Title of the Project

Developing and validating measures of unintended pregnancy and reasons for contraceptive non-use among married women in Nairobi's informal settlements

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Abstract

Measuring unintended pregnancies is important for demographers and public health workers worldwide. Pregnancy intentions and attendant fertility-related behaviors have significant implications on forecasting fertility rates, designing family planning programs and estimating the unmet need for contraception. However, most current estimates of the levels of unintended pregnancy in developing countries are derived from retrospective reporting on the last pregnancy or childbirth in Demographic and Health Surveys (DHS). An unintended pregnancy in these surveys is classified as one that is reported to have been mistimed (occurred earlier than planned) or unwanted (occurred when no more children were desired). Such measures of pregnancy intentions, that are dichotomous and retrospective, have been shown to be overly simplistic and suffer from reporting bias. Application of measures which capture the multidimensionality of fertility intentions in a prospective longitudinal study have been proposed as being better approaches to capture the complexity of unintended pregnancy. Given the potential advantages of prospective measurements, it is unfortunate that only few studies of this nature have been undertaken in developing countries. The presence of numerous health and demographic surveillance systems (HDSS) in several developing countries offer the opportunity to strengthen the evidence on unintended pregnancy by developing and validating the use of such measures through their longitudinal data collection mechanisms.

The overall objective of this study is to develop and validate new measures of unintended pregnancy and reasons for non-use of contraceptives in developing countries. Such tools would

provide an improved understanding of the determinants and dynamics of pregnancy intentions, contraceptive decision-making and use, and the impact of fertility intentions on pregnancy outcomes, especially in settings where fertility intentions may be high or ambiguous and where contraceptive use is low and unmet need high. The study will be carried out in Korogocho and Viwandani in Nairobi, Kenya, where the African Population and Health Research Center (APHRC) has been running the Nairobi Urban and Health Demographic Surveillance System (NUHDSS) since 2002. The study is being implemented in two phases. In the first phase (completed), a conceptual framework and draft module, consisting of a questionnaire and a protocol for its administration was developed through a consultative process and review of the literature. The module was developed in collaboration with the London School of Hygiene and Tropical Medicine, the Population Council, and the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). During the second phase, the module will be administered three times to married or cohabiting women aged between 15 and 39 years old living in the demographic surveillance area: at baseline to generate baseline measures of the key variables, after twelve (12) months, and after twenty four (24) months. The implementation of the second and third wave will depend on receipt of additional funding.

Data will be collected through face-to-face interviews with eligible women randomly sampled from the NUHDSS. Predictive validity of pregnancy and contraceptive measures will be assessed using factor analysis and multivariate regression analysis to assess the independent net effect of explanatory variables on outcome variables of interest.

1.0. Background and Justification

1.1. Measurement of prospective pregnancy preferences

It is estimated that 80 million women in developing countries experienced an unintended pregnancy in 2012, resulting in 30 million unplanned births, 40 million abortions and 10 million miscarriages (1). These unintended pregnancies have well-documented health and socio-economic consequences for women, children and society, including increased risk of morbidities and mortality (through unsafe abortions), poor prenatal and postnatal care, depression and poor infant and child care (2). In Kenya, levels of unintended pregnancy have remained relatively high, though modest declines have been observed over time (2). Estimates from the 2014 Kenya Demographic and Health Survey showed levels for unintended pregnancy at 36%, a 7 percentage point decline from levels reported in 2008/09 (3). However, declines for sub-groups such as young people aged between 15 and 24 years was not observed, with levels remaining unchanged at 47% in the last five years. Consequently almost half a million abortions were procured in Kenya in 2012 (4). Further, of the women who sought treatment for unsafe abortion in health facilities, about 65% were married women and about 50% were young people between the ages of 10 and 24 years (4).

Mainstream discourse in research, program and policy assumes that the concept of unintended pregnancy is simple, straight forward and self-evident (5, 6). Most current estimates of the levels of unintended pregnancy in developing countries are derived from Demographic and Health Surveys (DHS). The standard DHS question asks "at the time you became pregnant, did you want to become pregnant then, did you want to wait until later, or did you not want to have any (more children)?" An unintended pregnancy is then classified as one that is reported to have been mistimed (occurred earlier than planned) or unwanted (occurred when no more children were desired) (7).

While this measure has proved useful in providing comparative information on unintended pregnancy and is widely used, there has been increasing discussion of its limitations. First, the measure is based on cross-sectional interviews and retrospective reporting by individual women. Retrospective reporting of pregnancies that occurred, often several years prior to the interviews, is subject to biases such as ex-post rationalization, as women may alter their feelings due to reluctance to report their children as unwanted (8) , which may produce substantial underestimates (9). Further, traditional cultural beliefs that a child is a "God gift" may complicate the situation. Third, these measures do not capture the temporal dynamics in intentions/attitudes and relationships. Yet, evidence shows that women's attitudes toward their pregnancies and births change over time (8-10). Furthermore, dichotomous classification of pregnancies as "intended" and "unintended" is simplistic and does not reveal the complexity of reproductive decision-making (5, 11), which is often ambivalent, contradictory and unclear (5, 6, 12-14).

Therefore, application of measures that capture the multidimensionality of fertility intentions in a prospective longitudinal study have been proposed to be better indicators of this complex phenomenon (15). Most of the research on improving these measures has been conducted in the United States. What has come out of this research is that pregnancy intentions are complex and encompass cognitive (intentions and timing), affective (happiness/surprise/fear), motivational (+/-desires and effort to achieve or avoid pregnancy), and contextual dimensions (partner/social influence) and as such, should be scaled (16-19).

- The cognitive dimension refers to intentionality or planning of the pregnancy. This includes whether the woman planned/ is planning to get pregnant; timing, that is, how long the woman would like to wait before having a child in the future.

- The affective questions include whether if the woman became pregnant in the next few weeks, the woman would be scared to tell her partner/husband, and whether she would be worried about how to financially support the child.

- The motivational dimension includes feelings (e.g., childbearing desires) and behaviors to achieve a reproductive goal. This includes both positive and negative feelings that are evoked by the children themselves. The second aspect of motivation is effort to achieve a reproductive goal. For childbearing, the two behaviors that have been identified are contraceptive (e.g. contraceptive use) to avoid a pregnancy and contraceptive non-use achieve a pregnancy (17, 20).

- The contextual dimension refers to how intentions are affected by the perceptions of one's partner, and one's own values about childbearing. This includes whether she wanted/wants a child with her partner at the time, and whether her partner wanted/wants a child with her; and partner discussion and agreement for the couple to achieve or avoid a pregnancy (17, 20).

Thus, this study will develop and validate measures that encompass strength and multi-dimensionality of fertility preferences in prospective longitudinal cohorts in three developing countries. In Kenya, this study will take place in Nairobi (Korogocho and Viwandani).

1.2. Measurement of retrospective pregnancy preferences

While longitudinal studies are the soundest strategy for identifying unintended births, reliance on retrospective reports is likely to continue for the foreseeable future especially for national population surveys. The standard items currently used are relatively concise and easily embedded in a birth-by-birth module containing other items of interest (e.g. ante-natal care, care at delivery, birth weight, etc.) and therefore is a core feature of cross-sectional demographic surveys (DHS, MICS).

Therefore, an improved retrospective item would be a major contribution to demographic data collection. The likelihood of widespread adoption is greatly increased if this remains simply one item (rather than a battery of items). Hence, through repeated follow-up surveys or routine demographic surveillance (round 1 and 2), the validity of alternative versions of one retrospective item will be tested by assessing consistency with the preconception prospective pregnancy intentions that will be collected in the prospective pregnancy preference module at the baseline.

1.3. Measurement of reasons for contraceptive non-use

For several decades, most investigations of contraception and unmet need for family planning have been based on the simple measures available in DHS. These measures include desire for another child and preferred timing, self-reported reasons for non-contraceptive use and discontinued contraceptive use, and intended future use of contraceptives. Previous research has primarily fallen within two domains: analysis of social and demographic correlates of current contraceptive use, such as education and number of living children; and analysis of DHS data on self-reported reasons for non-contraceptive use (20). Further research of the first type is unlikely to lead to any useful new insights. Analysis of the second type suffers from the limitations of direct enquiry into motivations and from lack of comparable information from users. For instance, side effects and health concerns are the dominant self-reported reason for contraceptive non-use (21)but, in the absence of information on whether side effects and health concerns are equally common among users, it is impossible to be confident that these two interrelated factors truly distinguish non-users from users. Perhaps the real underlying distinction is strength of desire to avoid pregnancy (21, 22). To address these limitations and to make progress in understanding, we need to measure hypothesized causal factors for users

as well as non-users (and past users) and infer causation by analysis rather than relying on direct testimony.

The African Population and Health Research Center (APRHC) aims to develop and validate a module that measures prospective and retrospective pregnancy intentions, and reasons for non-use of contraception and that can be used prospectively in longitudinal demographic surveillance systems or retrospectively in cross-sectional studies. Having the three components in one study will allow us to link detailed prospective measures of pregnancy intention with retrospective measures to assess consistency of intentions before and after birth, and with attitude and experiences of contraceptive use to explore reasons for non-use to better understand reproductive needs in the study populations. An improved understanding of pregnancy intentions in developing countries, where unintended pregnancy is high and contraceptive use is low, is necessary to inform policies to address unmet need for family planning.

2.0. Objectives

The overall objective of the study is to develop and validate prospective and retrospective measures of unintended pregnancy for use in Kenya. It is expected that the results will add to the body of evidence on unintended pregnancy and its outcomes as well as on factors that influence contraceptive adoption and continuation of use.

With a single cross sectional approach, the objectives are:

1. To assess whether a few additions to standard DHS questions on future fertility preferences add significant explanatory power to the probability of current contraceptive use and future intended use for those not currently at risk.
2. To assess the extent to which other possible influences, are significantly associated with current contraceptive use and future intended use and to identify the most powerful influences.
3. To assess the relationship between method-specific beliefs and perceived characteristics and method-specific contraceptive use and future intended use.

Using the longitudinal design, by means of repeated follow-up surveys, the additional objectives are:

4. To measure the validity of enhanced prospective fertility preference data in terms of their power to predict subsequent pregnancy/births.
5. To measure the validity of enhanced prospective fertility preferences and other possible influences to predict contraceptive use-continuation, adoption and unmet need for family planning.
6. To assess consistency of prospective fertility intentions and retrospective statements about intendedness

3.0. Research methods

This study will adopt a prospective longitudinal design that will involve repeated observation of the same women at regular intervals over a period of time. The selected cohort of women will be interviewed at three points: at baseline and after twelve and twenty four months. Because longitudinal studies allow for repeated collection of data from the same individual over time, we will be able to assess predictive power of measures on reproductive outcomes, contraceptive adoption and continuation of use and accurately observe and measure changes as they are able to exclude time-invariant unobserved individual differences. The data at baseline (round 0) will be compared with the data at round one (12 months) and round two (24 months) to determine the overall temporal trends and dynamics in pregnancy intentions and outcomes over a twenty-four month period.

Prospective, retrospective fertility intentions and reasons for contraceptive non-use
At baseline, we will collect data on women's reproductive history to identify women's fertility intentions and their parity status. Women will then be asked standardized questions at baseline and follow-up interviews (*see survey instruments in Appendix 6 and a Swahili version-Appendix 7*). At baseline, women who are not pregnant will be asked about their future pregnancy intentions. They will also be asked about their use of contraceptives. Those who are currently pregnant will be asked to report retrospectively on the planning status of their current pregnancy and also to report on future pregnancy intentions. Women with parity one and more will be asked to report retrospectively on the pregnancy planning status of the last births. They will also be asked about the outcome of the pregnancy.

In rounds one and two, taking place one year apart after the first survey, we shall follow up on the parity and pregnancy status of the women captured at baseline. We shall track the pregnancies reported in the preceding round to establish their outcomes (i.e., live birth or pregnancy loss). In the case of a live birth, women will be asked to report retrospectively on the planning status to identify any changes in intention post and pre- conception/delivery. They will also be asked about contraceptive use dynamics. If the outcome is a pregnancy loss, they will be asked about the nature of the pregnancy loss (i.e., abortion or miscarriage) and their contraceptive use dynamics. Further, through the repeated follow-up surveys, the validity of alternative versions of one retrospective item will be tested by assessing consistency with the prospective pregnancy intentions that will be collected in the prospective pregnancy preference module in the baseline.

The questionnaire items will be structured and closed, that is, they will use pre-set questions and pre-set answers in order to communicate the same frame of reference to all respondents in all settings and to provide standardized direction for interviewers. The questionnaire will adapt questions from several previously validated instruments including: The "Determinants of Unintended Pregnancy Risk in New Orleans" Study (15, 20); Demographic and Health Surveys (DHS); the US- based National Survey of Family Growth (NSFG); and the "Fog Zone" by the Guttmacher Institute. Where appropriate, questions will be modified in order to be relevant to the local context.

The module on unintended pregnancy and reasons for contraceptive non-use will include questions on women's socio-demographic characteristics; reproductive history; sexual activity; retrospective measures of pregnancy intentions; prospective measures of pregnancy intentions; method-specific attitudes and experiences of contraceptives; and contraceptive behavior (contraceptive use, switching, and discontinuation). Some of pregnancy intention questions will be measured using Likert-type scales. Prior to the actual fieldwork the module will be pretested on a sample of women (N=20).

3.1. Study population
The study population will be married or cohabiting women aged 15-39 years living in Korogocho and Viwandani (NUHDSS). Their husbands/partners will be excluded because it is because matched couple data analysis is beyond the scope of this study.

3.2. Sample size calculation
We assume both exposure/predictor and outcome variables are dichotomous, with say 20% in the unexposed and 40% in the exposed positive on outcome variable, such as current contraceptive use. Our sample size calculation will be based on the following formulae to be able to detect 20-50% differences in two proportions (Fleiss, Levin, and Paik 2003). We use power of 80% and 90% and significance level of 0.05. As the distribution of exposure is unknown, different ratios of sample size of the exposed to the unexposed (20% vs 80%, 30% vs70%, 80% vs 20%) are used to calculate sample sizes. The calculation for HDSS assumes a simple random sampling in the database.

$$n' = \frac{\left(z_{\alpha/2}\sqrt{2\bar{P}\bar{Q}} + z_{\beta}\sqrt{P_1Q_1 + P_2Q_2}\right)^2}{(P_2 - P_1)^2}$$

Where:

- n' is the required sample size of the individuals of target population;
- P is the proportion of outcome in exposed and unexposed groups;
- Q is 1-P;
- $z_{\alpha/2}$ is significant level (For a two-tailed test, $z_{\alpha/2}$ is equal to 1.96 and for a one-tailed test, $z_{\alpha/2}$ is equal to 1.64)
- z_{β} is one-sided percentage point of the normal distribution corresponding to 100% - the power (if power = 90%, z_{β} = 1.28. If power = 80%, z_{β} is 1.84).

In addition, the continuity correction factor is applied to the normal approximation of the discrete distribution. A 10% non-response rate is assumed.

The primary interest in the single round survey is women who are in need for family planning, i.e. women who are not currently pregnant, are not in postpartum amenorrhea, and do not want a child soon. Based on the latest KDHS survey, it is estimated that these women account for about 50% of women in union aged 15-39. Therefore, required sample sizes for women in need for contraceptives and the doubled size for the overall sample sizes are estimated as presented in Table 1.

Table 1: Sample size calculations for the single round survey

Significance level	Power	% of outcome in unexposed	Effect size (relative risk)	Sample size for women in need for FP	Overall sample size
0.05	80%	30%	30%(1.3)	1290	2580
0.05	80%	30%	40%(1.4)	750	1500
0.05	90%	30%	30%(1.3)	1740	3480
0.05	90%	30%	40%(1.4)	1010	2020

In addition, follow-up data collection to measure predictive validity of prospective intentions on reporting of pregnancy or childbirths, contraceptive use-continuation, adoption and unmet need for family planning, and the validity of retrospective fertility preferences are taken into account in the sample size calculations. It is estimated that about 15% of women[1] would report being pregnant or having had a birth at 1-year follow-up and 30% in 2 years among women among the unexposed group at the baseline. The sample sizes were calculated for the prospective study using the same formulae and assumptions used in the single round survey. It is estimated that women who are pregnant or want a child within 2 years accounts for about 30% of women aged 20-39, so the overall sample sizes are calculated by multiplying by 1.3 as shown in Table 2 below.

[1]This proportion is estimated from NUHDSS data published elsewhere [23]. The crude birth rate in the NUHDSS is 33.8 births per 1000 person-years. The sex ratio for the whole population is 130 males to 100 females, and the proportion of women aged 15-64 is 64% among females. So one quarter of the whole population in the 2 slums is women aged 15-64 years. As most of the births will occur among these women, birth rate among this group of women is estimated to be 33.8/250=13.5. Therefore we estimate that approximately 14% of women aged between 15 and 64 years would give a birth in Nairobi. The estimate will definitely be higher if we look at only married women aged between 15 and 39 years. We also do acknowledge that this is a conservative estimate for Nairobi, but this is a three country study and this calculation takes into account Bangladesh, which has a much lower birth rate.

Table 2: Sample size calculation for the prospective survey

Significance level	Power	% of outcome in unexposed	Effect size (relative risk)	Attrition	Sample size for women at risk of unintended pregnancy at baseline	Overall sample size
1-year follow-up						
0.05	80%	15%	30%(0.7)	30%	3680	4780
2-year follow up						
0.05	80%	30%	30%(0.7)	45%	2000	2600
0.05	80%	30%	40%(0.6)	45%	1120	1450

According to the calculations, if time and budget allows, it is desirable to recruit 2,600 women in union aged 15-39 to be able to detect at least 30% of differences with 80% of power both in single round and prospective surveys.

3.3. Data collection procedures

Data will be collected through face-to-face interviews with eligible women as described above using a module of questions (See Appendix 6 and 7 for English or Swahili survey instruments, respectively) designed to measure the multidimensionality of pregnancy intentions and outcomes in women. Table 3 shows a summary of the key observations and measurements in the module.

Table 3: List of observations and measurements for pregnancy intentions and outcomes in women

Sections	**Observations and measurements**
Background characteristics	Identification particulars and age in completed years, education, occupation (including casual work)
Marriage	Current marital status & co-residential status with partner
Sexual activity and postpartum susceptibility	Frequency of sexual activity, postpartum susceptibility, Knowledge of safe period during breastfeeding
Birth history	Number of ever born children, number of living children and their sexual composition, number of dead children and their sexual composition
Pregnancy	Current pregnancy status and duration of pregnancy
Pregnancy intentions (Retrospective)	
a) Pregnancy intentions	Retrospective reporting on wantedness of the last birth
b) Multi-dimensional measures of pregnancy intentions	4 dimensions of pregnancy intentions: cognitive (intendedness); affective (scared or happy to tell pregnancy); motivational (effort in avoiding a pregnancy); contextual (perceived partner's intentions)
Pregnancy intentions (Prospective)	
a) Pregnancy intentions	Pregnancy intentions in future

b) Multi-dimensional measures of pregnancy intentions	4 important dimensions of pregnancy intentions: cognitive (intendedness); affective (scared or happy to tell pregnancy); motivational (effort in avoiding a pregnancy); contextual (perceived partner's intentions) Possibility of future changes in pregnancy intentions
Outcome of pregnancy	Live births (and survival status), miscarriage, abortion
Contraception	
a) Generic	Knowledge of contraceptive methods, current use, reasons for non-use, intention for future use, use of emergency contraception
b) Reasons for non-use	Approval/opposition to contraceptive use, important features in choosing a method, perceived risk of getting pregnant
c) Method-specific	Familiarity, access, perceived effectiveness, safety, side effects, ease of use, appropriateness of someone like respondent, partner-related factors

Before conducting interviews, informed consent (see appendix 4 for English version) will be obtained. The consent forms are also translated into the local language (Swahili, appendix 5) and the interview will be conducted in the preferred language of the respondent. All interviews will be done at the convenience of the respondent in a private location in the home of the respondent. Every effort will be made to ensure that these interviews are undertaken in conditions of strict privacy and the interviewers will be carefully trained to maintain confidentiality. If a woman chooses to be interviewed elsewhere to ensure confidentiality, a suitable time and place will be arranged. All women wishing to withdraw from the study at any point are allowed to do so.

All attempts will be made to locate the selected women for interviews. If the woman is not located after three attempts they will be considered lost to follow up for that particular wave of interview and will not be replaced.

The interviews will be conducted by a team of interviewers under the supervision of the NUHDSS field supervisor. Interviewers and supervisors will be trained in the administration of the new module and will participate in a pilot survey. Special attention will be dedicated to the ethical principles of research with human participants, including safeguarding the confidentiality of the information obtained and the privacy of the research participants. The field team will also be trained on how to obtain informed consent (voluntary participation, right to withdraw). They will also be trained to listen and observe while maintaining neutrality and without displaying any judgmental attitude towards information they receive from the respondents. As a matter of procedure, all investigators have undergone the online NIH research ethics course and certification.

3.4. Sampling

Data collection will be carried out within the Nairobi Urban Health and Demographic Surveillance System (NUHDSS). The NUHDSS is located in Korogocho (area of 0.52 km2) and Viwandani (total area of 0.45 km2) slums 6 to 7 km from Nairobi city center. The NUHDSS covers 14 villages in both slum settlements. The NUHDSS follows a population of about 65,000 individuals living in about 24,000 households in the two settlements (23). Although there are marked differences between the slums – Korogocho has a more settled population while Viwandani is home to a young and highly mobile population, – both settlements are

characterized by high levels of unemployment, sub-standard and overcrowded housing, limited education and social services, high levels of crime and insecurity and inadequate water and sanitation infrastructure. Households covered by the NUHDSS are visited every 4 months to collect data on key sociodemographic and health measures including births, deaths, migration, immunization, livelihoods, as well as household amenities and assets. The NUHDSS also provides a platform for: one, nesting studies investigating the inter-linkages between poverty and health and other outcomes; and two, testing interventions to address challenges facing slum dwellers.

Using the NUHDSS database, a listing of all women aged between 15 and 39 years who are formal residents will be generated with identifying information including name, age, sex, and location and structure numbers. This listing will form the study population. Married participants between the ages of 15 and 39 years old will then be randomly selected from households in the DSS database. For each study participant, a new non-identifying unique ID will be generated and assigned to ensure anonymity. There are about 14,867 women aged 15 to 39 years from 25,243 households who were present in the demographic surveillance area in the most recent survey round. Of these, 5,835 were women resident in 9,181 households in Korogocho, and 9,032 were women resident in 16,062 households in Viwandani.

Field operations will be overseen by a research officer who will supervise all fieldworkers to ensure that all protocols are adhered to as required. He will also ensure that all logistics are in place. The field team will visit selected participants' households. After identifying the eligible participants, the field team will seek informed consent. Information collected from the respondent will be recorded on a separate form with the unique ID. The unique ID will be linkable to the main NUHDSS database through an encrypted key kept by the project PI and database manager.

3.5. Data analysis and management

Data will be collected using netbooks and directly saved to a purpose-designed database. Collected data will then be cleaned and stored on a computer drive whose access will be restricted to authorized research team members. Analytical files will be anonymized. Data analysis will be conducted using the Stata analytical software. Factor analysis will also be used to evaluate the internal structure of the multidimensional scale. We shall also derive univariate descriptive, bivariate and multivariate analyses. Chi-square tests will be used to test bivariate associations between two categorical variables, and a t-test and ANOVA for the relationship between categorical and continuous variables. Multivariate regression analysis will be done to assess the independent net effect of explanatory variables on outcome variables of interest.

Timeframe/Duration of Project

Milestones	Year 1	Year 2	Year 3
Obtain local research and ethical clearance			
Identify and recruit study participants			
Follow recruited participants			
Set up and train research team- data collectors			
Field Data collection and entry			
Analysis and documentation			

4.0. Ethical considerations

Risks and risk management: There may be potential risks involved with conducting this study. Women will be asked a number of questions that are sensitive in nature, including

experiences with pregnancy and various pregnancy outcomes. Therefore, careful steps have been taken in the questionnaire design to minimize potential discomfort to our study respondents. The study tools will be pre-tested among a small group of women with similar characteristics as the study population to identify potentially negative consequences and will be modified accordingly.

The selection criteria for data collectors will also be an important step in ensuring that we minimize any risk that may accrue from the process, and efforts made to provide a suitable and comfortable environment for the women interviewed. Specifically, the research team (comprised of women) will be trained to listen and record data without displaying any judgmental attitude towards the informants or the information received. Dealing with issues of unintended pregnancy and abortion will require that extreme caution be taken so that the women interviewed are not singled out, and so through the process of data collection, they will simply be referred to as respondents and not by names.

Informed Consent: Prospective study participants will be provided with information about the study before any consent to participate is sought. Participants will be adequately informed about the:

- Purpose of the study and methods to be used;
- Institutional affiliation of the research;
- Anticipated benefits and potential risks and follow-up of the study;
- Discomfort it may entail;
- The right to abstain from participating in the study, or to withdraw from it at any time, without reprisal;
- Measures to ensure confidentiality of information provided.

According to the Kenya law, the age of consent is 18 years and above. Legally some of our informants (15-17) will be considered emancipated minors because they are already married. In this regard, parental consent will not be sought and emancipated minors will provide individual written consent.

Data collectors will be trained on ethical issues to ensure that guidance on ethical conduct is clearly understood and implemented. Such training will include focused sessions and exercises regarding the meaning and process of informed consent, the importance of protecting the privacy of subjects, and confidentiality of the information obtained from them.

Ethical Training Certification and Clearance: The protocol has also been reviewed by APHRC's internal scientific committee and has been adjudged to be scientifically sound. See Appendix 3 for online ethical training certifications for all the investigators.

Benefits: No immediate tangible benefit is likely to accrue to the participants through their participation in this study and this will be made clear to them when obtaining their informed consent. However, the potential benefits of their participation to improved family planning services delivery for women in their community and beyond will be described so that they are fully aware that the data gathered will be used to provide recommendations to the Ministry of Health, as well as to health care providers and stakeholders in the health sector.

Confidentiality: Given the sensitive nature of the information to be gathered, protecting and respecting the confidentiality and privacy of our informants will be a critical consideration throughout the study. All interviews will be conducted in private. Identifying details will not be included in the results presentation. Confidentiality will be maintained at all times through training of data collectors on the meaning of confidentiality and ways of maintaining confidentiality during and after data collection. All data collection instruments will be kept under lock and key at all times in the field and in each study offices (in locked file cabinets). Additionally, data will be stored in password-protected computers, accessible only by the study

team members. All analytical datasets will also be fully anonymized. Results will be presented in reports in an aggregated manner such that responses cannot be traced back to individuals.

5.0. Expected Application of the Results:

The overall objective of the study is to develop and validate measures of unintended pregnancy for prospective and retrospective use in use in Kenya with the goal of contributing to the body of evidence on unintended pregnancy and its outcomes. The module developed is expected to improve our measurement of factors that influence contraceptive adoption and continuation of use. Feedback sessions will be held at the end of the data collection with key stakeholders and strategic partners (e.g., Community-Based Organizations leaders, Community Health Workers, National Council for Population and Development, Ministry of Health, Marie Stopes Kenya, program implementers, UNFPA, etc.). These stakeholders will also contribute to refining the research uptake strategy.

6.0. References

1. Singh S, Darroch JE. Adding it up: costs and benefits of contraceptive services: estimates for 2012. New York: Guttmacher Institute and United Nations Population Fund (UNFPA), 2012.
2. Mumah J, Kabiru CW, Mukiira C, Brinton J, Mutua M, Izugbara C, et al. Unintended Pregnancies in Kenya: A Country Profile. Nairobi: Kenya: African Population and Health Reseach Center; 2014.
3. Kenya National Bureau of Statistics, Ministry of Health, National AIDS Control Council, Kenya Medical Research Institute, National Council for Population and Development, International I. Kenya Demographic and Health Survey 2014. Calverton, Maryland KNBS and ICF Macro, 2015.
4. African Population and Health Research Center, Ministry of Health (MOH) K, Ipas, Institute G. Incidence and Complications of Unsafe Abortion in Kenya: Key Findings of a National Study. Nairobi, Kenya. APHRC, Ministry of Health (MOH), Kenya, Ipas, and Guttmacher Institute, 2013.
5. Santelli J, Rochat R, Hatfield-Timajchy K, Gilbert BC, Curtis K, Cabral R, et al. The measurement and meaning of unintended pregnancy. Perspectives on Sexual and Reproductive Health. 2003;35(2):94-101.
6. Santelli JS, Lindberg LD, Orr MG, Finer LB, Speizer I. Toward a multidimensional measure of pregnancy intentions: evidence from the United States. Stud Fam Plann. 2009;40(2):87-100.
7. Casterline JB, El-Zeini LO. The estimation of unwanted fertility. Demography. 2007;44(4):729-45.
8. Joyce T, Kaestner R, Korenman S. On the validity of retrospective assessments of pregnancy intention. Demography. 2002;39(1):199-213.
9. Koenig MA, Acharya R, Singh S. Do current measurement approaches underestimate levels of unwanted childbearing? Evidence from rural India. Population Studies 2006;60(3):243-57.
10. Bankole A, Westoff CF. The consistency and validity of reproductive attitudes: evidence from Morocco. J Biosoc Sci. 1998;30(4):439-55.
11. Rocca CH, Krishnan S, Barrett G, Wilson M. Measuring pregnancy planning: An assessment of the London Measure of Unplanned Pregnancy among urban, south Indian women. Demogr Res. 2010;23:293-334.
12. Agadjanian V. Fraught with ambivalence: reproductive intentions and contraceptive choices in a sub-Saharan fertility transition. Population Research and Policy Review. 2005;24(6):617-45.
13. Schwarz EB, Lohr PA, Gold MA, Gerbert B. Prevalence and correlates of ambivalence towards pregnancy among nonpregnant women. Contraception. 2007;75(4):305-10.

14. Speizer IS, Irani L, Barden-O'Fallon J, Levy J. Inconsistent fertility motivations and contraceptive use behaviors among women in Honduras. Reprod Health. 2009;6:19.
15. Moreau C, Hall K, Trussell J, Barber J. Effect of prospectively measured pregnancy intentions on the consistency of contraceptive use among young women in Michigan. Hum Reprod. 2013;28(3):642-50.
16. Santelli JS, Speizer IS, Avery A, Kendall C. An exploration of the dimensions of pregnancy intentions among women choosing to terminate pregnancy or to initiate prenatal care in New Orleans, Louisiana. Am J Public Health. 2006;96(11):2009-15.
17. Barber JS, Kusunoki Y, Gatny HH. Design and implementation of an online weekly journal to study unintended pregnancies. Vienna yearbook of population research / Vienna Institute of Demography, Austrian Academy of Sciences. 2011;9:327-34.
18. Barrett G, Smith S, Wellings K. Conceptualisation, development and evaluation of a measure of unplanned pregnancy. Journal of Epidemiology and Community Health. 2004;58:426-33.
19. Miller WB, Severy LJ, Pasta DJ. A framework for modelling fertility motivation in couples. Population Studies. 2004;58(2):193-205.
20. Sedgh G, Hussain R. Reasons for contraceptive nonuse among women having unmet need for contraception in developing countries. Studies in family planning. 2014;45(2):151-69.
21. Frost J, Singh S, Finer L. Factors associated with contraceptive use and nonuse, United States, 2004. Perspectives on Sexual and Reproductive Health. 2007;39(2):90-9.
22. Casterline JB, Perez AE, Biddlecom AE. Factors underlying unmet need for family planning in the Philippines. Stud Fam Plann. 1997;28(3):173-91.
23. Beguy D, Elung'ata P, Mberu B, Oduor C, Wamukoya M, Nganyi B, et al. HDSS Profile: The Nairobi Urban Health and Demographic Surveillance System (NUHDSS). International Journal of Epidemiology. 2015.

Appendices

Appendix 1: Role of Investigators

Dr. Joyce Mumah is the Principal Investigator (PI) and lead on the project.

Dr. Caroline Kabiru is the co-Principal Investigator (co-PI) and will provide technical assistance on the project.

Stephen Mulupi is one of the co-investigators and will provide overall coordination of the study implementation.

Clement Oduor is one of the co-investigators and as NUHDSS Field Coordinator, will support the training of data collectors and provide oversight on field work.

Appendix 2: Curriculum Vitae of Investigators

Appendix 3: Ethical Training Certificates for Investigators

Appendix 4: Informed Consent Form, Adults and Emancipated Minors – English

Appendix 5: Informed Consent Form, Adults and Emancipated Minors - Kiswahili

Appendix 6: Survey Instrument – English

Appendix 7: Survey Instrument – Kiswahili

Appendix 8: Study Budget

(For appendices 2-8, please refer to relevant folders, attached).