Randomized Controlled Trial to Address Unintended Pregnancy Rates in Low Resource Settings

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PROTOCOL

Complete Title: Randomized Controlled Trial to Address Unintended Pregnancy Rates in Low Resource Settings

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ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
AE	Adverse events
DiD	Difference-in-difference model
FGD	Focus group discussion
IDI	In-depth interview
IRB	Institutional Review Board
ISM	Independent safety monitor
KDHS	Kenya Demographic and Health Survey
LIC	Low-income countries
NIH	National Institutes of Health
UHC	Universal Health Coverage

PROTOCOL SYNOPSIS

Study Title	**Randomized Controlled Trial to Address Unintended Pregnancy Rates in Low Resource Settings**
Funder	Eunice Kennedy Shriver National Institute of Child Health and Human Development
Study Rationale	Unintended pregnancy is a major contributor to maternal and infant mortality in low-income countries (LICs). More than 300,000 women and 2.7 million newborns die *every year* in LICs due to complications from childbirth and pregnancy. Nearly half of the 200 million pregnancies occurring annually in LICs are unintended. High numbers of unintended pregnancy are primarily the result of non-use of contraception. Non-use of contraception is more likely to occur among potential users who experience poor provider care. Providers who are frequently absent, solicit informal payments from clients, and deny methods to unmarried or nulliparous women are a major barrier to women seeking family planning. Yet, removing these barriers is difficult due to low supervision and accountability in under-resourced public facilities. Such findings highlight the need for interventions that increase quality of care via alternative mechanisms for monitoring providers. The social accountability approach solicits citizen feedback with the goal of improving provider performance and service delivery. To date, there is limited rigorous evidence on the effectiveness of social accountability interventions to increase contraceptive use and on the conditions necessary for successful and sustainable scale-up of these interventions. Further, no prior study has rigorously assessed social accountability in a setting where Universal Health Coverage (UHC) is already operating. Based on these knowledge gaps, we propose to evaluate the impact of two social accountability interventions using rigorous methods. We propose this study in Kenya, which rolled out UHC in late 2018 and where one out of every 42 women will die from complications related to pregnancy and childbirth.
Study Objective(s)	Our *overall objectives* in this proposal are to (i) assess the impact of two social accountability approaches on contraceptive use, (ii) assess the impact of these approaches on community empowerment and quality of care, and (iii) assess the scalability of these approaches to additional settings.
Test Article(s)	Community Scorecard

(If Applicable)	In the Community Score Card approach, community members come together to document challenges they encounter when seeking services and develop a corresponding set of indicators that can be used to produce a validated facility score. The score is shared with the community and a collaborative process between key community members and facility staff takes place to develop feasible solutions and a strategic joint action plan, to be carried out by both providers and community members over the coming months. Citizen Report Card In the Citizen Report Card approach, individual-level feedback is collected from actual clients of target facilities, via a structured questionnaire, to assess facility performance and generate a public record of service quality. In addition to sharing the final report card with communities, engaged policymakers are invited to use the citizen feedback to improve service delivery.
Study Design	Our study design is a three-arm cluster-randomized controlled experiment in which all 147 public healthcare facilities in the county will be randomized to one of three study arms: 1. Community Score Card treatment, 2. Citizen Report Card treatment or 3. control.
Subject Population **key criteria for Inclusion and Exclusion:**	For this study, all women are included if they reside in randomly selected households and are between the ages of 18-49 years. Women who are less than 18 years old or older than 49 years will be excluded from the individual-level women's questionnaire. Providers will be eligible for inclusion in the survey if they provide family planning or reproductive health services within a public-sector healthcare facility located in Kisumu County. Qualitative In-Depth Interviews (IDIs) and Focus Group Discussions (FGDs): Key intervention facilitators will be eligible to participate in the post-intervention focus group discussions. In-depth interviews will be conducted with providers and community members who participated in the interventions. All qualitative data collection will be among individuals 18 years and above.
Number Of Subjects	5500 individuals
Study Duration	Each subject’s participation will last twenty minutes to three hours. The entire study is expected to last approximately two years.

Study Phases **Screening** **Study Treatment** **Follow-Up**	This is a three-arm cluster randomized experiment in which all 147 public healthcare facilities located in Kisumu county will be randomly assigned to one of three study arms: 1. The Community Score Card treatment arm, 2. The Citizen Report Card treatment arm, and 3. The control arm. Each study arm will contain approximately 48 facilities, which, on average, serve approximately 2,500 households each. Prior to randomization, we will ensure the three arms each contain similar numbers of each type of facility by first stratifying by facility type, a designation that includes three categories: 1. clinics and dispensaries (the smallest public facility type); 2. health centers; and 3. hospitals (sub-county or county hospitals). Individual-level data will be collected form women of reproductive age (18-29) in the catchment area of each facility. Pre-intervention/baseline data collection will be conducted in 2021, with a repeated cross-sectional endline survey conducted in 2022/23.
Efficacy Evaluations	Individual level questionnaires with women of reproductive age Facility level data on family planning quality of care
Safety Evaluations	Given our focus on improving quality of care among health care providers and the fact that we are not administering drugs or invasive measures, we anticipate a limited number of adverse events. Nevertheless, community monitoring of provider performance may increase stress for either community members or providers; therefore, facility staff and community members participating in any study component will be instructed to report any perceived adverse events related to any portion of this study to local project personnel, who will in turn inform Dr. Tumlinson throughout the trial.
Statistical And Analytic Plan	Our approach to testing the working hypothesis will be to use a difference-in-difference (DiD) model to estimate differential change in contraceptive use over time in each of the two treatment areas versus the control area. Contraceptive use will be a binary variable (0=non-use; 1=use), attained by asking participants, “Are you (or your partner) currently doing something or using any method to delay or avoid getting pregnant?” We will define modern contraceptive methods to include female or male sterilization, intrauterine device, implant, injectable contraception, oral contraceptive pill, or male or female condom.

DATA AND SAFETY MONITORING PLAN	The intervention and measurement protocols pose minimal risk to participants. Because of this low-risk status, the data and safety monitoring plan for this trial focuses on close monitoring by the principal investigator (Dr. Tumlinson) and a local co-investigator in conjunction with an Independent Safety Monitor (ISM), along with prompt reporting of any serious adverse events to the NIH and to the University of North Carolina IRB and the Kenyan IRB committee reviewing the research protocol.

1 BACKGROUND AND RATIONALE

Social accountability interventions are designed to improve the performance of service providers via public monitoring and the use of feedback mechanisms to address deficiencies in service delivery, but little is known about their true impact on contraceptive use, especially in the context of Universal Health Coverage. This study aims to implement and evaluate two social accountability interventions: the community score card and the citizen report card.

1.1 Introduction

Family planning saves lives but is underutilized in low-income countries (LICs) where healthcare providers often discourage family planning use by engaging in negative behaviors. These negative behaviors include absenteeism, solicitation of informal fees, and withholding methods from young or unmarried clients. Recent data collected by the PI in Western Kenya revealed more than 50% of public-sector providers are absent at any one time, contributing to long wait times and abbreviated family planning counseling. Additionally, 23% of public-sector family planning clients are asked to pay for free commodities and 14% are unable to obtain any method due to provider bias towards women who are unmarried or nulliparous. These negative behaviors are reinforced by a disempowered clientele who lack knowledge of their patient rights and are further enabled by weak supervision of providers. Yet, increased supervision often is not feasible in resource-constrained settings.

An alternative and promising approach, known as social accountability, is to engage local citizens in monitoring publicly funded healthcare facilities. What remains lacking, however, is a strong evidence-base for the impact of social accountability approaches on contraceptive use, particularly in settings that have implemented Universal Health Coverage (UHC). Therefore, there is a critical need to estimate the impact of social accountability interventions on provider performance and client contraceptive use in the UHC context and to ascertain the scalability of this approach. Without sufficiently addressing negative behaviors among providers, progress towards reducing unmet need for family planning will likely be limited.

Our study design is a three-arm cluster-randomized controlled experiment in which all 147 public healthcare facilities in the county will be randomized to one of three study arms: 1. Community Score Card treatment, 2. Citizen Report Card treatment or 3. control. Our central hypothesis is that social accountability efforts will result in increased community empowerment, provider performance, and service utilization which, in turn, will increase contraceptive use. The rationale for this project is that a determination of highly impactful strategies for reducing unmet need is vital for countries burdened with high rates of maternal and infant mortality.

1.2 Name and Description of Investigational Product or Intervention

The following social accountability tools will be developed, applied, and evaluated in a three-armed cluster randomized controlled trial.

- Community Score Card
- Citizen Report Card

In the *Community Score Card* approach, community members come together to document challenges they encounter when seeking services and develop a corresponding set of indicators that can be used to produce a validated facility score. The score is shared with the community and a collaborative process between key community members and facility staff takes place to develop feasible solutions and a strategic action plan.

In the *Citizen Report Card* approach, individual-level feedback is collected from actual clients of target facilities, via a structured questionnaire, to assess facility performance and generate a public record of service quality. In addition to sharing the final report card with communities, engaged policymakers are invited to use the citizen feedback to improve service delivery.

1.3 Non-Clinical and Clinical Study Findings

Intended participants of this study are:

- Women of reproductive age (18-49 years),
- Family planning providers at public facilities
- Community members involved in intervention activities

There are no anticipated or know potential risks for the participants in this study, besides potential breach of confidentiality. Participants in all surveys will be informed during the consent process that they may refuse to participate or may refuse to answer any question they do not want to answer, and no harm will come to them regardless of their participation decisions. All enumerators employed in any aspect of this research will receive extensive training on research ethics and confidentiality and will pledge to adhere to a strict confidentiality policy. (For more details on data management and collection see section 10.)

There are no or minimal prospects of benefits to subjects participating in this study. Respondents will gain from contributing to research that will inform improvements in maternal and child health. The new knowledge generated through this study can benefit the local society and its members through improved accountability and delivery of health care services. The study has budgeted for dissemination plans. This will include communicating our findings to local and national representatives of the Ministry of Health and other interested parties. The research team will also present to any other Kenyan counties who would be interested in scaling up the social accountability interventions. Additionally, the research team will publish the results in peer-reviewed journals and present at international conferences.

There are also substantial benefits to the scientific research, policy, and health communities: extensive research using these data will be published in health policy and public/reproductive/sexual health journals. We hope that this study will ultimately lead to improvement in understanding of the key community-level factors related to improved service delivery within public-sector healthcare facilities and improved health outcomes for women and children in Kenya.

Because the risks to subjects are very minimal, they are reasonable in relation to the anticipated benefits of improved understanding of factors contributing to increased contraceptive use.

1.4 Relevant Literature and Data

- Bjorkman, M. and J. Svensson, Power to the people: evidence from a randomized field experiment of a community-based monitoring project. Quarterly Journal of Economics, 2009. 124(2): p. 735-69. Gullo, S., et al., Effects of a social accountability approach, CARE's Community Score Card, on reproductive health-related outcomes in Malawi: A cluster-randomized controlled evaluation. PLoS One, 2017. 12(2). PMCID: PMC5302808
- Gullo, S., C. Galavotti, and L. Altman, A review of CARE's Community Score Card experience and evidence. Health Policy Plan, 2016. 31(10): p. 1467-78. PMCID: PMC5091339
- Björkman, M. and J. Svensson, when is community-based monitoring effective? Evidence from a randomized experiment in primary health in Uganda. Journal of the European Economic Association, 2010. 8(2-3): p. 571-581.
- Hoffman, K.D., The Role of Social Accountability in Improving Health Outcomes: Overview and Analysis of Selected International NGO Experiences to Advance the Field. 2014, CORE Group: Washington, DC.
- CARE Malawi, The Community Score Card (CSC): A generic guide for implementing CARE's CSC process to improve quality of services. 2013, Cooperative for Assistance and Relief Everywhere, Inc.
- Waglé, S., J. Singh, and P. Shah, Citizen Report Card Surveys - A Note on the Concept and Methodology, in Social Development Notes: Participation and Civic Engagement. 2004, The World Bank: Washington, DC.
- Asian Development Bank (ADB) and Asian Development Bank Institute (ADBI), Improving Local Governance and Service Delivery: Citizen Report Card Learning Tool Kit. 2007.

2 STUDY OBJECTIVE

Our *long-term goal* is to develop, evaluate, and implement evidence-based strategies that reduce unmet need for family planning in LICs.

2.1 Primary Objective

Our *overall objectives* in this proposal are to (i) assess the impact of two social accountability approaches on contraceptive use, (ii) assess the impact of these approaches on community empowerment and quality of care, and (iii) assess the scalability of these approaches to additional settings. The proposed aims will be carried out in Kisumu County (Kenya) in close collaboration with the county health department.

Aim 1: Estimate the impact of two social accountability interventions on modern contraceptive use. We will collect pre- and post-intervention measures of current modern contraceptive use in a representative sample of 2,268 women of reproductive age residing in Kisumu, using two independent cross-sectional surveys. We will use a *difference-in-difference (DiD) model* to estimate differential change in contraceptive use over time in each of the two treatment areas versus the control area.

Aim 2: Estimate the impact of two social accountability interventions on community empowerment and quality of care. In addition to measuring contraceptive prevalence, our pre- and post-intervention surveys will

measure changes in community empowerment and the quality of family planning service delivery as important outcomes along the causal pathway from treatment to increased contraceptive use. Understanding the impact of the interventions on these intermediate outcomes will increase knowledge of the mechanisms by which the social accountability approach impacts health outcomes. As in Aim 1, we will use DiD models to estimate differential change for these intermediate outcomes over time.

Aim 3: Using implementation science methods, assess the quality, scalability, and replicability of two social accountability interventions for uptake by the public-sector healthcare system. Little is known about how citizens and providers experience monitoring of providers. Negative perceptions from citizens or providers could ultimately reduce engagement in these approaches and hinder positive and sustainable outcomes. We will use validated measures of provider job satisfaction in the facility survey, as well as in-depth interviews with providers and community members, to assess local perspectives on citizen monitoring. Additionally, we will conduct focus groups with key facilitators in the two interventions to better understand implementation challenges and potential barriers to scale-up.

3 INVESTIGATIONAL PLAN (brief overview)

3.1 Study Design

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This is a three-arm cluster randomized experiment in which all 147 public healthcare facilities located in Kisumu county will be randomly assigned to one of three study arms: 1. The Community Score Card treatment arm, 2. The Citizen Report Card treatment arm, and 3. The control arm. Each study arm will contain approximately 43 facilities, which, on average, serve approximately 2,500 households each. Prior to randomization, we will ensure the three arms each contain similar numbers of each type of facility by first stratifying by facility type, a designation that includes three categories: 1. clinics and dispensaries (the smallest public facility type); 2. health centers; and 3. hospitals (sub-county or county hospitals).

Before and after implementing the two treatments, individual- and facility-level pre- and postintervention surveys will be conducted. The *individual*-level surveys will be conducted within a representative sample of women of reproductive age, stratified by study arm and cluster, and will be used to establish the primary outcome, modern contraceptive use, in all three study arms, pre- and post-treatment. The individual-level surveys will also measure multiple linking constructs such as community empowerment and quality of care. The *facility*-level surveys will be conducted in a census of all public-sector facilities located in Kisumu county and will be used to measure quality of family planning service delivery and negative provider behaviors.

3.2 Allocation to Treatment Groups

This is a three-arm cluster randomized experiment in which all 147 public healthcare facilities located in Kisumu county will be randomly assigned to one of three study arms: 1. The Community Score Card treatment arm, 2. The Citizen Report Card treatment arm, and 3. The control arm. Each study arm will contain approximately 43 facilities, which, on average, serve approximately 2,500 households each. Prior to randomization, we will ensure the three arms each contain similar numbers of each type of facility by first stratifying by facility type, a designation that includes three categories: 1. clinics and dispensaries (the smallest public facility type); 2. health centers; and 3. hospitals (sub-county or county hospitals).

3.3 Study Duration, Enrollment and Number of Subjects

Mystery clients and unannounced visitors: All 147 public-sector healthcare facilities in Kisumu County will be included in this study. Each facility will receive two unannounced visitors and three mystery client visits at baseline and then again at endline.

Provider interviews: Provider interviews will be conducted in all 147 public facilities in Kisumu County at baseline and endline. The total number of provider interviews conducted per facility will depend on the facility size but will average three per facility and will range from one to ten. The unannounced visitor will take a roster of providers who offer family planning services that are scheduled to work that day. If the facility has more than ten providers who provide family planning services scheduled to work that day, then ten providers will be randomly selected to participated. If the facility has less than ten providers scheduled to work that day, then all providers who offer family planning services will be interviewed.

Individual-Level Interviews: 18 women will be sampled from each of the 42 clusters in each of the three arms. Households will be selected at random and approached by trained enumerators who will discuss the study and survey with the household head and then approach eligible women to review the consent process. This cross-sectional survey will be conducted at both baseline and endline.

In-depth interviews: Thirty qualitative in-depth interviews will be conducted at endline with providers and community members to explore nuanced perspectives on formal feedback mechanisms and impact on provider job fulfillment. The UNC-based and local research teams will use convenience sampling to ensure that community members and providers who participated in the interventions are included. Once potential respondents have been identified, the local partner will invite potential respondents to participate in the interviews.

Focus Group Discussions: Four focus group discussions will be conducted at endline with two groups per intervention arm. These discussions will bring together key facilitators who were instrumental in the implementation of the two interventions. The UNC-based team will work with our local partner to identify key figures in the implementation process and invite them to join these discussions. Approximately 55 individuals will be recruited to participate in these focus group discussions.

Focus Group Discussions for Citizen Report Card Approach: Formative qualitative data collection will happen before the baseline survey to inform the contents of the Citizen Report Card. Three focus group discussions will be conducted with family planning clients (2 FGDs) and providers (1 FGD) to identify the most important indicators to include in the Citizen Report Card. The UNC-based and local partner teams will work with local community health workers to identify participants to include in these discussions. Approximately 40 individuals will participate in these focus group discussions.

3.4 Study Population

For this study, all women are included if they reside in randomly selected households and are between the ages of 18-49 years. Women who are less than 18 years old or older than 49 years will be excluded from the individual-level women's questionnaire.

Providers will be eligible for inclusion in the survey if they provide family planning or reproductive health services within a public-sector healthcare facility located in Kisumu County.

Qualitative In-Depth Interviews and Focus Group Discussions: Key intervention facilitators will be eligible to participate in the post-intervention focus group discussions. In-depth interviews will be conducted with providers and community members who participated in the interventions. All qualitative data collection will be among individuals 18 years and above.

4 STUDY PROCEDURES (what will be done)

Please see Section 7 for a description of the research methods (procedures, observations, and measures). Please see Section 8 for a description of the treatment and related protocols.

1.1 Not applicable.

4.1 Subject Completion/ Withdrawal procedures

Respondents will be reminded during the consent process that they are free to withdrawal from the survey or interview whenever they desire. Following the survey, respondents will have completed their involvement with the study.

5 STUDY EVALUATIONS AND MEASUREMENTS (how measurements will be made)

- **The baseline evaluation and planned measures are described in subsequent Sections.**

6 STATISTICAL CONSIDERATION

1.1 Primary Endpoint

Aim 1 Methods: Estimate the Impact of Two Social Accountability Interventions on Modern Contraceptive Use.

Overview. Weak accountability mechanisms in public-sector facilities result in poor provider performance, creating barriers to family planning use among women with a desire to space or limit future pregnancy. The *objective* of this aim is to estimate the impact of the Community Score Card and the Citizen Report Card, relative to the control arm, on current use of a modern contraceptive method. To attain this objective, we will test the *working hypothesis* that social accountability efforts result in increased community empowerment, provider performance, and service utilization which, in turn, increases contraceptive use. Our *approach* to testing the working hypothesis will be to use a difference-in-difference (DiD) model to estimate differential change over time in each of the two treatment areas versus the control area. The *rationale* for this aim is that the results will contribute to a nascent body of literature on the impact of social accountability interventions on family planning use. *We expect* to identify the potential contribution of social accountability efforts to increased contraceptive use. Such findings are important because they inform much needed knowledge of effective strategies for reducing unmet need for women living in LICs.

Research Design. To assess the causal effect of the interventions, we will use a difference-indifference (DiD) model to estimate differential change over time in each of the two treatment areas versus the control area. The DiD model is commonly used in the social sciences [45, 46] and is described as follows:

$$Y=\beta 0 + \beta 1POST + \beta 2T1 + \beta 3(POST*T1) + \beta 4T2 + \beta 5(POST*T2) + \beta 4X + ui \quad (1)$$

In this equation, Y is a binary variable for current modern contraceptive use (0=non-use; 1=use), attained by asking participants, "*Are you (or your partner) currently doing something or using any method to delay or avoid getting pregnant?*" We will define modern contraceptive methods to include female or male sterilization, intrauterine device, implant, injectable contraception, oral contraceptive pill, or male or female condom.

Stacking pre- and post-data, POST is an indicator variable (0=baseline;1=endline) and T1 and T2 are indicator variables for assignment to the Community Score Card or Citizen Report Card, respectively (1), or control (0).

The interaction between POST and T1 or T2 gives the difference between the change in the value of Y in either treatment group versus the same change in the control group. Equation (1) also includes a vector, X, of demographic characteristics. For any covariates that are not balanced across the study arms we will control for them in the regression, using their baseline values [47]. These covariates could include age, religion, ethnicity (tribal group), marital status, literacy/education, parity, distance to public facility, and household wealth. This model can also be used to test whether there is a large difference between the treatments by testing the equality of $\beta 3$ and $\beta 5$.

Expected Outcomes. This aim is expected to provide critical knowledge of whether social accountability efforts can increase family planning use in LICs. Additionally, this aim will determine whether the two primary approaches to community engagement are largely different in their impact on women's contraceptive behavior. This work is crucial to global efforts to address facility-level barriers to contraceptive use.

Potential Problems and Alternative Strategies (for Aims 1 & 2). Our working hypothesis for this aim is that community engagement activities impact the contraceptive use of community members. Although our preliminary data strongly support this hypothesis – as does prior work by Bjorkman (2010) and Gullo (2017) – there is the remote possibility that contamination between arms of the trial could invalidate our hypothesis. Contamination is unlikely given community units are well-defined and mutually exclusive, but it is possible that those on the border of the community units, or those that move to a different community during the one year of treatment, could introduce contamination. If this happens, we would conduct a contamination adjusted intention to treat analysis. Towards this end, we will collect data in the individual-level survey that will allow us to ascertain movement between clusters during treatment as well as the actual facility used. Notably, it is unlikely that providers working at different facilities to supplement their income will contaminate across study arms because these supplemental positions occur within the private sector and not in other public facilities. Finally, we are unable to test for heterogeneity of treatment effect (i.e. variation in how specific sub-groups respond to the two treatments) due to necessary sample size restrictions. However, as described below, we will measure the intermediate outcomes that occur along the causal pathway between treatment exposure and the outcome of increased contraceptive use, helping to better understand how social accountability interventions work and which populations are likely to benefit most or least.

Empowerment and Quality of Care.

Overview. The changes that take place between intervention activities and the primary health outcome are referred to as *linking constructs* and are important in the evaluation of social accountability interventions. The *objective* of this aim is to estimate the impact of the two treatments, relative to the control arm, on several outcomes that potentially occur along the causal pathway from the treatments to the primary outcome of increased contraceptive use. To attain this objective, we will test the *working hypothesis* that social accountability efforts result in increased community empowerment and quality of care. Our *approach* to testing this working hypothesis will be to, once again, use a DiD model to estimate differential change over time in each of the two treatment areas versus the control area. Our *rationale* for this aim is that, currently, little is known about the causal mechanisms through which community monitoring activities impact health behaviors. *We expect* to identify the primary intermediate outcomes between the intervention and outcome. Such findings are important because they provide valuable information on which specific components of the interventions produce the change in contraceptive behavior.

Research Design. As in Aim #1, we will use DiD models to estimate differential change in each of the

two treatment versus the control areas over time for each of the outcomes described below. In constructing the indicators that will fulfill this aim, we will refer to Kuhlmann et al.'s 2017 Malawi study; as in the Malawi study, we will invite Kisumu county health officials to provide select additional indicators of high relevance. Following Kuhlmann's approach, community empowerment will be measured via questions related to individual knowledge and awareness of patient rights such as the right to receive family planning regardless of age, the right to free family planning services (without making informal payments), and the right to complain when encountering a provider who is disrespectful. As a subset of community empowerment, we will also include indicators of community engagement designed to gauge *collective efficacy* (i.e. How sure are you that the people in your community could work together to improve how women are treated at the health facility?) and *social participation* (i.e. In the past six months have you joined together with other people in your community to improve health services for women?). These measures will be included in the individual pre/post surveys.

The individual-level pre- and post-intervention surveys will also include measures of *perceived* quality of care (choice of methods, information, and appropriate follow-up as well as informal fee solicitation and respectful care for all ages, regardless of marital status or parity). *Actual* quality of care will also be measured during pre and post-intervention *facility*-level surveys including mystery client surveys (standardized across enumerators) and unannounced enumerator visits (to ascertain absenteeism). Facility-level data collection will also include a provider survey that will ascertain changes in provider self-efficacy (as a subset of service quality), via questions related to provider confidence in their ability to speak up in community meetings as well as their ability to improve their own performance.

Expected Outcomes. This aim is expected to identify the intermediate outcomes that occur along the causal pathway between treatment exposure and the outcome of increased contraceptive use. This work is critical for understanding the mechanisms of effect for improvement and replication of social accountability interventions in additional settings.

Aim 3 Methods: Using Implementation Science Methods, Assess the Quality, Scalability, and Replicability of Two Social Accountability Interventions for Uptake by The Public-Sector Healthcare System.

Overview. Despite steadily growing popularity of the social accountability approach, little is known about how communities and providers experience giving and receiving formal feedback.

Research Design. To assess provider burnout and professional fulfillment, we will include a short module in the facility-level provider survey, using the validated Professional Fulfillment Index. We will also conduct in-depth interviews (n=30) with providers and community members to explore nuanced perspectives on formal feedback mechanisms and impact on provider job fulfillment. Additionally, we will conduct four focus groups (two/arm) with key facilitators in the two intervention approaches to better understand implementation challenges and potential barriers to scaling up these interventions to other regions or countries. Finally, we will obtain estimates of the parameters needed to estimate the costs to scale up each intervention.

Expected Outcomes. This aim is expected to increase knowledge of how community members and providers experience the community monitoring process and will also identify challenges to intervention replication and scale up. This knowledge will be important for further uptake of social accountability efforts.

1.1 Statistical Methods

Our approach to testing the working hypothesis will be to use a difference-in-difference (DiD) model to estimate differential change over time in each of the two treatment areas versus the control area. The rationale for this aim is that the results will contribute to a nascent body of literature on the impact of social accountability interventions on family planning use. We expect to identify the potential contribution of social accountability efforts to increased contraceptive use. Such findings are important because they inform much needed knowledge of effective strategies for reducing unmet need for women living in LICs.

6.1 Sample Size and Power

For the *individual*-level surveys, we estimate a design effect of 1.56 for modern contraceptive prevalence due to our cluster-based sampling procedure, based on information provided in the 2014 Kenya Demographic and Health Survey (KDHS) Final Report, Appendix B, Table B2. We calculate our necessary sample size assuming 1.) 50% current modern contraceptive prevalence in Kisumu; 2.) 42 clusters in each study arm [clusters=facility catchment areas (All public facilities have a catchment area which is clearly defined, mutually exclusive, and exhaustive); we are allowing for potential closure of one facility per arm)]; 3.) an effect size of two standard deviations (which correlates to a change in the prevalence of modern contraceptive use of approximately 10 percentage points). With these parameters, we will need to survey 18 women in each of the 42 clusters in each of the three study arms, resulting in a total sample size of 2,268 women of reproductive age in the individual-level surveys. The 18 women sampled from each cluster will be selected at random. We will follow KDHS procedures in cases where there is more than one eligible woman in the household.

For the *facility*-level surveys we will measure family planning service quality and negative provider behaviors via interviews with one to ten providers, depending on total staff at each of the 147 facilities. This will result in approximately 385 provider interviews, with approximately 128 in each study arm. Unannounced visitors and mystery clients will also be deployed to secure less biased estimates of provider absenteeism, informal fee solicitation, and disrespectful/biased treatment of clients; mystery clients will also collect data on traditional measures of family planning service quality such as choice of methods and information on side effects. All 147 facilities in Kisumu will receive two unannounced visits and three mystery client visits.

Post-treatment, we will repeat the individual-level survey, within a newly sampled cross-section of the population. We will also repeat all facility-level data collection in all 147 public facilities in the county. The changes in contraceptive use, quality of care, and community engagement resulting from the Community Score Card and the Citizen Report Card interventions will be evaluated via data collected in these pre- and post-intervention surveys. The sampling frame for both individual-level surveys will come from the Kenyan National Bureau of Statistics, which completed a new household-level census in all counties in Kenya in August 2019.

7 STUDY INTERVENTION (drug, device or other intervention details)

- **Description**

The Community Score Card Approach

In the Community Score Card approach, community members come together to document challenges they encounter when seeking services and develop a corresponding set of indicators that can be used to produce a validated facility score. The score is shared with the community and a collaborative process between key community members and facility staff takes place to develop feasible solutions

and a strategic action plan.

Step 1: Preparation (3 months). During this phase, the PI will consult with the Kisumu County Health Director to confirm the geographic coverage of the community score card intervention (the catchment area of the 43 public healthcare facilities in this arm). Training manuals and facilitation guides will be developed. Experienced facilitators will be identified and trained in the community score-card approach. The communities and facility staff will be engaged and sensitized to the community score card via a meeting that discusses the community score card purpose and approach; a date, location, and general process for conducting the community score cards will be selected/designed.

Step 2: Conducting the community score card with target communities (1 month). During this phase, all communities associated with the targeted facilities will assess the primary barriers to quality family planning service delivery and develop corresponding indicators, assisted by an experienced facilitator. The communities will then each complete the score card and generate ideas for quality improvement.

The first activity in this phase will be to divide the community into groups based on shared characteristics. Groups will be determined using a social mapping exercise with a diverse group of community members who know the community well and are able to identify vulnerable households. The social mapping exercise is designed to ensure marginalized populations are included in the score card activities. Possible groups determined by the social mapping exercise may include women, young women, men, young men, female headed-households, households with orphans, and people living with HIV/AIDS.

Once the groups have been determined, a facilitator with a relationship of trust within each group will be identified and assigned to facilitate each group in a participatory manner. Of note, groups will meet in separate areas when developing their scorecard. Each group will be invited to generate a list of issues related to the delivery of healthcare services, with an emphasis on family planning services. The facilitator will elicit issues by asking questions like, "*How are things going with health services at your public facility? What is going well? What is not going well?"* For all issues generated, the facilitator will ask for suggestions of how to improve service delivery. Additionally, because a large number of issues may be identified, group members will also be asked to prioritize issues by agreeing on the most important and urgent issues to resolve first. This information will be fed into an issue matrix. Each group will decide for themselves the issues, solutions, and priorities in their matrix.

Information from the issue matrix will be used by study team members to develop the scorecard indicators for the larger community. Each of the groups will be given a scoring matrix of final indicators and will score these indicators (a suitable scoring system will be developed with community input). Study team members, collaborating with community members, will meet to consolidate scores across groups.

Step 3: Conducting the community score card with family planning providers (1 month – simultaneous with Step 2). Family planning providers in the target facilities will meet and determine the barriers to high quality family planning service delivery. Providers will decide on priority areas and make suggestions for improving service delivery. This step will be similar to step 2, using the same participatory facilitation methods, but the pace may be quicker as providers generally form only one group and have a higher literacy level. Providers may derive a similar list of issues/indicators as the community. When scoring the indicators, the facilitator will be sure to include the views of quieter providers.

Step 4: Connecting the patients and providers and determining an action plan (1 month). This is where community members and service providers share their respective scorecards and jointly develop an action plan. A skilled facilitator with strong negotiation skills will ensure the meeting is positive and productive. Family planning patients and providers - as well as community leaders and process facilitators - will come together to present their findings and to jointly determine the priority areas and develop an action plan. Within the action plan, agreed upon responsibilities will be assigned and a timeline will be communicated. For example, one priority issue may be punctuality of staff and the determined action may be for staff to observe official hours. This action would be led by the providers, in collaboration with the facility manager, and the expected timeline/date of completion may be the following month.

The Citizen Report Card Approach (CRC)

In this approach, individual-level feedback is collected from actual clients of target facilities, via a structured questionnaire, to assess facility performance and generate a public record of service quality. In addition to sharing the final report card with communities, engaged policymakers are invited to use the citizen feedback to improve service delivery.

Step 1: Preparing for data collection and dissemination (1 month). The PI will consult with the Kisumu County Health Director to confirm the geographic coverage of the citizen report card. The PI will also collaborate with staff in the county health office to develop a post-survey publicity strategy. The strategy could include community dialogues, radio call-in shows, television, and newspaper coverage.

Step 2: Designing the CRC survey (3 months). We will conduct three focus groups (two with family planning clients stratified into younger versus older women and one with service providers). This will help to identify key service challenges and inform the content of the CRC questionnaire by allowing citizens to articulate and prioritize relevant indicators for monitoring and reporting on service provider performance. Focus groups with service providers may elicit suggestions for the type of feedback they would find most useful for improving their service delivery. *In general, both providers and clients will be asked about the problem areas related to family planning service delivery*. Once focus group discussions are completed and the data are analyzed, investigators will identify the prominent themes related to family planning service delivery that emerge from the focus group data. In turn, these themes will inform the main content of the CRC questionnaire.

All survey questions wll be grouped into modules including demographic characteristics (age, marital status, education, etc.), contraceptive use, and service quality indicators. Survey questions will be translated into local languages and retranslated back to English to confirm accuracy of translations. Once drafted and translated, the CRC questionnaire will be field-tested in a neighboring county. Prior to survey implementation, communities in the catchment area of the selected facilities will be sensitized to the survey, in collaboration with the county health director and the primary elder for each community.

Step 3: Execute the survey (3 months). The survey will be administered within a representative sample (N=300, ideal size to capture representative community opinions on facility performance, per recommendation of report card developers) of reproductive age women in the catchment areas of facilities randomized to the Citizen Report Card study arm. To obtain a representative sample of women from each catchment area, we will use a multi-stage sampling design in which government census enumeration areas from the 2019 national census will serve as primary sampling units. Within each selected unit, a random sample of 25 households will be selected, during which a list of usual household residents will be obtained. To obtain the list of household residents, a trained enumerator will approach the household head to explain the

study and obtain permission to list household residents. All eligible women aged 18–49 on the household list will be approached by a trained and experienced female enumerator who will explain the study purpose. Eligible women will be asked to participate in the survey via an informed consent protocol; those providing written consent will be interviewed by a female enumerator who will record responses on a password-protected and encrypted electronic device. The interview will not exceed 30 minutes. Pre-survey filters will exclude those women who do not use family planning obtained from a public facility (this cannot be ascertained during the household listing with the household head (often male) as women may use family planning covertly). Thorough quality checks (spot monitoring of interviews and data checks for inconsistent responses) will be conducted.

Step 4: Analyze the data (2 month). We will analyze data from the CRC questionnaire and translate results into a report card. Prior to dissemination, we will conduct cognitive interviews with a convenience sample of 20 people to inform the design and presentation of 'user-friendly' results; this will help to ensure citizens can easily and quickly absorb the findings. The report card will also be translated into the local languages (Kiswahili and Dholuo) so that it is accessible to a broad range of stakeholders.

Step 5: Disseminate results to the community (1 month). Extensive dissemination activities will ensure the Citizen Report Card is widely shared with members of the community. Report card findings will be presented at a high-profile press conference and press kit materials with short, readable stories will be distributed to members of the print, radio, and television media. The goal is to create a public record of service quality

8 SAFETY MANAGEMENT

A *Data and Safety Monitoring Plan* has been developed for the purpose of this study. Below is an extract from this plan:

The intervention and measurement protocols pose minimal risk to participants. Because of this low-risk status, the data and safety monitoring plan for this trial focuses on close monitoring by the principal investigator (Dr. Tumlinson) and the local co-investigator (Dr. Onyango) in conjunction with an Independent Safety Monitor (ISM), along with prompt reporting of any serious adverse events to the NIH and to the University of North Carolina IRB and the Kenyan IRB committee reviewing the research protocol. Our proposed plan entails regular safety reports which will be prepared by Dr. Tumlinson, with input from Dr. Onyango. Dr. Tumlinson will be responsible for assembling the data and producing these reports, as well as assuring that all parties obtain copies of these reports. The research team will meet with the ISM twice during each project year to review the reports and discuss any concerns that arise.

Qualifications and responsibilities of the Safety Monitor: The Independent Safety Monitor (ISM) will be a researcher, independent of this research team, identified through the Kisumu County Health Department and with expertise in the areas of reproductive health and community engagement. The ISM will review safety reports and will determine whether there is any corrective action, trigger of an ad hoc review, or stopping rule violation that should be communicated to the study investigators, institutional IRBs, and the NIH program officer.

Review Process: Dr. Tumlinson will provide the ISM with administrative reports describing the study progress, subject recruitment, subject demographic data, subject status, and inclusion/exclusion criteria. These reports will be reviewed by Drs. Tumlinson, Onyango, and additional study team members prior to being presented to the ISM. Dr. Tumlinson will notify the ISM if any events pose statistical concern or occur in disproportionate

numbers throughout the intervention and control groups. A summary of the administrative reports produced each project year will be included in the annual report to NICHD for R01 HD101453-01A1.

Independent Safety Monitor (ISM) Activities: The ISM will review the protocol to ensure adequate measures are designed to ensure subjects' safety and identify any needs for modification. The ISM will provide review of recruitment data, protocol adherence, as well as identify needs regarding subject safety. Additionally, the ISM will make recommendations for appropriate analyses and suggestions for recruitment and safety issues.

Measurement and reporting of adverse events: Given our focus on improving quality of care among health care providers and the fact that we are not administering drugs or invasive measures, we anticipate a limited number of adverse events. Nevertheless, community monitoring of provider performance may increase stress for either community members or providers; therefore, facility staff and community members participating in any study component will be instructed to report any perceived adverse events related to any portion of this study to Dr. Onyango, who will in turn inform Dr. Tumlinson and the ISM throughout the trial. Dr. Tumlinson will immediately report any adverse events to the institutional IRBs, and the NIH program officer.

Stopping rules: In this minimal risk intervention trial it is unlikely that excess adverse events will occur and require stopping the trial. Other issues relating to stopping rules for this trial include significant new information. It is exceedingly unlikely that any new information will become available during this trial that would necessitate stopping the trial.

Process for Handling and Reporting Adverse Events (AEs): We will institute two primary mechanisms for handling AEs.

1. Facility staff and community members participating in any study component will be instructed to report any perceived adverse events related to any portion of this study to Dr. Onyango, who will in turn immediately inform Dr. Tumlinson and the ISM.
2. Additionally, for each data collection activity, all enumerators will participate in a weekly briefing with a senior field officer (SFO), during which time any concerns can be conveyed. The SFO will immediately relate any concerns to the Assistant Field Manager who will immediately communicate with Drs. Onyango and Tumlinson.

Across both mechanisms, Dr. Tumlinson will immediately report any adverse events to the institutional IRBs and the NIH program officer and will follow any additional AE reporting requirements according to the protocols approved by the IRBs at the University of North Carolina at Chapel Hill and the local Kenyan IRB.

9 DATA COLLECTION AND MANAGMENT

No private identifiable information will be collected from either individual or facility-level survey participants or from any of the participants in the qualitative study components. No previously collected data or records will be used in the proposed activities. All individual and facility-level (and qualitative) data will be collected by a team of Kenyan supervisors and enumerators. The field team will undergo a major training program led by PI Tumlinson prior to baseline; before end-line data collection the team will undergo additional and extensive training.

The primary risks posed to individuals who have contributed information to this study derive from the threat of breach of confidentiality, although this risk is minimized given that we are not collecting any personally

identifying information for any of the three study aims. Further, PI Tumlinson has received extensive training regarding the protection of human subjects and has had prior experience with the conduct of primary data collection. Dr. Tumlinson will draw upon this training and experience and take all necessary precautions to ensure that no individual's confidentiality is breached. The Carolina Population Center houses several projects based on confidential data and the systems personnel developed data security protections that meet all federal standards.

The quantitative data that is collected electronically (mystery client observation, unannounced visits, provider surveys, and individual-levels interviews with women) will be collected on an encrypted, password-protected electronic device using Survey CTO, an electronic data collection program. This program offers encryption for all data. The data will be transmitted to the UNC research team via a secure cloud-based server. The data will then be downloaded by the UNC PI and the unannounced visitor portion that contains provider names will be immediately de-identified. The names of facilities will also be immediately de-identified. The identifiers will be stored separately, as described above, and accessible only to the UNC study PI. The thoroughly de-identified data will be accessed by members of the UNC team via UNC's OneDrive. Once transcribed and translated, all data from the focus group discussions and in-depth interviews will be transmitted to the UNC research team via a secure cloud-based server. This data will be entirely anonymous and will be accessed by members of the UNC team via UNC's OneDrive.

Data sources: Quantitative data for this project will be collected using electronic questionnaires implemented by highly experienced and carefully trained local enumerators. Qualitative data will be sourced from focus group discussions and in-depth interviews, guided by semi-structured questionnaires with responses captured by audio recording.

Data security: All quantitative data will be collected on encrypted, password protected electronic devices and uploaded to a secure cloud-based server where it can be accessed daily by Drs. Tumlinson and Onyango. All qualitative data will be audio recorded and the recordings will be stored in a locked cabinet in a locked office at the official Kisumu offices of Innovations for Poverty Action. Once transcribed and translated, all data from the focus group discussions and in-depth interviews will be transmitted to the UNC research team via a secure cloud-based server. Original audio recordings will be destroyed after a period of three years. Across all types of data, electronic communication with outside collaborators will involve only unidentifiable information.

Quality assurance: For the individual and facility-level baseline and endline questionnaires, mystery client observations, and unannounced visits, local senior field officers will regularly conduct random spot checks in the field to ensure enumerators are visiting the correct locations at the scheduled times. Further, two senior research associates will execute daily data quality assurance checks and provide weekly reports on progress to Drs. Tumlinson and Onyango. Drs. Tumlinson or Onyango or senior study staff will review all data collection forms on an ongoing basis for data completeness and accuracy as well as protocol compliance.

10 RECRUITMENT STRATEGY

For the individual-level survey in aims 1 and 2, households are selected at random, and women of reproductive age will be invited to participate. For the facility-level survey in aims 1 and 2, providers at all public facilities will be invited to participate (up to 10 at each facility). For all qualitative data collection, we will use snowball sampling to recruit study participants.

After households are randomly selected, a female resident of reproductive age will be selected at random (if there is more than one in a household) and a female enumerator will read a consent script outlining the purpose of the study, potential risks to respondents, the time commitment involved in the study, and the potential benefits to respondents of participating in the study. For research involving children: The age of majority in Kenya is 18 and we will invite women between the ages 18 to 49. There is only minimal risk to participants in this age group, who may feel uncomfortable answering questions about contraceptive use. However, we will take steps to minimize discomfort, including conducting the interview in private and with a female interviewer. The benefit of including this age group is high as this age group is particularly vulnerable to unplanned pregnancy as well as the potentially negative outcomes of an unplanned pregnancy including loss of educational attainment, employment, and social stigma in the case of unmarried adolescents. Therefore, it is extremely important to include this group and we will follow all local ethical regulations, customs, and research norms regarding assent/consent of this age group for studies on contraceptive use.

11 CONSENT PROCESS

All providers will be asked to participate through an informed consent process. A trained data collector will explain the purpose and confidentiality of the study to selected service providers; those that provide consent will be asked about their demographic characteristics, quality of care delivered, and self-efficacy and professional fulfillment. The information is not sensitive, and the provider's participation is brief, voluntary, and anonymous. There is minimal risk to providers who participate. For visits from mystery clients and unannounced visitors (both will be highly experienced and well-trained data collectors), informed consent will be obtained from facility supervisors. The research assistant will explain the purpose and confidentiality of the study to the facility-in-charge or facility supervisor (but will not tell the manager when the visits will occur in order not to disrupt the study design). Those facilities with a supervisor who provides documentation of consent will be eligible to participate and will receive mystery client and unannounced visits during baseline and endline data collection. The participation of facilities is brief, voluntary, and anonymous. There is minimal risk to facilities who participate in mystery or unannounced visits. Data Page 118 Protection of Human Subjects Contact PD/PI: Tumlinson, Kat collectors serving as mystery clients will undergo extensive training to ensure they are fully able to avoid any unwanted exams or procedures that may be suggested by the service provider. As no identifying information is collected, participants will be asked to provide verbal consent. All those selected for participation will have the opportunity to opt out of the study if they do not wish to participate. All recruitment and informed consent protocols will be reviewed and approved by the UNC-CH IRB.

12 PLANS FOR PUBLICATION

Findings from this study will be disseminated through publications in peer reviewed health policy and public/reproductive/sexual health journals, written in conjunction with Innovation for Poverty Action and all co-investigators and collaborators.

Publications based on data from study will comply with applicable NIH data sharing and dissemination policies for NIH-funded trials. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers by contacting the Principal Investigator.