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Evaluating the impact of a countrywide, market-based roll-out of multiple micronutrient supplementation on low birth weight in Bangladesh: protocol for a two-arm, quasi-experimental and mixed-methods evaluation study

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ABSTRACT

Introduction Multiple micronutrient supplementation (MMS) during pregnancy has a greater potential for reducing the risk of low birth weight (LBW) compared with the standard iron–folic acid supplementation. WHO recently included MMS on their Essential Medicines List. The Social Marketing Company (SMC) in Bangladesh is implementing a countrywide, market-based roll-out of MMS to pregnant women. We aimed to evaluate the implementation of the supplementation programme and its impact on reducing LBW.

Methods and analysis A two-arm, quasi-experimental and mixed-methods evaluation design will be used to evaluate the impact of this 36-month roll-out of MMS. In the intervention areas, pregnant women will purchase MMS products from the SMC's pharmacy networks. Pregnant women in comparison areas will not be exposed to this product until the end of the study. We will collect 4500 pregnant women's data on anthropometric, socioeconomic, nutrition-related and relevant programme indicators during recruitment and bimonthly follow-up until the end of their pregnancy. We will measure children's birth weight within 72 hours of birth and evaluate the changes in LBW prevalence. We will observe market-based MMS service delivery-related conditions of the pharmacies and the quality of the provider's service delivery. Concurrently, we will carry out a process evaluation to appraise the programme activities and recommend course correction. Cluster-adjusted multivariable logistic regression or log-binomial regression analysis of quantitative outcome data will be performed. For qualitative data, we will follow a thematic analysis approach. We will consolidate our study findings by triangulating the data derived from different methods.

Ethics and dissemination This study received ethical approval from the institutional review board of icddr,b (PR number 21001). We will recruit eligible participants after obtaining their informed written/verbal consent (and assent where needed) with full disclosure about the study. The results will be disseminated through peer-reviewed publications and conference presentations.

Trial registration number NCT05108454.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The mixed-methods approach will provide qualitative insights on the acceptability, feasibility and sustainability of the countrywide roll-out of multiple micronutrient supplementation (MMS) and quantitative measures to capture the impact in the reduction of low birth weight.
⇒ The large sample size collected from five of eight administrative divisions should make results representative of the 'real-life' country context.
⇒ The rigorous monitoring of implementation activities will help to identify gaps in MMS programme implementation and provide guidance for course correction.
⇒ For ethical reasons and given the countrywide implementation, use of clean controls is not possible; as such, we are limited to a quasi-experimental study design.
⇒ Measuring birth weight within 24 hours of childbirth is not feasible, given the widespread geographical location and related logistical obstacles, so we have had to widen the window of birth weight measurement up to 72 hours after childbirth.

INTRODUCTION

Multiple micronutrient deficiencies are common during pregnancy due to a combination of inadequate dietary intakes and increased nutrient requirements of the mother and developing fetus. These

deficiencies can negatively impact the health of the mother, contribute to adverse pregnancy outcomes and impact the health of the newborn baby. This includes being born with low birth weight (LBW, defined as a birth weight of less than 2500 g) due to preterm birth, foetal malnutrition or both.[1] An estimated 14.6% of births totalling 20.5 million had LBW globally in 2015, mainly in South Asia and sub-Saharan Africa.[2] Babies with LBW include preterm or having foetal malnutrition and being small for gestational age (SGA) but not LBW.[3] Such babies have a far greater risk of stunting, impaired cognitive development and adult-onset chronic diseases.[4]

WHO endorsed the provision of iron–folic acid (IFA) supplements as part of routine antenatal care (ANC) for decades.[5] Evidence from recent reviews proposes that newborns of mothers who receive multiple micronutrient supplementation (MMS) are significantly less likely to be LBW or SGA compared with those who receive IFA supplements.[6–8] The recent *Lancet* series on maternal and child undernutrition in 2021 also includes MMS as one of the priority interventions.[9] Recently, in October 2021, MMS has been included in the WHO's model Essential Medicines List (EML) as an antenatal supplement for pregnant women.[10] Based on new evidence, in July 2020, the Executive Guideline Steering Group updated the antenatal nutrition recommendations and recommended MMS during pregnancy.[8]

Based on updated guidelines and recommendations, the Global Alliance for Improved Nutrition (GAIN) and the Social Marketing Company (SMC) are implementing a countrywide, market-based roll-out of MMS to pregnant women in Bangladesh, funded by the Children's Investment Fund Foundation (CIFF). The project aims to set up a sustainable business model with the delivery of affordable and quality MMS to pregnant women in Bangladesh through the SMC's pharmacy networks and demonstrate a reduction in LBW. GAIN is providing support to the SMC to implement the project through a government-led National Technical Committee to harmonise standards on MMS, support a transition to high-quality local production and advocate for its inclusion in Bangladesh's EML and national standard treatment guidelines for ANC.

Market-based MMS will be rolled out countrywide through SMC's existing pharmacy networks in Bangladesh, known as the Star Network Providers, including Blue Star Provider (BSP) and Green Star Provider (GSP) pharmacies, Gold Star members and Pink Star Providers. The pharmacy networks are the key sales agent covering the entire country, selling various SMC products. SMC developed a digital interface for supply chain management from procurement to stock in the warehouse, logistics movement of vans and area sales officers. This digital interface will be adapted to track consumers at the grassroots level and increase compliance for MMS.

The objectives of this current evaluation study are to evaluate the effect of the market-based, countrywide roll-out of MMS in the reduction of the prevalence of LBW and to measure the fidelity, reach and mechanism of the impact of the intervention. This work is especially crucial to public health as it could inform the robust, achievable and ethically designed MMS programme that could easily be adapted and scaled up by the government.

Study objectives

Outcome evaluation

The primary objective was to evaluate the effectiveness of a market-based distribution of MMS intervention on the prevalence of LBW (less than 2500 g) in the infants born to women in the intervention area who received the intervention compared with those born in control areas.

The secondary objective was to estimate the differences between the intervention and control groups on

- Prevalence of preterm (less than 37 weeks of gestation) and SGA births.
- Duration of gestation in the intervention and control groups.
- Pregnancy outcome—ANC coverage, childbirth/miscarriage/stillbirth/maternal morbidity, etc.
- Side effects, compliance with MMS.
- The proportion of pregnant women reached by the programme by the end of the fifth year.
- The proportion of pregnant women—both onetime buyers and repeated buyers over time.
- Aherence in consumption.
- The proportion of pregnant women who heard about the new MMS product from any media.
- Contact coverage—the proportion of pregnant women who ever consumed MMS.
- Effective coverage—the proportion of pregnant women who consumed MMS in line with the recommendations.

Process evaluation

The process evaluation will be complementary to the outcome evaluation to deliver course correction to the stakeholders through the identification of gaps in programme implementation. Examining the quality (fidelity) and quantity (dose) of what was implemented in practice and the extent to which the intervention reached its intended audiences is vital in establishing the extent to which the outcome evaluation represents a valid test of intervention theory. The following are the questions that would be addressed through the process evaluation:

- Was the intervention implemented as the implementing partner determined it in the programme roll-out plan? (fidelity)
- What was the extent to which pregnant women came into contact with the BSPs/GSPs and the extent to which its delivery was of sufficient quality? (reach)
- How much of the intervention was delivered? (dose)
- What is the motivation for pregnant women to repurchase MMS?
- Do the pregnant mothers share their overall experience while consuming MMS within their neighbourhood network?

- What was the mechanism of the impact of the intervention? (participant response and interaction, mediators and unanticipated pathways like spillover effect)
- How do external factors influence the delivery and functioning of interventions?

METHODS AND ANALYSIS

Study design

The study will comprise concurrent process and outcome evaluation and will adopt a two-arm, cluster-based, open cohort, quasi-experimental mixed-methods design. Random allocation of the intervention was not possible, as the programme implementers have already selected the intervention areas.

Study site and sampling frame

The evaluation will be conducted in five out of the eight divisions in Bangladesh: Barishal, Chattogram, Dhaka, Rajshahi and Sylhet. We applied a multistage sampling design to select the study sites. During the first stage of sampling, one district was selected randomly from each of the five divisions. In the second stage, two Upazilas (subdistricts) from each of the districts were selected. In total, 10 Upazilas were selected: 5 from the intervention Upazilas and another 5 from the control Upazilas. Then seven unions were selected randomly from each Upazila as a sampling unit. Unions are the smallest rural administrative and local government units in Bangladesh. We will perform a door-to-door household screening at the union level to prepare the sample frame based on inclusion and exclusion criteria. Then, the households will be selected by systematic sampling from the sampling frame (figure 1).

Intervention description

Multiple micronutrient supplement is a nutritional supplement for use during pregnancy based on United Nations International Multiple Micronutrient Antenatal Preparation formulation following WHO specifications. It contains 15 micronutrients, including IFA (iron 30 mg) at dosages that approximate the recommended dietary allowances for pregnancy. The recommended dosage is one tablet per day starting in pregnancy as soon as possible, with the consumption of 180 tablets for 6 months throughout the pregnancy. The MMS will be familiarised with using behaviour change communication (BCC) messages on pregnancy and nutrition in the community. The intervention product will be available in all the pharmacies in intervention areas only including the SMC network (Blue Star and Green Star pharmacies) until the end of the evaluation study. SMC will organise countrywide training workshops in the intervention areas to develop skills and awareness among pharmacists. In addition, different types of BCC and promotional materials will be circulated and courtyard meetings will be organised with target pregnant women. The digitally enabled interface will be used to track buyers' interest, sales and resale figures to measure coverage/compliance. Both IFA and MMS are available in the intervention area. IFA is free of charge only at government health facilities. However, the availability and compliance of IFA across Bangladesh are still suboptimal.

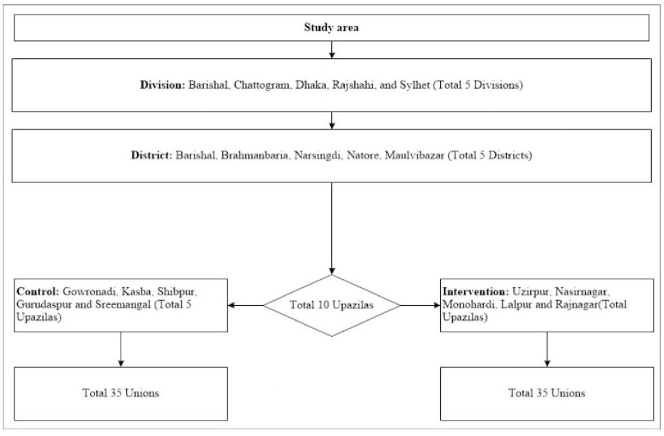

Figure 1 Sampling procedure.

Control description

SMC will ensure no MMS is available in the control areas, including SMC network (BSP and GSP) pharmacies and other drug stores/pharmacies until the end of the evaluation. Associated components such as SMC-organised training workshops and skill development of pharmacy staff, promotional materials on MMS and community courtyard meetings for pregnant women will not be available until the end of the study.

Outcome evaluation

We will perform the outcome evaluation to investigate whether the new MMS product in the intervention area has any effect on reducing the occurrence of LBW compared with the control area, where no MMS product will be available. As part of the outcome evaluation, we will recruit and follow up a cohort of pregnant women at different gestational periods of their pregnancy residing in the intervention and control areas.

Pregnant women screening and recruitment

We will prepare a list of pregnant women through door-to-door visits, following the sampling frame. We will use a structured questionnaire to collect data on demographic characteristics (name, age, address and multiple mobile contact numbers) of the pregnant women along with pregnancy-related information (date of last menstrual period, gestational age, expected delivery date (last menstrual period (LMP) and/or ultrasonogram (USG) based), expected delivery place along with contact information, etc) during screening. After reviewing the screening information, we will create a concise list of eligible women using defined inclusion–exclusion criteria. Finally, we will recruit eligible pregnant women after obtaining their informed written/verbal consent (and assent where needed).

Eligibility criteria

Inclusion criteria include

- Willingness to participate in the study and provide consent.
- Singleton pregnancy identified/reported through ultrasonogram during antenatal check-up (ANC) or other available medical proof (preferably at their first trimester of pregnancy).
- Absence of severe malnourishment (body mass index less than 17 kg/m^2)/known chronic diseases, respiratory illness, hypertension, diabetes, tuberculosis, haemoglobinopathy, etc, through self-reporting and available documents.
- Able to provide at least two mobile numbers to contact and follow up.
- The place of delivery has been decided.
- Not enrolled in a nutrition programme/intervention.

Exclusion criteria include

- Inability to provide informed consent (due to illness, incapacity, inability to obtain permission, etc).
- Intent to move outside the data collection area.

Data collection

Immediately after the recruitment, we will collect baseline data using a structured questionnaire and conduct anthropometric measurements following a standard operating procedure. At baseline, we will collect data on household sociodemographic characteristics, household food insecurity status,[11] water, sanitation and hygiene practices, maternal general and reproductive health information including decision-making power, maternal dietary intake,[12] maternal pregnancy-related access to healthcare information and maternal anthropometric measurement. The cohort of recruited pregnant women will be followed up every 2 months through household visits until the end of their pregnancy. In between, the field staff will keep in contact with the pregnant women/her family members via mobile phone to make sure that the women are traceable and in good health. In case of any emergencies/adverse events like abortion/unforeseen events, the field staff will notify the investigators immediately and take applicable action, along with data collection at an appropriate time. We will collect follow-up and end-point data on maternal general and reproductive health, maternal dietary intake,[12] maternal pregnancy-related access to healthcare information, pregnancy outcome-related data and maternal anthropometry. Children's birth weight will be measured within 72 hours of birth using the Seca 727 Baby Scale (Hamburg, Germany), with an accuracy of 10 g. Pregnant women's weight will be measured with minimal clothing and without any shoes and accessories in kilogram using a portable Tanita scale with an accuracy of 100 g. All measuring tools would be placed on flat surfaces, and readings will be noted when participants become steady on the scale. All measurements will be taken twice unless there is a difference beyond the acceptable accuracy/precision between the two readings,

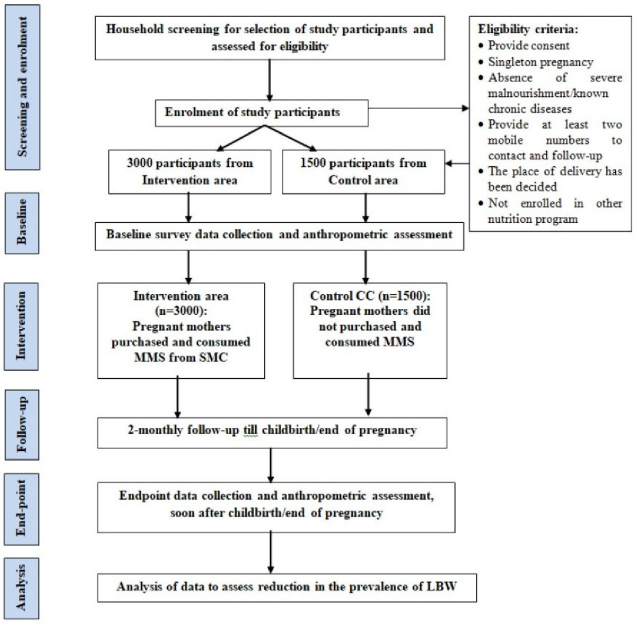

Figure 2 Flow of the participant diagram. CC, community clinic; LBW, low birth weight; MMS, multiple micronutrient supplementation; SMC, Social Marketing Company.

in which case a third reading will be taken. Data from the control areas will be collected following the same guideline to maintain consistency (figure 2), based on the Consolidated Standards of Reporting Trials diagram,[13] and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines.[14] The assigned field staff members will enter the data into a personalised digital assistant, which will be synchronised into the central server at icddr,b daily.

Process evaluation

For the process evaluation, we will use a mixed-methods design, primarily qualitative components, to measure the intervention mechanism in a real-life context. The participants will be recruited from the same areas of outcome evaluation. We have developed a programme impact pathway focusing on the following fundamental aspects: (1) understanding the health promotion programme and its proposed mechanism of action, (2) describing the intervention and its causal assumptions, (3) understanding the programme implementation process including fidelity, dose, adaptation and reach, and (4) considering the role of business model MMS context and programme characteristics that may affect the overall programme implementation (online supplemental table 1 and 2).

Follow-up data will be collected from the implementing partners at regular intervals (every 3 months) to measure the process indicators and monitor if the intervention is being implemented as planned and to provide suggestions for possible course correction if/when required as per the objectives (online supplemental table 3). A framework adapted from the UK Medical Research Council

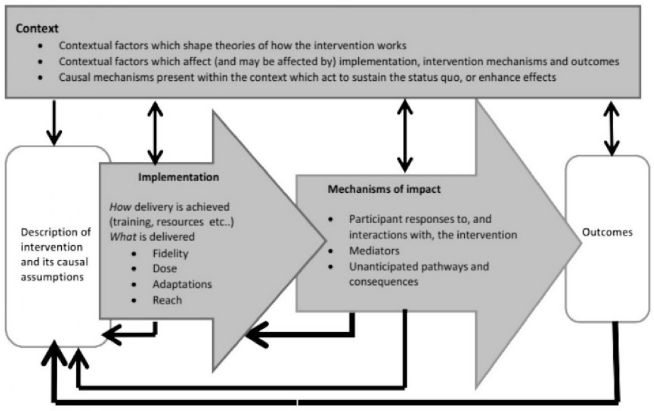

Figure 3 Key functions of process evaluation and relationships among them.

(MRC) guideline[15] for the linking process evaluation function has been given (figure 3). Based on this framework, we will focus on three conceptual parts of process evaluation that include examination of implementation, including fidelity, mechanisms of impact and contextual factors.

Study outcomes

The primary outcome of interest is the reduction in the prevalence of LBW in infants born to women in the intervention areas compared with those born in the control areas.

The secondary outcomes are

- The difference in the prevalence of preterm (less than 37 weeks of gestation) and SGA births in the intervention and control areas.
- The difference in the duration of gestation in the intervention and control areas.
- The difference in side effects, compliance, episodes of maternal infections and adverse perinatal outcomes.
- The proportion of contact and effective coverage for the intervention group only, that is, reach and use of MMS and compliance of pregnant women who consumed MMS.

Sample size

Quantitative survey

Based on national data, we assume that the proportion of LBW in the control areas will be 20%[16] and, due to the intervention, the prevalence of LBW will be reduced by 5% in the intervention group. The effect size of a difference of 5% point between the groups was considered the minimum difference worthy of the intervention. Based on that with a 5% level of significance (α), 80% power, design effect of 1.5% and 10% attrition, the minimum sample size is estimated to be 2988 with a sample size per arm of 1494. Assuming the MMS compliance of 50% among the pregnant women,[17] the sample size in the intervention group has been doubled to 1494×2=2988 and, therefore, the total sample size is 4482. We have rounded this to 4500 pregnant women.

Qualitative interviews

Trained moderators and interviewers whose native language is Bangla with purposively selected respondents will conduct the interviews. In-depth interviews (IDIs) will be conducted with pregnant women, BSP/GSP service providers and their supervisors. Key informant interviews (KIIs) will be conducted with the government and non-governmental organisation stakeholders and policymakers involved in the MMS programme implementation. The duration of each KII will be approximately 60–90 min. We have developed separate open-ended guidelines for conducting KII and IDI. The number of interviews will be decided following an iterative process to achieve saturation of information; that is, we will continue interviewing until no new information emerges. For BSP/GSP observation, a checklist will be used. The interview guidelines and questioning routes have been prepared in English and translated into Bangla thereafter.

Field procedure and quality control (QC)

There will be five teams in five sites comprising four members in each team, totalling 20 field staff for data collection. A separate monitoring and supervision team will make unscheduled field visits to supervise the field activities. The team will perform QC for 5% of the household surveys. The QC team will revisit and implement the QC questionnaire on the listed households within 1–2 days of the survey. If any inconsistencies are found, then the investigator's group, as well as the main survey team, will immediately be informed. The data management team, trainer and field managers will review those inconsistencies to identify possible reasons for the discrepancy and implement an appropriate solution. Trained staff on anthropometry will standardise the weight and height machines each day before data collection, following the WHO/UNICEF anthropometry training module.

Data quality management

The integrity of the database will be maintained following icddr,b's data policy. Each participant will have a unique identification (ID) number, and only the study ID number will be recorded in the final database to keep privacy. The investigators will contact the field teams to clarify inconsistencies or to collect missing information. Necessary checks of data analysis syntax and consistency of results will be conducted.

Data analysis

Quantitative data analysis

Descriptive statistics such as frequency and proportion for categorical variables, the mean and SD for symmetric quantitative variables, and median and IQR for asymmetric quantitative variables will be used to summarise data. The variables will be segregated by baseline/endpoint survey and by intervention/control group, as suitable. All estimates will be reported with a 95% CI. The χ^2 test for categorical variables and t-test/analysis of variance for continuous outcomes will be used to explore

any association. Relevant non-parametric analysis will be performed for non-normally distributed data. To test the hypothesis that consumption of MMS with standard dosage will reduce the prevalence of LBW, primarily simple logistic regression or binary log-binomial regression will be used to explore the bivariate relationship between LBW and intervention. To see the independent impact of the intervention, the necessary covariates will be selected based on stepwise forward selection as well as previous published literature and field experience. Important non-modifiable factors such as maternal age and nutritional status and child sex will be adjusted in the final models. The unions will be adjusted as a cluster during estimating inferential statistics. All statistical models (and study results) are based on assumptions, and the validity of the inferences that can be drawn will often depend on the extent to which these assumptions are met. We will check the data distribution and goodness of fit of the statistical model, and identify the outliers. Using postestimation, we will estimate the adjusted prevalence difference of LBW between the two groups. A time variable (month/quarter/year, whichever is suitable) will be adjusted in the model to assess the secular trend.

Qualitative data analysis

We will apply a 'phenomenological approach' for qualitative data analysis. We will follow the thematic analysis for all qualitative information. From transcribed interviews, responses will be coded according to themes (a priori), subthemes and emergent issues. We would adhere to trustworthiness by applying four principles: credibility, transferability, conformability and dependability. We will use intercoder or synchronic reliability, which refers to the amount of agreement between impendent coders of the data. We will measure the agreement during the analysis when the researchers coded the same interviews independently. We will furthermore perform triangulation between methods and participants. Data from different methods will be triangulated for information validation. Finally, qualitative analysis will include thematic descriptions, analysis and respondent quotations.

Patient and public involvement

Patients were not involved in the design of this study. The key stakeholder from the government will be the National Nutrition Services at the Institute of Public Health Nutrition. GAIN and the SMC will be the key non-government stakeholders. A technical advisory group will be formed by CIFF comprising 7–10 members who are both national and international experts.

ETHICS AND DISSEMINATION

The study protocol was approved by the institutional review board (IRB) of icddr,b (PR#21001, V.1.3, version date 24 October 2021). Formal approval for any important protocol modifications (eg, changes to eligibility criteria, outcomes and analyses) will also be taken from the IRB. The study was prospectively registered in November 2021 at ClinicalTrials.gov. Before all interviews, the field research staff will obtain written informed consent with full disclosure about the study from the participants. No major physical risk is involved in the study subjects who participated in this study. Privacy, anonymity and confidentiality of data/information identifying the study participants will be strictly maintained.

The results of this study will be presented at national and international conferences. The study investigators will disseminate study results at the national level via seminars and outreach events. A manuscript with the results of the primary outcome will be published in a peer-reviewed journal. Separate manuscripts will be written on the secondary aims, and these will also be submitted for publication in peer-reviewed journals. A committee consisting of the investigators of the protocol will publish the data, results and other findings resulting from this study only after the approval. The International Committee of Medical Journal Editors guidelines will be used to establish authorship on papers. The information collected from this study may be shared with other researchers if needed only for research purposes; however, it will be strictly followed to maintain confidentiality and privacy and as per the icddr,b's data access policy.

Study status

We completed the study site selection in August 2021. Door-to-door household visits, along with eligible pregnant women listings, were started from November 2021 and are ongoing. From December 2021, enrolment of eligible pregnant women has been ongoing. Participant recruitment is expected to end by November 2023.

DISCUSSION

Babies with LBW have an elevated risk of death in infancy and later childhood. In Bangladesh, around 20% of babies are born as LBW.[16] The major contribution of LBW is due to maternal micronutrient deficiency, as their regular diets frequently lack diversity. Moreover, fortified foods are less/not less available in the country and even less accessible to the majority of the population. The government of Bangladesh developed and approved the National Strategy for Prevention and Control of Anaemia, in which the IFA supplementation programme was identified as a critical intervention needed to address anaemia in pregnant women in 2007.[18] Under that policy, pregnant women are provided IFA supplements, with a daily dose of 60 mg of elemental iron and 400 µg folic acid throughout pregnancy and onwards until 90 days after delivery.[19] Although 37% of women never receive IFA, among those who take the IFA supplements, more than half start taking them in their third trimester and only 16% take them during the first trimester. The increasing concern that IFA alone may not be sufficient to replenish the coexisting micronutrient deficiencies that commonly occur in pregnant women has encouraged the launch

of multiple micronutrient supplements.[20] The scientific evidence establishes that compared with IFA, MMS supplements during pregnancy provide better or at least similar beneficial effects on maternal anaemia,[21] mean birth weight and the incidence of both LBW and SGA.[6 22]

Based on this recent evidence, WHO has strongly suggested that the change in the recommendation of MMS containing 13–15 micronutrients to replace the existing IFA supplementation should be well evaluated through context-specific rigorous research including evaluation of acceptability, feasibility, sustainability and equity. Therefore, we have planned to evaluate the implementation and effect of the MMS tablet by the SMC in Bangladesh. This study will have a large sample size, and we assume that data will be representative of a 'real-life' context. The mixed-methods approach with open cohort design will provide qualitative insights into the acceptability, feasibility, sustainability and equity of MMS, countrywide roll-out as well as quantitative measures to capture the impact in the reduction of LBW. The study results will also help to identify gaps in MMS programme implementation through rigorous monitoring of implementation activities and to address them through integrated approaches and help the programme implementers with course correction. One of the limitations of our study is that, as we are having multiple contacts for process and outcome assessment during the intervention period, it is likely that the visits may positively influence some good practices (Hawthorne effect). However, we assume the effect will be similar in both intervention and comparison areas due to the similar number of visits. For ethical reasons (availability of IFA from all Government of Bangladesh (GoB) facilities) and given the countrywide MMS implementation (fixed programme area), identifying clean controls was not possible. Hence, we are limited to choosing the quasi-experimental study design. However, the MMS programme implementors will ensure the unavailability of MMS in the control area until the end of the evaluation period, which would help to reduce bias and strengthen the causal inference of study results. Birth weight may vary widely based on the initial breastfeeding adequacy and weight loss up to 4%–8%.[23] For this nationwide evaluation, we have kept the window of measuring birth weight from 0 hour to 72 hours, which might not be the most precise way to assess LBW. However, measuring birth weight within the first hour immediately after birth or even within 24 hours is feasible mostly for a health facility-based childbirth, with the availability of trained staff and good quality and operational weighing scale. For this nationwide evaluation, we have kept the window of measuring birth weight from 0 hour to 72 hours for several reasons, which include (1) distance of the field office to the birth place; (2) place of delivery (home or facility); (3) if home, then how remote the place is; (4) if in a health facility, then what type of facility and numbers of health facilities in that community; (5) health condition of the newborn: if the newborn is in critical condition/too sick, then our field staff would not measure the weight immediately for safety purpose, but they would refer (in case of home delivery) the newborn to the nearest health facility and wait for the decision and clearance from a paediatrician for measuring birth weight; (6) parents and caregivers consent to measure child weight soon after birth: parents many times hesitate to measure their newborn soon after birth due to social/cultural taboo; (7) seasonal variation: transports during flood and monsoon season become extremely difficult; and (8) migration. If we limit only to 24 hours, we might lose estimating the birth weight of 50%–70% of newborns in the community at the household level. Hence, to overcome this, we will adjust for the timing of anthropometric assessment during data analysis, so the heterogeneity does not influence the ascertainment of relationships. Also, we would perform an imputation analysis to predict weight at birth using each infant's recorded weight and time to compensate for this limitation.

This is one of a kind programme where a business model will be implemented to curtail the burden of LBW. If this programme is successful, then MMS could be incorporated into GoB's essential drug list. In addition, the distribution system is already in place to deliver IFA tablets to pregnant women, which could be leveraged to distribute the MMS for improving pregnancy outcomes in the undernourished populations of Bangladesh.

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