AN EVALUATION OF THE EFFECTIVENESS OF A MATERNAL, NEONATAL AND CHILD HEALTH COMPONENT FOR MATASA MATAN AREWA AND SMART START TARGETING MARRIED ADOLESCENT GIRLS IN NIGERIA AND ETHIOPIA

Principal Investigator

Abednego Musau
Senior Research and Learning Lead: PSI and A360 Amplify
amusau@psi.org: +254 721 246450

In-Country Lead Investigator - Nigeria

Roselyn Odeh
Project Director: A360 Amplify Nigeria- SFH
rodeh@sfh.org

In-Country Lead Investigator - Ethiopia

Bekele Belayihun
Director, Evidence and Learning: PSI Ethiopia
bbelayihun@psiet.org

Co-Investigators

Erica Felker-Kantor Senior Research Advisor: PSI efkantor@psi.org	
Meghan Cutherell Senior Program Manager: PSI mcutherell@psi.org	**Alhaji Bulama** Regional Learning Advisor: A360 Amplify Nigeria-SFH abulama@sfh.org

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ACRONYMS

A360	Adolescents 360
AGYW	Adolescent Girls and Young Women
ANC	Antenatal Care
ARI	Autoregressive Correlation Structure
CAPI	Computer Assisted Personal Interview
CSA	Central Statistics Agency
GEE	Generalized Estimating Equations
EDHS	Ethiopia Demographic and Health Survey
EMwA	Ethiopia Midwives Association
FGDs	Focus Group Discussions
HCD	Human Centred Design
HEWs	Health Extension Workers
ICF	Inner City Fund
IDIs	In-depth Interviews
IRB	Institutional Review Board
KII	Key Informant Interviews
KPIs	Key Performance Indicators
LFH	Life Family and Health
MIPCAs	Male Interpersonal Communication Agents
MMA	Matasa Matan Arewa
MNCH	Maternal, Newborn, and Child Health
NPC	Nigeria Population Commission
PHC	Primary Health Centres
PSI	Population Services International
QuIP	Qualitative Impact Protocol
REB	Research Ethics Board
SNNP	Southern Nations and Nationalities of Peoples
SRH	Sexual Reproductive Health
SSN	Smart Start Navigators
TOC	Theory of Change
UNFPA	United Nations Family Planning Agency
WDA	Women Development Army
WHO	World Health organization
PII	Personal Identifying Information

SUMMARY

CONTEXT

Population Services International, Inc. ("PSI") implements A360 Amplify in Nigeria, Kenya, and Ethiopia. A360 Amplify has developed innovative and unique interventions for each geography to support adolescent girls to access voluntary modern contraception according to their needs and preferences. As part of the current project phase, A360 completed the design of a maternal, neonatal and child health (MNCH) component in 2023 that will be layered on Matasa Matan Arewa (MMA) in Nigeria and Smart Start interventions in Ethiopia. The intervention components will target married adolescent girls 15-19 in both countries with an expansion to include 20-24 years old in Ethiopia. There is paucity of evidence on the effectiveness of upstream interventions at creation demand and access to antenatal care (ANC) among adolescent girls and young women (AGYW) from the regions where A360 operates. Consequently, parallel to the implementation of these two components, A360 has designed an evaluation to determine the effectiveness of these components in improving the comprehensive knowledge of what is needed to pursue healthy pregnancies, increase girls' self-efficacy to access ANC and increase support from their key influencers to pursuing healthy pregnancies.

OBJECTIVES

The main objective of this evaluation is to determine the effectiveness of MNCH intervention components leveraged existing A360 interventions at increasing comprehensive knowledge, self-efficacy and key influencer support to pursue healthy pregnancies among married AGYW in Nigeria and Ethiopia. The secondary objectives of the evaluation are: (a) to evaluate the component's effectiveness at increasing comprehensive knowledge of what care is required to attain healthy pregnancies, (b) to evaluate the component's effectiveness at increasing self-efficacy to attend ANC and (c) to determine the component's effect at eliciting support from AGYW's key influencers when they are pursuing healthy pregnancies and (d) to surface the system-level barriers, facilitators, and opportunities for program improvement during the implementation of the intervention components.

METHODS

The MNCH component is implemented in the same geographies where MMA and Smart Start are implemented in Nigeria and Ethiopia. In Ethiopia, Smart Start is implemented in Oromia, Sidama, SNNP, Amhara and South-Western. In Nigeria MMA is implemented in four states (Kaduna, Nasarawa, Jigawa and Kano. In Nigeria the MNCH component will be implemented in Jigawa and Kaduna, while the South-Western region in Ethiopia will be avoided. Selected woredas and local government areas will host the MNCH component, and these locations will host the MNCH intervention. The evaluation will use an implementation-effectiveness hybrid design, blending an outcome evaluation and an implementation science component. The outcome evaluation will constitute of a quantitative survey using a longitudinal approach with two study arms, an

intervention, and a comparison arm. It will have three assessment timepoints; a recruitment phase, and two follow-ups (3 months after baseline and 8 weeks post-partum (only for pregnant AGYW). Follow-ups will be conducted three months after recruitment and eight weeks after the expected date of delivery (for pregnant girls only). The sample size will be 545 participants for the intervention and 545 for the comparison arm for each country . In Ethiopia, an additional 240 participants will be recruited (specifically those who are pregnant) to cover for a deficit that occurred in the just completed recruitment in four regions – Central Ethiopia, South Ethiopia (previously called SNNPR), Sidama and Amhara). From these regions, we recruited 683 participants - data collection is pending in the Oromia region. For the approved sample of 1,090 participants in Ethiopia (we intended to have 70% of the sample as pregnant girls i.e., 382/545 in each group adding up to 764/1,090 for each country. Out of the 683 participants already recruited, 238 were pregnant (34.8%) against 478 who were expected - a deficit of 240 participants. The rest (445) were non-pregnant. If we maintain the 30% rate to be non-pregnant girls, we should have recruited 205 (30%) pregnant girls, so we exceeded the sample for non-pregnant girls by 240 cases. This is the same as the deficit for pregnant girls. Following the current trend, we will not be able attain the projected sample size for pregnant girls. Although we are implementing strategies to ensure data collection in Oromia does not violate the projected ratio but that will not even up the deficit that has occurred for the completed regions. The failure to attain the projected sample for pregnant girls means that we will lose statistical power and therefore be unable to perform a robust sub-analysis for the ANC and post-natal outcomes which only pertain to them. To preserve the power for this sub-analysis, we propose to recruit 240 additional participants on top of the 1,090 approved for Ethiopia so that we are able to reach the 763 pregnant participants that had been planned.

These computations are summarized in the schema below

	Attained sample	# Pregnant	# Non-pregnant	Expected pregnant sample (70%)	Deficit (F-D))	Current ratios of pregnant AGYW by region
Amhara	272	88	184	190	102	51%
CE	139	34	105	97	63	48%
Sidama	136	76	60	95	19	61%
SE	136	40	96	95	55	50%
	683	**238**	**445**	**478**	**240**	

The proposed additional participants will be drawn from the same woredas where participants were initially recruited, though new but from adjacent kebeles might be required in case adequate sample is not generated from the recruitment from the initial kebeles. An exception to the woredas is Tehuldere in Amhara where we have selected a complementary intervention woreda (Nineth) because after attempting to recruit participants from multiple kebeles, the recruitment yield was extremely low. Anecdotal reports suggest that there are existing MNCH programs in the woreda

which have been supporting women to adopt contraceptives and MNCH interventions. Since our eligibility criteria is AGYW who are not using a contraceptive method and who have not started ANC, this implies that it might not be feasible to recruit the desired sample from the same woreda even after exhaustively recruiting participants from all kebeles in the woreda. The total sample size for the survey therefore increases from 2,180 participants to 2,420 participants – 1,090 in Nigeria and 1,330 in Ethiopia. These numerical adjustments only affect the excess sample for non-pregnant girls since sample for pregnant girls that had been projected is preserved – we are topping up to maintain the earlier projection. In both countries, participants in the comparison arm will receive services as is expected based on the Ministry of Health guidelines in Ethiopia and Nigeria. Therefore, this group will be a partial control group.

For the implementation science component, we will employ eight (8) focus group discussions (FGDs) and 48 semi-structured in-depth interviews (IDIs) with AGYW, 10 IDIs with husbands (Nigeria only) and 35 key informant interviews (KIIs) with providers and mobilizers (female mentors, ANC providers and male interpersonal communication agents- MPICAs). The participants will be shared equally between Ethiopia and Nigeria except MIPCAs who will only be from Nigeria. All the FGDs, IDIs and KIIs will be conducted with individuals who have been involved in the MNCH components. The qualitative impact protocol (QuIP) approach will guide the execution of this component. It will be conducted mid-way through the implementation of the intervention. Participant recruitment will be conducted using recruitment scripts after obtaining oral consent and the administration of a set of screening questions to assess eligibility. Full consenting procedures will be conducted, and written consent obtained prior to involvement in any of the evaluation components. A structured questionnaire will be used to gather quantitative data from the survey using a Computer Assisted Personal Interview (CAPI) approach. Furthermore, FGD, IDI and KII facilitation guides will be used to gather qualitative data and all sessions will be audio-recorded. Audio records will be transcribed verbatim and translated. Data will be collected by trained enumerators certified to conduct human subjects' research through Viable Knowledge Masters (VKM) in Nigeria and Deep Dive Research and Consulting Inc who have been contracted as local research partners (working as consultants) in Nigeria and Ethiopia respectively.

Analysis of quantitative data will follow a repeated measures approach using Wald Z-test employing generalized estimating equations. The repeated measurements of each subject will be made at two times and using an autoregressive correlation structure. Between group t-tests and chi-square tests of comparison will be conducted to identify secondary outcomes which show statistically significant differences between the intervention and comparison groups. The qualitative data transcripts will be rigorously analyzed using NVivo or Dedoose. Open-coding and closed-coding will be utilized to identify themes in the qualitative data. Claim statements attributing change to key intervention drivers will be drawn from narrative stories of program beneficiaries guided by the intervention's theory of change.

The evaluators will seek ethical approvals from Ethiopian Midwives Association (EMwA) Institutional Research Ethics Review Board (IRB) and the PSI Research Ethics Board (REB) prior to the enumerators training and field data collection. The IRB approval letters will be submitted to

Oromia, Sidama, Amhara and SNNP Regional Health Bureaus and the Kaduna and Jigawa state health departments for their reference and support in the management of the field work.

TIME FRAME

The evaluation is expected to take twelve months from August 2023 to August 2024.

1.0 BACKGROUND INFORMATION

1.1 INTRODUCTION

Adolescent pregnancy remains a major global health challenge. Annually, 21 million adolescent girls conceive, a majority of these in low and lower middle-income countries. Conception during adolescence is highly prevalent such that one in every three women will have had their first pregnancy by their twentieth birthday. Further, half of these adolescent pregnancies occur before the age of seventeen(United Nations Family Planning Agency (UNFPA), 2022). It is estimated that nearly half of girls who conceive before adulthood will have a repeat birth by the time they exit adolescence, further doubling the risks associated with pregnancy at this age. Pregnancies occurring at this age are associated with multiple health, developmental and socio-economic consequences for the adolescent girl, their family and communities (World Health Organization (WHO), 2020). The leading causes of adolescent pregnancy include early marriage, gender and sexual violence, poverty, limited educational and employment opportunities, and underutilization of contraceptives due to various individual, cultural and health system barriers(WHO, 2020).

The consequences of adolescent pregnancy are diverse. Pregnancy and childbirth are a leading cause of morbidity and mortality among adolescent girls. In 2021, maternal conditions were the fourth leading cause of disability-adjusted life years and the second leading cause of mortality among adolescent girls 15-19(UNFPA, 2023). The negative health consequences of teen pregnancies include pregnancy complications (pre-eclampsia, unsafe abortion, anaemia, maternal depression), birth complications (pre-term birth, obstructed labour, obstetric fistula), post-partum complications (post-partum haemorrhage, puerperal sepsis, neonatal death, low birth weight neonates and postpartum depression) and death. Further, pregnancy at adolescence is associated with multiple socio-economic outcomes such as discrimination, rejection, social isolation, school discontinuation and economic deprivation(Huda et al., 2022). Despite the recognition of these consequences and the need to careful monitoring and care needed during pregnancy, most pregnant girls receive poor health care. Fewer pregnant girls, compared to their older counterparts, initiate ANC, make the recommended number of ANC visits, receive high quality ANC care, are supervised during birth by a skilled health worker or receive postpartum care(UNFPA, 2023). There is growing global attention for health systems to make strategic investments to avert teen pregnancies and to deliver high quality, user-friendly and timely interventions for the adolescent girls who conceive.

Motherhood is a key aspiration for most women including those in adolescence. In patriarchal societies, where early marriage is common, girls are expected to begin childbearing immediately

after their marriage to prove their fertility. At this age, married adolescent girls lack comprehensive knowledge about pregnancy and childbirth, and have limited agency and decision-making power to determine what is the best care for them(Ricker & Ashmore, 2020). Delivering high quality and timely antenatal care (ANC) is a crucial intervention that could avert most of the risks associated with adolescent pregnancy(Hackett et al., 2019). Initiating ANC in early pregnancy provides health workers an opportunity to perform health promotion and education, conduct risk assessment and action, and monitoring and timely management of pregnancy complications. Yet ANC outcomes for pregnant adolescents are wanting. Studies have documented various reasons why ANC attendance is poor for adolescent girls(Hackett et al., 2019; Pell et al., 2013; Sewpaul et al., 2022). These include health system factors such as the tense relationships with providers, the low level of service quality, and long distances to health facilities; social factors such as level of support from the male partner and community norms; and individual factors such as age, level of education, autonomy, knowledge of the importance of ANC, place of residence, financial factors, pregnancy disclosure, parity and marital status(Sewpaul et al., 2022). Holistically addressing the factors influencing the timing, consistency and completeness of ANC attendance and improving the quality and user-centredness of ANC for adolescent girls using a socio-ecological model could improve the pregnancy outcomes for pregnant teens and reduce the avoidable complications(Mweteni et al., 2021).

Several interventions have been trialled to increase demand for, utilization and completion of ANC among adolescent girls who are pregnant. These include group ANC(Teasdale et al., 2022; Vandermorris et al., 2021) and home visits by community health workers(Esopo et al., 2020). Findings from these studies has shown a promising outlook on the interventions' ability to increase ANC adherence, reduce the gestational age at first ANC attendance, improve the satisfaction with ANC services and skilled attendance at birth(Esopo et al., 2020). Yet not all expected outcomes from these interventions were attained and only two of the five studies in a systematic review of interventions to increase ANC adherence showed positive results. Group ANC has shown good results at increasing the awareness of at least three pregnancy danger signs among pregnant adolescent girls(Vandermorris et al., 2021). In a separate study conducted in Kenya, nutritional and health knowledge relevant to pregnant women were not substantially different between ANC and non-ANC attendees (Nandita. et al., 2013). In a similar study in Tanzania, only 40.2% of women were knowledgeable on the danger signs of pregnancy(Massenga et al., 2023). A study in Indonesia demonstrated good results of a trial to increasing knowledge across the pregnancy continuum (Nuraini & Parker, 2005).

Although intervening to increase demand and timeliness of initiating ANC, doing so in the pre-conceptual period, when girls and their partners are considering to conceive offers the most opportune window to create awareness of what things they need to do to attain a healthy pregnancy. This would include what health issues can affect fertility, the desired nutritional behaviours and the signs and symptoms of pregnancy. This would also alert the couple on what things are expected in early pregnancy including access to early ANC. Intervening prior to conception is important, because it provides health workers an opportunity to screen health risks

that could prevent conception, but also those which could negatively affect pregnancy outcomes. Despite the recognition of the value of pre-conceptual interventions, there is huge gap of evidence on what interventions would work for adolescent girls at risk of pregnancy to increase demand of and relevance of ANC. First, interventions in this period are less prioritised by health systems and providers. Second, when such interventions exist, they vary widely between geographies with very few of these in developing countries and interventions not being tailored to the needs of adolescent girls. This was affirmed by a scoping review conducted in 2017 which demonstrated that only 6 of the 27 studies on preconceptual interventions were conducted outside of the United States, only one in Lebanon (Hemsing et al., 2017). Although, most of the interventions demonstrated improvement in preconceptual knowledge, change in dietary habits and use of folic acid, none of the studies tracked the impact of the interventions on ANC outcomes, when pregnancy occurred.

The lack of adolescent-specific evidence and the recognition of the number of teen pregnancies in Africa, does present a valid opportunity for programmers to design, implement and evaluate pre-conceptual and early pregnancy interventions to document their impact on ANC, maternal and neonatal and post-partum outcomes. Since late 2012, Population Services International (PSI) and its consortium partners, with funding from Bill & Melinda Gates Foundation, employed human centred design (HCD) techniques to design a user-centered intervention component targeting married adolescent girls in northern Nigeria and Ethiopia under the A360 Amplify project. This component would be layered on two signature aspirational sexual and reproductive health interventions, Smart Start for Ethiopia and Matasa Matan Arewa (MMA) for northern Nigeria. These interventions have shown promising results at increasing demand for and uptake for voluntary modern methods of contraception and counselling services in primary care outlets among married adolescent girls.

1.2 A360 AMPLIFY

A360 amplify stands for Adolescents 360 Amplify. Adolescents 360 (A360) was a blueprint project led by PSI since 2016 and 2020. It was implemented in Nigeria, Ethiopia, and Tanzania and employed HCD and alongside other public health disciplines to develop four interventions, each suited for a unique geographic region in these countries: Kuwa Mjanja for Tanzania, Smart Start for Ethiopia(Meghan Cutherell; Claire Cole, 2019), 9Ja Girls for southern Nigeria and MMA for northern Nigeria. A360 used adaptive implementation to steward implementation targeting adolescent girls in the four geographies. By the end of the investment, the interventions had reached over 600,000 girls with information on contraceptives and over 420,000 girls had adopted a modern method of contraception. Following this success, the A360 donors, Bill & Melinda Gates Foundation and Children's Investment Fund Foundation funded a follow-on investment A360 Amplify that runs between 2020 and 2025. Kenya was added as a fifth geography. This phase seeks to adapt the interventions to provide an expanded package of services that meet the needs and aspirations of the girls more wholistically. This expanded package included a component on economic strengthening that equips girls with technical and vocational skills to plan, and implement income generating activities to increase earnings, savings and increase their contribution to household expenses as well as increase their economic autonomy.

Additionally, the interventions in Ethiopia and northern Nigeria would be expanded to include a maternal and child health component that would target adolescent girls at risk of pregnancy, those actively trying to conceive and those in early pregnancy, with a component to stimulate demand for preconceptual care and ANC. Between November 2021 and May 2023, design teams in Nigeria and Ethiopia engaged married adolescent girls, their spouses, mothers in law, mothers, health providers and managers and community mobilisers to co-create these components. The component for northern Nigeria is called the Expanded MMA and that in Ethiopia is called Smart Pathways.

1.3 DESCRIPTION FOR THE MNCH COMPONENTS

Expanded MMA with MNCH

In northern Nigeria, MMA is supported through the Society for Family Health and is implemented through primary care centres (PHCs) in four states: Kaduna, Nasarawa, Jigawa and Kano. MMA targets married adolescent girls who are mobilized through trained female mentors who directly engage girls in the communities and link them to MMA-supported PHCs. Additionally, trained male interpersonal communication agents (MIPCAs) engage men in spots where they congregate to illustrate the value of birth spacing to attaining good health of the mother and the child. Men who express interest in birth spacing are given referral cards to give to their wives, who walk into PHCs to receive counselling and services. At the PHCs girls receive services directly through a trained youth-friendly provider and could participate in life, family and health (LFH) classes. LFH consists of four guided mentorship sessions conducted over a four-week duration convened by trained mentors. During these sessions girls receive information including nutrition, child spacing, interpersonal communication, financial management and gains life and vocational skills(Sarah. et al., 2021).

The MNCH component for MMA is built on the LFH classes. Girls who are at risk of pregnancy and who don't want to use a method of contraception or who suspect that they are pregnant are mobilized by female mentors or through their husbands to attend LFH sessions at PHCs. Those who walk in to receive services are offered the services directly and introduced to the LFH classes. The sessions take two hours, are moderated by trained female mentors and attended by ANC experts (trained providers) who offer information and counselling on attaining health pregnancies. MIPCAs facilitate community sessions with men whose wives (15-19) are pregnant and refer them to access ANC services. All mobilized girls who test positive for pregnancy undergo routine ANC, enhanced with gestational age-specific messages about the expectations of ANC, birth preparedness, nutrition during pregnancy, danger signs and how to avoid them and postpartum family planning (PPFP).

Smart Pathways

This component is layered on Smart Start. Smart Start targets married adolescent girls 15-19 and their spouses in Ethiopia in five regions: Oromia, Amhara, SNNPR, Sidama and South Western. Smart Start is implemented as part of the national Health Extension Program (HEP) through health

posts. Using a Smart Start discussion guide called a 'goal card' health extension workers (HEWs) engage married adolescent girls alone or with their husbands to discuss how the use of modern contraceptive methods to plan their families can facilitate financial planning and enhance the financial security of their families. This seamlessly creates relevance of contraceptives within a context where a direct conversation on modern contraceptives would be difficult. Smart Pathways (the MNCH component) is an expansion of Smart Start. Unlike Smart Start, it targets AGYW 15-24. In the communities, a team of trained FMOH-recognized community mobilizers consisting of members of the women development army (WDA) and Smart Start Navigators (SSNs) approach married adolescent girls from their communities and introduce them to Smart Start. Married girls who express interest to take up birth spacing are linked to HEWs who are working in the community or at health posts to receive the Smart Start intervention (pathway 1).

For girls who are ambivalent to receiving contraceptive counselling and services or those who intend to conceive soon, the trained mobilizers link them to an HEW who takes them through the Smart Pathways component for non- pregnant girls. When they land at the HEW, the HEW uses the Smart Pathways guide to discuss issues related to Preconception Care Counselling and early ANC initiation (pathway 2). For girls who have missed their periods or suspect that they are pregnant, the trained mobilizers link them to health centres or health posts where HEWs or midwives take them through a seven-step process that covers pregnancy testing, building demand for ANC, the benefits and components of ANC, danger signs of pregnancy, smart nutrition, preparation for delivery and post-partum family planning (pathway 3). Girls in Pathway 2 who conceive are referred to navigate through pathway 3 when that time comes. The three pathways are illustrated in Figure 1.

As married pregnant AGYW navigate through ANC, they are offered services based on the Ethiopia Federal Ministry of Health antenatal care guidelines (Ministry of Health of Ethiopia, 2022).

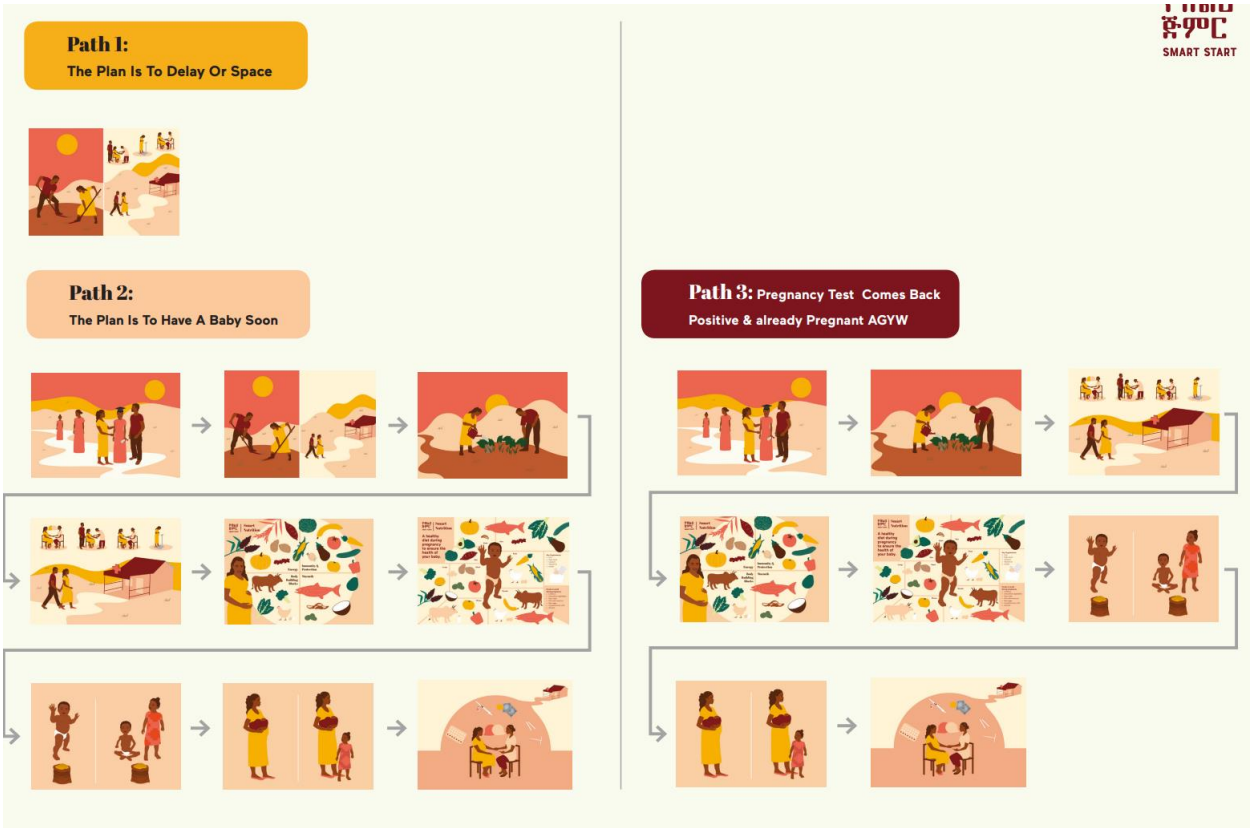

Figure 1: Smart Steps pathways

1.4 JUSTIFICATION FOR THE RESEARCH

Ethiopia and Nigeria have poor MNCH indicators particularly regarding to adolescents, although older women are not spared either. According to Ethiopia Mini Demographic Health Survey (EMDHS) of 2019, among women 15-49 years old who had a live birth in the five years preceding the survey, 74% had at least one ANC visit and only 43% attended four or more ANC visits. The rates of ANC attendance were lower among women under 20 years (Ethiopian Public Health Institute & ICF, 2019). Earlier in the 2015 EDHS, the median age at first ANC visit was 4.7 months and only 20% of women had started ANC by the gestational age of 20 weeks. In that same survey, among women 15-49 years who had a live birth in the past five years, 45% were informed of danger signs or pregnancy complications during ANC visit, 56% were informed about birth preparedness and 11% were informed of the place of birth during ANC. Four in five women 15-49 years who had birth in two years before survey did not have a postnatal check-up within 48 hours of delivery(CSA and ICF, 2016).

In Ethiopia, early marriage is common since 17% of adolescent girls aged are married. Teen marriage increases to 60% among 20-24-year-old women. Among currently married girls 15-19 years, 42% have at least 1 living child. Among girls 15-19 who had a live birth or pregnant at time of survey, 13% had started childbearing, 10% had birth, and 2% were pregnant. In the 2015 EDHS,

among girls under 20 years who had a live birth in past 5 years, 33% had no ANC visit. Further, among girls 15-20 years who had ANC for the most recent live birth in the past five years, 60% received nutritional counselling, 68% had a blood sample and 66% had urine collected while 68% had a blood pressure check. Among the same cohort of girls who had received ANC in the most recent live birth in past 5 years, 38% were informed of pregnancy complications and 50.5% were informed about birth preparedness. Further, among girls 15-20 years with live birth in past 5 years, 67% had a home delivery while 87% had no postnatal check within 48 hours of delivery (among those with live birth in past 2 years)(CSA and ICF, 2016). According to the survey, the main barriers to accessing ANC among girls 15-19 years are lack of financial resources (51%), long distance to health facility (47%), not wanting to go home alone (44%), and the need for permission (33%). Overall, 68% reported to experience at least one problem in accessing ANC.

For Nigeria, among women 15-49 who had a live birth in five years preceding the 2021 Malaria Indicator Survey (MIS), 76.3% had at least 1 ANC visit and 51.5% had four or more ANC visits. The first ANC visit happened between 4-5 months of gestation; the median was 4.7 months (National Population Commission- NPC, 2021). In the 2018 Nigeria Demographic Health Survey, among girls who had at least 1 ANC visit for most recent birth, 94% had blood pressure checked, 86% provided urine sample, and 88% also had a blood sample collected. Among this age group, 39% of women delivered their most recent birth at a health facility and only 42% of women who gave birth in past two years had postnatal care within 48 hours of delivery (NPC, 2021. Specifically for adolescent girls 15-19 years in 2018, 19% of girls had started childbearing; 14% had given birth, and 4% were pregnant. In the 2021 MIS, among girls who had a live birth in the five years preceding the survey, 35.2% of girls had not received ANC, only 44.7% received ANC from a skilled service provider (compared to >63% for older women), most girls (63.1%) attended under four ANC visits, and median gestational age for first ANC visit was 4.9 months (NPC, 2021). In the 2018 NDHS, 70% of births among girls 15-19 years occurred at home. Further, 64% of girls below 20 years had no postnatal check-up within 48 hours of delivery. The main barriers reported for girls 15-19 seeking ANC were lack of financial resources (44%), long distance to the facility (25%), not wanting to go alone (22%) and the need to secure permission (14%)(NPC & ICF, 2019).

The disproportionately low uptake of ANC by pregnant adolescent girls, delayed initiation of ANC and poor adherence to ANC guidelines in Nigeria and Ethiopia warrant that an adolescent-friendly intervention that creates a value proposition for adolescents at risk or intending to conceive. Further, the paucity of evidence on what interventions or strategies work to increase access to preconceptual counselling by adolescents intending to conceive and promote ANC among adolescent girls at risk of pregnancy invites for thorough investigation of any interventions targeted at this age group. This evaluation is poised to employ mixed methods to document the outcomes of the intervention and uncover implementation barriers, facilitators, and opportunities for institutionalization within existing health systems.

1.5 OBJECTIVES

The main objective of this evaluation is to determine the effectiveness of MNCH intervention components leveraged on existing A360 interventions at increasing comprehensive knowledge, self-efficacy and key influencer support to pursue healthy pregnancies among married AGYW in Nigeria and Ethiopia.

The secondary objectives of the evaluation are:

(a) To evaluate the component's effectiveness at increasing comprehensive knowledge of what care is required to attain healthy pregnancies.
(b) To evaluate the component's effectiveness at increasing self-efficacy to attend ANC.
(c) To determine the component's effect at eliciting support from AGYW's key influencers when they are pursuing healthy pregnancies.
(d) To surface the system-level barriers, facilitators, and opportunities for program improvement during the implementation of the intervention components.

Apart from fulfilling the objectives above, this evaluation will also be used to generate indicator values (baseline and follow-up) for the results framework, that are submitted to the donor. Specific questions have been uniquely crafted to address these needs. The results framework that has been agreed with the donor is included as Appendix V in this protocol.

2.0 METHODOLOGY

2.1 STUDY DESIGN

This evaluation will use an effectiveness-implementation hybrid study design so that we are able to evaluate the impact of the intervention in real-world settings (i.e., effectiveness) and to assess best approaches to implement the intervention (implementation research). This approach has been established to accelerate the translation of evidence into practice and to increase the usefulness and relevance of research findings for policy decisions(Curran et al., 2012). The hybrid design will employ mixed methods consisting of a quantitative survey, routinely collected program data and qualitative data. A similar approach was used to evaluate group ANC for adolescent girls in Senegal(Vandermorris et al., 2021). For the implementation research element, the qualitative impact protocol (QuIP) approach will be employed alongside traditional qualitative methodologies. To use this approach, independent qualitative researchers who are not familiar with the interventions' theory of change or who have limited knowledge of the expected changes from the intervention perform exploratory interviews with the beneficiaries to document change stories highlighting what might have contributed to the most significant change in their lives. This reduces the bias associated with an inquiry that focuses on the change specifically brought about by the intervention where beneficiaries might intentionally or unintentionally attribute change to an intervention even when those changes were caused by other factors. This approach involves the use of open-ended and exploratory tools starting with the expected changes and rolling back to associate these with activities that were happening prior to the evaluation(Copestake et al., 2019). The QuIP methodology with be conducted parallel to the quantitative survey and routinely collected program data to triangulate the findings.

Routinely collected data will constitute aggregated data abstracted from program records employed by mobilizers during field activities, the ANC and family planning facility registers maintained by the health extension workers and health providers and monthly reporting tools at the facilities. The registers used in our study will be those approved by the Ministries of Health in the two countries. This element is not detailed in this protocol because it is non-research.

2.2 STUDY SITES

This study will be conducted in Ethiopia and in Nigeria. It will constitute an intervention and a comparison group. In Nigeria the study will be conducted in two states i.e., Kaduna and Jigawa. For the intervention group, the study will be conducted in the specific LGAs where the MMA program enhanced with the MNCH component is implemented. For the comparison group, the study will be conducted in LGAs implementing MMA without the MNCH component. At the LGAs, the study will be conducted in specific PHCs which have been purposely selected to host the evaluation and the catchment areas that are served by the PHCs.

In Ethiopia, the study will be implemented in four out of the five regions that implement the Smart Start interventions (avoiding the South Western region which started implementing Smart Start in 2023). Specifically, the intervention group will be based in nine (9) woredas in the four regions where Smart Start with Smart pathways is implemented. The comparison group will be based in 8 woredas geographically distant from those offering Smart pathways but offering Smart Start. In Ethiopia, the evaluation will be conducted in health centres and health posts that offer comprehensive ANC services.

For both Nigeria and Ethiopia, comparison areas will be locations implementing the current MMA or Smart Start intervention without the MNCH component. These will be carefully selected to ensure they match the intervention locations in terms of the demographics of married adolescent girls and based on the economic and health indices. Because of comparing the intervention outcomes against the current package of interventions, this study will ideally be measuring the incremental effectiveness of the expanded interventions and not with a counterfactual (as would have been if the comparison was done against routine government-led MNCH components).

2.3 STUDY PARTICIPANT GROUPS

The primary target group for this study will be married AGYW aged 15-19 years from the two states in Nigeria and 15-24 years who reside in four regions in Ethiopia. Given that this study explores the experiences of AGYW related to planning for pregnancy and experiencing pregnancy, birth and the postpartum periods, the study will work to recruit a mix of married AGYW who have both experienced a prior pregnancy and those who have not (but at risk of pregnancy).

The secondary target groups for this study will include:

i. Male partners (husbands) of married AGYW who have received the MNCH intervention in Nigeria
ii. Health providers and community health mobilizers from the intervention locations

All husbands, health providers and community mobilizers will be over the age of 18 years. The inclusion and exclusion criteria for all groups are provided in Table 1.

Table 1: Inclusion and exclusion criteria

Group	Inclusion	Exclusion
Married AGYW (survey)	• Aged 15 to 19 (Nigeria) and 15-24 (Ethiopia) • Married • Resident in a study site • If pregnant should be at most 24 weeks gestation • If not pregnant, at risk of pregnancy (not using a contraceptive method at the time of the survey with or without intend to conceive) • Consent to participate in the study	• Married AGYW, aged 15-19 (Nigeria) or 15-24 (Ethiopia) who decline to give consent • If pregnant, has an advanced pregnancy (≥ 25 weeks gestation) • If not pregnant, currently using a contraceptive method
Married AGYW (FGDs and IDIs)	• Married and aged 15 to 19 (Nigeria) and 15-24 (Ethiopia) • Currently pregnant or in the post-partum period (after recent delivery) • Participated in the full MNCH components of MMA or Smart Start • Consent to participate in the study	• Married AGYW aged under 15 or over 19 (Nigeria) or over 24 (Ethiopia) • Not pregnant or not in post-partum period • Did not participate in MNCH component • Decline to consent
Husbands of AGYW (Nigeria only)	• Male aged 18 years and over • Husband of an AGYW aged 15 to 19 • Has participated in husband sessions (at the community or facility) of the MNCH component • Consent to participate in the study	• Males under 18 years • Did not participate in the husband sessions for the MNCH component • Husband who decline to give consent
Health worker / community health mobilizer	• Employed as a health worker (can be nurse, midwife, etc.) or mobilizer (female mentor, member of WDA or MIPCA) within the study site. • Served at the facility or community for this role for six or more months. • Provides services along the MNCH continuum of care (e.g., ANC, delivery, PPFP, etc.)	• Recently employed health worker or mobiliser (< 6 months) • Not familiar with MNCH or FP services • Unwilling to consent

2.4 PARTICIPANT RECRUITMENT

The following section outlines how each group will be recruited to participate. The recruiters' role will be to invite potential participants to the evaluation, briefly assess eligibility and to seek their

permission to share their contact details with the research team. They will be guided by a recruitment script (see Appendices A-F) so that the procedure is standardized. The recruitment procedures for each study group are detailed in the sub-sections below.

2.4.1 Recruitment of married AGYW

Different recruitment procedures will be used for the Quantitative survey and the Qualitative component.

(i) For the quantitative survey in both Nigeria and Ethiopia, the research team will leverage already existing trained mobilizers (female mentors in Nigeria & members of WDA and female SSNs) to perform recruitment procedures. The mobilizers will be trained to identify and recruit AGYW from the community guided by a recruitment script. The mobilizers in Nigeria and Ethiopia are familiar with their communities and will approach potential participants directly by face-to-face contact during their routine household visits, in clinics and/or during community gatherings.

When a mobilizer approaches a married AGYW, she will ask her for verbal consent to speak to her in private. She will ask her the four screening questions (in the recruitment script) after providing brief details about the nature of the evaluation. If the potential participant is eligible and has expressed interest to participate, the mobilizer will obtain the contact details (name, phone number and details of residential address) and record these in a recruitment confidential contacts' list (Appendix Q attached to the submission). Details of residential address are collected because a substantive number of AGYW in these locations might not own or have access to a phone as reported in recent surveys – 40.2% in Ethiopia and 6-21% in northern Nigeria (Krug et al., 2021a, 2021b). These lists will be passed to a data collector (research assistant) working in the study locality on a daily basis. The AGYW will also be notified that they should expect a call or a visit from a female enumerator at a future date. During the period when we execute a modification to increase the number of pregnant girls in Amhara, South, and Central Ethiopia and Sidama, recruiters will only identify, approach and invite pregnant girls only. To do so, they will be trained not to field the screening question on contraceptive use (question 3) in the recruitment script - the rest of the procedures and questions will be fielded as they are. During this period, they will only capture contact details of eligible pregnant girls in the confidential recruitment contact lists.

Trained enumerators will employ these lists to contact potential participants to provide more information about the study guided by the information sheets (attached to the submission) and to set an appointment date for the interview (if contact is on phone). If the AGYW listed does not have a phone contact, the call is unanswered or the call doesn't go through, the data collector will arrange to pay a physical visit to the AGYW's residence to make an in-person contact. Upon arrival at the residence, the data collector will introduce herself and request to speak to the AGYW, without directly disclosing reproductive health. During the visit, the data collector will offer brief information about the study. If the AGYW is willing and available for the interview at that time, she will continue and perform consenting procedures then conduct the interview if consent is granted. This will make it convenient for the participant and the study.

However, if the AGYW is unavailable for the interview on during that visit date and time, an appointment will be scheduled.

For the AGYW with an appointment, on the date of the scheduled interview the research team will provide detailed information and obtain informed consent form. Thereafter, the data collector will perform the interview. For recruitment in the Oromia region only, enumerators will be assigned quotas (numbers of pregnant versus non-pregnant girls) to survey from a health post. As they continue to consent participants and perform interviews, they will keenly monitor these numbers. Once they had reached the allocated sample for a particular group (in most cases it will be non-pregnant girls), thereafter they will confirm the pregnancy status of the AGYW remaining on the list when contacting them (using the information sheet approved) and if an AGYW is not pregnant, they will let them know that the sample has been reached and that they will not be included in the study going forward but appreciate them for their interest to join the study. They will not invite these AGYW for in-person contact. This will prevent AGYW from spending time and effort travelling to the facility when they will not be recruited. If an AGYW is confirmed to be pregnant, the study procedures will continue as described earlier.

The personal identifying information (PII) collected during recruitment will be destroyed under the instruction of the PI following the completion of recruitment and will not be recorded alongside any data collected in this activity.

(ii) For the qualitative component, AGYW will be recruited primarily through Smart Start and MMA program staff, particularly health extension workers and health providers working at the facilities implementing the MNCH component. The recruiters will be provided with guidance on who should be recruited for FGDs and IDIs. They will identify AGYW from the service delivery records which are used to document the attendance of AGYW to MNCH sessions. They will use the instructions provided by the study team to purposely sample enough potential participants from the client records. Only AGYW who have phone numbers indicated in the client records will be selected. This is because tracing AGYW who do not have documented phone contacts will be impossible since detailed physical addresses are not routinely collected by providers. Furthermore, the communication of the scheduled date, time and venue for the IDIs and FGDs will be impossible without phone contacts.

Using the recruitment script, recruiters will contact the identified AGYW through the phone contacts documented in the program records. During the phone call, once the recruiters have introduced themselves and obtained verbal consent, they will ask the potential participants if that is a good time to speak. They will also request the AGYW to identify a secluded place that offers privacy and then provide a brief description of the evaluation. This will ensure that no one could hear what is being communicated during the phone call. Thereafter, they will field the screening questions to determine eligibility and then proceed to gather contact details which will be documented immediately on the confidential contact lists.

Once recruitment is completed, the contact information will be compiled together and transferred to the lead investigators for each country. The investigator will then coordinate so that the qualitative researcher in the team contacts the participant by phone to complete the recruitment procedures. The qualitative researcher will then schedule an appointment and

venue for the IDI or FGDs. On the scheduled date of the FGD or IDI, full consenting procedures will be executed. Similar to the quantitative survey, all PII details will be destroyed by the PI once recruitment is completed.

2.4.2 AGYW's husbands in Nigeria

Husbands will be recruited from the same communities as the primary target group. For the IDIs with husbands, recruitment will be implemented through male IPCAs who are facilitating the MNCH components that involve husbands. They are also familiar with the communities they are working in a will be trained to identify potential participants based on the specific criteria and specific instructions given on the caliber of husbands to select. Male IPCAs will conduct purposive sampling to select husbands from the program activity registers and reach each one by one. Only husbands with phone contacts in the activity records could be selected. When male IPCAs have reached the required number of husbands, they will start contacting them, on phone (only). The male IPCAs, while guided by a recruitment script, will provide brief information about the study to the selected husbands (from the attendance records they maintain) who have been involved in the intervention and obtain their verbal consent. Husbands who express interest to participate will then be invited to respond to a few screening questions to determine eligibility. Eligible husbands will be asked to share their contact details which male IPCAs will document on the confidential contact lists. The remaining steps of the recruitment procedures employed for the AGYW IDIs (step 2 and 3) will be replicated for husband IDIs once the confidential contact lists have been developed except than a male qualitative researcher will execute these procedures.

2.4.3 Health workers and mobilizers

This group will be approached by the research team through contacts shared by the project field team. These contacts will be shared with the qualitative researcher who will execute the bulk of recruitment procedures. A brief description of the evaluation will be explained to the selected potential participants, screening questions fielded and those who express interest invited to propose a date and time for the KII.

2.5 CAPTURING OF PERSONAL-IDENTIFYING INFORMATION (PII) FOR RECRUITMENT

As described earlier, PII will be collected as part of the recruitment process. Mobilizers, male IPCAs and field program staff will provide the research team with the name, physical address or contact details of potential participants. In Nigeria, the recruiters working under SFH will work closely with Viable Knowledge Masters' (VKM) personnel and for Ethiopia recruiters under MOH Ethiopia will work with personnel from Deep Dive Research and Consulting PLC. VKM and Deep Dive Research and Consulting PLC will be the primary recipients of the PII on behalf of PSI and SFH. The PII will be used exclusively for the purpose of inviting participants to participate. The in-country lead investigators will be responsible for ensuring that this information is stored securely (in a secure location – locked room by VKM and Deep Dive Research and Consulting PLC offices) until recruitment has happened. Participant trackers for the survey will be hosted in PSI SharePoint

Folder and the access to these files will be restricted to specific VKM and Deep Dive Research and Consulting PLC staff. The PI will authorize VKM and Deep Dive Research and Consulting PLC to destroy the PII immediately after recruitment has been completed. These data will never be linked to data collected as part of the study, nor shared beyond authorized members of the evaluation team. In-country Lead investigators will oversee the handling and storage of the PII collected for recruitment.

2.6 SAMPLE SIZE ESTIMATION AND SAMPLING PROCEDURES

The sample size for the quantitative survey is estimated using a two-sided Wald Z-test using GEE methods, accounting for repeated measures and clustering within groups and assumes no change of the estimate for the primary outcome for the study within the comparison group. The primary outcome will be a binary measure, which documents whether the AGYW has met criteria for 'comprehensive' knowledge of what is needed at conception to attain a healthy pregnancy. It will be estimated from a composite measure made from a combination of questions assessing AGYW about their knowledge about behaviors (proper nutrition, screening tests and treatment for HIV and sexually transmitted infections, use of prenatal vitamins, and avoidance of harmful substances). These questions are curated from a systematic review conducted in Ethiopia on the knowledge of preconceptual care and which is also relevant for Nigeria(Ayele et al., 2021). This study established a pooled estimate of good knowledge of preconceptual care of 30.9%. In our study, an AGYW will be comprehensively knowledgeable if she responds to the affirmative to all the questions. The questions will be fielded at the time of recruitment and repeated 3 months later.

To detect an effect size of 10% (between recruitment and 3 months later assuming no change in the comparison group), with a power of 80% at the 95% confidence level (two-sided), we would need a sample size of 991 participants in each country equally split between the comparison and intervention group. This assumes an adjustment of 10% for non-response and a design effect of 1.2. Appendix R (page 57) summarizes sample sizes with different scenarios of estimated effect sizes. We adjust this sample upwards by 10% to account for attrition that might occur between recruitment and the follow-up after 3 months at arrive at a sample size of 1,090 which when split between the groups would be 545 AGYW. Cumulatively for Nigeria and Ethiopia, the final sample size would entail 2,180 participants. This sample is increased by 240 to 2,420 to account for recruitment adjustments for Ethiopia.

A two-group repeated measures design with a binary response and with 2 measurements for each subject will be used to test whether there is a difference in group slopes. The comparison will be made using a Wald Z-test using GEE methods. The repeated measurements of each subject will be made at 2 times and using an autoregressive correlation structure (AR1). The initial proportions P1(0) and P2(0) are estimated at 0.3 based on estimates in the literature (preconception care knowledge). P2(1) proportion assumes no change in the primary outcome over the course of the intervention. Estimates are adjusted by 10% missing/non-response rate and a design effect of 1.2 to account for within community or group clustering.

Table 2 shows estimated total sample sizes for the primary and secondary target populations included in this study.

Table 2. Sample size estimates for MNCH OE

	# of participants in Ethiopia	# of participants in Nigeria	Cumulative Sample size	Total samples
Quantitative survey				
Intervention arm	545+116=661	545	1,206	2,420
Comparison arm	545+124=669	545	1,214	
Qualitative component				
FGDs with married AGYW	40*	40	80	173
IDIs with married AGYW	24	24	48	
IDIs with husbands (Nigeria only)	-	10	10	
KIIs with health providers and mobilizers	10	25	35	
Cumulative sample for the study				2,593

*Each FGD recruits a maximum of 10 participants

2.7 DATA COLLECTION PROCEDURES

2.7.1 Quantitative survey

Upon receipt of the confidential recruitment lists from mobilisers, trained enumerators from VKM and Deep Dive Research and Consulting PLC will contact the potential participants to arrange for the interview date and time (using Information Sheet in Appendix G) as explained in 2.4.1. This will be done through a phone contact or a physical visit to the participant's residential address. In case it is a call, enumerators will ensure that only when the AGYW is comfortable to speak and in a location that guarantees auditory privacy before that can proceed and make the scheduling call. As they schedule the interview, enumerators will guide the AGYW to elect where they would be comfortable to take the interview between a selected community safe space, a health facility or at their residence. Enumerators will also remind participants that it is voluntary to participate. For Oromia region, a slight modification will be made so that enumerators will confirm pregnancy status (as they administer the information sheet during the call), as soon as the sample of non-pregnant girls allocated to them has been reached. This will prevent them from exceeding the sample quotas.

On the date of the baseline interview and upon arrival at the venue for the interview, the enumerator participant will confirm that the location offers auditory and visual privacy and ensure everything is ready. When the AGYW arrives, the enumerator will introduce herself (all interviewers will be conducted by trained young women for gender sensitivity). Before executing the interviews, the

enumerator will perform detailed consenting procedures. During the consenting the enumerator will explain to the participant why obtaining contact details to facilitate future follow-up is necessary. This will also include explaining the reasons for obtaining secondary contact information, details about how it will be used and what will be said to camouflage the real details of the study. They will also be informed about sharing of the de-identified data in a data repository. Informed consent of the participant will then be obtained, and a signature or thumb print impression made on a consent form. For both emancipated minors and girls with legal right to consent, the same document will be used to obtain consent. After consent is obtained and the enumerator verifies that there is auditory and visual privacy, she will conduct the interview. When she has completed the interview, the enumerator will provide adequate information about the follow-up surveys and obtain contact and physical locator information for the purpose of these surveys.

Before participants leave, they will be issued a unique Study ID and given a study Contact Card (Appendix O) on which this number is written (no names will be written on the card). The Card will also bear contact details of In-Country Lead Investigator and contact details of the local REB that has approved the study just in case girls want to follow-up to receive additional information about their rights to participation. The enumerator will the record the participants details (name, contact address- primary and alternative or secondary (another phone number through a which a participant can be reached if their main contact number is not working), physical address and Study ID) in a password protected electronic study tracking register hosted on the data collection devices (institutionally-owned) which will be serially completed. This information will enable the confirming of the identity of the participant at the follow-ups. Once data is captured on the electronic tracking register (Appendix P), the data collector will not be able to edit the entries, nor will the entries be downloadable. The tracking register will be hosted in secure cloud in SFH and PSI's SharePoint and only the PI will have authority to decrypt the entries- once the time for the follow-ups start. Once all the girls in the confidential contact lists used during recruitment have been engaged, these lists will be destroyed immediately. The survey questionnaire will be hosted on the Open Data Kit (ODK) platform, specifically SurveyCTO. Survey CTO is a secure android-based data collection platform that enables remote data collection and permits intermittent synchronization with a secured server. Data will be submitted to the server at least once in a day.

During follow-up, the enumerators will be provided access to the decrypted registers and only the specific record they are responsible for. They will be expected to contact participants two weeks before the expected date of the follow-up interview (after 3 completed months after the initial interview and 8 complete weeks after the expected data of delivery – pregnant AGYW only). As a rule, enumerators will employ the participant's primary contact details. We will only use secondary contact details if the use of the primary contact details is unsuccessful or impossible as can occur if the AGYW doesn't own a phone. Enumerators will attempt at most five times if the mobile contact is not going through or is not picked. During these calls, the enumerator will first introduce

herself, then confirm that the person speaking on the other side is the AGYW, establish that the AGYW is comfortable to speak and has auditory privacy before she can proceed. Enumerators will be guided by the follow-up script (Appendix S). During the call, enumerators will also remind participants that it is voluntary to participate in the follow-up interviews.

We will also use locator information (physical address details) collaborating with mobilizers to physically locate participants from their residences and schedule dates for interviews. For participants who are reached on phone, the exact date and venue of the interview will be decided by the participant, ensuring that convenience of the participant is prioritized. In much as possible we will suggest that enumerators synchronize the interview date to clinic visits or when the AGYW visit places near the study site such as market days.

During these follow-up calls, if a participant has provided phone details of another person, enumerators will ask to speak to the participant without disclosing the exact reasons why we are calling her (citing that we are conducting a general health wellbeing follow up from the nearest health facility) and without using terms such as sexual and reproductive health or family planning. If the participant is not within the proximity of the person who received the call when the phone call is made, the enumerator will leave a message that the participant could call or beep back the enumerator's number when she is available so that the enumerator can initiate the call. Only when the enumerator is assured that the participant is the one on the other side and has auditory privacy will the conversation continue. Otherwise, enumerators will ask the participant to suggest a safer time when they could call back. AGYW who are not reached within a one-month period since their due data for follow-up will be designated as lost to follow-up and the exact reason for not being reached documented in their study record.

When contacted for follow-ups, participants shall be sensitized on the available options where the data collection could take place so that they can voluntarily select their preferred venue and are familiar with what to expect. At data collection, the unique Study ID of the participants documented in the tracking register will again be entered into the Survey CTO system. Enumerators will confirm participant details through the electronic register that was created at recruitment and also using the Study Contact Card that was given to the participant at the same time. AGYW will be encouraged to carry their Contact Cards when they turn up for follow-ups, although it will not be a mandatory requirement for participation since the register will be sufficient. Once data collection is completed, participants will be appreciated, and an entry made on the register that a follow-up has been completed.

As explained earlier the second follow-up will target AGYW who are pregnant at baseline and those found to be pregnant at the first follow-up (if they were not pregnant at baseline). The participant tracking register will be customized to auto-calculate the expected date of delivery (EDD) (using Naegele's rule) using the last menstrual period as a reference(Edwards & Itzhak, 2019). The register will then estimate 8 completed weeks from this date. This will be a rough estimate from

the date of delivery as the EDD is an approximated value subject to error. This follow-up will be done on the first date of week 9 since the EDD. As with the first follow-up, the enumerator will be prompted to initiate a scheduling call two weeks before this date. They will use the follow-up script, but in this case, they will say the information specific for this follow-up. Enumerators will be thoroughly trained to identify and handle scenarios where AGYW are uncomfortable to schedule an interview that might be speaking about a pregnancy that had an unfavourable outcome. To manage the sensitivities of this follow-up, voluntary participation and withdrawal will be emphasized during the calls, visits and when conducting the interview. This will reduce pressure on the AGYW who are uncomfortable from participating when they do not.

The follow-up interviews will follow the same format as the initial interview though the questions will be slightly different. Once a follow-up is completed, no entries will be possible on the same study record. Some attrition is to be expected, but measures will be taken to reduce this as much as possible. This includes multiple call attempts using the primary and secondary contacts, use of physical tracing with the help of trained mobilizers and provision of a small stipend (equivalent to $2 in local currencies (Naira for Nigeria and Birr for Ethiopia) given in cash for each successful baseline and follow-up interview) to reimburse for transport incurred to visit the data collection location. Those who participate in phone follow-up interviews will receive $1 airtime on their phones. Immediately after all the follow-ups are completed the registers will be destroyed by the PI. Participants will not be required to sign any document to confirm the receipt of the reimbursements, neither will their personal details be captured in a study document to account for the money reimbursed for transport or send as airtime to your phone. Instead, research assistants will sign against a document that summarizes the number of participants who have received the reimbursement or airtime without capturing any personal information. The field supervisors from VKM and Deep Dive Research and Consulting PLC will countersign the summary document for each study site to affirm that the cumulative amount of reimbursements given matches the number of participants interviewed. This summary will be submitted to the finance departments to account for the resources received.

2.7.2 Qualitative component

The qualitative component will constitute individual in-depth interviews (IDIs) with married AGYW and husbands of AGYW (Nigeria alone), focus group discussions (FGDs) with married AGYW and key informant interviews (KIIs) with health providers and mobilizers. Participants for this component will have been purposely sampled with the assistance of the program team and then approached and the primary contact details for those who express interest to participate gathered and shared with the research team. No secondary contact details will be collected. Only AGYW, husbands and health workers and mobilizers working in the intervention areas will be eligible for this component – comparison areas will be excluded.

A few days prior to the date of the IDI, FGD or KII, potential participants will be contacted and asked if they are still interested to participate in the study (using Appendix G, H or I). Individuals who are still interested will be invited to congregate in a specific venue (a health facility or a community social hall) at a specific date and time. This component will be executed at the same time and in concurrency (there will be FGDs, KIIs and IDIs scheduled on the same day) and there will be limited flexibility on where data collection could occur. This will reduce the costs related to the logistics of moving the qualitative team between multiple venues. On the date of the IDI, FGD or KII prior to their participation, individual written consent will be obtained. Selected potential participants who decline to participate at this point will be replaced. For the FGDs, KIIs and IDIs, the sessions will be conducted in quiet secluded venues. The sessions will be recorded (voice only) using digital voice recorders and transcribed verbatim subsequently. Potential participants who decline to have their sessions audio recorded at the time of consenting will not be allowed to participate.

2.8 DATA MANAGEMENT

2.8.1 Quantitative data

The quantitative data will be gathered using a Computer Assisted Personal Interview (CAPI) approach. SFH and PSI Ethiopia will avail institutional tablets to VKM and Deep Dive Research and Consulting PLC for collecting quantitative data at all phases of the evaluation. A data entry template shall be developed through Survey CTO software. The survey tool shall be designed in English and local languages of the study regions with a drag and drop user interface. Thus, data collection as well as data entry shall be accomplished at the same time, accurately and timely. The data will be transferred (exported) into STATA software. Before analysis, further data check-up will be made. Preliminary analysis such as skewedness and kurtosis tests will be conducted to check and confirm that the data set is free from outliers. Appropriate statistical measurements will also be made to correct such data.

Data collection tools will be rigorously pretested before they are used for actual data collection. This will involve conducing mock interviews by the core study team (investigators) to detect any errors and by the enumerators and the field supervisors during the training prior to data collection. Because enumerators and supervisors will be native speakers of the local languages, this pre-testing will enable the study to identify issues that might have emerged during the translation of the tools. By the end of the enumerator training, each enumerator will be expected to have conducted a minimum of five mock interviews. All the feedback gathered through the pre-testing process will be used to make minor tweaks (such as the framing of questions) to the tools before they are ready for fielding to actual participants. Should be any substantive changes such as dropping or adding new questions, an amendment submission will be made to the REBs. Pre-testing will also enable checks to the electronic version of the tool and check for any skip logic errors.

When building the tool in Survey CTO software automated live data checks, extensive validations and cross-checks will be programmed. This will reduce errors and inaccuracies during the personal interview. Data shall be uploaded to the cloud daily, to enable the PI and data manager carry-out a range of consistency checks daily. Global positioning system (GPS) coordinates will be collected for all survey participants (as part of the study record) and will be used to validate the location of enumerators and specifically where data has been collected. It will also be used to uncover unusual patterns of participant recruitment. Furthermore, the GPS data will also be used to track if there are differences in the locations where study participants are interviewed from the initial and follow-up interviews. GPS data will be stripped out of the dataset during data cleaning and de-identification. The data will be synchronized with a web-based server intermittently. The mobile devices will be password protected and handled only by the enumerators. All phone call logs from the phones used to recruit and schedule follow-ups with participants will be deleted immediately after each survey phase is completed, under the supervision of field supervisors. Data collection will only be performed using institutionally-owned tablets (owned by SFH or PSI-Ethiopia).

2.8.2 Qualitative data

The IDIs, FGDs and KIIs will be recorded using digital voice recorders with consent from study participants. Audio files will be stored in a password-protected file in the PSI SharePoint until transcription is complete. Audio files will be destroyed after transcription is complete. When collecting data, we will ensure that the data collected are of high quality so that they can be reliably used as the basis to make sound decisions.

2.8.3 Quality assurance

The following data quality assurance measures shall be taken throughout the evaluation implementation to ensure the collection of high-quality data. The field team members from VKM and Deep Dive Research and Consulting PLC will be provided with a three-days' intensive training to undertake the field data collection effectively and efficiently. All data collection tools, recruitment scripts and consent forms will be translated to local language (Affan Oromo, Sidamayya and Amharic languages in Ethiopia and Hausa for Nigeria) and back translated to English.

On site supportive supervision, which includes over-the-shoulder observation of enumerators will be carried out in every study area by field supervisors from VKM and Deep Dive Research and Consulting PLC shadowed by the Co-Investigators from PSI Ethiopia and SFH. The evaluation field supervisors shall conduct back-check interviews revisiting about 10% of conducted interviews, to observe and make sure whether enumerators were properly administering interviews, as per the evaluation protocols. Information about the back-checks has been provided as part of consenting procedures but it will be voluntary. It will be guided by a back-check script (Appendix T). Back checks will only be conducted among AGYW who have been reached through their primary contact details on phone, those reached in-person or through other people's numbers will be excluded. By the end of each field day, a debriefing session will be held. The sessions will be led by the field supervisors and will give an opportunity for enumerators to reflect their observations, challenges

encountered and other issues. After each debriefing, strategies and mechanisms will be disseminated to the entire team to avoid duplication of similar challenges and issues.

For Ethiopia to address the mishap resulting to over sampling non-pregnant girls, the following measures will be executed. We will (1) develop a daily recruitment log, illustrating the proportion of participants who are pregnant versus those who are not, at the site level and aggregating these upwards to the regional level (2) daily monitoring of the records submitted to Survey CTO using the Monitor menu in the software, (3) manual tallying of recruited participants in the Amhara region where internet issues were being experienced and therefore the electronic monitoring was impossible, (4) allocating the sample quotas to enumerators so that when they reach the allocated number of non-pregnant girls, they stop recruiting them and just focus on recruiting pregnant girls alone and (5) moving recruitment to an adjacent kebele if the sample numbers for were not reached in one kebele but paying closer attention to the study group most affected by the low recruitment numbers, (6) more intimate engagement with Deep Dive through a progress review meeting twice weekly so that any challenges are discovered and action implemented immediately.

2.9 DATA ANALYSIS

2.9.1 Quantitative analysis

Quantitative data will be analyzed using univariate, bivariate and multivariate analysis to address the objectives of the study under the stewardship of PSI. Between group t-tests and chi-square tests of comparison will be conducted at recruitment phase to identify any areas in which there are statistically significant differences between the intervention and comparison groups and also compare within individual differences between the initial phase and follow-up phases. The analysis for the outcomes of interest will follow a difference-in-difference design (DiD). For the primary outcome, a two-group repeated measures design with a binary response and with two measurements for each subject will be used to test whether there is a difference in group slopes. The comparison will be made using a Wald Z-test using GEE methods. The repeated measurements of each subject will be made at 2 times and using an autoregressive correlation structure (AR1). At the follow-ups and within reason, any statistically significant differences between the intervention and comparison groups will be attributed to the intervention. Generalized linear mixed affects models will be employed to control for confounding correcting for individual and cluster-level standard errors.

2.9.2 Qualitative analysis

The qualitative researchers from VKM and Deep Dive Research and Consulting PLC who conduct the FGDs, IDIs and KIIs will transcribe and translate the audio records into written verbatim. A second person will check the transcript for quality. The transcripts will be de-identified before they could be granted to the analysis team. De-dentification will involve stripping out names of participants which might be mentioned (any names in the verbatim will coded) or other people or other relevant information in the transcripts that could enable someone to tell who provided the

information. All transcripts will be assigned a unique numerical code, the type of qualitative data and participant group e.g., 01_FGD_Married AGYW. This de-identified data will also be published publicly upon conclusion of the assignment as a requirement by the open access and transparency policies by the A360 donors (Bill & Melinda Gates Foundation, 2021; Children's Investment Fund Foundation, 2019). The qualitative data will be rigorously analyzed using NVivo or Dedoose as tools for data management. Open-coding and closed-coding will be utilized to identify emergent themes. Furthermore, a coding book will be established to systematically guide the analysis. Two coders will be trained on the codebook. Intercoder reliability will be calculated using Scott's Pi to determine whether or not the coders are consistently coding the data.

Table 3: List of Data Collection Tools

Tool	Timepoint and number of sessions
1. Quantitative Tool for adolescent girls	Recruitment phase, and follow-ups
2. Qualitative In-depth Interview Guide for married AGYW	Midline - once
3. Qualitative Focus Group Discussion Guide for married AGYW	Midline - once
4. Qualitative In-depth Interview Guide for husbands of AGYW	Midline - once
5. Qualitative Key Informant Interview Guide for health providers and community mobilizers	Midline - once

2.10 DATA OUTPUTS

A report of the findings of the study shall be prepared and disseminated in the countries and to the A360 donors. Initially the draft report will be written by VKM and Deep Dive Research and Consulting PLC, then reviewed by SFH and PSI. VKM and Deep Dive Research and Consulting PLC will revise the report incorporating the feedback provided to arrive at a final report. The final report will be made available through the A360's website- a360learninghub.org. The report will describe the intervention components and provide the rationale for the study. It will also describe the findings and make recommendations on how the findings can be replicated by other programs to contribute to improved MNCH outcomes. Further, we shall convene a dissemination webinar which will be widely advertised by the participant organizations. The target for the dissemination event will include representatives from the A360 donors, SFH, PSI, Federal and State Ministries of Health and MNCH implementing partners. Evidence from the study will also be presented at different national, regional and global conferences to share learnings about the intervention.

Several manuscripts shall be prepared for submission to peer-reviewed journals to document and share the findings of the study globally.

2.11 LIMITATIONS

This evaluation will have its own limitations. First, the intervention outcomes will be measured between participants who receive the revamped MMA and Smart Start interventions against the current package of SRH interventions. So far, it is possible that the current package could be delivering some elements of maternal and child health (especially in Nigeria). An ideal comparator would have been participants receiving services through routine government facilities that are not supported at all by the A360 project. Unfortunately, the recruitment to the evaluation might not be feasible. Second, this study will only recruit AGYW from catchments of health facilities (as clusters). The clustering of effects within AGYW from specific facility catchments cannot be controlled. Third, this evaluation will rely on self-reports to collect data on the primary and secondary outcomes. Using self-reports is amenable to social desirability biases. Although we plan to meticulously order the survey questions so that sensitive items are only fielded when the rapport between the enumerator and the participant has been formed. Furthermore, we will triangulate the two main sources of data for this study when processing the findings and complement these with comparison of routinely collected program data before we can interpret the data and draw conclusions. Fourth, the qualitative component will only involve AGYW, husbands and health workers and mobilisers who own a functional primary mobile number. This excludes individuals without access to a mobile number and could create a participation inequity. This is unavoidable given that the study heavily relies on a phone contact during the recruitment procedures.

2.12 DISSEMINATION AND DATA USE

The primary purpose of this study is for internal program improvement purposes, however learning from this study will also function as a global good for the A360 project. All possibly identifying information will be removed from all datasets from the quantitative and qualitative components by the data analyst under the supervision of the PI, whether for internal or external sharing. Well labelled files of de-identified data and accompanying metadata will be deposited in accredited virtual databases that are recommended by the A360 donors once the publications have been developed so that they are accessible for researchers for secondary analysis across the globe.

Program improvement: Findings will be distilled into digestible formats for A360 implementation teams to be able to use in their implementation of the program. Findings will also be shared with key stakeholders, particularly government stakeholders to further their understanding of the program.

Global program deliverables: As a global project, A360 has deliverables required by its two foundation donors which are tied to the activities within this study. The insights synthesis and different concepts / prototypes tested may be distilled into a design report which will be submitted to and discussed with the project's donors.

Global learning documents: As a project, A360 is committed to radical transparency about what is learned through its continuous improvement processes. As such, the findings from the data collected will be used in global thought leadership pieces and disseminated through conference abstracts, presentations, webinars, technical publications and peer review journal articles.

3.0 ETHICAL CONSIDERATIONS

3.1 REGULATORY REQUIREMENTS / HUMAN SUBJECTS PROTECTION

This study has been determined to be human subjects research and as such will be reviewed by the PSI REB and concurrently reviewed by the Ethiopia Midwives Association (EMwA) Institutional Research Ethics Board in Ethiopia and National Health Research and Ethics Committee (NHREC) in Nigeria prior to being fielded.

3.2 RISKS AND MITIGATING RISKS

The possible risks from participating in this study are risk of breach of confidentiality, particularly since this study involves adolescents, and risk of psychological discomfort. Regarding risk of breach of confidentiality, field research teams will not keep records with any identifying information from adolescents in any way that it can be traced to the survey records.

Research respondents may experience some psychological discomfort in being asked to discuss culturally sensitive topics, such as sexual activity, early and unspaced pregnancy, or the use of contraception. Potential participants will be informed of this risk prior to being asked for their consent to participate, and informed that they can refuse to answer any questions or stop the data collection process at any time, or even just pause for a few minutes before continuing. Participants will be informed of their right not to answer any questions and ability to withdraw from the study at any time they wished without any consequences.

Finally, there is a potential risk that the study could divulge information (directly or indirectly) that the girls are recruited in the process of accessing pregnancy -related and contraception services. To mitigate this risk, the study team will maintain utmost privacy during data collection and confidentiality of collected information. The key risks and mitigation measures are summarized in Table 4.

Table 4: Key risks and their mitigation

	Key risk	Mitigation measures
a.	Breach of privacy and confidentiality	All members of the study team will undertake a mandatory protection of Human Subjects in Research (HSR) training. Only individuals with a valid HSR certificate will be involved as study personnel. This risk and its mitigation will also be included as part of enumerators' training. A

		strict data management protocol will be adhered to throughout the study.
b.	Social risks related to post partum contraception	Conduct the study in locations that guarantee visual and auditory privacy. Allow participants to use real or proxy names when signing consent forms. Tactfully engaging individuals who accompany the AGYW to the facilities to seek their permission without disclosure of the full details of the study especially on contraception use and child spacing. The requirement for parental consent is avoided, to reduce the risk that AGYW were engaging with a reproductive health program associated with use of contraceptives.
c.	Psychological discomfort	Participants are informed of the voluntary nature of participation and given room to withdraw throughout the recruitment and data collection processes. Participants will be encouraged to share their discomfort or unfavourable emotions with the enumerators. Questions on the pregnancy, perinatal and neonatal outcomes (for follow-up 3) will be optional to cushion AGYW from the pressure of responding about their unfavourable outcomes and negative experiences. Use of female enumerators and qualitative researchers to increase gender sensitivity.

Interviewers for the project shall be selected from a pool of existing female enumerators that have worked with VKM and Deep Dive Research and Consulting PLC on previous research projects. If there are none in the location of the study, care will be taken to ensure identified enumerators have experience conducting such kind of assignments. They will be trained on ethics of collecting data from minors and sensitivity to cultural issues. They will also sign a code of conduct which stipulates stringent criteria on how to collect data from minors. Only female enumerators will be engaged on this project since the participants involved in the study are female for gender-sensitivity.

3.3 SPECIAL CONSIDERATIONS FOR GENDER-BASED VIOLENCE (GBV)

While this research study does not have a direct intent of identifying individual experiences of GBV or community norms related to GBV, it is possible that experiences of violence and abuse may arise during the data collection process, including witnessing of or actual experiences with violence, abuse or coercion. Although participants will not be asked questions about their own experiences of violence, these discussions could produce some psychological distress if a participant has experienced or witnessed violence in the past.

We plan to take the following measures to address the possibility of participants reporting on GBV:

- PSI, SFH, VKM and Deep Dive Research and Consulting PLC field teams will be trained on safe research practices, particularly as it relates to GBV, as part of the inception of this research. Field research teams will be trained to record any disclosure of violence, abuse or coercion (witnessing or direct experience) in a non-judgmental fashion. If a participant expresses discomfort or stress during the interview, the interviewer will remind the participant that they are free not to answer any questions which make them uncomfortable and will give the participant time to recover before proceeding with the interview. Field research teams will be instructed not to probe on any instance of violence, abuse or coercion, because the topic is not directly related to the study's objectives, and to transition the conversation to another topic when the participant is ready to do so. If there is any possibility that confidentiality cannot be maintained while the participant is disclosing experiences with violence, members of the field research team will be instructed to stop the conversation, move to a more private location, if possible, and ask the participant if they wish to continue. In the likely event that there are disclosures relate to perpetration of violence, the field research team will uphold confidentiality but could propose that the participant seeks mental health assessment and counselling. The field team will maintain a directory of facilities where such services are provided and share these with the participant.
- Field research teams will be instructed to provide that person with the physical address, contact and phone numbers of available support services.
- Counseling services from MOH psychological services providers will also be made available to field research teams as required. The availability of this service will be included in training materials, and field research coordinators will be instructed to check on their teams through daily de-briefs to assess whether team members need this support.
- If there is any indication that a research participant is becoming belligerent or abusive to a member of the field research team, team members will be instructed to end the interaction and leave the area.
- Our study team will continuously familiarize themselves with all the reporting requirements on IPV/GBV based on existing laws and guidelines including handling perpetrators who self-disclose engaging in violent acts.

3.4 BENEFITS

All research participants will be informed that they will not receive any direct benefit from participating in this research. However, they will be informed that their participation will support the improvement of services for adolescents in their communities, in Nigeria, and possibly in other African countries. A small stipend worth $2 will be offered for the follow-up surveys and for the FGD and IDI participants.

3.5 CONSENT PROCESS

3.5.1 Married AGYW

All AGYW who express interest to participate in this research will be screened using the eligibility criteria prior to obtaining informed consent. An informed consent from eligible AGYW will be documented after the informed consent script has been read by the enumerators/researchers. The personnel administering the consent script will be the same sex to study participants. For group discussions, consenting procedures will be administered individually before the start of the interview. Each participant will be asked to give his/her written consent to participate in the study, afterwards the person obtaining consent will sign the informed consent form (see Appendices J-M for Informed Consents for all participants). No parental consent will be required for married girls 15-17 since they are precluded from this requirement based on the Policy Statement Regarding Enrollment of Children in Research in Nigeria (Policy Regarding Enrollment of Children in Research in Nigeria, 2016). According to the Ethiopian National Ethics Guidelines, 2014 section 6.19.3 (Page 51) which recognizes married AGYW under 18 years as emancipated minors grants a provision for them to give informed consent on their own. It also provides for REBs to grant a waiver of parental consent for emancipated minors and children when dealing with sensitive subjects(Ethiopia Federal Ministry of Science and Technology, 2014). A waiver of parental permission will thus be requested from the PSI and local REBs.

3.5.2 Adults

Husbands, health providers and mobilizers will be formally consented before they participate. The inclusion criteria for these two groups is age 18 years and over and so individuals will be mandated to consent on their own. Prior to their involvement in KIIs or IDIs, the member of the qualitative researchers will read the informed consent form to each study participant and provide him/her with an opportunity to ask questions. Similar to the AGYW, written consent will be employed. The researcher obtaining consent will be required to sign the form to affirm that consenting procedures have been conducted as mandated.

3.6 MANAGEMENT OF CONSENT DOCUMENTATION

Signed consent documentation will be collected by the field research team from VKM and Deep Dive Research and Consulting PLC and stored in a locked box. They will be collected, packaged and deposited under the oversight of the in-country investigator. At the close of data collection in the field, field coordinators will be expected to transport signed forms in a locked box for storage at the SFH and PSI Ethiopia offices. Consent forms will not be retained for longer than one year from the completion of data collection. Consent forms will include the unique ID code for the participant, to permit consent and other study documentation to be linked anonymously.

3.7 CONFIDENTIALITY AND PRIVACY

Protecting research participants' privacy is a major goal for this study. Field research teams will be trained on study procedures and research ethics to ensure they are sensitized to risks and respect of privacy. As previously described, all identifying information needed for the recruitment

of study participants, whether adults or AGYW, will be destroyed at the completion of data collection. No identifying information will be collected during individual or group discussions.

All the data from the field will be thoroughly reviewed for identifying information and all these stripped off – personal names, phone numbers or addresses. The Investigators will instead devise a coding scheme to indicate their sex, age group for AGYW (18-19 or 20-24), and standing in the community (health provider, mobilizer, husband), and geographic region. This coding scheme will be applied to data outputs before data analysis. Any quotes used in study outputs or shared publicly will use this coding scheme (sex, age/community standing, geography) exclusively.

3.8 SUBJECT COMPENSATION

Research participants will not be financially compensated for participation in this research. Participants will receive a small stipend (equivalent to $ 2) to cover the costs of transportation or as airtime (for those who are involved in phone follow-up interviews) from VKM and Deep Dive Research and Consulting PLC. The $ 2 may cover a private ride home or a quality meal at a modest café. Survey participants interviewed on phone will receive airtime worth $1 directly to their phones. This is based on past experiences and inflation rates in the countries.

3.9 UNANTICIPATED PROBLEMS

As part of the research inception, field research teams under the stewardship of the In-country Lead Investigators will be instructed on how to identify any ethical and safety concerns, and they will be asked to report concerns to the Investigators.

Serious ethical and safety concerns may include, but are not limited to:

- Incidents when a research participant's safety is at risk because of participation in the study
- Any threats of violence to the research team while conducting the study
- Any incident where the confidentiality of research participants is jeopardized
- Any event related to the research process that results in serious injury, death or arrest (e.g. motor vehicle accidents)

The in-county lead investigator (with guidance from the PI) will be responsible for advising field researchers on incidents that have ethical or safety concern, or any event that may constitute a violation of this protocol. The following actions may be taken when an incidence occurs. (a) Field researchers will immediately report the event to the In-country Lead Investigator who will immediately escalate the incidence to the PI. (b) The PI will coordinate a rapid documentation of the incident and escalate it to the local IRB and PSI REB using an adverse event report. (c) The PI will issue strict instructions to pause any field activities pending feedback from the REBs. (d) Once feedback is received from the REBs, the PI will oversee the implementation of the course of action.

4.0 ACTIVITY PLAN

The activities for the study will be conducted during the following quarters in 2023 to 2025. Many activities will overlap, so that the study is efficient.

	Q3 2023			Q4 2023			Q1 2024			Q2 2024			Q3 2024			Q4 2024			Q1 2025		
Activities																					
1. Finalize study protocol and the tools																					
2. Submit protocol to PSI and Nigeria % Ethiopia IRBs																					
3. Recruitment of enumerators																					
4. Training enumerators and piloting the tool																					
5. Data collection																					
6. Data cleaning and coding																					
7. Data analysis																					
8. Report writing																					
9. Dissemination																					

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