternal health (37). Published literature has demonstrated several maternal health issues such as a higher proportion of teenage pregnancy (38), and lower utilization of available maternal health care services (39) in disadvantaged caste/ethnic groups (Dalit and Aadibasi/Janajati). Specific health measures in Nepal should, therefore, be targeted to those vulnerable caste/ethnic groups, and those who are in lower economic strata to improve the burden of PTB.

Similar to the previous reports from other low-and-middle-income countries (21, 23, 40), we also found maternal factors such as birth order first-second, birth spacing ≤ 2 years, having < 4 antenatal (ANC) visits, not having the recommended amount of IFA intake (< 180 tablets), not having adequate rest and sleep during pregnancy had higher odds of having PTB. Since very few studies from Nepal reported such predictors of PTB, we recommend further studies to confirm such findings.

Interestingly, we found some maternal dietary behavior-related factors such as mothers who did not consume additional meals, milk and milk products during pregnancy were positively associated with PTB. Pregnant women are encouraged to take adequate dietary constituents during pregnancy to meet the increased physiological requirements for themselves and their babies. Nonetheless, the exact mechanism of whether adequate dietary intake with the optimum mix of essential dietary constituents consumed by pregnant women will reduce the likelihood of PTB, and the impact of dietary intervention during pregnancy seems inconclusive whether reduces PTB. While there is some convincing evidence of the beneficial impacts of dietary (reduced probability of cesarean sections, and gestational diabetes), and physical activity intervention during pregnancy, there are variable reports of such interventions (41–43). As such, a meta-analysis conducted by Rogozińska et al. (41) demonstrated no significant effect of the diet and lifestyle intervention on PTB whereas a prospective cohort study from Denmark showed maternal intake of a Mediterranean-type diet (MD) reduced PTB (43). Additional studies might therefore be necessary to validate such results.

Given that there is limited research in Nepal that examines the predictors of PTB, this study is important to narrow down the literature gap and provide new insights that might be useful to formulate and implement evidence-based health strategies in the current study setting and other similar settings. There are some important strengths of the study to mention: First, this study has a high response rate (94%). Second, it used study instruments adapted from the NDHS 2016. However, this

study had some specific limitations that had to be considered while interpreting the results. First, this study did not examine many other known risk factors (maternal obstetrical and medical conditions) and some other dietary factors as the data were unavailable. Second, this study was cross-sectional, which limits the possibility to establish a causal association between exposure and outcome. Third, the study setting and sample size were relatively small, which reduced the external validity. Furthermore, we used the Cochran formula (31) to calculate the sample size although the primary aim was to determine the risk factors of PTB and not PTB prevalence. Finally, self-reported results might have been influenced by recall bias although we collected the specific information from maternity service registers. However, local area studies have their own importance in terms of local area-specific customized health strategy formulation to reduce the burden of health problems. We recommend additional follow-up studies be conducted to validate the study outcomes.

Conclusion

This study found that some socio-demographic (Dalit and Aadibasi/Janajati caste/ethnicity, family income in the first tercile), maternal (birth order third, birth spacing, < 4 antenatal ANC visits, intake of the recommended amount of IFA, not having adequate rest and sleep during pregnancy) and dietary behavior related factors (mothers who did not consume additional meals, and milk and milk products during pregnancy) were independently associated with PTB. In the current setting of Southeastern Nepal, health promotion strategies should target disadvantaged groups (Dalit and Aadibasi/Janajati caste/ethnicity and those economically deprived). In addition, it is recommended to have some specific measures such as promoting antenatal mothers to use the available antenatal care services and counsel to have an adequate diet to a level that meets their daily requirements. Additional studies are needed to explore the obstetrical, medical, and additional dietary factors associated with PTB in Nepal.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by Research Ethics Committee of Janaki Medical College, Janakpur, Nepal (Approval Number: 11-077-078). The patients/participants provided their written informed consent to participate in this study.

Author contributions

DA, SG, and JS: conceptualized the study, performed investigation, data collection, formal analysis, and writing—original draft preparation. TGP, AL, AG, and KL: formal analysis, review and editing, and writing—review and editing. All authors contributed to the article and approved the submitted version.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships

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Determinants of neonatal near-miss among neonates delivered in public hospitals of Ilu Abba Bor Zone, Southwest Ethiopia: An unmatched case-control study during the COVID-19 pandemic

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Background: The neonatal period is the time with the highest risk of neonatal and infant mortality. The COVID-19 pandemic diverted resources from routine maternal health services, which raises the possibility of neonatal near misses (NNMs). To implement prompt treatments that could improve the standard of infant care and lower neonatal mortality, it has been theorized that pinpointing the determinants of NNM during this outbreak is crucial. In light of this, the current study identified the determinants of NNM in neonates delivered in public hospitals of Ilu Abba Bor Zone, South West Ethiopia.

Methods: An institution-based unmatched case-control study was conducted among randomly selected 303 (101 cases and 202 controls) neonates admitted to Mettu Karl Comprehensive Specialized Hospital (MKCSH) and Darimu Primary Hospital (DPH) from 1 November to 28 December 2020. Data were collected using interviewer-administered structured questionnaire and checklist. The collected data were coded and entered into Epi-Data version 4.6 and then exported to SPSS version 20 for analysis. Adjusted odds ratios (AOR) along with a 95% confidence interval was used to assess the strength of the association, and a p -value < 0.05 was considered to declare the statistical significance in the multivariable logistic regression analysis.

Result: A total of 303 (101 cases and 202 controls) neonates admitted to MKCSH and DPH were included in the study making a 97.4% response rate. In the multivariable logistic regression analysis, no formal maternal education [AOR = 3.534, 95% CI: (1.194–10.455)], Breech presentation during birth [AOR = 3.088, 95% CI: (1.029–9.268)], < 4 antenatal care (ANC) visits [AOR = 1.920, 95% CI: (1.065–3.461)], cesarean section delivery [AOR = 4.347, 95% CI: (1.718–10.996)], antepartum hemorrhage (APH) [AOR = 3.37, 95% CI: (1.23–9.24)], and hypertensive disorders of pregnancy (HDP) [AOR = 4.05, 95% CI: (2.36–11.05)] were independent determinants of NNM.

Conclusion: The study's result revealed that factors such as education level, birth presentation, ANC visit, mode of delivery, APH, and HDP continued to be important determinants of the NNM in Ethiopia during this pandemic. Therefore, much work is needed to improve neonatal health by providing adequate ANC services and other identified potential determinant factors that predispose the newborn to life-threatening (near-miss) conditions especially during this pandemic.

KEYWORDS

neonatal near miss, determinants, COVID-19, Ilu Abba Bor Zone, Ethiopia

Introduction

The first 28 days of the neonate's lifespan is the principal challenging period for the continuity of life for children (1), and it is the most susceptible period that constitutes 50% of neonatal and 75% of infant deaths (2). Although the global mortality rate decreased by 49% from 37 deaths in 1990 to 19 deaths in 2016 per 1,000 live births, a million newborns continued to die in the early neonatal period (3). In Sub-Saharan Africa (SSA), neonatal morbidity and mortality continue to be a large component of the burden of NNM and its rates reflect the efficiency and effectiveness of health care services (4).

Ethiopia was found to be the third highest contributor to neonatal mortality with 187,000 in 2015 (5) and the neonatal mortality rate was 29 per 1,000 live births according to the 2016 Ethiopian Demographic Health Survey (6). Despite a 41% reduction in neonatal mortality in Ethiopia from 49 per 1,000 live births in 2000 to 30 per 1,000 live births in 2019 (7, 8), nearly one out of every ten babies born does not survive to celebrate his/her first birthday (8, 9).

A neonatal near miss (NNM) case refers to an infant who nearly died but survived during birth or within 28 days of extra-uterine life and is being used as a tool to evaluate and improve the quality of care, especially obstetric care (10). In the quest for equitable access and management of quality perinatal care, NNM can be used as a part of the audit system and policymaking together with medical issues (11). Assessing NNM cases provides an all-inclusive predictive factor in neonates delivered from mothers with various obstetric complications (12).

The near-miss approach was used in neonatal health as a revolutionary tool to improve the quality of perinatal care (13), and it provided valuable information to sightsee the quality-of-care issues and set priorities for in-depth healthcare improvements in newborn health (14, 15). Due to its contribution to advancements in the quality of care, healthcare teams are more interested in dealing with morbidity than mortality case reviews (16).

Different studies showed that the NNM rate was 2.6- to 8-fold higher than the neonatal mortality rate (13, 14, 17). The

incidence of NNM cases ranged from 21.4 to 85.5 per 1,000 live births (12–14, 17–19). According to the study done in Northwest Ethiopia, the rate of NNM was reported to be 233 per 1,000 live births (20). Although it was planned to end preventable deaths of newborns by 2030 in the Sustainable Development Goal (21), the neonatal morbidity rate still remains high in developing countries (10). To halt this problem, the Ethiopian government has formulated and implemented many policies, including the integrated management of newborn and childhood illness strategy (22), kangaroo mother care (23), and a health sector development plan (24) for the society. Despite these policy and intervention initiatives, currently, Ethiopia has the third highest reported number of newborn deaths in Africa and ranks fifth having the highest number of deaths globally (25).

Due to mild symptoms or remaining asymptomatic and limited testing in developing countries, pregnant women experience an increased risk of maternal morbidity, which increases the likelihood of preterm delivery and admission of their babies to the neonatal unit during the COVID-19 pandemic (26). This maternal and neonatal morbidity is said to be higher among pregnant women in low-income countries (27). In Ethiopia, the outbreak of Coronavirus Disease 2019 (COVID-19) sidetracked resources from routine health services to the control of a pandemic, which has high impact on access to maternal health services (28). All this evidence supports the necessity of assessing the determinants of NNM during the COVID-19 pandemic.

Different studies in SSA countries, including Ethiopia, reported the increment of NNM during the COVID-19 pandemic (29–33). This could be due to the interruption of essential maternal newborn and child health services which has impacted millions of lives across the world (34). Data from various studies indicate that access to routine antenatal, postnatal, and pediatric care is decreasing as a result of the COVID-19 pandemic (35). This indicates that identifying the determinants of NNM is very important and commendable during this pandemic. Thus, the present study aimed to identify determinants of NNM among neonates admitted to selected public hospitals of the public

TABLE 1 Sample size calculation to identify determinants of NNM among neonates in public hospitals of Ilu Abba Bor Zone, 2020.

Determinant factor selected	% Control exposed	Ratio of control to case	AOR	Power	CI	Sample size		Total
						Case	Control	
Distance from a health facility (36)	44.4%	2	2.11	80	95	94	188	282
Pregnancy type (36)	43.3%	2	2.3	80	95	71	141	212
Birth weight (17)	5.44%	2	4.9	80	95	54	107	161

hospitals of Ilu Abba Bor Zone, South West Ethiopia, in 2020.

Methods and materials

Study area and study period

The study was conducted in public hospitals of Ilu Abba Bor Zone, which is found in Oromia regional state, South West Ethiopia. The zone is located 554 km far away from Addis Ababa, the capital city of Ethiopia. The MKCSH and DPH are the two public hospitals located in the Ilu Abba Bor area. These hospitals have major clinical departments such as internal medicine, surgery, pediatrics, and gynecology/obstetrics. On average, 56 and 32 neonates were admitted to the neonatal ward of MKCSH and DPH monthly, respectively.

Study design and period

An institution-based unmatched case-control study was conducted at the MKCSH and DPH from 1 November to 28 December 2020.

Source population

Cases: The source population for the cases were all neonates admitted to the neonatal ward with neonatal near miss cases within 28 days of birth in MKCSH and DPH.

Control: The source population for the control were all neonates admitted to the postnatal ward who are free from neonatal near miss cases within 28 days of birth in MKCSH and DPH.

Study population

Cases: Admitted neonates who fulfilled any of the NNM criteria as indicated from their medical records after being identified by a physician within 28 days of birth during the study period in both hospitals.

Control: Neonates who are free from any of the NNM criteria as indicated from their medical records after being identified by a physician within 28 days of birth during the study period in both hospitals.

Inclusion and exclusion criteria

Inclusion criteria

Selecting cases: All neonates diagnosed with NNM and those who were delivered and admitted to the neonatal ward of both hospitals during the study period were included in the study.

Selection of controls: All neonates with no complication indicated for the selection of cases (free from NNM cases) that were admitted to postnatal care by a pediatrician or a neonatologist or a gynecologist or a resident were enrolled as a control.

Exclusion criteria for cases and controls

A neonate with unknown birth history or incomplete medical information was excluded from the study.

Sample size and sampling procedure

The sample size was estimated using Epi Info-7 software by assuming the confidence level of 95%, power of 80%, and the case-control ratio of 1:2 and by taking the expected percent of exposure in control and odds ratio from previous studies in Ethiopia and presented in Table 1.

The final sample size is the maximum of the three, which is 282 (94 cases and 188 control) from the above tables. We added 10% of the non-response rate to both cases and controls and the final sample size was 311 (104 cases and 207 control). The sample was distributed proportionally to the two public hospitals in the zone depending on the number of cases they each handled on a daily basis. Because MKCSH has a monthly case of 56 and DPH has a monthly case of 32, the sample was appropriately distributed using the average total load case. Consequently, the sample size allotted for each hospital was as follows: for MKCSH = 198 (66 cases and 132 controls) and for DPH = 113 (38

cases and 75 controls). Then, the subjects were selected using simple random sampling techniques using registration number as a sampling frame.

Study variables

Neonatal near miss was the primary outcome of this study and was defined using pragmatic and/or management criteria of the Center Latino-Americano de Perinatology (CLAP) (37). Using pragmatic criteria, a neonate with <1,750 g birth weight, a gestational age (GA) of < 33 weeks, and < 7 Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) score at 5 min was used to define NNM. From management criteria, any intubation, parenteral therapeutic antibiotics in the early neonatal period and before 28 days of life; cardiopulmonary resuscitation; phototherapy within the first 24 h of life; the use of anticonvulsants, vasoactive drugs, blood products, surfactants and steroids for hypoglycemia, any surgical procedure, parenteral nutrition, and congenital malformation were used to identify a near miss. A neonate who exhibited at least one of the near miss pragmatic or management criteria but survived this condition within the first 28 days of life was considered a near miss (38). All mothers were followed by a phone call about their child until 28 days after the birth to avoid misclassification of cases and control. Those who died within 28 days of their birth after being classified as a case or control were excluded from the study. As independent variables, we included sociodemographic characteristics, obstetrics-related factors, and maternal- and neonatal-related factors.

Data collection tool and quality assurance

A pre-tested structured questionnaire, initially prepared in English and translated into Afaan Oromoo, was used to collect the data. The tool contains four parts: sociodemographic-, maternal-, obstetric-, and neonatal-related factors. An interviewer-administered structured questionnaire adapted from relevant literature was used to collect maternal data (10, 13, 16, 36, 38–40). Data on neonate-related factors were collected from medical charts using a standardized checklist and NNM events were collected from neonates' medical records according to the CLAP criteria (37). Two BSc midwives from each hospital and two MPH holders from Mettu Health Science College were recruited for data collection and supervisory duties, respectively. Data collectors were trained for 2 days on the data collection tools and procedures. The data were collected from the postnatal and neonatal wards of both hospitals. Other than this, supervisors were following the data collection process every day during the period of data collection.

Data processing and analysis

The collected data were coded and checked for their completeness and consistency before data entry. The data were then entered into Epi-Data version 4.6 before being exported to SPSS version 20 for further cleaning and analysis. Data were summarized using the mean with standard deviation for normally distributed continuous variables and the median with interquartile range for non-normally distributed continuous variables, as well as a frequency table with percent for categorical variables. The characteristics of the cases and controls were compared using Pearson's Chi-square test to establish any association between independent variables and the outcome variable. A variable with a p -value < 0.2 in a bivariable analysis was a candidate variable for multivariable logistic regression analysis. A sensitivity analysis was conducted to handle the missing data. To evaluate the multicollinearity, a pseudo variance inflation factor (VIF) was used. Then, a multivariable logistic regression analysis was used to identify the presence of the association between dependent and independent variables. The goodness of fitness of the model was checked by the Lemshow–Hosmer test. Statistical significance was determined using 95% confidence intervals of adjusted odds ratios and a p -value of < 0.05.

Results

Sociodemographic characteristics of mother

A final analysis was done using 303 participants, making a response rate of 97.4%. The mean age (SD) for the cases and the controls was 25.56 (6.386) and 25.94 (5.119), respectively. Less than one-third (23.8%) of cases and 32.2% of controls were found within the age group of 25–29 years. More than two-thirds (71.3%) of mothers in the cases lived in rural areas. In total, the mothers of 39 (38.6%) of cases and 50 (24.8%) of the controls came from at least 5 km away from health facilities. Moreover, the mothers of 91 (90.1%) of cases and 178 (88.1%) of controls were married. In total, the mothers of 43 (43.6%) of the cases and 49 (24.3%) of the controls were housewives (Table 2).

Obstetric characteristics of the mothers

In the near-miss group, nearly half (46.5%) of the neonates' mothers were primipara, whereas in the control group more than half (52.0%) of the mothers/caretakers were multipara. More than three-fourths (78.2%) of the fetal presentation during delivery for cases and 184 (91.1%) for the control group were cephalic at birth. Of the neonates' mothers, more than half (59.4%) of the cases and 177 (87.6%) of the control group had

TABLE 2 Socio-demographic characteristics of mothers of neonates admitted ($n = 303$) to public hospitals of Ilu Abba Bor Zone, 2020.

Variable	Category	NNM status		
		Case (%)	Control (%)	<i>P</i> -value
Age in years	15–19	19 (18.8)	24 (11.9)	0.003
	20–24	25 (24.8)	61 (30.2)	
	25–29	24 (23.8)	65 (32.2)	
	30–34	16 (15.8)	42 (20.8)	
	35+	17 (16.8)	10 (5.0)	
Residence	Urban	29 (28.7)	81 (40.1)	0.052
	Rural	72 (71.3)	121 (59.9)	
Distance from health facility	<1 h/5 km	62 (61.4)	152 (75.2)	0.013
	≥1 h/≥5 km	39 (38.6)	50 (24.8)	
Marital status	Never married	4 (4.0)	12 (5.9)	0.002
	Married	91 (90.1)	178 (88.1)	
	Divorced/widowed	6 (5.9)	12 (5.9)	
Educational level	No formal education	20 (19.8)	12 (5.9)	0.002
	Primary	42 (41.6)	84 (41.6)	
	Secondary	30 (29.7)	86 (42.6)	
	More than secondary	9 (8.9)	20 (9.9)	
Occupation	Government	8 (7.9)	26 (12.9)	0.015
	Farmer	25 (25.8)	72 (35.6)	
	Housewife	44 (43.6)	49 (24.3)	
	Merchant	20 (19.8)	42 (20.8)	
	Others*	4 (4.0)	13 (6.4)	

Other*, student, daily laborer.

mothers with gestational age at birth between 37–41 weeks. In total, mothers of 65 (65.3%) of the neonate cases and 141 (69.8%) of controls had wanted and planned pregnancy. Mothers of nearly two-thirds (65.9%) of the neonates of the cases had less than four antenatal care (ANC) visits, but those of 96 (51.6%) of the controls had > 4 ANC visits during their pregnancy. More than half of the neonates (54, 53%) in cases and (136, 67%) in controls were born *via* spontaneous vaginal delivery (Table 3). In total, 88 (87.1%) of the cases of NNM was due to maternal complications during labor-delivery. Obstruction of labor affected 60.3% of the neonates in cases and 66% of the controls (Table 4).

Neonatal-related factors

More than half (61.4%) of the neonates in cases and 164 (81.2%) of the control group had a normal weight at birth. Two-thirds (67.4%) of the cases had less than an APGAR score at the 5th min of birth (Table 5). An APGAR score of < 7 at the 5th min (22.44%) from pragmatic criteria and the use of intravenous antibiotics up to 7 days and before 28 days of life (26.73%) from management criteria were the most common causes of

TABLE 3 Obstetrics characteristics of mothers among neonates admitted ($n = 303$) to public hospitals of Ilu Abba Bor Zone, 2020.

Variables	Category	Near miss status		
		Case (%)	Control (%)	<i>P</i> -value
Parity	Primipara	47 (46.5)	85 (42.1)	0.012
	Multiparous	39 (38.6)	105 (52.0)	
	Grand multiparous	15 (14.9)	12 (5.9)	
GA at birth	≤36 weeks	35 (34.7)	23 (11.4)	0.000
	37–41 weeks	60 (59.4)	177 (87.6)	
	≥42 weeks	6 (5.9)	2 (1.0)	
Fetal presentations during birth	Cephalic	79 (78.2)	184 (91.1)	0.007
	Breech	14 (13.9)	10 (5.0)	
	Transverse/brow/face	8 (7.9)	8 (4.0)	
Current pregnancy type	Wanted planned	66 (65.3)	141 (69.8)	0.418
	Wanted unplanned	18 (17.8)	38 (18.8)	
	Unwanted unplanned	17 (16.8)	23 (11.4)	
ANC during this pregnancy	Yes	88 (87.1)	186 (92.1)	0.167
	No	13 (12.9)	16 (7.9)	
Number of ANC visit	< 4 visits	58 (65.9)	90 (48.4)	0.007
	≥4 visits	30 (34.1)	96 (51.6)	
Delivery mode	SVD	54 (53.5)	136 (67.3)	0.001
	C/S	20 (19.8)	13 (6.4)	
	Instrumental	27 (26.7)	53 (26.2)	

Others, oligohydramnios and polyhydramnios; ANC, antenatal care; C/S, cesarean Section; GA, gestational Age; SVD, spontaneous vaginal delivery.

NNM. Any surgical procedure, congenital malformation, use of corticosteroid for the treatment of refractory hypoglycemia, or use of anticonvulsants, surfactants, and vasoactive drugs were unidentified criteria (Table 6). Birth asphyxia was the most common (34.9%) birth complication of neonates, followed by neonatal sepsis (29.36%) (Figure 1).

Determinants of neonatal near miss

The relationship of individual independent variables with the dependent variable was separately analyzed using bivariable analysis. In bivariable analysis, variables such as residence of mother, educational level of the mother, distance from health institution, pregnancy type, parity, fetal presentation, APH, HDP, number of ANC visits, and mode of delivery were

significantly candidates for multivariable logistic regression at a p -value ≤ 0.2 . The variance inflation ranged from 1.42 to 3.20, indicating an absence of multicollinearity among independent variables.

The Hosmer–Lemeshow test was insignificant ($p = 0.576$), indicating the satisfaction of the goodness-of-fitness model. In multivariable logistic regression, maternal education, fetal presentation at birth, number of ANC visits, APH, HDP, and mode of delivery were independent significant determinants of NNM. Accordingly, neonates who were born to mothers with no formal education [AOR = 3.534, 95% CI: (1.194–10.455)] and <4 ANC visits [AOR = 1.920, 95% CI: (1.065–3.461)] had higher odds of experiencing NNM than their counterparts. Neonates with breech presentation [AOR = 3.088, 95% CI: (1.029–9.268)], APH [AOR = 3.37, 95% CI: (1.23–9.24)], and HDP [AOR = 4.05, 95% CI: (2.36–11.05)] had a higher risk of NNM. Neonates who were born *via* caesarian section delivery had higher odds of experiencing NNM than neonates born by spontaneous vaginal delivery [AOR = 4.347, 95% CI: (1.718–10.996)] (Table 7).

TABLE 4 Maternal complication during labor and delivery among mothers of neonates admitted ($n = 303$) to public hospitals of Ilu Abba Bor Zone, 2020.

Variables	Category	Near miss status		
		Case (%)	Control (%)	P-value
Maternal Complication during labor and delivery	Yes	88 (87.1)	165 (81.7)	0.167
	No	13 (12.9)	37 (18.3)	
Type of maternal complication during labor and delivery (among yes)				
Obstructed labor	Yes	44 (60.3)	66 (66.0)	0.440
	No	29 (39.7)	34 (34.0)	
HDP	Yes	12 (16.4)	8 (8.0)	0.086
	No	61 (83.6)	92 (92.0)	
Hemorrhage	Yes	16 (21.9)	8 (8.0)	0.009
	No	57 (78.1)	92 (92.0)	

HDP, Hypertensive disorders of pregnancy.

TABLE 5 Neonatal-related characteristics of NNM among neonates admitted ($n = 303$) to public hospitals of Ilu Abba Bor Zone, 2020.

Variables	Category	Near miss status		
		Case (%)	Control (%)	P -value
Birth weight of the baby	<2.5 kg	33 (32.7)	30 (14.9)	0.001
	2.5–4 kg	62 (61.4)	164 (81.2)	
	≥ 4 kg	6 (5.9)	8 (4.0)	
APGAR score at 5th min	<7	68 (67.3)	15 (7.4)	0.000
	≥ 7	33 (32.7)	187 (92.6)	

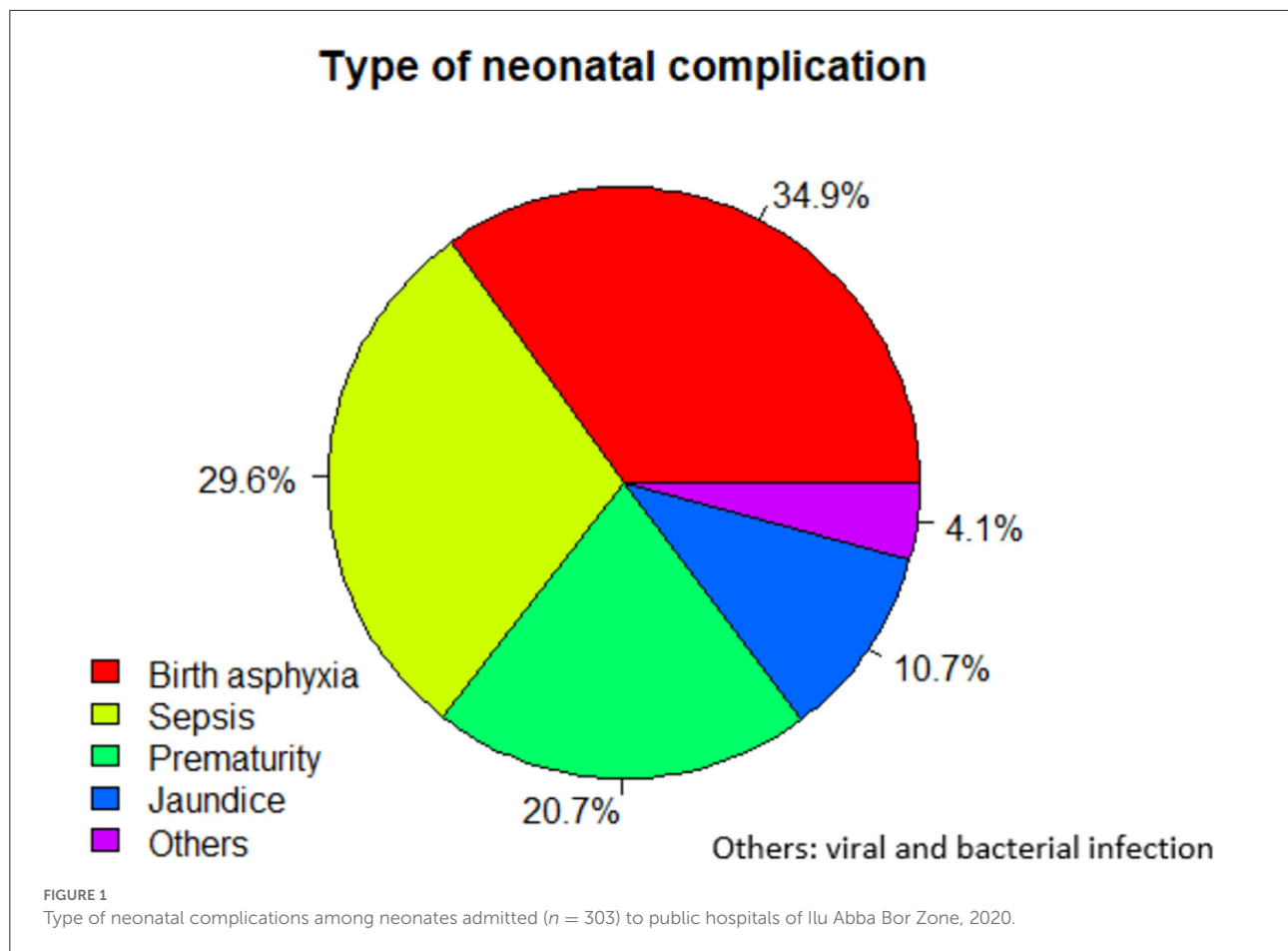
Discussion

Identifying the determinants of NNM in SSA countries such as Ethiopia is very important to decrease neonatal mortality during this pandemic period. Therefore, the current study disclosed the determinants of NNM cases in Ethiopia. Of the characteristics that were assessed, maternal education, number of ANC visits, fetal presentation, mode of delivery, APH, and HDP were found to be determinants of the NNM.

Cases whose mothers had no formal education had higher odds of experiencing NNM than controls. This is consistent with studies done in northeast Ethiopia (41), Ghana (42), and India (13), which showed the significant effect of having an education on NNM. The reason might be that mothers who had no formal education have low or delayed health-seeking behavior and fail to utilize appropriate medical/health care services compared with educated mothers, but these factors may vary from country to country.

TABLE 6 Distribution of NNM conditions among neonates delivered in public hospitals of Ilu Abba Bor Zone, 2020 ($n = 303$).

Neonatal near miss (NNM) criteria	Frequency	Percent (%)
Pragmatic criteria		
Gestational age < 33 weeks	4	1.32
Birth weight < 1,750 g	5	1.65
5th min APGAR score < 7	68	22.44
Management criteria		
Use of phototherapy in the first 24 h	16	5.28
Cardiopulmonary resuscitation	24	7.92
Any intubation	10	3.30
Transfusion of blood derivatives	1	0.33
Nasal continuous positive airway pressure (NCPAP)	68	22.44
Use of intravenous antibiotics up to 7 days and before 28 days of life	81	26.73



Fetal presentation during birth was another factor significantly associated with NNM cases. Neonates with the breech presentation were more likely to have NNM compared to those with the cephalic presentation. This finding is congruent to evidence from southern Ethiopia (16), Southwest Ethiopia (43), and Australia (44). Those studies found that neonates who had a non-vertex presentation were more likely to become near miss as compared to vertex presentation. This might be due to a high risk of birth asphyxia, trauma, and other complications caused by malpresentation during pregnancy (45). Malpresentation may lead to obstructed and prolonged labor, which can result in NNM through different complications to the newborn (45).

In the present study, NNM was higher among neonates whose mothers had < 4 ANC visits, which was supported by studies in Ambo University Referral Hospital and Ambo General Hospital (36). This finding indicates that health facilities need to continue encouraging mothers to receive more frequent ANC visits, which is also emphasized in the WHO recommendation on ANC (46). This finding is also supported by the findings in India (10) and Brazil (38, 47), which revealed higher odds of NNM events among pregnant mothers who had taken

less than the minimum required ANC visits during their pregnancy. This could be due to the pregnant woman avoiding preventable risk factors after receiving ANC, through early identification, treatment, and screening for issues that occurred during pregnancy (16). The other possible reason for this finding could be the impact of the COVID-19 pandemic on ANC follow-up. Due to fear of contracting the virus and over-stretched health systems with disrupted supply chains, ANC follow-up is being decreased and below the World Health Organization recommendations, especially in developing countries including Ethiopia (35). However, other studies in Brazil (41) and Morocco (42) revealed insignificant associations between NNM and ANC follow-up. The reason for this difference might be due to varieties in study population and difference in coverage of ANC in different countries.

The current study shows that neonates who were born by cesarean delivery had higher odds of experiencing NNM than neonates born by spontaneous vaginal delivery. Similar studies done in Ethiopia revealed that neonates who were born at the government hospital and health institutions by cesarean section had a higher risk of NNM (48). In line with this study, evidence from Brazil indicated that cesarean section delivery increases

TABLE 7 Determinants of NNM among neonates admitted ($n = 303$) to public hospitals of Ilu Abba Bor Zone, 2020.

Variables	Neonatal near miss		COR (95% CI)	AOR (95% CI)
	Case N ^o	Control N ^o		
Residence of mother				
Urban	29	81	1.00	1.00
Rural	72	121	1.66 (0.99–2.78)	1.04 (0.54–1.99)
Distance from health facility				
<1 h/5 km	62	152	1.00	1.00
≥1 h/≥5 km	39	50	1.91 (1.15–3.19)	1.07 (0.54–2.13)
Educational level of mother				
No formal education	20	12	3.70 (1.28–10.73)	3.53 (1.19–10.45)***
Primary	42	84	1.11 (.47–2.65)	1.81 (0.91–3.60)
Secondary	30	86	0.78 (.318–1.89)	0.28 (0.07–1.11)
More than secondary	9	20	1.00	1.00
Parity				
Primipara	47	85	1.00	1.00
Multipara	39	105	0.44 (.191–1.02)	0.60 (0.33–1.10)
Grand multipara	15	12	0.30 (0.13–0.69)	0.52 (0.14–1.90)
Fetal presentation during birth				
Cephalic	79	184	1.00	1.00
Breech	14	10	3.26 (1.39–7.65)	3.09 (1.03–9.27)**
Transverse/brow/face	8	8	2.33 (0.84–6.43)	1.28 (0.36–4.54)
Current pregnancy type				
Wanted planned	66	141	1.00	1.00
Wanted unplanned	18	38	1.01 (.54–1.90)	0.961 (0.445–2.073)
Unwanted unplanned	17	23	1.579 (.79–3.15)	1.158 (0.455–2.952)
Number of ANC visit				
< 4 visits	58	90	2.06 (1.22–3.49)	1.92 (1.07–3.46)***
≥4 visits	30	96	1.00	1.00
Mode of delivery				
SVD	54	136	1.00	1.00
C/S	20	13	3.87 (1.80–8.34)	4.35 (1.72–10.99)**
Instrumental	27	53	1.28 (0.73–2.25)	1.01 (0.52–1.97)
APH				
No	194	85	1.00	1.00
Yes	8	16	4.56 (1.88–11.07)	3.37 (1.23–9.24)***
HDP				
No	194	89	1.00	1.00
Yes	8	12	3.27 (1.29–8.28)	4.05 (2.36–11.05)***

Indicates p-value of ≤ 0.01 and * p-value of < 0.001 ; ANC, antenatal care; APH, antepartum hemorrhage; C/S, cesarean Section; HDP, hypertensive disorder of pregnancy; SVD, spontaneous vaginal delivery.

the likelihood of experiencing NNM than vaginal delivery (42, 49). This might be due to an increased risk of low 5th min APGAR score, preterm birth, and neonatal resuscitation by cesarean delivery, all of which jointly predispose NNM (50, 51). In other words, as a result of fear of contracting COVID-19, most pregnant mothers are preferring to deliver at home, which

may lead to maternal and neonatal complications, including prolonged labor. These impacts might increase the number of cesarean section deliveries.

Hypertensive disease of pregnancy increased the odds of NNM by four times as compared to those mothers who had no HDP.

This finding was similar to the study conducted in Brazil (19, 52), Suriname South America (53), and Ethiopia (43, 54, 55). The study conducted in 29 low- and middle-income countries reported that HDP causes 9% of fresh late fetal deaths and 10% of early neonatal deaths (56). In Ethiopia, HDP account for approximately 7% of perinatal mortality, which may be responsible for the highest perinatal mortality rate in SSA (57). This could be due to the disturbance of vascular manifestations, oxidative stress, and endothelial damage that results from HDP (58). These effects may result in poorer perfusion and nutrient supplementation to the fetus, which enhances adverse perinatal outcomes (58). The possible reason might be that HDP may cause intrauterine fetal complications such as intrauterine growth restriction and preterm delivery and also causes birth asphyxia (59).

The odds of facing NNM were four times higher among neonates born to mothers who had APH in the recent pregnancy than those who had no APH. In congruent with the current finding, studies done in Ethiopia (16) and Zimbabwe (60) found a significant positive effect of APH on NNM. The possible reason could be because bleeding causes oxygen inadequacy for fetal circulation in the uterine, which in turn leads to neonatal morbidities (61, 62).

The current study's findings were intended to provide health professionals with information about factors that determine NNM so that they might take action to minimize risk and increase prevention efforts. In addition, the findings of this study are significant for improving public health since they will help to minimize the financial loss caused by this problem.

Despite its strength, this study was not done without limitations. This study did not incorporate some of the variables that are addressed in the community, such as wealth index and nutritional status.

Conclusions and recommendations

This study found that the lack of formal education, non-vertex presentation during birth, < 4 ANC visits, cesarean section delivery, APH, and HDP are all significant determinants of NNM. Current findings may provide information that can contribute to the global neonatal and maternal morbidity research agenda about the most frequent complications related to the NNM. In line with our findings, more attention is needed during delivery by healthcare providers, and they need to strengthen and advise all pregnant women for ANC follow-up. Furthermore, targeted ANC follow-up of women is required for a practical approach to reduce NNM by helping at-risk mothers plan for delivery.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

Ethical clearance and approval letter to conduct the study was obtained from Research and Ethical Review Committee of Mettu University, College of Health Science. The patients/participants provided their written informed consent to participate in this study.

Author contributions

All authors equally contributed to the conception, design of the study, acquisition of data, supervision of data collection, analysis and interpretation, and drafting or revising of the article. They have agreed on the journal to which the article will be submitted, gave final approval of the version to be published, and agreed to be accountable for all aspects of the work.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Respectful maternity care among women who gave birth at public hospitals in Hadiya Zone, Southern Ethiopia

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Background: A compassionate and respectful care during pregnancy and childbirth is one of the essential components of safe motherhood. However, most of the women in developing countries experience disrespectful and abusive maternity care during childbirth. Hence, this study assessed the status of respectful maternity care and associated factors to bridge the gap.

Methodology: Facility-based cross-sectional study was conducted among mothers who delivered in public Hospitals in the Hadiya Zone, South Ethiopia from March 01 to 30, 2020. Data were collected using a pretested questionnaire through face-to-face interviews. Descriptive statistics was computed and multivariable logistic regression was fitted to identify predictors. Adjusted Odds Ratio (AOR) with 95% Confidence Interval was used to show the strength of association and level of significance was declared at P -value < 0.05 .

Result: This study showed that 67.8 % (95% CI: 62.4–70.8%) of mothers received respectful maternal care. Being married [AOR: 2.17, 95% CI (1.03–6.93)], Cesarean section delivery [AOR: 2.48, 95% CI (1.03–5.97)], and absence of complications during child birth [AOR: 4.37, 95% CI (1.41–13.56)], were significantly associated with respectful maternity care.

Conclusions: The level of RMC in this study was moderate. Being married, Cesarean section delivery, and absence of complications during child birth were identified predictors of respectful maternity care. Therefore, tailored interventions aimed at improving respectful maternity care should target unmarried women, and women with complications of labor regardless of mode of delivery.

KEYWORDS

respectful maternity care, childbirth, public hospitals, Hadiya Zone, Southern Ethiopia

Background

Pregnancy and childbirth are critical events in the reproductive life of women and denote a period of high susceptibility. Thus, compassionate and respectful care should be given for all pregnant women during labor and child birth to promote safe motherhood. Respectful maternity care refers to harmonized care given to all women to the highest possible standard and safeguards them from harm and mistreatment during labor and childbirth (1, 2).

Globally, averting maternal mortality has remained unfinished agenda of sustainable development goals (SDG) (3, 4). Despite the tremendous effort to reduce maternal mortality, the rate is still as high as 239 per 100,000 live births in low-income countries. Furthermore, MMR in Ethiopia is still 412/per 100,000 live births. This figure is very far from the target under the SDG by 2030, which is <70/100,000 (5). Even though skilled birth attendance (SBA) prevents a toll of maternal death, about 75% of mothers do not deliver in health institution in developing countries (5, 6).

Disrespectful and abusive maternity care is one of the main reasons for not utilizing maternal health services. Mistreatment and humiliation during labor and delivery can hinder women from accessing maternal health care for subsequent deliveries (7, 8).

Despite the negative effect of disrespectful and abusive care on the use of skilled birth care, there is currently no international consensus on how disrespect and abuse should be scientifically defined and measured (9, 10). In the perspective of this gap, Bowser and Hill identified seven categories of traits that describe disrespectful and abusive care during facility based child birth. The categories are physical abuse, non-consented care, non-confidential care, non-dignified care, discrimination, abandonment/neglect of care, and detention in facilities until hospital bills are paid (11).

Studies in Ethiopia portrayed the prevalence of disrespectful and abusive care ranging from 21.1 to 98.9% and the pooled prevalence found to be 49.4% (12–14), which are unacceptably high levels of obstetric violence and mistreatment.

The Ethiopian government in its 5-year health sector transformation plan tailored compassionate and respectful maternity care incorporating it in maternal health services packages (15). Although such investment was in place to alleviate this burning problem, their implementation in the national context is not promising.

TABLE 1 Sociodemographic characteristics on respectful maternity care among mothers who gave birth at Hadiya Zone public hospitals Southern Ethiopia, 2020 ($n = 451$).

Variables	Category	Frequency (%)
Maternal age	15–19	36 (7.9)
	20–24	142 (31.2)
	25–29	178 (39.1)
	30–35	76 (16.9)
	>35	19 (4.2)
Residence	Urban	214 (47.9%)
	Rural	237 (52.1%)
Marital status	Single	28 (6.2)
	Married	398 (88.2)
	*Others	25 (4.5)
Religion	Protestant	319 (70.7)
	Orthodox	91 (20.2)
	Muslim	35 (7.8)
	**Others	6 (1.3)
Ethnicity	Hadiya	280 (62.1)
	Kambata	88 (19.5%)
	Siltie	26 (5.8 %)
	Gurage	36 (8%)
	***Others	21 (4.6%)
Educational status	No formal education	103 (22.8%)
	Primary education	159 (35.3%)
	Secondary education	81 (18%)
	College and above	108 (23.9%)
Occupation	House wife	203 (45.01%)
	Government employee	100 (22.2%)
	Private employee	68 (15.1%)
	Merchant	58 (12.8%)
	****Others	22 (4.8%)
Average monthly income	<2,000 birr	152 (33.6)
	2,001–3,000 birr	130 (29.2)
	3,001–4,000	113 (24.8)
	4,001–5,000	34 (7.5)
	>5,000 birr	22 (4.8)

Others = *divorced, widowed, **catholic, pagans, etc., *** Amhara, Oromo, Tigre etc., **** daily laborer, housemaid etc.

Assessment of respectful maternity care during facility-based childbirth is necessary for the design, monitoring, and evaluation of interventions to promote respectful care during childbirth, especially in low-resource settings. In Ethiopia, few studies were conducted and evidences on the status of respectful maternity care and associated factors is limited. Therefore, this study assessed the status of respectful maternity care and associated factors in public Hospitals, in Hadiya Zone, Southern Ethiopia.

Abbreviations: ANC, Antenatal Care; AOR, Adjusted Odds Ratio; CI, Confidence interval; D&A, Disrespect and Abuse; RMC, Respectful Maternity Care; MMR, Maternal Mortality Rate; SDG, Sustainable Development Goal; SBA, Skilled Birth Attendant.

TABLE 2 Provider related and obstetric characteristics of the respondents among mothers who gave birth at Hadiya Zone public hospitals Southern Ethiopia, 2020 ($n = 451$).

Variables	Category	Frequency (%)
ANC follow up	Yes	439 (97.3%)
	No	12 (2.7)
ANC visits	<2 times	144 (32.1%)
	2–4 time	253 (56.1%)
	>4 times	54 (11.9%)
Parity	Only one	216 (47.8%)
	Two	153 (33.9%)
	Three	51 (11.3%)
	Four and above	31 (6.8%)
The profession of HCP	Midwife	347 (76.9%)
	Doctor	80 (17.7%)
	Others	24 (5.3%)
Sex of health care provider	Female	108 (23.9%)
	Male	343 (76.1%)

ANC, Antenatal care; HCP, Health care provider.

Methods and materials

Study area and period

The study was conducted at public hospitals in the Hadiya Zone, Southern Ethiopia. The zone has one teaching and referral hospital, two primary hospitals, 72 public health centers, 311 health posts, and 142 private clinics (16). The study was conducted from March 01 to 30/2020.

Study design and population

A hospital based cross-sectional study was conducted among all mothers who gave birth in Hadiya Zone Public Hospitals during the study period. Seriously ill women who were unable to respond and who were referred from other health facilities after the second stage of labor were excluded from the study.

Sample size and sampling procedure

The sample size was determined by using the double population proportion formula considering factors that are significantly associated with the outcome variable at ($p < 0.05$), a two-sided confidence level of 95%, a margin of error of 5%, power of 80%, and the ratio of exposed to unexposed 1:1 using Epi-calc statistical software. Taking the average monthly income as an exposure variable: outcome among exposed (79.6%) and among unexposed (67%) (17), and adding a 10% non-response rate the final sample size was 460.

All public hospitals were included in the study. Sample size was allocated to each hospital proportionally by considering the average number of attendants. A systematic random sampling was applied to select study participants using delivery registration logbook as a sampling frame.

Data collection tool and procedure

A pre tested and structured questionnaires were prepared by reviewing literatures pertinent to the topic (7, 18–20). The tool contains socio demographic characteristics, obstetric characteristics of the participants and categories of RMC that women will get during facility based child birth. The status of RMC was measured using a validated tool for assessing RMC which was adapted from the Maternal and Child Health Integrated Program (18). Data were collected through an exit interview during discharge. Each eligible woman was approached privately in a separate room within the hospital environment. The data were collected by eight health professionals working outside the study Hospitals. A 2-day training was given to both the data collectors and the supervisors regarding the objective of the study, data collection tools, and ways of data collection. The collected data was checked by supervisors for its completeness and consistency daily.

Data processing and analysis

Data were entered into the computer using Epi-data version 4.2 and exported to SPSS version 23 for analysis. Bi-variable analysis was carried out to see the association of each of the independent variables with the outcome variable (Respectful maternity care). Hosmer and Lemeshow's goodness-of-fit test was used to assess whether the necessary assumptions were fulfilled. All variables with a p -value ≤ 0.2 were taken into the multivariable model to control for all possible confounders. Finally, the results of multivariable logistic regression analysis were presented in the adjusted odds ratio with 95% confidence intervals. The level of statistical significance was declared at p -value < 0.05 .

Measurements

In this study, women were considered to have respectful maternity care during labor and childbirth if they answered yes to all of those questions assessing RMC or verification criteria used for assessing the seven categories (performance standards) of RMC during labor and childbirth (19–22).

Women were considered as experienced disrespect and abuse if they answered no to one or more of those questions

TABLE 3 Respectful maternity care categories among mothers who gave birth at Hadiya Zone public hospitals, Southern Ethiopia, 2020 (n = 451).

Categories	RMC	
	Yes (%)	No (%)
Abuse free care		
Never used physical force/abrasive behavior with the woman	409 (80.6%)	42 (19.4%)
Never physically restrains woman	424 (82.1%)	27 (17.9%)
Never separates woman from her baby unless	430 (85.3%)	21 (14.7%)
Provides comfort/pain-relief as necessary	397 (88.3%)	54 (11.7%)
Does not deny food or fluid to women in labor	430 (85.3%)	21 (14.7%)
Total	82.6%	17.4%
Confidential care		
Never discussed private information in a way that others could hear	364 (70.7%)	87 (29.3%)
Used drapes/covering/screen appropriately to protect woman's privacy not to be seen by other people (apart from health providers) during delivery	341 (65.6%)	110 (34.4%)
Total	58.1%	41.9%
Informed consent		
Great and introduces self to woman and companion	327 (62.5%)	124 (37.5%)
Encourage the women and companion to ask questions	329 (62.9%)	122 (37.1%)
Respond the women's question with politeness and truthfulness	366 (71.2%)	85 (28.8%)
The provider explains what was being done and what to expect throughout labor and delivery	340 (55.4%)	111 (44.6%)
the provider gives periodic updates on status and progress of labor	351 (67.8%)	100 (32.2%)
The provider allows the women to choose birth position as she wants	347 (66.9%)	104 (33.1%)
The provider obtains permission/consent prior to any procedure	349 (67.4%)	102 (32.6%)
Total	56.3%	43.7%
Dignified care		
The health care provider speaks politely to woman and her companion	401 (68.9%)	50 (31.1%)
Allows woman and her companion to observe cultural practices as much as possible	417 (72.5%)	34 (27.5%)
Never makes insults, intimidation, threats, shouted at, scolded, laughed, scorned or coerces woman or her companion	425 (84.2%)	26 (15.8%)
Total	75.2%	24.8%
Abandonment-free care		
The health care provider never ignored or abandoned the woman when she called for help	416 (72.2%)	35 (27.8%)
The provider never leaves woman alone or unattended during on the delivery couch	434 (76.2%)	17 (23.8%)
Total	74.2%	25.8%
Free of discrimination		
Speaks to the woman in a language and at a language-level that she understands	432 (78%)	19 (22%)
The health care provider didn't discriminate the women based on any specific attribute	414 (74%)	27 (26%)
Total	76%	24%
Never detained or confined against her will		
Facility doesn't have a policy to detain women who don't pay.	434 (86.2%)	17 (13.8%)
The women don't been forced to stay against their will	420 (75.3%)	31 (24.7%)
Total	80.7%	19.3%
Overall self-reported respectful maternity care	Yes (67.8%)	No (32.2%)

assessing RMC or verification criteria used for assessing the seven categories of RMC (18, 23, 24).

Results

Socio-demographic characteristics of the respondents

A total of 451 mothers participated in the study; which yields a response rate of 98.04%. Among mothers, 178 (39.1%) of the study participants were within the age group of 25–29 years. The mean age of the mothers was 28.6 (SD \pm 4.04) years.

Concerning their marital status and residency, 398 (88.2) of them were married and 237 (52.1%) of the respondents were from urban. Of the total 159 (35.3%) of them attended primary education and 203 (45%) are housewives (Table 1).

Obstetric characteristics of respondents

Of the total respondents, 439 (97.3.0%) had antenatal care follow up and 234 (51.4%) had two or more ANC visits. Regarding the gravidity of participants, 216 (47.5%) were multigravida. More than half 240 (53.2%) gave birth vaginally while 41 (14.4%) gave birth by caesarian section (Table 2).

Status of respectful maternity care

Overall, 67.8% (95%; CI: 62.4, 70.8%) of the women received respectful maternity care. Out of all participants, 41.9% didn't receive confidential care and 43.7% complained that HCPs (health care providers) did not take informed consent before any procedure (Table 3).

Factors associated with respectful maternity care

The bivariable analysis result showed that marital status, educational status, parity, the profession of health care provider, sex of health care provider, mode of delivery, birth outcome, length of hospital stay, complications during labor, and delivery were significantly associated with respectful maternity care. After adjusting for other variables; marital status, mode of delivery, and complications during labor and delivery remained significantly associated with respectful maternity care in multivariable logistic regression.

Married women were two times more likely to obtain respectful maternity care than single women [AOR: 2.17 (1.03–6.93)]. The odds of respectful maternity care were 2.48 times higher among mothers who delivered by cesarean section

compared to those who gave birth by spontaneous vaginal delivery [AOR: 2.485, 95%CI (1.03, 5.97)]. The odds of respectful maternity care were four times higher among those women who did not face complications during childbirth as compared to their counterparts [AOR: 4.37, 95% CI (1.41–13.56)] (Table 4).

Discussion

A compassionate and respectful care during pregnancy and childbirth is one of the essential components of safe motherhood. In this study, the overall magnitude of respectful maternity care during labor and childbirth was 67.8 % (95% CI: 62.4–70.8%). On the other hand, about one-third of women (32.2%) reported disrespect and abusive (D&A) care during labor and childbirth which was unacceptably high.

The magnitude of RMC in this study is by far higher than the study conducted in Addis Ababa (21%) (20), Harar (38.4%) (21), West Shewa, Oromia region (35.8%) (22), and the study conducted in public Hospitals of Benishangul Gumuz Region, Ethiopia (12.6%) (23). However, this study finding is lower than the study finding from Tanzania (85%) (24) and Kenya (80%) (25). The difference could be due to study setting differences, methodological variation, participants' educational and socio-economic status, service quality, and the ability of participants to report disrespect and abusive care.

This study revealed that married women were two times more likely to receive respectful maternity care compared to those who are not in a marital union. This finding may be a result of companion, which indicates that providers are more likely to be cautious about how they act and speak to a client when a companion of the client is present. This finding is also supported by many other studies (17, 23, 25–27).

Furthermore, participants who gave birth by cesarean section were 2.48 times more likely to receive respectful maternity care compared to participants who gave birth by spontaneous vaginal delivery. The result is in contrast with the study done in Bahirdar, Northwest Ethiopia, and Addis Ababa, Ethiopia (17, 28). This could be justified by study setting differences, case flows, staff workload, and attitude of health care providers.

Unexpectedly, women who didn't face complications during childbirth were about four times to receive RMC as compared to those who faced complications during birth. This is aligned with other studies conducted in Ethiopia (17, 21, 28). This might be because those mothers who develop complications are admitted and stayed for an extended time and they might perceive poor quality of care provided by health professionals during their stay.

TABLE 4 Factors associated with respectful maternity care among mothers who gave birth at public hospitals of Hadiya Zone, southern, Ethiopia 2020 ($n = 451$).

Variable	Category	Respectful maternity care		COR (95% CI)	AOR (95% CI)	<i>p</i> -value
		No	Yes			
Monthly income	<2,000	44 (28.8%)	109 (71.2%)	1	1	1
	2,001–3,000	48 (36.4%)	84 (63.6%)	0.706 (0.43–1.16)	0.560 (0.265–1.181)	0.914
	3,001–4,000	41 (36.3%)	72 (63.7%)	0.709 (0.422–1.191)	0.553 (0.241–1.271)	0.128
	4,001–5,000	8 (24.2%)	25 (75.8%)	1.261 (0.529–3.01)	0.553 (0.241–1.271)	0.463
	>5,000	7 (38.9%)	11 (61.1%)	0.634 (0.23–1.74)	0.691 (0.161–2.964)	0.235
Marital status	Single	9 (32.1%)	19 (67.9%)	1	1	
	Married	124 (31.3%)	272 (68.7%)	1.526 (1.164, 2.577)	2.17 (1.031–6.933)*	0.001
	*Others	15 (60%)	10 (40%)	0.351 (0.116–1.062)	0.580 (0.154–2.180)	0.081
Residence	Rural	60 (28%)	154 (72%)	1	1	1
	Urban	88 (37.4%)	147 (62.6%)	1.361 (0.92–2.03)	2.23 (0.96–4.32)	0.136
Educational status	Primary	17 (28.3%)	43 (71.7%)	1.763 (1.02–3.04)	0.98 (0.39–2.465)	0.079
	Secondary	33 (40.7%)	48 (59.3%)	0.821 (0.461–1.461)	0.53 (0.208–1.357)	0.551
	≥College	32 (24.2%)	100 (75.8%)	1.427 (0.73–2.795)	1.52 (0.53–4.35)	0.283
ANC visit	No	7 (58.3%)	5 (41.7%)	1	1	1
	Yes	141 (32.3%)	296 (67.7%)	2.939 (0.917–9.423)	0.615 (0.07–5.39)	0.792
Parity	Only 1	63 (41.7%)	88 (58.3%)	1	1	1
	2	51 (23.6%)	165 (76.4%)	2.316 (1.47–3.63)	1.005 (0.459–2.203)	0.059
	3	19 (37.3%)	32 (62.7%)	1.206 (0.63–2.317)	0.61 (0.22–1.69)	0.642
	4	11 (50%)	11 (50%)	0.716 (0.29–1.75)	0.79 (0.199–3.14)	0.188
	≥5	4 (44.4%)	5 (55.6%)	0.895 (0.23–3.466)	0.86 (0.09–8.137)	0.974
Profession of provider	Doctors	35 (43.8%)	45 (56.2%)	1	1	1
	Midwives	102 (29.5%)	245 (70.6%)	1.861 (1.13–3.06)	0.576 (0.22–1.48)	0.153
	**Others	11 (64.7%)	13 (67.3%)	0.848 (0.335–2.15)	0.31 (0.069–1.411)	0.861
Sex of HCP	Female	48 (44.4%)	60 (55.6%)	1	1	1
	Male	100 (29.5%)	241 (70.7%)	1.93 (1.235–3.01)	0.768 (0.328–1.802)	0.439
Type delivery	SVD	84 (25.2%)	249 (74.8%)	1	1	1
	Cesarean	51 (59.3%)	35 (40.7%)	4.59 (2.80–7.54)	2.48 (1.03–5.97)*	0.004*
	Instrumental	13 (43.3%)	17 (56.7%)	1.98 (0.856–4.58)	2.262 (0.24–21.33)	0.216
Birth outcome	Alive	120 (29.5%)	287 (70.5%)	1	1	1
	Dead	28 (66.7%)	14 (33.3%)	4.783 (2.43–9.40)	2.472 (0.757–8.067)	0.062
Stay at HF	<12 h	88 (26.7%)	242 (73.3%)	1	1	1
	12–24 h	7 (38.9%)	11 (61.1%)	3.018 (1.85–4.92)	1.23 (0.494–3.076)	0.065
	>24 h	8 (53.3%)	7 (46.7%)	1.725 (0.61–4.86)	2.005 (0.25–16.007)	0.403
	>2 days	45 (52.3%)	41 (47.7%)	0.960 (0.32–2.88)	0.60 (0.048–7.63)	0.891
Delivery complication	Yes	53 (43.4%)	69 (56.6%)	1	1	1
	No	95 (29.1%)	232 (70.9%)	1.876 (1.22–2.88)	4.37 (1.41–13.56)*	0.000*

Significant at * $P < 0.05$, 1 = constant, CI, Confidence Interval; COR, Crude odds Ratio; AOR, Adjusted Odds Ratio; HCP, Health care provider; HF, Health facility; Others = *divorced, widowed, **professionals like Nurses, Health officers.

Finally, as a limitation this study was based on self-report, hence it was not possible to validate claims made by respondents in the course of questionnaire administration. There might be the possibility of underestimating disrespect and abusive care within short duration of data collection period due to its sensitive nature. To minimize this bias, the data were collected in a private room within the hospital setup.

Conclusion

The level of respectful maternity care in this study was moderate in comparison with other studies in the country. But still, about one-third of women experienced disrespect and abusive care while they gave birth at a health facility. Therefore, concerned body and stakeholders should

devise strategies to avoid disrespect and abusive care during labor and childbirth. Furthermore, due emphasis should be given for improving RMC among unmarried women, and women with complications of labor regardless of mode of delivery.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by Institutional Health Research Ethics Review Committee (IHRERC) of the College of Health and Medical Sciences, Haramaya University. The patients/participants provided their written informed consent to participate in this study.

Author contributions

TMe drafted the study. TY and MD monitored the study process. TMu and AA was involved in report writing and drafted the manuscript. All authors have read and approved the final manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Nationwide-free preconception care strategy: Experience from China

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Preconception care has emerged as a developing field in maternal and child healthcare worldwide. This care type provides couples of reproductive age with the opportunity for early detection and management of biomedical, behavioral, and social health problems. In 2010, the Chinese government launched a nationwide preconception care program as a welfare project. During the past decade, this project has received international attention, and experiences from the project have been published in the literature. In this review, we summarize the history, implementation, and evaluation of preconception care services in China, and its related maternal and children's health service initiatives, to thereby provide knowledge for policymakers and clinicians in other countries.

KEYWORDS

preconception care, preconception health, reproductive health, China, prenatal care

Introduction

The preconception period is defined as the 3 months prior to conception (1, 2). It comprises a biological perspective (several days or weeks from gamete maturation to embryo formation), an individual perspective (a conscious intention to have a baby), and a public health perspective (months or years beforehand), in which pre-pregnancy risk factors can be addressed (3). To improve the health of couples with pregnancy intention, increase the chance of having a healthy baby, and optimize pregnancy outcomes, preconception care has been paid more and more attention in recent years. In this review, we summarized the history, implementation, and effectiveness evaluation of preconception care in China, which was initially named as National Free Preconception Health Examination Project, to thereby share the Chinese experience of a nationwide-free preconception care strategy.

It is estimated that in China, more than 54 million fertile couples are older than 35 years, of which ~50% are between 40 and 49 years old (4). With the increasing rate of advanced maternal age and the use of artificial reproductive techniques, the number of reproductive women at risk has increased. It is, therefore, critical to provide couples who are preparing for pregnancy with preconception care, which could help them to avoid potential behavioral and environmental risk factors and achieve the healthiest possible pregnancy (5–8). Preconception care is also an essential part of primary and preventive care (9); therefore, its integration with prenatal care—including prenatal screening and diagnosis as a secondary intervention to form a continuum of care—is expected to further reduce maternal and childhood mortality and morbidity at the population level (10).

Despite its known benefits, the implementation of preconception care varies across the world. In the United States, clinical guidelines related to preconception have recommend that couples with conception intention should have a preconception examination (11). In European countries, such as Belgium, Denmark, Italy, the Netherlands, Sweden, and the United Kingdom, preconception care is offered to women with high-risk factors; however, it tends to be done opportunistically for those without pre-existing medical conditions, except for a national strategy in the Netherlands (12). Maternal and child health have always been a priority in China. Since the launch of the National Free Preconception Health Examination Project in 2010, the Chinese government has been devoted to this nationwide welfare initiative and has achieved some progress, which may set an example for other countries and areas in the world.

The history of preconception care in China

Premarital medical examinations were used as a prototype of preconception care. During the period 1995–2003, premarital medical examinations were mandatory for couples; however, this requirement was canceled in 2003. Currently, the premarital medical examination is voluntary, and its rate has been reduced by almost 50% (13). In addition, the National Stocktaking Report on Birth Defect Prevention (2012) revealed that the incidence of birth defects was 5.6%, with ~900,000 new cases reported annually in China. This figure has been increasing for 15 years (14, 15). Although neonatal and maternal mortality in China has been continuously decreasing, to 5.4 and 0.169%, respectively, in 2020 (16), the incidence of birth defects in China has plateaued. Thus, the Chinese government initiated free preconception care in the purpose to reduce the incidence of birth defects and other adverse pregnancy outcomes.

The National Free Preconception Health Examination Project was introduced by the State Council of China in 2010 and was operated under the charge of the Chinese National Health and Family Planning Commission and the Ministry of Finance. Well-known experts in the perinatal care field from representative hospitals across the nation brainstormed in a series of meetings to reach a consensus and design this project (17). This well-organized project provides 19 preconception health service items, including health education, health examination, risk evaluation, and medical consultation (17, 18). In particular, the preconception health examinations recommended by expert workgroups are important for obtaining a health profile for further risk evaluation and medical interventions. Specifically, preconception care in China is aimed at couples contemplating pregnancy within the next six months; this is different from the United Kingdom and Australia, where all reproductive couples across the entire reproductive

life span are eligible for care (19, 20). In the United States, reproductive planning and health promotion are recommended to be integrated into women's routine healthcare, irrespective of their desire to become pregnant (21).

Initially, the Chinese government provided preconception 164 care as a pilot program in 100 rural counties in 18 provinces, then expanded it to 220 rural counties in 31 provinces after 1 year (17). Free preconception care was also extended to urban communities in some relatively developed regions, such as Guangdong and Chongqing. Hebei, Guangdong, and Gansu provinces have been commended for their service quality, and supervisors from these areas often share experiences with others *via* conference calls (22). Finally, preconception care covered almost all rural and urban areas—2,790 counties in China—since 2013 (17).

The practical models of preconception care in different areas vary, to some extent. Due to different accessibilities to medical resources, couples living in urban areas are more likely to have preconception care services in tertiary comprehensive or specialized maternity hospitals, while couples living in rural areas usually receive preconception healthcare from trained physicians in primary health centers close to their resident villages and are referred to tertiary hospitals when necessary. Furthermore, additional items related to preconception health examinations are provided where necessary. For example, in Guangdong Province, where incidences of thalassemia and favism are much higher than that in other places, additional screening for these two diseases is routinely performed (23).

While preconception care is a component of regional or state public health programs in most Western countries (9), the Chinese government earmarks a national fund for its free preconception care program as a welfare project to ensure that each couple has the opportunity to achieve a healthier pre-pregnancy condition. The nationwide preconception care service covers more than 80% of couples who plan to conceive within 6 months in China (15), and more than 95% of target couples received preconception health education. From 2010 to 2020, more than 73 million target couples benefited from this welfare project (15–17, 24–27).

Implementation of preconception care in China

China operates an extensive household registration system, and therefore, basic family information—such as family size and phone numbers within jurisdictions—is available to community workers. These workers can therefore call potential participants, especially married couples with no child, in their local community to determine pregnancy intention and briefly introduce the free national preconception care service. For couples who plan to conceive within 6 months, a health examination would be arranged, with their informed consent

(18). In addition, their follow-ups in terms of pregnancy outcomes in future are also arranged *via* telephone.

During the arranged health examination, primary healthcare providers and clinicians who are especially trained in obstetrics collect the following: a thorough individual health history and family history relating to infectious, chronic, or congenital diseases; previous contraception conditions and pregnancy-related difficulties; current medicine use; dietary habits and lifestyles; exposure to toxic substances; and socioeconomic and mental stress (17, 18). A general examination—including height, weight, blood pressure, and heart rate—and a basic physical examination of the body are also performed to determine couples' general health status. Laboratory tests are also a significant component of preconception care in China. A full blood count, blood type identification, urinalysis, liver, kidney, and thyroid function, as well as gynecological ultrasound scans, are routine check-up items in China; these items are quite rare in other country preconception care services (28). Microbiological tests of genital swabs (*Candida*, *Mycoplasma*, *Chlamydia*, and *Gonococcus*), TORCH (*Toxoplasma gondii*, cytomegalovirus, and rubella virus), and serum assays for hepatitis B virus and syphilis infection (29, 30) are also performed to determine participants' infection and immunization status. In terms of the examination of sperm, a compact measure to evaluate the husband's reproductivity has been recommended and implemented. Finally, all the records are uploaded to a web-based electronic data collection system.

A novel risk classification system with “ABCDX” categories was generated to stratify couples' preconception health status. In this system, preconception risk factors are categorized into five classes, based on their amenability to prevention and treatment (29). Clinicians then review all health history and diagnostic examination results of the couple to conduct a risk evaluation, based upon which detailed health education, timely patient-centered medical interventions, close supervision during the perinatal period or contraceptive services, and necessary referrals to tertiary hospitals are provided (29, 31).

It is important to build a holistic quality control system for such a large preconception care program. Several guidelines and booklets on health education, health examinations, risk evaluation, and medical consultations have been published (32–37). As 13 of the 19 items provided in this project are laboratory tests, regular training courses for laboratory technicians, as well as internal and external quality assessments of laboratories, were implemented to standardize the operation and to ensure the accuracy of the test results (38). National and provincial quality control centers of laboratories were established for the analysis of the uploaded results from inferior institutions and the arrangement of unannounced inspections.

Recently, a mini mobile application (app) called the “National Premarital and Preconception Health Examination Information Service Platform” was launched to enable easy access for couples planning their pregnancies. This platform

contains information on 2,998 institutions that provide preconception care services and automatically recommends the nearest hospital to the participants, based on their location. An appointment can then be made directly (39).

Evaluation of preconception care in China

Preconception care is believed to have a positive effect on various health outcomes. To evaluate the necessity and effectiveness of preconception care in China, we selected several reports and articles about preconception care based on the Chinese population for this review. Herein, the effect of preconception care on adverse pregnancy outcomes, nutrition intervention, infection and immunization, pre-existing medical conditions, and healthy behaviors is being evaluated.

Adverse pregnancy outcomes

Studies demonstrate that preconception care services reduce the incidence of maternal and fetal complications. Two intervention studies conducted in Zhejiang Province and the Xinjiang Uyghur Autonomous Region reveal that integrated maternal healthcare (preconception and antenatal care) improved pregnancy outcomes among women of advanced maternal age (≥ 35 y). The incidence rates of premature delivery, gestational hypertension, gestational diabetes mellitus, low birth weight, and cesarean section were significantly lower among women who received integrated perinatal care (40, 41). This corresponds with the results in other countries, which show reports of 70% lower risk for preterm birth, 60% lower risk of low birth weight and maternal complications, 54% lower risk of neonatal complications, greater odds of obtaining antenatal care, and lower rates of neonatal mortality among women receiving preconception care (8, 42). Meanwhile, the results from the CARNATION study, where a prospective cohort of Chinese women with pre-gestational type 1 diabetes received comprehensive preconception-to-pregnancy management in 11 centers from eight Chinese cities from 2015 to 2017, showed that the continuum of maternal care can achieve substantial improvements in pregnancy outcomes (43). Furthermore, a recent Chinese birth cohort study reports that the prevalence of birth defects is 2.5% (44), which is a significant decrease from 5.6% (14). The improvement shown in this prospective longitudinal mega cohort may be related to the nationwide-free preconception care service system, which could provide timely primary intervention, to some extent. However, further cohort studies are required to assess the contribution of preconception care in improving pregnancy outcomes.

Nutrition intervention

Nutrition is one of the most common modifiable factors related to conception (45). In the Chinese preconception care project, weight control, folic acid intake, and anemia were the three key factors.

First, abnormal preconception maternal weight is prevalent among Chinese women.

On the one hand, maternal obesity is closely associated with an increased risk of infertility (46, 47), preeclampsia, gestational diabetes (48), and an adverse intergenerational impact on offspring (49). On the other hand, low maternal weight is associated with low birth weight and premature birth (50, 51). In China, the incidence of being overweight and obese among adults has increased to 34.3 and 16.4%, respectively, by 2020 (52). Another study involving 2,120,131 Chinese women—aged 21–49 and from 220 pilot counties in 31 provinces—who participated in the National Free Preconception Health Examination Project from 2010 to 2012 revealed that the prevalence of preconception maternal low BMI increased from 10.4% in 2010 to 14.14% in 2012 (53), especially among women younger than 35 years (51). It is therefore possible that a more complex nutritional challenge, involving malnutrition and overnutrition, is prevalent among Chinese women of reproductive age.

Interestingly, paternal weight may also play a role in offspring birth weight. Guo et al. conducted a retrospective study based on preconception data of 256,718 small for gestational age and 506,495 large for gestational age neonates in more than 4.7 million Chinese couples aged 20–49 between 2013 and 2016. Their results reveal a non-linearly dose-response relationship between lower paternal BMI and small for gestational age, as well as between higher paternal BMI and large for gestational age infants (54). These findings suggest that both ideal maternal and paternal weights seem beneficial for improved pregnancy outcomes and offspring health. It would therefore be meaningful to provide person-centered health education, involving nutritional advice and lifestyle changes, to achieve and maintain a more normal weight before pregnancy.

Second, folic acid supplementation is widely recommended for couples with pregnancy intention to reduce the risk of neural tube defects in their offspring (55). In a cohort who took part in the preconception care program, preconception folic acid supplementation reduced the risk of spontaneous abortion and preterm birth (56, 57). Moreover, an earlier start of taking folic acid supplements is important. After adjusting for covariates, women with at least three months of folic acid supplementation prior to conception had 10% and 5% lower risks of spontaneous abortion and preterm birth, respectively. Conversely, among women who initiated folic acid supplementation 1–2 months before conception, in 44%, the protective effect of folic acid supplementation against spontaneous abortion still exists after conception, while there was no meaningful reduction in preterm

birth. In addition, a review of the association between folic acid and multivitamin supplementation and neurodevelopmental disorders in offspring indicates that supplementation reduced children's risk of autism spectrum disorder by 36% (RR 0.64, 95% CI: 0.46, 0.90) (58). It, therefore, appears to be necessary to strengthen a full course folic acid supplementation during the preconception period to maximize its protective effect.

Third, anemia is common among women of reproductive age and requires early intervention before conception. A routine blood test is performed during the preconception health examination in China to determine maternal iron levels. In a Chinese population-based study in 2012, the prevalence of anemia was 24.80% among women of reproductive age in rural areas (59), while the prevalence of severe anemia was 0.24% (60). Although this incidence was lower than the global average of 29.0%, reported by the World Health Organization in 2011 (61), it varied in terms of different areas and among women of different races in China (62, 63). Between 2014 and 2018, the incidence of anemia in China declined from 23.0% to 16.4% (63), indicating the effectiveness of nutritional strengthening. In addition, there is a U-shaped relationship between hemoglobin concentration and adverse outcomes, according to many studies generated from the National Preconception Health Examination Project in China. Both severe anemia and a hemoglobin concentration higher than 150 g/L prior to pregnancy were associated with an increased risk of spontaneous abortion (64), very early preterm birth (65), low birth weight, and small for gestational age infants (66). Therefore, screening for anemia during the preconception period is of great public health significance to enable timely intervention (67).

Infection and immunization

Some bacteria, viruses, and other organisms can be passed from mother to child. These are typically TORCH (toxoplasma, rubella virus, cytomegalovirus, herpes simplex virus, and other pathogens) pathogens that can pass across the placenta or the female reproductive tract, thereby greatly increasing the risk of adverse outcomes, such as miscarriage, abortion, stillbirth, sterility, preterm birth, and birth defects—specifically, congenital heart diseases (68, 69). In China, TORCH screening prior to pregnancy makes the preconception period a window to take action to block vertically transmitted infections.

Several articles based on the Chinese population reveal the seroepidemiological status of individuals. The overall prevalence of rubella virus IgG seropositivity increased from 58.4% in 2012 to 81.97% in 2015, and the overall prevalence of rubella virus IgM seropositivity was 0.89% (70, 71). This may be attributed to the nationwide Expanded Programme on Immunization, which includes rubella virus vaccines for adolescents and women of childbearing age in China (72, 73). However, ~20% of women are susceptible to rubella in the preconception period,

which requires accelerating the elimination of rubella through supplementary immunization activities to reduce the burden of congenital rubella syndrome (73, 74). The overall IgG seropositivity prevalence of HSV-(1+2) in reproductive-aged women is 90.15% (70). *Toxoplasma gondii* IgG seropositivity among Chinese women of reproductive age was 1.71–2.3% and that of IgM positive was 0.3–0.4%, which was relatively low (70, 75). Substantial differences among regions in the prevalence of these infectious pathogens are common; this may be related to imbalanced socioeconomic conditions, the availability of health resources, and cultural differences across China. Thus, healthcare service providers should consider local resources and culture when devising preconception care strategies.

Pre-existing medical conditions

In the preconception period, any comorbidities should be carefully treated and well-controlled. A cross-sectional seroepidemiological survey of preconception hyperglycemia on more than 2.2 million Chinese women revealed that 1.4% and 12.9% of women had diabetes and prediabetes, respectively (76). This indicates the necessity of routine diabetes screening in preconception care. In Guangdong Province, women of childbearing age with type 1 diabetes mellitus had poor awareness of preconception care, with a much lower frequency of self-monitoring of blood glucose than recommended (77), suggesting that preconception glycemic control by appropriate methods is one of the most important aspects of preconception care. In addition to hyperglycemia, abnormal thyroid function is more common during the preconception period. Maternal hypothyroidism is related to preterm birth and impaired neurodevelopmental function (78–82). Sufficient thyroid hormone levels are essential for fetal growth, especially brain development, and timely medication should be initiated and continuously monitored during pregnancy.

Healthy behaviors

Smoking and alcohol consumption are two recognized risk factors that can be modified through appropriate pregnancy education programs. Based on the well-established association between maternal smoking, alcohol intake, and poor birth outcomes (83–85), behavioral interventions are mostly conducted among women. Interestingly, among married Chinese couples, nearly one-third of fathers and only 3% of mothers consumed alcohol before pregnancy (29, 86). Further evidence from the database of the National Free Preconception Health Examination Project in China revealed that paternal smoking and alcohol consumption during the preconception period may increase the risk of birth defects, including congenital heart disease, limb abnormalities, and neural tube

defects (85, 87); this suggests that parental smoking cessation and sensible alcohol consumption prior to conception should be emphasized.

Discussion

The Chinese government has made substantial investments in preconception care services, which have benefited more than 73 million couples. High-quality clinical studies, such as the CARNATION study, indicate the clinically important effect of preconception-to-pregnancy care. By taking advantage of the large database of the National Free Preconception Health Examination Project, abundant original and compelling evidence has been published. For example, representative studies link preconception paternal smoking and alcohol intake to birth defects (87, 88) and reveal surprising protective effects of preconception folic acid supplementation to reduce spontaneous abortion (57); these great successes have gained wide attention. They further demonstrated the necessity of a nationwide-free preconception care strategy in China.

However, preconception care in China has some limitations, and the following aspects may indicate directions for future optimization. First, the integration of preconception and antenatal care must be strengthened. The continuum of care may have the potential to promote maternal health (89), as conventional prenatal care excludes the critical period of fetal organogenesis to provide primary interventions (before the 12th gestational week). In addition, the appropriate arrangement of preconception health examinations and premarital medical examinations should be considered, to thereby improve cost-effectiveness. Second, the implementation of preconception care in urban areas should be improved. Nearly 42.2% of couples in Shanghai, one of the most prosperous cities in China, report that they have attended preconception care, and the rate of intended pregnancy is still relatively low (90, 91). Raising awareness of planned pregnancy and preconception health will enable the implementation of preconception care services. At the same time, actions to address the uneven distribution of wider determinants, such as housing, education, and family income, and the provision of additional support for families with socioeconomic deprivation (91, 92) are required for a universal preconception care strategy in China. Third, associated local guidelines in terms of common infections, immunization, and pre-existing medical conditions should be updated, based on more population-based evidence. More focus is needed for proper inter-pregnancy interval and re-pregnancy management in “the post-caesarean section era” (93), which affects pregnancy outcomes and is an important issue for discussion in Western countries. In addition, genetic interventions through new technologies in pre-pregnancy screening, an important focus point in current research (94), may be specifically recommended for high-risk couples. Finally, with the rapid development

of fifth-generation mobile communication technology and artificial intelligence, personalized preconception care services will be the future direction. Mass data concerning preconception health examination, prenatal care, and puerperal and newborn outcomes will be stored in a cloud server and automatically matched by a unique ID to establish a personal standardized profile of reproductive health and family planning in the future. Big data analysis will enable researchers and policymakers to adjust their local strategies based on evidence.

Summary

Preconception care in China is a robust public health program that runs a universal implementation model. Furthermore, its valuable database has provided epidemiological evidence for the necessity and effectiveness of preconception care, to some extent. The successful experience of maternal and children's health service initiatives in China is available in this review to inform policymakers in other countries around the world.

Author contributions

JX, XL, and QZ contributed to the study conception and design. JX searched the databases, collected the evidence, and wrote the first draft of the manuscript. XL and QZ revised the manuscript. All authors contributed to the manuscript 380 revisions, read, and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Knowledge, attitudes, and practices of health providers regarding access to and use of contraceptive methods among adolescents and youth in urban Guinea

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Introduction: The objective of this study was to analyze providers' knowledge, attitudes, and practices regarding access to and use of contraception by urban adolescents and youth.

Methods: This is a cross-sectional study of 1,707 health care providers in 173 selected private and public health facilities in the capital city of Conakry and the seven administrative regions of Guinea. Factors associated with health care providers' attitudes and practices were then analyzed using logistic regression.

Results: Among the 1,707 health providers, 71% had a good level of Knowledge about modern contraceptive use among adolescents and youth. In addition, 62% had positive attitudes, and 41% had good prescribing practices toward using modern contraceptive methods by adolescents and youth. Being a midwife (aOR: 1.39, 95%CI: 1.02–1.89), Being aged 25–34 years (aOR: 1.7, 95%CI: 1.2–2.3), 35–44 years (aOR: 2.1, 95%CI: 1.4–3.0), and 45 years, and older (aOR: 2.4, 95%CI: 1.3–4.2), an increase of years in professional experience (aOR: 1.05; 95%CI: 1.02–1.08) were factors significantly associated with provider positive attitudes. However, being a medical doctor (aOR: 2.37, 95%CI: 1.04–4.42), an increase of years in professional experience (aOR: 1.07; 95%CI: 1.04–1.10) and a positive attitude (aOR: 3.16, 95%CI: 2.48–4.01) were factors associated with good practice in delivering modern contraceptive methods to adolescents and youth.

Conclusion: Positive attitudes and good practices toward the use of contraceptive services by adolescents and youth were found among providers. However, many health care providers still have unfavorable attitudes and practices toward delivering FP services to urban adolescents and youth. Therefore, future intervention programs should focus on training health care

providers in youth- and adolescent-friendly reproductive health services and promoting contraception among adolescents.

KEYWORDS

contraception, knowledge, attitudes and practices, health provider, adolescents and youth, Guinea

Introduction

Despite the relative decline in the overall adolescent birth rate worldwide, from 56 births per 1,000 women aged 15–19 in 2000 to 44 per 1,000 in 2018, it remains high (101 per 1,000) in sub-Saharan Africa (1).

Thus, reducing the frequency of pregnancies among adolescents and young people is becoming a priority in sub-Saharan Africa, where frequent complications related to unwanted pregnancies (2, 3). In this context, although the provision of family planning (FP) services is guided by the principle of informed client choice, a number of barriers limit their availability and use (4, 5). These barriers partially sustained high unmet needs, particularly among adolescents and youth in sub-Saharan Africa contexts (4–6).

In Guinea, half the population is under 24 years. However, in 2018, more than a third (38%) of sexually active adolescent and young unmarried women aged 15–24 had an unmet need for FP (7). The existence of the unmet need for FP can result from factors including lack of delivery of services (e.g., low coverage or quality of FP services, attitudes, and practices of providers) or demand (Knowledge of FP, socio-cultural norms, access to services, etc.) (8, 9). For example, certain socio-cultural norms or individual considerations may influence health care providers' attitudes that limit adolescents' and youths' access to and use of sexual and reproductive health services (10). Thus, provider attitudes and communication problems, real or perceived, may contribute to the unmet needs for contraception (2, 11).

In addition, several studies in Africa have found that providers have restrictive practices or attitudes toward the delivery of contraceptive services to adolescents and youth (12–15). In this context, non-marital sexual relations are very poorly perceived by some health providers, leading to negative attitudes on their part in providing FP services to unmarried young women (12, 16). Other providers reported feeling very uncomfortable or reluctant about delivering a modern contraceptive method to adolescents and youth because of their young age (6, 17). In Senegal, a study examined the role of provider restrictions on young women's access to and

use of contraception. These biases and provider restrictions contributed to youth's lack of access to contraception (18).

Furthermore, the perception that contraceptive use can lead to infertility or that it represents a practice contrary to religious belief justifies the negative attitude of some providers (19, 20). Moreover, providers' lack of knowledge about the eligibility criteria for modern contraceptive methods among adolescents and youth encourages irregular prescription of contraceptives (21).

However, favorable attitudes toward contraception among youth were most likely to be found among health providers with more education or those who had received sufficient continuing education on adolescent sexuality and reproductive health (16, 20, 22). Thus, health providers need sufficient knowledge and a positive attitude toward adolescent contraceptive users to better play their role in prescribing contraceptives to prevent unplanned pregnancies among adolescents and young women (21).

Although the various studies mentioned above examine the attitudes and perceptions of providers in delivering family planning services to adolescents and young women, certain aspects remain little studied, for example, the specific factors that influence providers' practice in urban areas.

Systematic analysis of the factors associated with the attitudes and practices of these providers would generate useful information for improving contraceptive use in this target population. In addition, it would help to address the challenges that are slowing down the repositioning of FP and the promotion of sexual and reproductive health among adolescents and youth in urban areas (23, 24).

The objective of this study was to analyze providers' knowledge, attitudes, and practices (KAP) regarding access to and use of contraceptive methods by adolescents and youth in urban areas. Specifically, it describes the KAPs and analyzes the factors associated with providers' attitudes and practices.

Materials and methods

Type and period of study

This cross-sectional study was conducted between November 1st, 2020, and January 31st, 2021.

Abbreviations: AOR, Adjusted Odds Ratio; CI, Confidence Interval; DHS, Demographic and Health Survey; FP, Family Planning.

Study setting

The study was conducted in public and private health facilities (hospitals, communal medical centers (CMCs), health centers, and private clinics) in the capitals of the eight (8) administrative regions of Guinea, including the capital, Conakry.

Study population

The study population consisted of all health care providers (medical doctors, nurses, midwives, and pharmacists) involved in delivering FP services in the study sites' public and private health facilities.

Sampling

A multistage sampling technique was used to select health facilities and study participants. Then, at the level of each region, we proceeded to the exhaustive selection of national and regional hospitals and CMCs. Then, health centers, private clinics, practices, and NGOs were selected using a simple random sampling procedure according to public or private type.

The list of public and private health facilities or approved associations involved in delivering family planning services was used to select the health facilities participating in the study.

Of the 328 operational health facilities identified, 173 (52.8%), including 19 hospitals/CMCs, 69 health centers, 41 private hospitals/clinics, and 54 private practices or health centers, were surveyed in the five communes of Conakry and 11 health districts. In each of the involved health facilities included in the study, the health providers present in the services on the day of the survey were interviewed.

Data collection

We used the ODK (Open Data Kit) electronic data collection system to collect data from health workers. A standardized electronic questionnaire, pre-tested and integrated with tablets, was also administered individually to health care workers by previously trained collection agents. Data collection was done under the direct supervision of the principal investigator and his two research assistants.

The information collected focused on the socio-demographic characteristics, knowledge, attitudes, and practices of health workers regarding the use of modern contraceptive methods among adolescents and youth in urban Guinea.

Variables

Outcome variables

The variables of interest in this study were positive attitudes and good practices of health providers toward contraceptive use by adolescents and youth. The design questions for defining the variables were derived from the literature review of studies conducted in Nigeria, Botswana, and Ethiopia (12, 21, 25).

Providers' positive attitudes were defined based on 10 questions on providers' attitudes toward contraceptive use by adolescents and youth. Measurement was done by Likert scales of 0 to 4 points with 0 corresponding to strongly disagree and 4 to strongly agree (26). Providers who scored at or above the mean of 26 out of 40 were considered to have a positive attitude toward contraception for adolescents and youth. Those with a score below the average were considered to have a negative attitude.

Providers' good practices were defined based on three questions for which a Likert scale ranging from 0 (never) to 4 (always) was also used. Providers, who gave positive answers to all the questions, i.e., often, or always prescribe and counsel methods to adolescents and youth and never scold them when they expressed the need to use a contraceptive method, were classified as having good practices. Conversely, those who did not give positive answers to all three questions were classified as not having good practices.

Independent variables

The independent variables included the socio-demographic characteristics of providers of FP methods to adolescents and youth and their level of knowledge about FP. Socio-demographic characteristics included age (20–24, 25–34, 35–44, or 45 and over), sex (male or female), marital status (married/married or single/divorced/widowed), socio-professional category (medical doctor, midwife, nurse, nurse-assistant, or pharmacist), religion (Muslim or Christian), number of years of experience, ethnic group (Soussou, Peulh, Malinke, or Forestier), use of modern contraceptives, direct involvement in the provision of FP services, type of facility (public or private), and administrative region (Conakry, Kindia, Boké, Mamou, Labe, Kankan, Faranah, or Nzerekore), and training on FP in the past 12 months.

Knowledge variables (defined as a good level of Knowledge about modern contraceptive use among adolescents and youth) included having high confidence in prescribing contraceptive methods to adolescents and youth; high confidence in explaining contraceptive methods to adolescents and youth; Knowledge of the existence of FP policy and legislation for adolescents and youth, and Knowledge of the rights of adolescents and youth to receive FP before marriage). Confidence variables were measured using a scale ranging from 1 (very poor) to 5 (very good). Those who had four or five scores were classified

considering as having high confidence toward prescribing or explaining contraceptive methods to adolescents and youth.

Data analysis

Descriptive variables were presented as means (with standard deviations) and proportions (with 95% confidence intervals). Knowledge, attitudes, and practices of health care workers were described as proportions. Factors associated with health care workers' attitudes and practices were then analyzed using logistic regression. Multi-collinearity was checked before including the independent variables in the regression model.

Unadjusted and adjusted odds ratios were then calculated with 95% confidence intervals. The significance level was set at 5%. Data were analyzed using Stata 16.0 software (StataCorp 4905 Lakeway Drive College Station, Texas 77845 USA).

Results

Socio-demographic characteristics of participants

Table 1 presents the socio-demographic characteristics of providers surveyed about contraceptive use among adolescents and youth.

One thousand seven hundred seven ($n = 1,707$) health care providers were interviewed. One-quarter of them resided in Conakry ($n = 450$; 26.4%), and most were female ($n = 1,825$; 77.7%) and worked in public health facilities ($n = 1,406$; 82.4%). The mean age of the providers was 32 ± 8.4 . Midwives were the most represented socio-professional category in the sample ($n = 799$; 46.8%).

In addition, most participants were married or in union ($n = 1,199$; 70.2%) and Muslim ($n = 1,205$; 70.6%), the majority of providers interviewed ($n = 1,170$; 68.5%) had previously used a modern contraceptive method and were directly involved in providing contraceptive services in public health facilities ($n = 1,421$; 83.2%).

Providers' self-reported confidence in providing FP to youth and awareness of the policy framework

Table 2 shows providers' self-reported confidence in providing FP to youth and knowledge of relevant policies. Most providers reported being confident in explaining the mode, duration of action, advantages, and disadvantages of contraceptive methods ($n = 1,428$; 83.7%) and in prescribing a contraceptive method ($n = 1,407$; 82.4%) to adolescents and youth. The majority of participants reported being aware of the

TABLE 1 Demographic characteristics of surveyed providers on contraception use among adolescents and youth, Guinea, January–March 2021 ($n = 1,707$).

Variables	Number	%
Average age (ET)	32 ± 8.4	
Age group		
20–24 years	252	14.8
25–34 years	928	54.4
35–44 years	369	21.6
45 years and more	158	9.3
Gender		
Female	1,406	82.4
Male	301	17.6
Professional category (IQ)		
Medical doctor	213	12.5
Midwife	799	46.8
Nurse	287	16.8
ATS	361	21.1
Pharmacist	47	2.8
Work experience in FP	4.1 ± 1.2	
Marital status		
Married/in union	1,199	70.2
Single/divorced/widowed	508	29.8
Religion		
Muslim	1,205	70.6
Christian	502	29.4
Ethnic group		
Malinke	515	30.2
Peulh	458	26.8
Forestier	553	32.4
Soussou	181	10.6
Ever use of FP by the provider		
No	537	31.5
Yes	1,170	68.5
FP training in the last 12 months		
No	1,008	59.1
Yes	699	40.9
Type of facility		
Public	1,421	83.2
Private	286	16.8
Nature of facility		
Hospital/CMC	457	26.8
HC/HP	957	56.1
Clinic	293	17.2
Natural region		
Conakry	450	26.4
Lower Guinea	257	15.1
Upper Guinea	517	30.3
Middle Guinea	195	11.4
Forest Guinea	288	16.9

TABLE 2 Providers' knowledge of contraceptive use among adolescents and youth, Guinea, January-March 2021 ($n = 1,707$).

Variables	Number	%
Confident in explaining FP methods to adolescents/youth		
Low confidence	279	16.3
High confidence	1,428	83.7
Confidence in prescribing FP methods to adolescents/youth		
Low confidence	300	17.6
High confidence	1,407	82.4
Knowledge of the existence of adolescent FP policy and legislation in Guinea		
No	716	41.9
Yes	991	58.1
Knowledge of the right of adolescents/youth (15–24 years) to receive FP before marriage		
No	151	8.8
Yes	1,556	91.2

existence of FP legislation policies for adolescents and youth in Guinea ($n = 991$; 58.1%), as well as the right of adolescents and youth aged 15–24 to receive contraception before marriage ($n = 1,556$; 91.2%).

Providers' attitudes about contraceptive use among adolescents and youth

Table 3 displays providers' attitudes about contraceptive use among adolescents and youth. Most providers surveyed agreed that health care staff should provide contraceptive services to married and unmarried adolescents and youth in facilities ($n = 11,391$; 81.5%) and that adolescents and youth should receive contraceptive counseling before becoming sexually active ($n = 1,519$; 89.0%). In addition, more than half of the providers surveyed agreed that unmarried adolescents and youth do not need parental consent before receiving contraceptives ($n = 937$; 54.9%). On the other hand, half of the providers interviewed were opposed stating that adolescents or unmarried youth should not receive contraceptives because their culture does not support premarital sex ($n = 904$ 53.0%) and that it is better to tell adolescents and youth to abstain from sex when they ask for contraceptives rather than provide them ($n = 1,030$; 60.3%). Furthermore, two-thirds of participants felt that it is not immoral for adolescents and youth to use contraceptives ($n = 1,146$; 67.1%) and that their religion allows their use ($n = 835$; 48.9%). Overall, about six out of ten providers (61.6%) had positive attitudes toward the use of modern contraceptive methods by adolescents and youth.

Provider practices regarding contraceptive use among adolescents and youth

Table 4 presents providers' practices regarding FP service use by adolescents and youth. Providers who prescribed contraceptives to adolescents and youth predominated in our study ($n = 890$; 52.1%). Most of them reported that they counsel advise adolescents and youth on the use of contraceptives ($n = 1,185$; 69.4%) and that they never scold adolescents and youth when they ask for contraceptives ($n = 1,368$; 80.1%). Providers who gave positive responses to all three questions were classified as having "good" practices regarding contraceptive provision to adolescents and youth. Overall, two in five (41.4%) were thus classified.

Factors associated with providers' attitudes and practices regarding contraceptive use among adolescents and youth

Table 5 presents factors associated with providers' attitudes about contraceptive use among adolescents and youth.

The bivariate analysis showed statistically significant associations between providers' positive attitude toward the use of modern contraceptive methods by adolescents and youth and the following variables: age, socio-professional category, and experiences in the provision of FP services, religion, ethnic group, and type of facility and region of residence.

However, after adjustment using logistic regression, only age, socio-professional category, number of years of experience in the provision of FP services, ethnic group, and region of residence were statistically significantly associated with providers' positive attitude toward the use of modern contraceptive methods by adolescents and youth. Indeed, compared to young providers (20–24 years), those aged 25–34 years (aOR: 1.68, 95%CI: 1.24–2.26), 35–44 years (aOR: 2.05, 95%CI: 1.41–2.98) and 45 years and older (aOR: 2.35, 95%CI: 1.32–4.17) were respectively 1.7–2.4 times more likely to have a positive attitude toward the use of modern contraceptive methods by adolescents and youth. Midwives (aOR: 1.39, 95%CI: 1.02–1.89) were 1.39 times more likely to have a positive attitude than another professional category. Providers residing in lower Guinea (aOR: 1.48, 95%CI: 1.05–2.07), Middle Guinea (aOR: 1.47, 95%CI: 1.01–2.15), Forest Guinea (aOR: 2.73, 95%CI: 1.84–4.04) and Upper Guinea (aOR: 2.67, 95%CI: 1.92–3.71) had better attitudes toward the use of modern contraceptive methods by adolescents and youth compared to providers in Conakry. Positive provider attitude increased significantly by 5% for each additional year of experience ($p = 0.003$).

TABLE 3 Providers' attitudes about contraceptive use among adolescents and youth, Guinea, January–March 2021 ($n = 1,707$).

Variables	Disagreeing (%)	Neutral (%)	Agreeing (%)
I am comfortable with prescribing contraceptives for adolescents and youth	121 (7.1)	57 (3.3)	1,529 (89.6)
Health personnel should provide contraceptive services to married and unmarried adolescents and youth in facilities	252 (14.8)	64 (3.7)	1,391 (81.5)
Adolescents and youth should receive counseling on contraception before becoming sexually active	160 (9.4)	28 (1.6)	1,519 (89.0)
Unmarried adolescents and youth should not have parental consent before receiving contraceptives	633 (37.1)	137 (8.0)	937 (54.9)
My religious belief influences the way I prescribe contraceptives	898 (52.6)	149 (8.7)	660 (38.7)
Giving contraceptives to teens or unmarried youth can promote sexuality	516 (30.2)	138 (8.1)	1,053 (61.7)
Teenagers or unmarried youth should not be given contraceptives because our culture does not support premarital sexual intercourse	904 (53.0)	139 (8.1)	664 (38.9)
It is better to tell adolescents and youth to abstain from sexual intercourse when they ask for contraceptives than giving them contraceptives	1,030 (60.3)	117 (6.9)	560 (32.8)
My religion does not allow the use of contraception by unmarried adolescents and youth	835 (48.9)	148 (8.7)	724 (42.4)
It is immoral for adolescents and youth to use contraceptives	1,146 (67.1)	132 (7.7)	429 (25.1)

TABLE 4 Provider practices regarding contraceptive use among adolescents and youth, Guinea, January–March 2021 ($n = 1,707$).

Variables	Never	Rarely	Always
Prescription contraceptives to adolescent and youth	139 (8.1)	678 (39.7)	890 (52.1)
Counseling adolescents and youth on the use of contraceptives	105 (6.2)	417 (24.4)	1,185 (69.4)
Scolding adolescents and youth when they ask for contraceptives	1,368 (80.1)	209 (12.2)	130 (7.6)

The bivariate analysis in Table 6 shows statistically significant associations between provider practices and the following variables: age, gender, socio-professional category, ethnic group, provider use of FP, type of facility, positive attitude of health providers, number of years of experience, and region of residence.

After adjustment, only socio-professional category, ethnic group, number of years of experience in the provision of FP services and region of residence, and providers' positive attitude were significantly associated with good provider practice in offering modern methods to adolescents and youth. Physicians (aOR: 2.37, 95%CI: 1.04–5.42) were twice as likely to have good practice compared to pharmacists. Ethnic group Malinke (aOR: 1.50, 95%CI: 1.09–2.06) were about 1.5 times more likely to have good practices compared to Peulh ethnic group.

Providers residing in lower Guinea (aOR: 4.50, 95%CI: 3.06–6.62), Upper Guinea (aOR: 2.98, 95%CI: 2.08–4.27) were more favorable in offering modern contraceptive methods services to adolescents and youth compared to providers in Conakry. Having good practice to provide modern contraceptive method services was significantly associated with positive provider attitude toward adolescents and young (aOR: 3.16, 95%CI: 2.48–4.01). In addition, favorable practice increased significantly by 7% for each additional year of experience ($p < 0.001$) in providing modern method service delivery to adolescents and young.

Discussion

This study is one of the first to explore FP providers' knowledge, attitudes, and practices with regard to adolescents and youth and their determinants in Guinea.

The data from the survey of providers' attitudes and practices regarding the provision of FP counseling and services to adolescents and youth revealed a degree of tension between personal moral beliefs and perceived obligation or duty to provide services. Substantial minorities (close to 40%) of providers thought that teenagers and unmarried youth should abstain from sex and that contraceptive use by them was immoral and contrary to religious beliefs and cultural norms. A majority thought that provision of contraception would only encourage sexuality. Yet close to 90% were aware of the right of young people to receive family planning advice and services and over 80% agreed that health personnel should provide contraceptive services to unmarried as well as married

TABLE 5 Factors associated with provider attitudes toward contraceptive use among adolescents and youth, Guinea, January–March 2021 (*N* = 1,707).

Variables	cOR	IC95%		p-value	aOR	CI95%		p-value
		Lower	Upper			Lower	Upper	
Age group								
20–24 years	Ref.				Ref.			
25–34 years	1.77	1.34	2.35	<0.001	1.68	1.24	2.26	0.001
35–44 years	2.49	1.79	3.46	<0.001	2.05	1.41	2.98	<0.001
45 years and more	3.29	2.13	5.08	<0.001	2.35	1.32	4.17	0.004
Gender								
Female	1.14	0.89	1.47	0.309				
Male	Ref.							
Professional categories								
Medical doctor	0.97	0.68	1.38	0.857	1.15	0.77	1.73	0.502
Midwife	1.34	1.02	1.76	0.038	1.39	1.02	1.89	0.038
Nurse	Ref.				Ref.			
ATS	1.26	0.92	1.72	0.159	0.95	0.67	1.34	0.765
Pharmacist	0.93	0.50	1.73	0.815	0.95	0.49	1.86	0.890
Experience (Average)	1.07	1.04	1.09	<0.001	1.050	1.020	1.080	0.003
Marital status								
Married/in union	1.12	0.91	1.39	0.283				
Single/divorced/widowed	Ref.							
Religion								
Muslim	Ref.				Ref.			
Christian	2.15	1.71	2.70	<0.001	1.18	0.71	1.96	0.521
Ethnic groups								
Malinke	1.28	0.99	1.65	0.057	0.98	0.74	1.32	0.912
Peulh	Ref.				Ref.			
Forestier	2.58	1.98	3.35	<0.001	1.69	1.01	2.85	0.047
Soussou	1.25	0.88	1.77	0.210	1.31	0.90	1.90	0.688
Ever use of FP by the provider								
No	Ref							
Yes	0.99	0.80	1.22	0.888				
FP training in the last 12 months								
No	Ref							
Yes	1.10	0.83	1.23	0.931				
Type of facility								
Public	1.50	1.16	1.94	0.002	0.94	0.70	1.26	0.688
Private	Ref.				Ref.			
Natural region								
Conakry	Ref.				Ref.			
Lower Guinea	1.53	1.12	2.09	0.007	1.48	1.05	2.07	0.023
Upper Guinea	2.15	1.66	2.80	<0.001	2.67	1.92	3.71	<0.001
Middle Guinea	1.13	0.81	1.58	0.478	1.47	1.01	2.15	0.047
Forest Guinea	2.92	2.11	4.03	<0.001	2.73	1.84	4.04	<0.001

young people. Similar high proportions expressed confidence in counseling and service provision to young people and only 15% admitted that they sometimes or often scolded young people when they requested contraceptives.

Interpretation of these findings should be cautious because of the danger that responses may have been influenced by social desirability bias. Yet it does appear probable that most providers with moralistic reservations about premarital sex and

TABLE 6 Factors associated with providers' good practices in prescribing contraceptive methods to adolescents and youth, Guinea, January-March 2021, (N = 1,707).

Variables	cOR	IC95%		p-value	aOR	CI95%		p-value
		Lower	Upper			Lower	Upper	
Age group								
20–24 years	Ref.				Ref.			
25–34 years	1.63	1.20	2.20	0.002	1.28	0.90	1.82	0.171
35–44 years	2.12	1.51	2.98	<0.001	1.23	0.80	1.89	0.339
45 years and more	3.80	2.50	5.78	<0.001	1.77	0.97	3.24	0.065
Gender								
Female	1.34	1.03	1.73	0.027	1.19	0.81	1.75	0.376
Male	Ref.				Ref.			
Professional categories								
Medical Doctor	1.86	0.91	3.79	0.087	2.37	1.04	5.42	0.041
Midwife	2.70	1.38	5.28	0.004	2.20	0.99	4.90	0.054
Nurse	1.23	0.61	2.48	0.568	1.23	0.55	2.75	0.623
ATS	1.98	0.99	3.94	0.052	1.63	0.72	3.68	0.239
Pharmacist	Ref.				Ref.			
Experience	1.1	1.08	1.12	<0.001	1.07	1.04	1.1	<0.001
Marital status								
Mary/in union	1.13	0.91	1.39	0.269				
Single/divorced/widowed	Ref.							
Religion								
Muslim	Ref.				Ref.			
Christian	0.87	0.70	1.08	0.204	0.92	0.56	1.52	0.743
Ethnic group								
Malinke	170	1.32	2.21	<0.001	1.50	1.09	2.06	0.013
Peulh	Ref.				Ref.			
Forestier	1.27	0.98	1.64	0.069	1.50	0.89	2.55	0.131
Soussou	1.48	1.04	2.09	0.030	1.18	0.78	1.79	0.436
Use of FP by the provider								
No	Ref.				Ref.			
Yes	1.53	1.24	1.89	<0.001	1.17	0.90	1.52	0.233
FP training in the last 12 months								
No	Ref.				Ref.			
Yes	1.19	0.98	1.44	0.085	1.04	0.83	1.30	0.742
Type of facility								
Public	1.56	1.20	2.04	0.001	0.92	0.66	1.28	0.637
Private	Ref.				Ref.			
Natural region								
Conakry	Ref				Ref.			
Lower Guinea	4.36	3.14	6.04	<0.001	4.50	3.06	6.62	<0.001
Upper Guinea	2.86	2.19	3.72	<0.001	2.98	2.08	4.27	<0.001
Middle Guinea	0.93	0.64	1.34	0.701	1.25	0.90	1.93	0.327
Forest Guinea	0.66	0.47	0.92	0.017	0.59	0.39	0.91	0.018
Positive attitude								
No	Ref.				Ref.			
Yes	3.16	2.55	3.91	<0.001	3.16	2.48	4.01	<0.001

contraception do manage to put aside their personal feelings when confronted by young people requesting FP advice and services. This verdict is supported by results from the 2018 DHS in which over 40% of sexually active single women aged 15–24 reported use of injectable or implants (7), both methods that require a visit to a health facility and attention from a trained provider.”

Factors simultaneously associated with positive attitudes and good practices among providers in this study included socio-professional category, number of years of experience in delivering contraceptive services, and region of residence. In addition, provider age was associated with positive provider attitudes in delivering modern methods to adolescents and youth.

About four out of five health care providers were aware of national policies and rights regarding provision of modern contraceptive use among adolescents and youth. The majority (83.7%) reported being confident in explaining the mode, duration of action, advantages, and disadvantages of contraceptive methods to adolescents and youth. Our results are consistent with those of Tshitenge et al. (21) in Botswana, who found that 91.2% of providers felt confident in explaining to adolescents how to use contraceptive methods. There are several possible explanations for this result. In recent years, considerable efforts have been made to improve the availability and use of contraceptive methods by the population, particularly adolescents and youth. For example, the national FP repositioning plan (2014–2018) aimed, among other things, to stimulate the delivery of FP services in all health facilities, including private ones; as well as to strengthen the training program and the equipment of private and public health facilities (27). The effects of these strategies, including the repositioning plan, could explain the level of knowledge of the providers interviewed in our study. In addition, most of the providers interviewed aged were less than 35 years and had a qualifying medical education. This could also explain their good level of knowledge and confidence in explaining the mode, duration of action, advantages, and disadvantages of contraceptive methods to adolescents and youth.

Even most providers had a positive attitude toward the use of modern contraceptive methods by adolescents and youth, some of them had social considerations that might influence their practices in providing FP services to adolescents and youth. Other studies have also revealed the presence of important contextual and social norms that lead to health providers negative attitudes toward the delivery of modern method contraceptive services to adolescents and youth (12, 13, 15–17, 21).

More than one-third (39%) of the providers felt that unmarried youth should not receive contraceptives because their culture does not support premarital sex. Nearly one out of four providers felt that it was immoral for adolescents and youth to use contraceptives. These results corroborate the findings

of Nalwadda et al. in Uganda and Ahanonu in Nigeria, who reported that more than one-third of maternal and reproductive health providers said they would not provide contraceptives to unmarried, school-going, and childless people under age 18 because of social norms (12, 17). Health care providers may believe that they owe adolescents and unmarried youth a duty to protect them from sexual practice. However, this perception does not match reality, as evidenced by the high rates of sexual activity, sexually transmitted infections, and unwanted pregnancies and their implication for school dropout among this group. This negative attitude of health care providers is a major challenge to national efforts to ensure young people's right to sexual health, to protect their lives and their future. Positive attitudes among health care providers are a key element in improving contraceptive use among adolescents and youth. It is important that attitudes against contraceptive use by sexually active adolescents and youth be revised to reflect the realities of their sexuality. For example, sexual abstinence should be encouraged by providers for those adolescents and youth who are ready to practice it. For those who are sexually active and want to use contraceptives, access to contraceptive services should not be confronted with religious considerations, as it is better to prevent unwanted pregnancies and STIs than to face the consequences that may result. Only two in five providers had good practices regarding contraceptive use by adolescents and youth. This result is similar to those of other authors in Uganda (17, 28). This result could be explained by the persistence of the weight of socio-cultural factors such as religious beliefs on health care providers in delivering FP services.

Our results showed that being a midwife, having several years of professional experience, and residing in the Lower, Upper, middle, and Forest Guinea regions were simultaneously associated with positive attitudes and good provider practices toward modern contraceptive use by adolescents and youth. This result corroborates that of other authors in Nigeria (12) and in South Africa (29, 30) who argue that providers' region of residence, socio-professional category, and years of experience influence their attitudes and practices toward delivering FP services to adolescents. The simultaneous association of professional experience with positive attitudes and good practices could be explained by the acquisition of skills and confidence over the years in providing health services to adolescents and youth. The association of midwifery with positive attitudes and good practices regarding the use of modern contraceptive methods by adolescents and youth is explained by the frequent exposure of this group of providers to training on sexual and reproductive health issues, including among adolescents and youth.

The study also showed that the likelihood of having positive attitudes toward the use of modern contraceptive methods by adolescents and youth increased with provider age. This finding supports our initial observations of a positive relationship between increasing years of work experience and positive

provider attitudes. It also corroborates the findings of Jonas et al. in South Africa, who found a positive association between the number of years of experience of health workers and their likelihood of providing maternal and child health services to adolescents (30). This result can be explained by the fact that the older the health worker, the more he or she is exposed to realities that influence his or her perceptions of adolescent contraception.

Our study also finds a positive association between gender, midwives' socio-professional category, and a positive provider attitude. Our results are consistent with those of Jonas et al. in South Africa, who found that years of experience as a nurse or midwife were associated with stronger intentions to provide FP services to adolescents (30). Furthermore, midwives are the ones most involved in the provision of contraceptive methods and therefore are exposed over time to training and work experience that improves their practices. Another explanation for the association between female gender and a positive provider attitude may be that women are more predisposed to understanding the needs of adolescents for birth control once they are sexually active, particularly when they are unmarried.

In addition, providers living in the countryside had better attitudes toward using modern contraceptive methods by adolescents and youth than providers in Conakry. The reason for this finding remained speculative. One possible reason is that health system actors put substantial efforts in improving health indicators in rural and remote areas, thereby neglecting health personnel capacity-building needs in the Capital. Further studies are needed to understand the underlying reasons for this finding.

Our results also showed that being a medical doctor and having several years of professional experience were significantly associated with provider practices in delivering modern methods to adolescents and youth. Medical doctors were also more likely to have good practices regarding the use of contraceptive methods by adolescents. This would be especially important if they are involved in providing reproductive health services in general. Our result would be explained by the fact that medical doctors are the ones who face the most serious consequences of adolescents' unmet need for contraception, such as complications from clandestine abortion. Paul et al. (30) in Uganda found that, beyond considerations for existing socio-cultural values of chastity, health personnel involved in delivering FP services had a better understanding of the vulnerability of girls and the consequences of adolescent pregnancy, and especially when they are unmarried.

Limitations

Our study has some limitations that are inherent in any cross-sectional study. First, the cross-sectional nature of the study does not allow for a temporal relationship between the independent variables and the outcome of

interest. Second, there is the possibility of social desirability bias that may lead to an overestimation of the level of good attitudes and practices in the delivery of FP services to adolescents and youth. However, the study has the advantage of using a sample that includes health personnel involved at several levels in the delivery of FP services to adolescents. It also has the advantage of having attempted to understand the factors that may influence the attitudes and practices of FP service providers for adolescents and youth in Guinea.

Conclusion

Knowledge, attitudes, and practices of health care providers affect the delivery of FP services to adolescents and youth in Guinea. Most health care providers were confident in explaining their use, advantages, and disadvantages to adolescents and youth. However, a disparity exists between the level of Knowledge of health care providers and their attitudes and practices toward delivering FP services to adolescents and youth. Factors concurrently associated with positive attitudes and good practices of providers in this study included socio-professional category, number of years of experience in delivering contraceptive services, and region of residence. Future intervention programs should focus on training health care providers in youth- and adolescent-friendly reproductive health services and on popularizing regulations for adolescent contraception. This intervention should also include developing and implementing a continuing education program on the provision of contraceptive services for health providers who are nurses and midwives and have less than two years of experience in contraceptive provision. Additional efforts will also be needed to improve the attitudes and practices of health care providers toward the delivery of FP services in Guinea. Health care providers' attitudes should be based on the sexual realities of adolescents and youth. Further studies are needed to understand the underlying reasons for the health providers attitudes toward using modern contraceptive methods by adolescents and youth.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by National Committee of Ethics for Health Research in Guinea (No: 045/CNERS/19). Written informed consent to participate in this study was provided by the participants prior to participating in the study.

Author contributions

SS, AD, DK, BSC, and SK designed the study and developed the study protocol. SS, FMG, and AD designed the analysis plan. SS, DK, and FMG, performed the data analyses, interpreted the results, and the manuscript was drafted by SS with critical inputs from DK, SK, BSC, and AD. All authors critically revised and approved the final manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Community health workers' involvement in mother–child care during the 1st year after birth, in Kaya health district, Burkina Faso: A contribution analysis

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Introduction: Maternal and infant morbidity and mortality remain high in sub-Saharan Africa. However, actions to strengthen postpartum care are still weak and mainly limited to health facilities (HFs). In Kaya health district, Burkina Faso, community health workers (CHWs) were involved in mother and child care during the 1st year postpartum through home visits, outreach sessions and accompanying mothers to health facilities. The aim of this study was to assess the contribution of CHWs to postpartum women's attendance at the health facilities.

Methods: We conducted an effect assessment using Mayne and Lemire's contribution analysis framework. Qualitative and quantitative data were collected through project documents review and individual semi-structured interviews with key-informants.

Results: All the participants interviewed acknowledged that the number of women, who came to postpartum care, had increased since the implementation of the project activities. Postpartum consultation rates within the 1st week postpartum increased from 29% in 2011 to 80% in 2015 and from 19 to 50% within 6 weeks. Others interventions such as Performance based financing, Save The Children nutritional project and the health services component of Missed Opportunities in Mother and Infant Health (MOMI) were the alternative explanations.

Conclusions: CHWs involvement in women care contributed to improve their adherence to postpartum consultations in Kaya health district.

KEYWORDS

mother-child care, contribution analysis, community involvement, postpartum care, community health worker (CHW)

Introduction

Maternal and infant morbidity and mortality remain high in the world and particularly in sub-Saharan Africa. In 2017, the number of women who died from pregnancy or delivery complications was estimated at 295,000 (1).

Almost all maternal deaths (94%) occur in developing countries and most could have been prevented. Sub-Saharan Africa and Southern Asia accounted for approximately 86% (254,000) of the estimated global maternal deaths in 2017. Sub-Saharan Africa alone accounted for roughly two-thirds (196,000) of maternal deaths, while Southern Asia accounted for nearly one-fifth (58,000) (1).

Although most maternal deaths occur between the third term of pregnancy and the 1st week after childbirth, women still face a high death risk beyond 6 weeks postpartum (2, 3).

In 2013, in sub-Saharan Africa, 17.6% of maternal deaths occurred in the intrapartum period and within the 24 h following delivery, 47.8% between 24 h and the 42nd day. Some women (13.1%) died from postpartum complication between the 43rd day and a year after delivery (4).

Despite a clear pattern of mortality and morbidity during the postpartum period, actions to improve postpartum care remain poor and are mostly implemented at the health facility level, sometimes not including the communities (3).

However, since the Alma Ata conference, communities have been largely involved in the health systems in most developing countries through community health workers (CHWs).

Studies on community involvement in the improvement of maternal and child health in general, and specifically in the postpartum period, have already been conducted in several countries through different approaches (2, 4–7). The evaluation of these programs has shown that CHWs can contribute to community health development by acting as a bridge between the community and health services.

However, most of these evaluations have focused on the effectiveness, feasibility (8, 9) or impact of these programs (10). Few impact evaluation studies have examined the context and mechanisms that led to the observed results (11, 12). In addition, the majority of these evaluations used counterfactual elements or control vs. intervention groups to attribute an observed result to a given program (13). However, in complex interventions, it is often difficult to fully attribute observed effects to the intervention (14–17). It would therefore be interesting to determine the contribution of each component of an intervention or a programme to the achievement of the obtained results, in order to optimize and improve strategies for public health interventions (11, 12, 14).

Missed Opportunities in Mother and Infant Health (MOMI) project was implemented in four countries of sub-Saharan Africa, including Burkina Faso in 2011 for 5 years; the project aimed at improving maternal and child health with a focus on

the year following birth through two components, community and health services.

Our study aims to analyse the effect of the intervention of community health worker as component of the MOMI project in the Kaya health district in Burkina Faso, by using a mechanistic approach rather than a counterfactual one.

The specific aims of this study are to analyse the contribution of CHW involvement in the achievement of the effect, in particular the attendance of health facility in postpartum women; to identify the factors that have contributed to or limited women's access to postpartum health services; and to identify elements of the intervention that contributed to health facility attendance by women during one the year after birth.

Description of the MOMI project

The Missed Opportunities in Maternal and Infant Health (MOMI) project is funded by the European Union and implemented in four African countries: Kenya, Malawi, Mozambique and Burkina Faso. In Burkina Faso, the project was implemented in 12 health facilities in Kaya health district, including eight rural and four urban HF. These 12 health facilities were selected based on the low rate of postpartum consultation and their location in the Kaya health demographic site (Kaya HDSS) (18). The objective of the MOMI project at the community level was to improve maternal and child health through women's adherence to postpartum consultations. Through the involvement of the CHWs, the project aimed at increasing the rate of postpartum consultations in these 12 health facilities. These CHWs were the same individuals selected by the community and were already working in collaboration with health workers. They were involved in health promotion and their routine activities were only focused on pregnant women (accompany some women for delivery, home visit...) but were not interested in postpartum women.

MOMI project introduced activities for postpartum women and their child (home visit, outreach sessions, reference of mother/child to HF and accompaniment for postpartum consultation). However, because of the context, only female CHWs were involved in MOMI project activities. These CHWs were trained during 3 days and retrained annually until the end of the project. Using picture boxes, the training focused on prenatal consultations, assisted deliveries, family planning, post-natal consultations, recognition of danger signs in mothers and children, the tasks of CHWs in the MOMI project, and data collection tools for CHWs.

The MOMI project included three intervention components selected through a participatory process. One component was implemented at the community level; specifically, the support of the mother-infant by the CHWs in the 1st year following delivery. The other two interventions were implemented at the health facility level—specifically, improved immediate

postpartum care and integration of maternal and infant health services (19).

At the community level, each CHW had to carry out three home visits to any mother and infant in her coverage area during the 1st year following delivery. The first one was before the 10th day from the delivery, the second visit was between the 6th and the 8th weeks and the last visit was between the 9th and the 12th months.

These home visits corresponded to the different periods of postpartum consultation or immunization at the health facility level. In our context, according to the ministry of health schedule, the first postpartum visit occurs between the 6th and 8th day after delivery and the second between the 6th and 8th week. Vaccination against measles takes place between the 9th and the 12th month.

During home visits, the CHW had to take care of both mother and child, look for signs of danger and refer if necessary. They must also refer home delivery women to the HF. Depending on the visit time period, using a picture box, the CHW also carried out outreach sessions on the signs of danger, family planning, and the importance of postpartum consultations, etc. Outreach sessions were carried out in households, at HFs, during wedding or baptism ceremonies, or during any other activity involving a group of women.

As much as possible, the CHW was to accompany the woman to the health facility for postpartum consultations.

The project was initiated in 2011 with a situational analysis. After the stakeholders training, the implementation of activities at the community and health facility level began in September 2013 and ended in December 2015.

CHWs were supervised 1 month after the training and then every 3 months until the end of the project. This supervision was led by the project team in collaboration with the Kaya health district management team.

The project opted for a non-financial motivation, CHWs were not provided any incentives for carrying out the activities. They received bicycles at the project beginning and during each supervised session, meeting and training, they were compensated with a daily subsistence allowance and transportation fees. They received certificates of participation at the end of the project.

Materials and methods

Study setting

The MOMI project was implemented in the Kaya health district, which is located in the Center Nord health region of Burkina Faso. The health district of Kaya covers 342 villages and seven urban areas. This district is centered on a regional hospital center (CHR) with 60 health facilities, including 54

health and social promotion centers (CSPSs) and a central private medical center with surgical satellite facilities (CMA). Kaya Health District is a pilot site for several reproductive health interventions, but reproductive health indicators remain low (18).

At the community level, there are two CHWs per village, usually a man and a woman responsible for carrying out health promotion activities and malaria case management, diarrhea, etc.

Study design

We carried out multiple case study design using a mixed method approach (qualitative and quantitative). The cases were the sites where the intervention was implemented. The cases chosen are contrasted according to location (urban vs. rural) and performance (low vs. high). The indicators used for the performance classification were: « Proportion of mother/infant pair who received postpartum care at the health facility », « Proportion of mother/infant pair who received CHWs home visit ». We mobilized longitudinal quantitative data, cross-sectional qualitative data and document review. The qualitative study was conducted from June to September 2015.

Sampling approach and sample size

The sample for the quantitative study included all 12 study sites that were selected for intervention implementation, based on maternal health indicators in the Kaya health district. All the 72 CHWs involved in the MOMI project were also included. The present study focused on the community level component of the MOMI project.

For qualitative study, we use purposeful sampling to select four cases sites taking into account geographical variation and implementation degree. So, two sites with low implementation effectiveness and two with high were selected. As many of providers as possible were interviewed with the objective of interviewing at least two per health facility. In addition, a minimum of two community health workers assigned to each facility and a minimum of three women postpartum, one who had delivered in the facility, one who had delivered at home and one who was attending for infant vaccination were also interviewed. The numbers of interviewees determined aimed to sample with maximum diversity whilst minimizing the number to what was feasible in terms of research capacity. In addition to the case study interviews, key members of the MOMI teams and other stakeholders who had been involved throughout the period of implementation were interviewed to track the process of implementation and identify barriers and facilitators along

the way. A more detailed overview of the data collection is available elsewhere (20).

As for saturation, we listened to some of interviews again to ensure that the information sought according to our objectives had been captured. In addition, we re-read notes taken during the interviews to ensure the completeness of the information.

Data collection

We collected non-concomitant quantitative and qualitative data.

Quantitative data

Quantitative data on CHW's activities and women postpartum attendance were collected quarterly by the research team through the tools put in place within the project framework: the ideogram, reference card, CHW diaries and postpartum care records. Data on women HF attendance concerned the period before and after the intervention in the 12 health facilities were collected monthly, 12 months before the implementation of the intervention (Sep 2012 to Aug 2013) and 27 months throughout the project (Sep 2013 to Dec 2015). CHWs' activities data were collected during the implementation period through CHW's diaries, referral cards, and report. Data were captured by the CHWs using diaries and then compiled by them through ideogram a kind of monthly record. These monthly report are compiled by research team every 3 months into Excel file.

The variables of interest were the proportion of home visits from a CHW, postpartum women accompanied to the HF for post-natal consultation, mother/child reference to health facility for danger sign, postpartum consultations in health facilities and the number of sensitizations.

Qualitative data

Qualitative data were collected by the researchers with master degree in sociology, through semi-structured interviews and document reviews. The interviews were conducted in French and Mooré (local language) at the HF level and in the policymaker's office, using an interview topic guide. They were all audio-recorded with participants' permission, lasting between 30 and 75 min.

The data sources for document review included supervision reports, policy advisory board (PAB) meeting minutes, stakeholder and community leader meeting minutes, the critical review of the policy report (Work package or WP2) (21), the situational analysis report (WP3) (22), the selection of interventions report (WP4) (19), and the event log.

Data analysis

Quantitative and qualitative data were analyzed separately. The themes that emerged from the qualitative analysis were compared with the quantitative data in the same facilities to determine the plausibility of the program theory given the data.

Theoretical framework

For our evaluation, we used the six steps of the contribution analysis framework proposed by Mayne, combined with Lemire's framework, the Relevant Explanation Finder (REF) (23).

Based on the observation that the rates of postpartum consultations had increased since the introduction of the MOMI project interventions in the Kaya health district, we developed cause-effect questions, which we would answer to throughout the analysis (Steps 1–3):

- Did the involvement of the CHW in the care of women and their children contribute to increasing the use of postpartum health services by women?
- Which factors contributed to or limited the use of health services by women during the postpartum period?
- What aspects of the intervention have contributed?

To answer these questions, we retrospectively developed the programme theory at the community level (Figure 1) and then tested the assumptions contained therein.

Then we used Lemire's framework, REF (steps 4, 5), to examine the mechanisms of change and to understand the influencing factors and alternative explanations. REF components are presented in Table 1.

Finally, we wrote the contribution story (Step 6), which is an iterative process of identifying the elements of the intervention that contributed to increase postpartum women's use of health services.

To reinforce the plausibility of the results of the contribution evaluation, our analysis focused on the two main assumptions used in the REF (Table 1). The conceptual framework of contribution analysis is represented in Figure 2.

Quantitative data

Quantitative data were entered using Epi data and analyzed with Excel 2007 and Stata 13 software. We realized descriptive statistical analyses. Women HF attendance was represented by monthly proportion of pair mother-child received at the HF for postpartum visit. The monthly proportion of mother-child who received CHW visit or accompaniment designed CHWs activities.

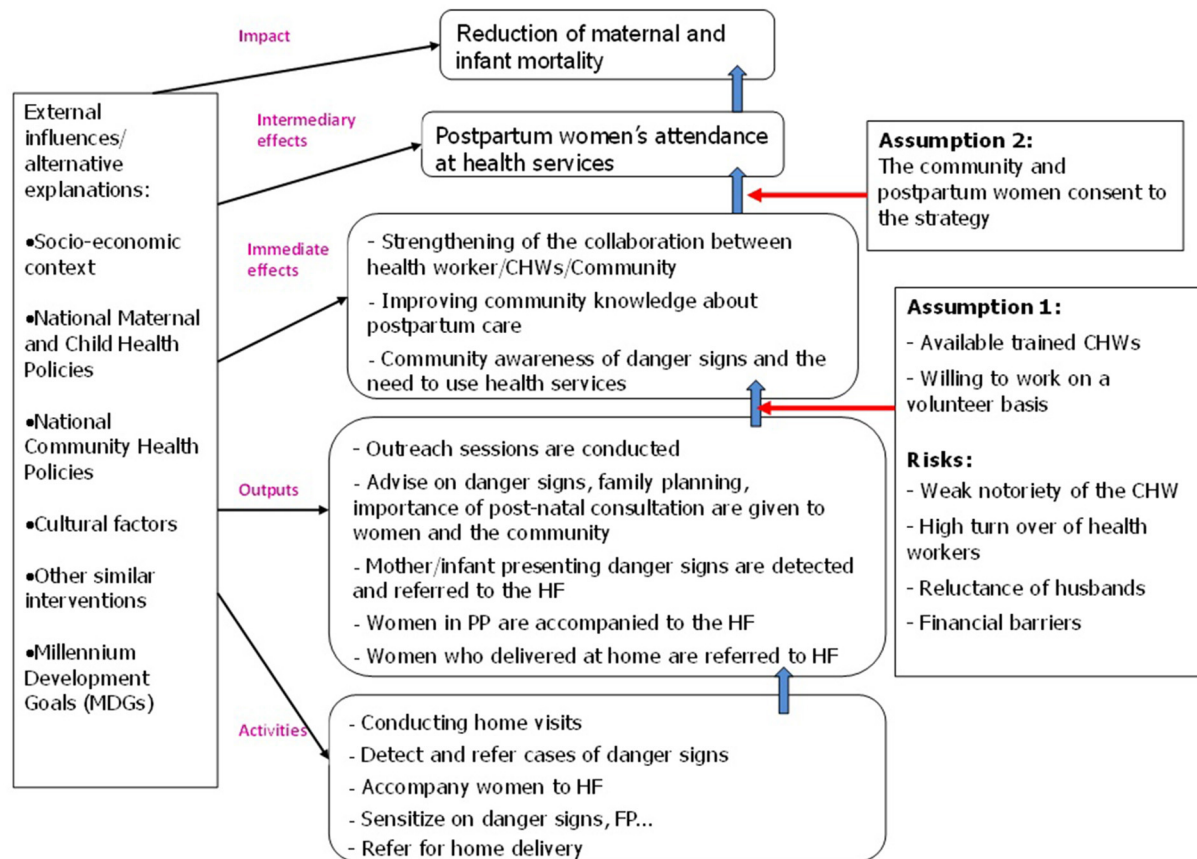


FIGURE 1

Logic model of the MOMI project at the community level. Adapted from Mayne's 2012 model, quoted by Stocks-Rankin.

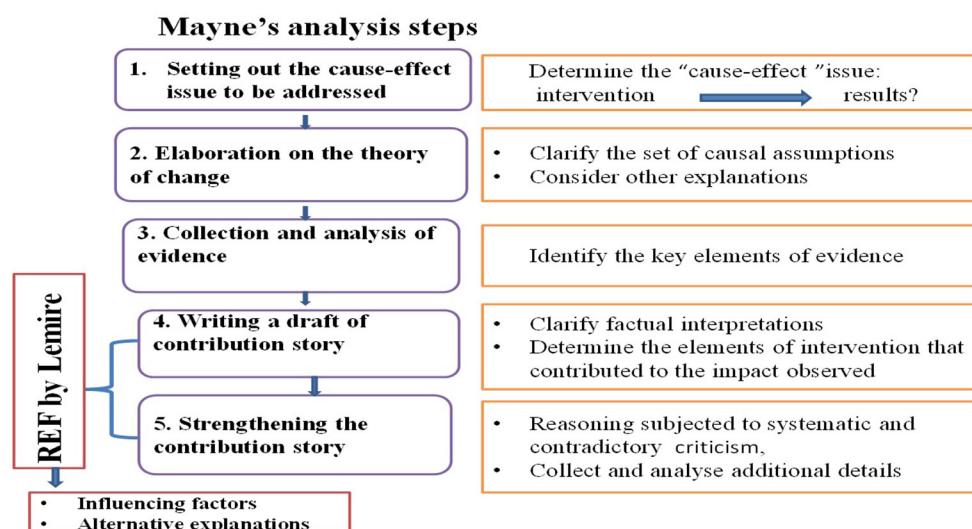


FIGURE 2

Conceptual framework: contribution analysis.

TABLE 1 Relevant explanation finder (REF).

Assumptions	Mechanism	Influencing factors/alternative explanations	Type of rival	Level	Degree of influence				
					Certainty	Robustness	Range	Prevalence	Evidence
Trained CHWs are available and agree to conduct home visits, outreach sessions and accompany women to HFs without being paid	Promotion activities led by CHWs boost their trust in the role they are playing for the improvement of PPCs	The participatory approach used by the project to select interventions and CHWs	Primary rival	Structural	High	High	High	High	High
	CHW support systems such as trainings, supervision and non-financial incentives build their capacities and encourage them to carry on their activities.	The adherence of CHWs and health workers to the project strategy	Primary rival	Individual	High	High	High	High	High
	The CHW is a community member; therefore, she can easily conduct home visits, and advise, she can be more trustworthy, and she can serve as link between the community and health facilities	Collaboration between CHWs and health workers	Primary rival	Interpersonal	High	High	High	High	High
		Motivation system adopted by the project	Commingle rival	Individual	Medium	High	Medium	Medium	High
		The educational level and social status of some CHWs	Direct rival	Individual	Low	Low	Low	Low	High
	The interventions are carried out in order to motivate community leaders to get more involved.	Cooperation of the Policy advisory board (PAB)	Implementation rival	Institutional	Medium	Medium	Medium	Medium	High
		Monitoring/assessment of the activities	Implementation rival	Institutional	High	High	High	High	High
		Mother and child health national policy	Implementation rival	Institutional	Medium	Low	Medium	Low	High
Women who delivered in the community are receptive to the advice given by CHWs; they understand and apply recommendations.	The CHW represents a link between the community and health service, which helps remove barriers such as fear and suspicion of the community toward health workers.	Postpartum women's attitude, enthusiasm and interest in postpartum care	Primary rival	Individual	High	High	High	High	High

(Continued)

TABLE 1 (Continued)

Assumptions	Mechanism	Influencing factors/alternative explanations	Type of rival	Level	Degree of influence				
					Certainty	Robustness	Range	Prevalence	Evidence
		Trust between the CHWs and women	Primary rival	Individual	High	High	High	High	High
	Women's adherence depends on their husbands or their mothers-in-law.	Weak decision-making power of women mainly in rural areas	Primary rival	Institutional	Medium	Medium	Medium	Medium	Medium
	Behavioral change is adopted when postpartum care is promoted within the community.	The low purchasing power of some women represents a financial barrier	Implementation rival	Individual	Medium	Medium	Low	Low	Medium
	Women who were supported by CHWs share their experience with other women.	Peer-to-peer education	Implementation rival	Individual	High	Medium	Medium	Medium	High
	Men are more receptive to men's or leaders' messages	Involvement of the community through community leaders and male CHWs	Implementation rival	Institutional	High	Medium	Medium	Medium	High
	The attendance at health facilities can be motivated by other interventions.	HF component with inclusion of care for mother and child.	Implementation rival	Institutional	High	High	Medium	Medium	High
		PBF with more involvement of health workers	Implementation rival	Institutional	Medium	Medium	Medium	Medium	High
		Food distribution by the project VIM to women who attend HF appointments	Implementation rival	Institutional	High	Medium	Medium	Medium	Medium

Qualitative data

All interviews were numerically recorded, then transcribed in verbatim by qualified transcribers. Each transcript was translated into French for those who were in local language, and coded with Nvivo 11 software by the researcher team. We performed a content analysis based on the themes from the conceptual framework (contribution analysis).

Findings were discussed and triangulated between research and evaluation team to identify influencing factors, alternative explanations and contribution elements. The contribution story was then written by a member of the research team. This narrative was then discussed iteratively among the research team, evaluators, and resource persons from health ministry to identify the real contributions of CHWs to women's use of health services.

To avoid conflict, researcher who conducted evaluation are different from those who conduct implementation.

The quantitative method measured the degree of implementation, and the qualitative method enabled us to assess the context and collect additional details on the degree of implementation through the document review and the interviews. Thus, by triangulation, the factors affecting the implementation, the alternative explanations and the elements of contribution were identified.

Results

Characteristics of the studied population

Of the 72 CHWs trained, 65 completed the activities to the end of the project. The majority of them lived in rural areas (84.6%) with a low level of education (66.2%) and used to accompany women to health facilities for childbirth prior to the installation of the MOMI project (61.5%). The average age was 47 (± 10) years. Length of service ranged from 3 to 32 years with an average of 11 (± 8) years.

A total of 49 participants were interviewed during the case study, including 13 CHWs, 13 postpartum women, 16 health workers, 04 policymakers, and 03 project team members in Burkina Faso. The health workers included four head nurses, three maternity officers, four Expanded Program on Immunization (EPI) officers, and five other staff. Among the rural participants were six postpartum women, five CHWs, and six health workers.

Contribution analysis (CA)

Applying Steps 1–3 of contribution analysis

The application of Steps 1 to 3 helped to define the causal issue, develop the theory of change, and gather evidence to

support the hypotheses made. The evidence collected at this step is the activities carried out by the CHWs and the use of postpartum services by women.

Intervention activities carried out by the CHW

The proportion of women giving birth who were visited by CHWs or accompanied to a health facility varied according to time period and setting ($>50\%$ in rural areas). Thus, 56.8% (6,633/11,675) of women received the first visit, 34.3% (3,999/11,675) the second visit and 9% (1,067/11,675) the third visit. [Figure 3](#) shows the evolution of home visits by month from September 2013 to December 2015. During the same period, respectively, 57.3% (3,803/6,633), 51.4% (2,056/3,999) and 32.5% (342/1,067) of women were accompanied to health facilities. A total of 5,681 awareness-raising activities were carried out.

Women's attendance at health services

The 6th day's consultation rates increased from under 40% at the beginning of the intervention to 80% after, and the 6th week's consultation (42nd day) rates increased from under 20% to over 50% for all the health facilities. All of the participants interviewed in this case study acknowledged that the number of women who came to postpartum care, including those who gave birth at home, had increased considerably since the implementation of the project activities. The observations during supervision and the data collected during monitoring confirmed this assertion. In addition, health workers who were interviewed reported that the number of women who received postpartum consultations was higher on the 6th day than in the 42nd day ([Figure 4](#)).

Applying the relevant explanation finder (Steps 4, 5)

These steps were used to understand the influencing factors and alternative explanations.

Influencing factors

Among the facilitating factors, we noted the participatory approach adopted by the project for the selection of CHWs and their activities, CHWs commitment, the involvement of community leaders, the health workers collaboration, the non-financial motivation system, the influence of the other women and regular supervision of the activities.

- *CHWs' commitment and motivation*

The majority of CHWs (90.3%) conducted the activities until the end of the project. Their main motivation was the moral

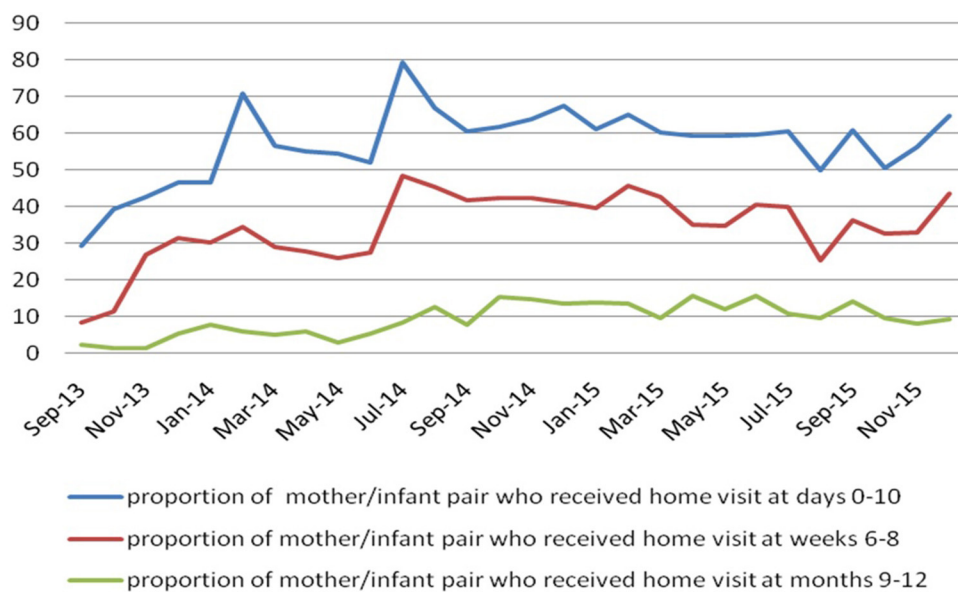


FIGURE 3
Home visit evolution per month from September 2013 to December 2015.

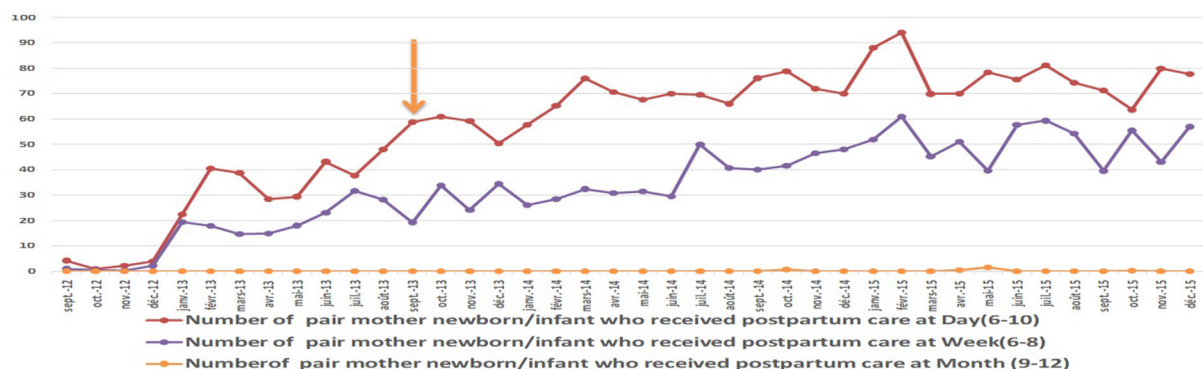


FIGURE 4
Proportion of pair mother /infant who received postpartum care before and after the intervention.

duty toward the community that had chosen them because they felt valued by this community. They had the conviction that their work had a positive impact on maternal and child health because they thought they were influencing women in the use of health services.

During the interviews, some of them expressed themselves as follows:

I agreed to do this work because when the members of your community meet and choose you to entrust you with a responsibility, you have the duty to do it otherwise it will seem like you are not concerned about people's health. (CHW from a rural HF)

It's for our well-being because health is priceless. And also, it is our village, and we have the duty to contribute to its development. If we are concerned about the development of our village, we must wholeheartedly support the well-being of the population. This is the reason for our involvement in contributing to the improvement of health. (CHW2, Rural HF)

However, 9.7% of CHWs left the project because of the non-financial incentive. During supervision and interviews, a CHW from the urban area who left the project expressed herself:

I warned you from the beginning that your volunteering story was not going to go far. Anyway, I am not visiting women anymore because we earn nothing in your project. I manage with my small business to feed my children and you want me to stop this and go visiting women with nothing in exchange? (CHW, urban HF)

● CHWs' bridging role

The baseline study showed that women's acceptance of the CHW would depend on her reputation within the community and her collaboration with health workers. Via this relationship, the CHWs conducted home visits and outreach sessions. Data from the various interviews confirmed this assumption.

Our CHW helps us a lot. Even at night, when a woman is in labor, she accompanies her to the HF without any hesitation. Sometimes she gets on her bike to follow (the woman) to the HF. (Postpartum woman, rural HF)

The messages they conveyed were welcomed by women. The women interviewed described them as a benchmark for maternal health in the village and advocates for women in interactions with their husbands and health workers. Their presence broke down barriers such as fear and mistrust that some women might feel in the presence of a health worker.

The following statements collected during the interviews confirmed these facts:

There are women who want to go to the HF, but they are afraid of health workers. But they say that if the CHW working with the health workers accompanies them, they will no longer be afraid and will express themselves freely because the CHW is there. (ICP, urban HF)

● Involvement of community leaders

The involvement of community leaders and male CHWs facilitated the work of the CHWs in the field. Several CHWs interviewed reported that the community members consented to participate in their activities since the community leaders themselves were involved in the project. Thus, they had access to households for outreach sessions, and women were receptive.

"They [women] simply believed that it is for their benefit because an activity that village leaders and authorities are involved in can only be beneficial to the community. So, they consent as well." (CHW6, urban HF)

However, other factors have limited women's access to these services, such as geographical and financial accessibility (especially during the rainy season), and the weak decision-making power of women, especially in rural areas. Women,

health workers and the CHWs interviewed confirmed these obstacles.

Here in the city, there is no problem because women are autonomous. But in the villages, men decide where, when and how their wives can go. They decide whether their wives must go to the HF or not. Sometimes women or children can fall sick for more than a week, but they are waiting because their husbands did not give permission to go to consultation. (Health worker, urban HF)

During the monitored supervision sessions, the CHWs reported that some women did not come to postpartum consultations because of the cost of consumables.

You know, madam, I will tell you the truth. Our women do not come on the 42nd day because your health workers asked them to pay for gloves, speculum, etc. So, if you do not have money and your husband also refuses to give you some, you have to stay home. (Rural CHW)

Alternative explanations

The health services component of the MOMI project, the performance-based funding (PBF) and the Save the Children NGO's project called "Victoire sur la Malnutrition" (VIM) implemented in 2014, were alternative explanations.

Indeed, the health services component of MOMI advocated the integration of maternal and infant health care so that some health workers would include postpartum visits with mothers and their infants during immunization visits or healthy infant consultations. For example, in some health facilities, appointments for postpartum visits on the 6th day were scheduled at the same time as the child's BCG vaccination, and the 6th-week appointments were scheduled at the same time as the child's PENTA1 vaccination or healthy infant consultation appointment. In addition, within all the health facilities, the health worker keeps the mother's health record after delivery. The records were delivered only on the sixth postpartum day. An urban health worker said the following during supervision:

Since we are keeping the health records, women come back, if only for their health records, and we seize this opportunity to treat them. But sometimes we are obliged to hand over the notebook before the consultation when the woman is not from the same location. (Supervision Report)

The performance-based financing (PBF) was funding some maternal health indicators, such as postpartum consultation rates. This led some health workers to become more involved in postpartum services. Their collaboration with the CHWs in the search for

women who were absent at the various appointments was intensified.

The VIM project distributed food to pregnant and breastfeeding mothers in rural areas. This distribution was based on the mothers' adherence to prenatal consultations and the immunization schedule for children. Another influence of the VIM project may lie in the fact that some CHWs who worked in the MOMI project were also working on the VIM project. These CHWs took advantage of the food distribution incentive to sensitize women. These facts were corroborated by supervisory data and interviews.

We also take advantage of the distribution of VIM to raise awareness on FP (family planning), the importance of meeting (health consultations) appointments, and signs of danger (for mother and child's health). We generally finish our sensitization before we start to share food; otherwise, women may leave. (Supervision Report)

Assembling the performance story of contribution (Step 6)

This is an iterative process of identifying elements of the intervention that contributed to increasing the attendance of health services by postpartum women. Among the causal links established in the theory of change, we believe that the participatory approach adopted by the MOMI project for the identification of the activities and the selection of the CHWs enabled the appropriation of the intervention by the different actors. The involvement of the community through male CHWs and community leaders helped boost female CHWs in their actions in the sense that they felt valued and considered. Regular training and supervision boosted the CHWs' self-esteem and confidence.

This perception of the importance of their role motivated them to carry out the project activities among women. These activities enabled women to become aware of the dangers that could arise after delivery and the importance of postpartum care at the health center, which explained their agreement to attending postpartum health services.

However, of all the activities carried out, we believe that home visits and outreach sessions, as well as a good collaboration between health workers and CHWs, contributed more to the attendance of health services by women.

On the other hand, the accompaniment of women to the HFs seemed to have a smaller contribution because this activity was not carried out by all the CHWs because of the lack of adapted means of transport: while the CHWs were riding a bicycle or were walking, the postpartum woman would ride a motorcycle or a bicycle.

Discussion

Relevant Explanation Finder element analysis showed that there was a link between the activities of the project and the use of health services by women during the postpartum period. The analysis also showed that some factors contributed to, or limited women's access to health services; however, other factors might also explain the increase in the use of postpartum services.

Activities and influencing factors

During the project implementation, most of CHWs provided home visits, accompanied women in health facilities and carried out outreach sessions. These activities varied according to the period and the health facility. In general, the health facilities located in rural areas had a home visit rate of more than 50%, while in urban areas are <50%. The participative approach adopted by MOMI project to select the intervention activities and CHWs and the commitment of the CHW can explain these results. Community involvement in the selection of interventions was significant in facilitating the work of community health workers within villages (24–26). In fact, community recognition was the main source of motivation of several CHWs to conduct the project activities. This has also been observed in several studies conducted in Nepal, Gambia and Ethiopia (25, 27, 28). CHWs were selected by their community, and they represented the resource persons of the community in these locations. Therefore, they were motivated to help their community in matters of health. We found, as in the other MOMI project countries (Kenya, Malawi, Mozambique), that the trust between CHWs and their community motivated them to provide an effective bridging function (12). The mutual trust between the CHW and her community, as well as the collaboration between the CHW and the formal health workers, made a bridge between the community and health services. The CHW was perceived as a real asset by the community and health services. The messages they conveyed were welcomed by women. However, CHWs were more respected and paid more attention to by the population in rural than the urban areas. This may explain the high rate of visits observed in rural areas. Other factors may also explain the high rate of visits, particularly the seniority of the CHWs, their advanced age and the dynamics of the voluntary CHWs in the health facility. In addition, elder CHWs had no young children, were supported by their loved ones and were freer to provide home visits than young CHWs. Sensitization through social networks with an appropriate timetable as implemented by the female CHW proved positive for behavioral change and raised attention to PPC (29, 30). Monitoring and supervision were revealed to be an important factor of success for the interventions (12).

Women in rural areas had a higher rate of home visits than women in urban areas. This situation in urban areas could

be explained by the difficulties encountered by the CHWs in conducting home visits, particularly difficulties relating to their social status. Therefore, the scaling up of such intervention must take this reality into account and consider only the rural environment in order to ensure the success of the intervention. Monica et al. found in a similar study in Uganda that the poor education level of community health workers negatively affected their activity in urban areas (31).

Alternatives explanations

On the other hand, the alternatives explanations to the health services component of the MOMI project, the performance-based financing (PBF) and the Save the Children NGO's project called "*Victoire sur la Malnutrition*" (VIM). Belemsaga et al. in their study had shown that key contextual factors of the successful upgrade of postpartum care interventions in Burkina Faso were the retention of the health book at the health facility until the day 6–10 visit (10). The fact that the PBF buys certain postpartum indicators (6th and 42nd day), health workers have stepped up their monitoring of postpartum women and strengthened their collaboration with CHWs in the search for those lost to follow-up. This has contributed to women's use of health services.

Contribution story

PBF and VIIM were mainly implemented at the health facility level. Moreover, these projects were established well after MOMI project and do not have community activities, although they are interested in postpartum women. The postpartum indicators collected in the HFs before and after the implementation of MOMI showed an increase in the use of postpartum services since the implementation of the project. This trend continued with the implementation of the other projects. That suggest that MOMI contributed to the observed effects, and the contribution elements could be attributed to CHWs activities, including home visits, outreach sessions, etc.

Sustainability

One of the difficulties encountered in implementing the interventions at the community level was the financial incentive of the CHWs. It was very difficult to find the kind of motivation that would suit everyone. While some people were advocating fee-for-service, others opted for non-financial motivation such as being equipping with a bicycle (32). To ensure the sustainability of the intervention, the project team had opted for a system of non-financial motivation of CHWs. But this type of non-financial incentive had a mixed impact on

the project implementation. In fact, it encouraged the majority of CHWs to carry out the activities, but it also resulted in the resignation of 9.7% of them. Studies conducted in Nepal and South Africa reported similar results (27, 33). In Tanzania and South Africa have studies had shown that while money was an incentive, non-financial learning incentives were favored (25, 27, 28). However, in 2016, the ministry of health decided to motivate the CHW with 60 USD (30 000 XOF per month).

The involvement of CHWs in the management of women during the postpartum period contributed to increasing the attendance of these women in health facilities. Several factors helped achieve these results, including the non-financial motivation system. However, although the system adopted by the MOMI project did not have a negative impact on the majority of CHWs, it should be noted that it is difficult to continuously work without being paid in a context of poverty. It is time to find a permanent mechanism to motivate CHWs or find other adapted interventions to ensure the sustainability of interventions involving the community. This could include the pooling of resources and integration of activities of all NGOs working in the field with the same CHWs.

Limitations

The limitations of our study were mainly related to the evaluation approach used, that is, the contribution analysis. How a contribution analysis-based approach can account for the "cause-effect" relationship remains controversial. However, the methodology used enabled us to collect high-quality data and reliable information that could raise questions for further research.

The benefit of the CA (contribution analysis) is that it focuses on examining contextual factors and other explanations that affect the success and outcomes of the programme.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The study received the approval of Ethics Committee for Research in Health of Burkina Faso under the deliberation number: 2015-5-074. This committee belongs to the health ministry. We obtained written informed consent and guaranteed the confidentiality of all participants prior to the interviews.

Author contributions

MT and SK designed the study. HT wrote the first paper. BB and RC analyzed the qualitative data. HT and AO the quantitative data. All authors review and approved the final version of this article.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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