Reducing barriers and sustaining utilization of a cervical cancer screening program in rural Senegal

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List of Abbreviations

ANOVA	Analysis of Variance
BL	Baseline
CG	Care Group
CITI	Collaborative Institutional Training Initiative
CHW	Community health workers
Co-I	Co-Investigator
Co-PI	Co-Principal Investigator
COPE	Client-Oriented, Provider-Efficient Quality Improvement Program
DCI	Data Collection Instrument
FG	Focus group
FIC	Fogarty International Center
IC	Informed Consent
IRB	Institutional Review Board
ISED	Institut de Santé et Développement (Institute of Health and Development)
LMIC	Low- and Middle-Income Country
MD	Medical Doctor
MG	Moderator Guide
MPH	Master of Public Health
MSAS	Sénégal Ministère de la Santé et l'Action Sociale
NIH	National Institutes of Health
OPRR	Federal Office for Protection from Research Risks
OPRS	Office for the Protection of Research Subjects
PCV	Peace Corps Volunteer
PhD	Doctor of Philosophy
PI	Principal investigator
RA	Research assistant
RIS	Research Information Sheet
RS	Recruitment Script
SAE	Serious Adverse Event
SD	Standard Deviation
SSL EV	Secure Sockets Layer Extended Validation
UCAD	Université Cheikh Anta Diop, Dakar, Senegal
UIC	University of Illinois at Chicago
US / USA	United States of America
VIA	Visual inspection of the cervix with acetic acid
WHO	World Health Organization

1.0 Research Summary/Abstract

GOAL: The goal of this study is to strengthen the **implementation** of a cervical cancer screening service in a decentralized, low-resource area of Senegal naïve to any cancer screening programs by investigating the barriers and facilitators of **initial uptake** and developing and adapting a peer education health promotion intervention to diverse and dynamic contexts to achieve **sustained utilization**.

RATIONALE: Equitable Access to many women's health services is lacking in low and middle income countries (LMIC), especially cancer prevention programs. Two of the top five World Health Organization priorities in cancer control and prevention research are to 1) reduce access barriers to the diagnosis of curable cancers and 2) apply cancer prevention strategies in the context of local culture and resources. Senegal ranks 15th in the world in cervical cancer incidence. However, the estimated participation rate for cervical cancer screening in Senegal (where incidence peaks between the ages of 45 and 54) is very low; 1.9% for women ages 40 to 49 and 0% for women over the age of 50. Since 2010 a partnership between the rural Kedougou Regional health system, the Cheikh Anta Diop University, the University of Illinois at Chicago, and the U.S. Peace Corps that has implemented a cervical cancer screening program. We have implemented a technical approach that has been proven affordable and effective in low-resource settings: visual inspection of the cervix with acetic acid (VIA). We made the screening service available to over 18,300 women region-wide by 2014. However, the utilization by eligible women, especially the high-risk older cohort, was very low. In 2014, only 509, roughly 5% of eligible women targeted through a mass campaign that year, were screened and only 10% were 45 years or older. I am currently conducting research investigating the supply-side (health service level) determinants of cervical cancer screening access in the Kedougou region to determine the extent to which screening availability is responsible for the low screening rates.

This research project will investigate the determinants of cervical cancer screening uptake and sustained utilization in this region and develop and evaluate a context-specific peer education behavioral intervention to improve uptake. Research supports the effectiveness of peer education in increasing cancer screening rates but, currently, no cervical cancer screening peer education program specific to rural Senegal exists. To inform the participatory development of this program, we will assess barriers and facilitators of screening at multiple levels: individuals (women aged 30 to 59), households (family or principle social unit of at-risk women), and the community (immediate village or neighborhood with common amenities of at-risk women). **We hypothesize that a peer education program that adapts to changing contexts over time and is targeted at a multi-level audience will result in early, widespread uptake and sustained use of the VIA cervical cancer screening program.** Study findings will inform programmatic planning in Kedougou and the peer education curriculum we develop can serve as a template for maximizing early impact of new cervical cancer screening services implemented in other areas of rural Senegal. Our long-term goal is to inform national-level policy to guide the implementation of cervical cancer screening programs in other rural Senegal regions.

BACKGROUND

Globally, there are over a half a million new cases of cervical cancer yearly, with nearly 90% of these cases in less developed nations.[31] The cervical cancer incidence rate in Senegal (41.1)[33] is over five times greater than that of the U.S. and Senegal ranks 15th in the world in the age-standardized incidence rate of cervical cancer.[34] When detected at an early stage, invasive cervical cancer is one of the most successfully treated cancers. The five year cervical cancer survival rate ranges from 60% to 70% in most countries.[35] Furthermore, technological innovation and efficacy testing of health service interventions including screening programs[36,37] has led to clear recommendations for improving cancer control.[38-40] However, the implementation of evidence-based cervical cancer screening programs is slow. Because of this, the estimated participation rate for cervical cancer screening in Senegal is low (6.9% of all women ages 18 to 69), especially in rural areas and in older age groups (1.9% of women ages 40 to 49 and 0% of women 50 or above).[42,43] Cervical cancer is an indicator of larger health system problems including poor access and the lack of culturally competent communication; factors that disproportionately affect poor women.[44] **This is illustrated by the large majority of rural Senegalese women currently having no access to cervical cancer screening.**

Preliminary Work in Kedougou: The University of Illinois at Chicago (UIC) has partnered with Kedougou, Senegal Regional Direction of the Ministry of Health and Social Affairs (MSAS) and Peace Corps Senegal since 2010[11] to improve access to cervical cancer screening. Between 2010 and 2013, this partnership worked to provide cervical cancer screening access to an estimated 18,305 women across the far southeastern rural Kedougou region. We implemented regional-level cervical cancer clinical guidelines, introduced the EngenderHealth-developed Client Oriented Provider Efficient (COPE®) cervical cancer quality improvement process,[45-47] and trained 63 health workers in the evidence-based screening technique of visual inspection of the cervix with acetic acid (VIA). VIA is performed by applying a vinegar solution to the cervix followed by a “naked-eye” visual inspection to identify precancerous lesions which are then treated through freezing. The VIA screening test has a sensitivity of 80% (79-82%) and a specificity of 92% (range, 91-92%)[48] and has been proven to be safe and cost-effective.[49-51]

2.0 Scientific Rationale

The goal of this study is to inform the sustainable implementation of cervical cancer screening services in low-resource areas of Senegal naïve to cancer screening programs by

1) investigating the access barriers and determinants of initial uptake and

2) developing and adapting a peer education health promotion intervention to diverse and dynamic contexts to achieve sustained utilization.

The study goal will be achieved through a partnership between the local communities and health system in Kedougou, Senegal; Peace Corps Senegal; the Cancer Institute and the Institute of Health and Development (ISED) at Cheikh Anta Diop University in Dakar, Senegal; and the University of Illinois at Chicago (UIC).

Framework: Implementation Science is the study of how proven technical solutions are applicable to real world settings. We will study how the implementation of VIA, as a proven intervention, can be optimized and how the screening service can best "fit" into the local context.[58] Established complementary frameworks will guide our study. We will apply

1) the Patient-Centered Access Framework to **assess the demand-side barriers and facilitators of uptake** in aim 1,

2) the Integrated Theory of Health Behavior Change to evaluate how a peer education program facilitates self-management behavior of women in aim 2, and

3) the Dynamic Sustainability Framework to **evaluate the initial uptake and sustained utilization** of the health service in aim 3.

We seek to understand the dynamic nature of the influential factors within the local context and the process by which we can facilitate responsive adaptations to the intervention in order to reduce barriers, maximize early uptake, and sustain utilization.

Overview of Study Data Collection: To achieve all aims, we will conduct a cluster-randomized stepped wedge study across three representative clusters (each containing a district center and two rural sites) in the Kedougou region. For each aim we will collect data at baseline and at 6-month intervals in each cluster (data collection intervals coincide with the initiation of the intervention in a new cluster). In aim 1, we will develop (through a participatory approach), pilot, and conduct surveys and interviews of eligible clients as well as focus groups (FG) (women ages 30-44 and 45-59) and interviews of men (ages 30-59). For aim 2, we will describe the development, piloting, implementation, and adaptation of an aim 1-informed context-specific multi-level peer education curriculum across clusters through the stepped wedge approach[59,60] in the Kedougou region. We will collect quantitative program reach data and qualitative process evaluation data at each time period. These data will be used to adapt the intervention over time. To achieve aim 3, we will collect aggregated health service level utilization data and individual surveys.

3.0 Research Goals and Aims

BROAD GOALS OF THE RESEARCH

The goal of this study is to strengthen the **implementation** of a cervical cancer screening service in a decentralized, low-resource area of Senegal naïve to any cancer screening programs by investigating the barriers and facilitators of **initial uptake** and developing and adapting a peer education health promotion intervention to diverse and dynamic contexts to achieve **sustained utilization**.

Through the SPECIFIC AIMS, we will

Aim 1: Assess cervical cancer screening access determinants in Kedougou, Senegal by identifying barriers and facilitators of service uptake over time at the person, household, and community levels;

Aim 2: Develop and deploy a wide-reaching, multi-level responsive peer education curriculum aimed at motivating eligible women to seek cervical cancer screenings in Kedougou, Senegal;

> **Hypothesis:** A cervical cancer peer education curriculum developed, implemented, and adapted through a Care Group model will reach 75% of the target audience, improve cervical cancer knowledge, and establish the rate of women and men recommending this screening service to others to 30% over the course of 24 months in the region of Kedougou, Senegal; and

Aim 3: Evaluate the impact of the peer education intervention on initial screening uptake and re-screening rates.

> **Hypothesis:** A context-specific peer education cervical cancer screening curriculum will increase the cervical cancer screening initial uptake rate (first 6 months) in target age women to 35% and will ensure 2 year re-screening rates of 30% in the Kedougou, Senegal study sites.

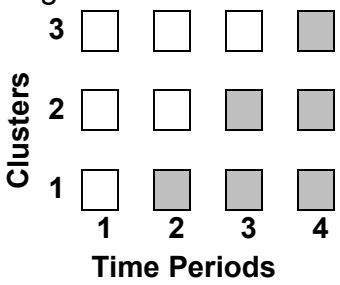
STUDY DESIGN AND PROCEDURES

TABLE 1: Primary Research Questions

AIM	Research Questions
AIM 1	What individual, household, and community factors influence a woman's decision to seek or not to seek cervical cancer screening in Kedougou, Senegal? How do these identified determinants change with time? How does age and gender specifically influence screening program opinions and motivations for screening?
AIM 2	What is the structure, process, and content of a peer education program that empowers eligible women to initially seek cervical cancer screening services in Kedougou, Senegal? What programmatic factors predict the reach and positive reception by a relevant audience of such a health promotion intervention?
AIM 3	How does a peer education program impact the cervical cancer screening service initial uptake by eligible women seeking a first-time screening and ensure sustained utilization and continuing impact of the cervical cancer screening service?

Study Design: Figure 2 is a schematic example for this trial design. In this example, Cluster 1 (randomly selected) crosses to the intervention arm at Period 2, Cluster 2 (randomly selected) crosses over to the intervention arm at Period 3, and so on. By the end of the study, all clusters will cross over to the intervention arm (one-way), though in random order. At the end of the final time period, the outcome of interest is compared between the intervention and control periods within each cluster. Differences in service utilization and recommendation will be compared, whereby clusters serve as their own controls as they cross over from the control to intervention group.

Figure 2: Stepped Wedge Trial Design



Shaded cell represent intervention periods

Peer Education: In Senegal, matrones are women who are selected by the community to provide outreach for women's health issues. These women are formally trained through the health system, are literate in French and the local languages, work closely with the Community Health Workers (CHW), and live permanently in the communities where they work. Our partnership has a strong existing relationship with matrones, with whom we will work through "Care Groups," (CG) a model of peer education developed by World Relief in 1995 and used extensively globally.[62-64] CGs are established in many Kedougou communities though none in our study area are conducting cervical cancer screening education. In our study, a CG will comprise 10-15 volunteer, community-based health educators at 3 health structures within each cluster who regularly meet together with a lead matrone for training and supervision. Each CG volunteer is responsible for regularly visiting 10-15 of her neighbors each month, sharing what she has learned and facilitating behavior change at the household- and individual-levels. Matrone led CGs will also develop and implement community-level interventions such as town hall discussions, radio announcements, and theatrical performances. The CGs will have only female membership but will work closely with the Health Committees (who are principally men) to facilitate the peer education of men in the community by working through the Elder's council (advisors to the village chief) and the youth group. One PCV per district will work with a district-level CG coordinator and a CG manager at the regional level will oversee the program. A representative group of CG administrators, leaders (matrones), and volunteers will meet biannually for a CG Meeting in the Kedougou regional capital. This group, through a participatory approach[65], will develop, deploy, and adapt a multi-modal peer education curriculum directed at a

multi-level audience and aimed at motivating women to seek cervical cancer screening services.[66] This group alongside PCVs will also develop and pilot all instruments and conduct the multi-level data collection.[67]

Research Procedures by AIM

AIM 1: Assess cervical cancer screening access determinants by qualitatively identifying barriers and facilitators of service uptake over time at the person, household, and community levels. (Table 2)

TABLE 2: Aim 1 - Demand-Side Access Data Collection

Methodology				Measures	Variables
Quant	a	Individual Baseline Survey BL / End DCI: 1601, 1602	Systematic sampled individuals (Women: 75 / cluster) (Men: 30 / cluster) ***Sample size:*** *n = 315*	**Demographics:**	# of people / roles in household, genders, # of eligible women, # of women seeking screening, health seeking decision making process / power, cost concern, facility proximity, health practices and opinions, knowledge and opinions of partners of eligible clients.
	b	Individual Interval Interview DCI: 1603, 1604	Systematic sampled individuals (Women: 45 / cluster) (Men: 30 / cluster *of sample a*	**Socio-demographics:** **Behavioral risk factors:** **Clinical risk factors:** **Health literacy / seeking:**	Age, gender, marital type/status, education level Sexual debut, lifetime sexual partners, gravity, parity, age at first birth, number of children, smoking status, diet History of STI, weight, long-term oral contraceptive use Cervical cancer screening history & knowledge, preventative care opinions, health service utilization
Qual	C	Women's Focus Groups DCI: 1605	Purposive-sampled groups (women, 30-44 or 45-59) *of sample a*	**Demand-side access** **Ability to perceive:** **Ability to seek:** **Ability to reach:** **Ability to pay:** **Ability to engage:**	ref Instruments [42] Health literacy, Health beliefs, Trust and expectations Personal and social values, culture, gender, autonomy Living environments, Transport, Mobility, Social support Income, Assets, Social capital, Health insurance Empowerment, Information, Adherence, Caregiver support

To achieve Aim 1, we will orient 3 CGs in each cluster. Through a participatory process involving CG leaders, health service leaders, midwives, and community members (women and men) we will develop, field test, and refine quantitative individual-level surveys that gather access barriers data corresponding to the variables listed in Table 2. We will conduct quantitative **a) Individual Baseline Surveys** with the same enrolled women (up to 25) and the same 10 men in each site per cluster. These data will be collected at baseline and at the end of the study period (after 3 years). We will also conduct **b) Individual Interval Interviews** with the same women (up to 25) and the same 10 men in each site per cluster. These data will be collected at baseline and every six months through the end of the study period (after 3 years). Therefore, these data will be collected six (6) times. These pre-tested, approved standard individual-level questionnaires (close ended) will be administered (face-to-face) by an RA of the same gender as the participant in the participants' preferred language (Malinke, Pulaar, or French). We will also conduct **c) Women's Focus Groups**. Through these FGs we will collect qualitative data, from women stratified by age, describing demand-side access barriers and facilitators (Table 2). The Research Assistant will moderate the 45 minute FGs in the preferred language (Malinke, Pulaar, or French) and two PCVs will observe and record written observations in real time. We will audio record the sessions (to be transcribed into both French and English). The Research Assistant and PCVs will review the audio record and confirm all notes. Below are described the recruitment and enrollment procedures for these data collection events.

Recruitment and Enrollment of Participants Followed within Households

We will utilize a random cluster sampling method to select ten (10) households in each of the three (3) sites per cluster. We will convenience sample one woman and one man in each of the households among those

who express a willingness to participate. We will ensure that the ten (10) chosen households fall within the households where the educational Care Group intervention takes place. Given that each Care Group will cover between 80 and 100 households, we are expecting to enroll participants from 10% of the households where the Care Group intervention occurs.

Detailed household sampling: The range of eligible **households** will be defined by the immediate community surrounding the health facility in each of the three sites per cluster. Using a map of the community, we will divide the community geographically into five clusters. We will designate one household on the map as the starting location. We will randomly select a number between one and the number of households in that section of the community. The Research Assistant (RA) will begin counting at the starting location and will approach the household corresponding to the random number. Eligible households must have at least one screening eligible woman (age 30 to 59) and one man (age 30 to 59). The RA will ensure that the household is eligible. The RA will follow the designated procedures for recruiting men and women into the study. This includes reading the RESEARCH INFORMATION SHEET and reading the RECRUITMENT SCRIPT. The RA will begin by asking if there is one woman AND one man in the house who would like to participate. From among those that express willingness to participate, the RA will convenience sample participants by alternate recruiting of a younger woman (Age 30 to 44) and an older woman (age 45 to 59) from households. By doing this, half of the homes (5) will have younger women participants and half (5) will have older women participants. Not all women and men participants from a home need to be married to each other, but it is preferable if at least half of the participating households have married partners as participants. The RA will recruit men between the ages of 30 and 59, with no differentiation between the number of younger and older men participating. If BOTH a man AND a woman in the same household agree to participate, the RA will continue with enrollment by reading the INFORMED CONSENT and obtain a signature with the SHORT FORM. IF the RA is NOT ABLE to recruit BOTH a man and a woman in the same household, this household and any individuals in it will be unable to participate in the study. The RA will thank them for their time and continue to the NEXT HOME designated through a randomly selected number to recruit participants until two households with one woman and one man each are included in the study. The RA will read the INFORMED CONSENT to each of the chosen participants separately and privately. The RA will obtain participant written consent with the SHORT FORM and will then enroll each participant by entering their contact information in the PARTICIPANT REGISTER**.** The RA will inform them separately of the data collection schedule.

Recruitment and Enrollment of Participants Followed within Care Groups

We will utilize a random sampling method to select five (5) Care Group Volunteers in the Care Group of each the three (3) sites per cluster. We will seek to enroll, longitudinally follow, and collect data on three (3) younger woman (age 30 to 44) and two (2) older women (age 45 to 59) in each care group over the course of the study. Given that each Care Group has between 8 to 15 volunteers, we are expecting to enroll 1/3 to 1/2 of all Care Group Volunteers across all sites.

Detailed Care Group Volunteer sampling: While visiting a care group meeting, the RA will read the RESEARCH INFORMATION SHEET. The RA will then read the RECRUITMENT SCRIPT and ask the women if they are interested to participate. The RA will record the names of each younger woman (age 30 to 44) who is interested in participating on separate pieces of paper. The RA will fold each piece of paper separately and place into a container. The RA will blindly draw three names. The RA will then record the names of each older woman (age 45 to 59) who is interested in participating on separate pieces of paper. The RA will fold each piece of paper separately and place them into a container. The RA will blindly draw two names. The RA will

read the INFORMED CONSENT and SHORT FORM to each of the chosen participants separately and privately. The RA will obtain participant written consent with the SHORT FORM and will then enroll each participant by entering their contact information in the PARTICIPANT REGISTER. The RA will inform them separately of the data collection schedule.

Recruitment and Enrollment of Participants for Women's Focus Groups
We will conduct two focus groups every six (6) months. Five (5) care group members will be convenience selected from each care group AND two to three (2-3) household women participants will be convenience sampled to participate in a younger women's (age 30 to 49) and an older women's (age 45 to 59) focus group every six (6) months over the course of the study.

Detailed Women's Focus Group Sampling: Recruiting from Household Participants: The RA will contact enrolled household women participants every six months to convenience sample women for both a Younger and an Older Women's Focus Group. **Younger women's focus group:** The RA will read the FOCUS GROUP RECRUITMENT SCRIPT and ask for interest to participate. The RA will invite the first two to three younger women (age 30 to 44) among those already enrolled in the study who express interest to participate in a focus group. The RA will provide instructions on where and when to go for the focus group. **Older women's focus group:** The RA will read the FOCUS GROUP RECRUITMENT SCRIPT and ask for interest to participate. The RA will invite the first two to three younger women (age 30 to 44) who express interest to participate in a focus group. The RA will provide instructions on where and when to go for the focus group. **Recruiting from Care Group Participants:** The RA will contact Care Group women participants. **Younger women's focus group:** The RA will read the FOCUS GROUP RECRUITMENT SCRIPT and ask for interest to participate. The RA will invite the first two to three younger women (age 30 to 44) among enrolled Care Group participants who express interest to participate in a focus group. The RA will provide instructions on where and when to go for the focus group. **Older women's focus group:** The RA will read the FOCUS GROUP RECRUITMENT SCRIPT and ask for interest to participate. The RA will invite the first two to three younger women (age 30 to 44) who express interest to participate in a focus group. The RA will provide instructions on where and when to go for the focus group. The RA will read the INFORMED CONSENT and SHORT FORM to each of the chosen participants separately and privately. The RA will obtain participant written consent with the SHORT FORM and will then inform them separately of the data collection schedule.

Aim 2: Develop and deploy a peer education curriculum to motivate eligible women to seek screenings. (See Table 3)

TABLE 3: Aim 2 - Peer Education Data Collection

Methodology				Measures	Variables
Quant	e	Document Review DCI: 1611	No human participants. Review of peer education program implementation records.	**Program Reach**	**A. # of individuals, households, communities directly receiving intervention** B. # of peer educators C. # of peer education sessions per educator
	b	Individual	Convenience and purposive-	**Program**	**A. Number/% of women and men recommending**

		Interval Interview DCI: 1603, 1604	sampled individuals followed over time. *of sample a*	**Recommendation & Knowledge**	**the service (age-stratified study participants)** **B. Knowledge of cervical cancer**
Qual	f	Focus Groups DCI: 1606	Purposively-sampled Peer Educators and Individuals *of sample a*	**Process & Program Satisfaction**	A. **Recipient and peer educator evaluation including Implementation, Mechanisms of Impact, Contextual Factors.** **B.** Recommendations for adapting or improving the Peer Education Program

Through aim 2 we will develop a curriculum intended for a multi-level audience to motivate women to seek cervical cancer screening services. The curriculum (informed by aim 1) will be adapted from the WHO "Comprehensive Guide to Cervical Cancer Control: A guide to essential practice. 2nd edition[68]" materials by key individuals (including health leaders, midwives, matrones, CHWs, screening eligible women, men, religious leaders, traditional healer, and PCVs). The curriculum will be comprised of educational materials in French and local language (Malinke and Pulaar). CGs will deliver the curriculum content. We will orient the CG leaders on the curriculum and provide comprehensive guidance on the research protocol throughout the study period. Each CG will transmit general health education from the initiation of the study. Only CGs within clusters that have crossed over into the intervention arm will be provided with the cervical cancer screening curriculum. We will collect quantitative program reach and recommendation data and qualitative process and program satisfaction data at each time period. The Individual Interval Interview data contributing to this aim will be collected through the same data collection event described for AIM 1. All data contributing to this AIM will be used to adapt the intervention over time. We will collect quantitative data through **document review** of CG records (number of individuals, households, and communities directly receiving the intervention) or through individual survey or interview (Table 3). We will also conduct one **FG** per site (3 per cluster) per data collection period (at baseline and every six months) through the end of the study (3 years) for aim 2 to gather qualitative data that describe the peer educator (volunteers from each CG) opinion of the peer education program (Table 3). The RA will moderate the 45 minute focus groups in the preferred language (French, Malinke or Pulaar) and two PCVs will observe and record written observations in real time. We will audio record the sessions (and transcribe into French and English). The moderating CG district coordinator and PCVs will review the audio record and confirm all notes.

Recruitment and Enrollment of Participants for Care Group Focus Groups
We will conduct one focus group every six (6) months in each site. All present Care Group members will be invited to participate.

Detailed Care Group Focus Group Sampling: At the beginning of a Care Group Meeting, the RA will explain that she will be conducting a short focus group. The RA will read the FOCUS GROUP RECRUITMENT SCRIPT and ask for interest to participate. The RA will invite all present members of the Care Group who express interest to participate in a focus group. The RA will read the INFORMED CONSENT and SHORT FORM to each of the chosen participants separately. The RA will obtain participant written consent with the SHORT FORM, separately and privately, and will invite them into the private focus group area and introduce them to the observers.

Aim 3: Evaluate the impact of the intervention on initial screening uptake and re-screening rates. (See Table 4)

TABLE 4: Aim 3 - Initial & Sustained Change Data Collection

Methodology				Measures	Variables
Quant	g	Document Review DCI: 1612	No human participants. Review of aggregated health service records.	**Initial Uptake/ Sustained utilization**	**A. Number/% of women screened for the first time, age stratified** 1 B. **Number/% of women being re-screened, age stratified** C. **Number/% of positive screened women referred/treated** (aggregated data only)
	a	Individual Interval Interview DCI: 1603, 1604	Systematic sampled individuals followed over time. ***Sample size:*** *n = 0 new of sample a*		

To achieve aim 3, we will follow cluster-wide trends through aggregated health service data[69] and participant-level impact through individual interviews. **Health service data** (# of initial and re-screenings stratified by age and number of referred women who completed treatment) will be reported by each cluster to the district center through the standard reporting structure. These de-identified data are reported to the regional level where they will be collected. Through the individual interviews described in aim 1 above (Table 2), we will collect impact data within our participant population in the form of first-time and re-screenings.

4.0 Recruitment, Eligibility and Enrollment

Recruitment
The PI (Dykens) and Senegalese Co-I's (Ndiaye and Dioukhane) will train all research assistants, matrones and community health committee leaders at a designated intervention cluster in the Kedougou Region, Senegal. Through our prior work, we have worked directly with each of these individuals. The research assistants, with oversight by the Peace Corps Volunteer research assistants and the Co-I's and PI, will recruit individuals, households, and focus group participants (as described above in section one). The lead Peace Corps Volunteer who is in charge of recruitment, informed consent, participant tracking, and data collection is a UIC MPH trainee (in Senegal as a Peace Corps Volunteer). She is listed as a key personnel on the protocol. These individuals will explain the purpose and activities of the study, and select those who: 1) are confirmed to meet the criteria; and 2) are able to give informed consent. See Inclusion Criteria above.

After the participants give consent, they will participate in the surveys, interviews or focus groups during each data collection period. Drs. Dykens and Dioukhane and a Peace Corps Volunteer (MPH level) will oversee preparation of the RA's for the moderation of interviews and focus groups. See detailed description of sources of material.

Human Subjects Involvement and Characteristics.
Throughout this discussion of Human Subjects, "subjects" are referred to as "participants." Inclusion criteria and procedures for each aim of the study are described below.

Determination of Subject Eligibility
The Principal Investigator, Co-Investigators, and onsite Research Personnel will oversee subject eligibility. Eligibility will be determined at the time of recruitment and consent. The Senegalese Co-Investigators (Ndiaye, Dioukhané), in collaboration with the U.S. Principal Investigator (Dykens) and Project Coordinator, will oversee recruitment. No compensation will be awarded for direct involvement in focus groups or for completion of surveys. However, refreshments may be provided at the time of the focus group. An eligibility checklist in the form of a recruitment script is attached.

Inclusion Criteria

The inclusion criteria are as follows:

Women. Criteria for inclusion include: 1) female Senegal citizen between the ages of 30 and 59, 2) Resident in Kedougou Region, 3) eligible to seek cervical cancer prevention services at a designated health structure in the Kedougou Region, Senegal, 4) willing to participate in survey or interview assessments; and 5) able to give informed consent.

Men. Criteria for inclusion include: 1) male Senegal citizen between the ages of 30 and 59, 2) Resident in Kedougou Region, 3) living in a household with at least one woman eligible to seek cervical cancer prevention services at a designated health structure in the Kedougou Region, Senegal, 4) willing to participate in survey or interview assessments; and 5) able to give informed consent.

Care Group Volunteer. Criteria for inclusion include: 1) Senegal citizen participating as a Care Group volunteer, 2) Resident in the Kedougou Region, Senegal, 3) willing to participate in survey or interview assessments, and 4) able to give informed consent.

Exclusion Criteria
Participants will be excluded if they are

- No additional exclusion criteria exist.

Excluded or Vulnerable Populations
Special considerations of the involvement of women and minorities and the justification of the exclusion of minors are detailed below.

The total planned enrollment / Inclusion of Women and Minorities

1. Planned distribution of participants by sex/gender, race, and ethnicity - The total planned enrollment is:
    a. Aim 1: 15 women from Care Groups for each site (3) per cluster (3) = 135. Ten women from households for each site (3) per cluster (3) = 90. Ten men from households per site (3) per cluster (3) = 90. This equals a total of 315 individuals (225 women and 90 men). There are no new participants in the focus groups.

    b. Aim 2: Individual interview (no new participants) + Focus Groups (no new participants) + Document Review (no human participants) = 0 new participants

    c. Aim 3: Individual interview (no new participants) + Document Review (no human participants) = 0

    Total participants = 315

    Of these we estimate that there will be 225 women and 90 men. Based on general population numbers for the Kedougou Region in the country of Senegal, we anticipate that 100% of participants will be from African descent. All participants (women and men) will be African and have been included in the "Black" category.

2. Subject selection criteria and rationale for selection –
    a. No exclusions will be made on the basis of gender for the baseline surveys or longitudinal individual interval interviews described in Aims 1, 2, and 3.
    b. Men will be excluded from the focus groups (these will be women only) described in Aims 1 and 2.
    c. No exclusions will be made on the basis of race for all Aims.

3. Rationale for proposed sample –
    a. The focus groups proposed in Aim 1 and 2 are intended to gather the perspectives of women. Therefore, men will be excluded from participation in this activity.

4. Outreach programs for recruiting
    a. Males are excluded from the Aim 1&2 focus groups in this study because:
        i. the research question addressed is relevant to only women;
    b. No racial and/or ethnic groups or subgroups are excluded from the study

Inclusion of Children.

This study will not involve the recruitment of participants under the age of 30 years. Therefore, no children will be recruited for data collection or involved in the study. The study will focus on the opinions and behaviors of women within the target age range (30 to 59 years old) for cervical cancer screening as stated in the Kedougou, Senegal Cervical Cancer Screening Health Service Regional Guidelines. We will also collect data on men in the corresponding age range (30 to 59 yo).

Sex as a biological variable.

Sex as a biological variable does not apply to this research as the proposed study is not pre-clinical or biomedical research that affects both sexes. Given that cervical cancer affects only women, our principal data collection and investigation will be directed at women within the guideline age range for screening. We will be collecting data from women outside this age range and from men but only to provide perspectives on how affected and targeted women make decisions and to provide insights into how gender and stigma impact decision making in target-age women.[22,23]

Addressing Gender and Stigma.

Gender roles and stigma are of significant consideration in our proposed research. By investigating the social context of the uptake of this newly implemented cervical cancer screening service we intend to describe as a primary question in aim 1, “How does age and gender specifically influence screening program opinions and motivations for screening?” In addition, in aim 2, we will be collecting data from both men and women describing the number and percent of women and men recommending the service to others. In addition to analyzing the process of a) the role of the social spread of information and b) the value of establishing societal norms (especially among peer groups that don’t readily access health services) we intend to provide a deeper understanding on how gender roles in households impact service uptake. We will also describe how social acceptance of a new health service such as cervical cancer screening that has potential stigma considerations (reflecting religious, cultural, or community norms and notions) impact service uptake and sustained utilization.

5.0 Sources of Material, Protection Against Risks and Informed Consent

Sources of Material.
Sources of research material will include: 1) **Individual Baseline surveys** of adults (21 and above) in households with screening eligible women, 2) **Individual Interval Semi-structured Interviews:** semi-structured interviews with target age women eligible for screening and receiving cervical cancer prevention services or men living in a household with target age eligible women, 3) **Focus Groups** with women or Care Group Volunteers, and 4) **Document Review:** de-identified, aggregated health service or care group data,

Individual Baseline surveys
The baseline survey will gather information through adults (age 30 to 59) willing and able to provide the requested information. Once surveyed, individuals from the same households will be followed over time and re-surveyed at each data collection period. The pre-tested standard individual baseline surveys (close ended) will be administered (face-to-face) in the participants' preferred language (Malinke, Pulaar, or French). These will be administered by a Senegalese Research Assistant with assistance by PCV research assistants. This data collection will occur at baseline and at the end of the data collection period. Peace Corps Volunteers will assist the PI and Co-I's in ensuring the fidelity of this data collection.

Individual Interval Semi-structured Interviews
All screening-eligible women and all men aged 30 to 59 in all selected households will be interviewed. The pre-tested standard individual-level questionnaires (semi-structured) will be administered (face-to-face) in the participants' preferred language (Malinke, Pulaar, or French). These will be administered by a Senegalese Research Assistant with assistance by PCV research assistants. Aim 1 (access determinants, cervical cancer risk), Aim 2 (screening recommendation), and Aim 3 (screening uptake / utilization) data will be collected through this interview. All sites will be monitored for consistent and accurate collection of this data. The data collection instrument will be employed at baseline and every 6 months during the data collection period. Peace Corps Volunteers will assist the PI and Co-I's in ensuring the fidelity of this data collection.

Focus Groups

Aim 1 Focus Groups:
There will be two **FGs** (women ages 30 to 44 and ages 45 to 59) per cluster every 6 months throughout the study period. Through FGs we will collect qualitative data, from women stratified by age, which describe demand-side access barriers and facilitators (Table 2). The Senegalese research assistant will moderate the 45 minute FGs in the preferred language (Malinke, Pulaar, or French) and two PCVs will observe and record written observations in real time. We will audio record the sessions (to be transcribed into both French and English). The Research Assistant and PCVs will review the audio record and confirm all notes. The women enrolled as individuals will make of the focus groups. There will be no new women enrolled for this data collection activity.

Aim 2 Focus Groups:

We will conduct two **FGs** per cluster per data collection period for aim 2. Through the FGs we will gather qualitative data that describe the peer educator (matrone and the volunteers from each CG) opinion of the peer education program (Table 3). The CG district coordinators will moderate the 45 minute focus groups in the preferred language (French, Malinke or Pulaar) and two PCVs will observe and record written observations in real time. We will audio record the sessions (and transcribe into French and English). The moderating CG district coordinator and PCVs will review the audio record and confirm all notes.

Participants will include 15 CG volunteers that comprise the FGs in each cluster (no new participants). The women participants are not newly enrolled and are the same as described in the FG activity in Aim 1.

This data collection will occur at baseline and every 6 months during the data collection period. Peace Corps Volunteers will assist the PI and Co-I's in ensuring the fidelity of this data collection.

Document Review – Uptake Data

At initiation of the study, all partners will identify and agree on specific population- and service-level quantitative outcomes indicators (Tables 2, 3, and 4) to guide the creation of a health service level data collection instrument to address Aim 3. These indicators will fall within current expected data collection at all sites. All sites will be monitored for consistent and accurate collection of this data. The data collection instrument will be employed at baseline and every 6 months during the data collection period. Peace Corps Volunteers will assist the PI and Co-I's in ensuring the fidelity of this data collection. All screening data will be de-identified, aggregated data.

Document Review – Care Group Data

Care Group Volunteers will document data describing program reach (number of households reached, number of individuals counselled, number and types of community-level interventions, etc.) These indicators will fall within current expected data collection by all Care Groups. All sites will be monitored for consistent and accurate collection of this data. The data collection instrument will be employed at baseline and every 6 months during the data collection period. Peace Corps Volunteers will assist the PI and Co-I's in ensuring the fidelity of this data collection. All screening data will be de-identified, aggregated data.

c. Potential Risks.

The important general concern that applies to our approach is Confidentiality. Patients, Care Group Volunteers, and Partners may worry that others (spouses, partners, families, colleagues or friends) may find out about their expressed opinions and personal reflections. It is also possible that, for service providers, advocates, and policymakers, there may be repercussions from their employers if their employers found out something about their work performance or attitudes that they found unfavorable. All participants will be assured their participation is voluntary and private.

ADEQUACY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent.

For all parts of the study, informed consent will be obtained by trained, experienced, and supervised interviewers who have been directly trained by the Co-I's of the research team. All participants will be told that they are free to withdraw from the study at any point in time should they desire to do so, and that this will not jeopardize their relationship with any of the collaborating organizations.

Because we anticipate the enrollment of participants whose primary language is not English, we will make specific accommodations to the consent procedures. We will prepare informed consent documents that are translated into French, Malinké, and Pulaar, the primary languages of the participants. We will prepare these informed consent documents with qualified translators using back translation. The translated consent documents will be submitted to the Senegal IRB and the UIC IRB for approval before their use. The Senegal team members responsible for recruitment, informed consent, and moderating interviews are fluent in the participants' languages.

WRITTEN CONSENT

Informed consent for participants will be obtained using a written consent procedure in a language understandable to the subject, usually either Malinke, Pulaar, or French. The Informed Consent Documents

are available in English, French, Malinke, and Pulaar. The Research Assistants consenting participants in the local languages. Since we are following the same participants over time, the written informed consent with the SHORT FORM will be completed upon study initiation and the informed consent will be confirmed prior to EACH data collection event.

The written consent will be conducted with the presentation to the potential participant of a short form written consent document that states the required elements of informed consent have been presented orally to the participant with an accompanying witness to the oral presentation, when the participant is illiterate. The witness can be a family member, friend, patient advocate, or someone independent of the research team.

PARTICIPANT REGISTRATION AND DE-IDENTIFICATION

For the Baseline Surveys and the Interval Surveys, we will be collecting data from the same participants over time. For this reason, we will need to register these participants. To ensure these individual's privacy, we will follow the procedures as described here. At the end of each data collection event, the RA will review all data collection sheets. The RA will ensure that the participant's name appears only on the last page of the data collection instrument. The RA will record the participants name and phone number on a single copy of the PARTICIPANT REGISTER. This PARTICIPANT REGISTER will be kept by the RA in a private, locked room and will be taken out and consulted only when data collection events are being scheduled or tracked. After each survey, the RA will update the PARTICIPANT REGISTER confirming completion of each data collection event during the present data collection time period. Each month, the RA will hand deliver the completed data collection sheets to the Lead Data Manager. The Lead Data Manager will review all data for completion and copy or update the information from the PARTICIPANT REGISTER into the PARTICIPANT DE-IDENTIFICATION KEY. This will assign each participant a unique random number (unique codes are already in place). The PARTICIPANT DE-IDENTIFICATION KEY will remain only with the Lead Data Manager and will not be consulted by anyone else. This key will be kept in a locked safe in a private location. The key will be consulted only at the time of delivery of data or during data cleaning and entry. On each submitted data collection form, the Lead Data Manager will look up the participant name (found on the last page of the data collection form) on the DE-IDENTIFICATION KEY. The Lead Data Manager will write the corresponding PARTICIPANT CODE onto top of page one Administrative area of the data collection form. She will double check the name and code. She will then tear off the final page of the data collection form (which has the participant name written on it) and destroy it. The Lead Data Manager will then update the DE-IDENTIFICATION KEY confirming completion of the data collection event for EACH participant for whom a completed data collection instrument was submitted during the present month. She will locate the correct row for data entry into the Data Aggregation Sheet and record the Participant CODE. She will then assign the data collection form an event number corresponding to the event number on the Data Aggregation Sheet Row of entry. The Lead Data Manager will then go through the data collection form and enter the Administrative and Participant Responses into the appropriate column of the Data Aggregation Sheet corresponding to the Data Collection Instrument. She will save the electronic Data Aggregation Sheet. She will then mark the hard copy data collection form as Data Entry Completed by writing the Date.

The PARTICIPANT REGISTER for each district will be collected at the end of the three-year study by the Lead Data Manager. The PARTICIPANT REGISTERS and the DE-IDENTIFICATION KEY will be destroyed at the completion of the study by the Lead Data Manager. All hard copy completed Data Collection Instruments will be retained but will no longer contain any personal identifiers of any type.

b. Protection Against Risk.

The procedures for protecting against the above risks are as follows:

Confidentiality. Because participants are likely to have concerns about confidentiality, we will take many precautions against breach of confidentiality. All participants will be told that data will not be disclosed

(including for service recipients, with their husband or families and for providers, within their organizations) unless their written permission is given to do so. Participants may elect at any point to terminate interviews or the experience sampling.

All members of the project staff will be asked to sign a confidentiality pledge. Access to all research data including completed assessments, data files, and analyzed data, will be strictly limited to the Principal Investigator and specifically designated members of the project team. All data access will be on a need-to know basis. No file will be permitted to leave the project office without careful analysis of potential confidentiality problems and no one will be given access to project data who has not signed a confidentiality pledge. Actual names and addresses (include that of other organizations) will never be on a file that contains data. Separate tracking files containing addresses and similar information will be kept to a minimum and tightly controlled. Only the Principal Investigator and project coordinator will have simultaneous access to identities and sensitive data. Since it may sometimes be possible, even without access to names, to identify some participants. Access to these files will be password protected. All data files sent via email or Internet will be encrypted. All team members will keep strictly confidential the identity and location of research participants. All data obtained by this research team will be kept confidentially in secure offices on secure servers. The data will not be transferred until they are encrypted. Doing so will minimize the risk of disclosing individual's confidentiality and privacy.

Throughout data collection, field notes and audiotapes will be either in direct possession of the investigators or secured in a locked location. When field notes and tapes are transcribed, no identifying information will be included. In Chicago, all data will be kept in the locked offices of the research team at Dr. Dykens' office at UIC (1919 W. Taylor Street). In Senegal, all data will be kept in the locked office of Dr. Elhadji Dioukhane. Research materials from field sites will be transferred weekly to these research sites via encrypted email. At all project offices, all paper data will be stored in locked files. Audio tapes will be held by the project in a separate locked cabinet at the same office. All laptops, external hard drives, and flash drives will be encrypted. Participants will be told that the surveys, interviews, raw field notes, transcripts, and audiotapes will be kept indefinitely by the Principal Investigator for documentary purposes. Every effort will be made to disguise the identity of participants in reports, publications, and/or presentations. However, because qualitative writing often includes individual data excerpts as evidence, it is possible that participants may be recognized by those who know them well. Research results will not be written up in a way that could produce harm through placing the participants at risk of criminal or civil liability or that could be damaging to participants' financial standing, employability, or reputation. Prior to publication or presentation of any documents, copies of manuscripts or other materials will be distributed to all members of the research team to assure that participants are not identifiable and to verify the interpretations and conclusions.

c. Training in the Responsible Conduct of Research.

The Federal Office for Protection from Research Risks (OPRR) has mandated that, "all UIC IRB members, IRB staff and research investigators are appropriately educated, on an ongoing basis, about the ethical principles and regulatory requirements for the protection of human subjects." To satisfy this requirement, UIC's Human Subjects Protection Program has established an investigator training program for all investigators who plan to conduct research with human subjects. All university-based investigators involved in this study have already attended an initial training session (Investigator Training 101) at UIC or their institution. We will take additional steps for this project.

In Month 1 and every 6 months, Dr. Dykens will also conduct a four-hour training on human subjects' issues for all new and current staff that will cover the ethical conduct of human subjects research, FG, survey, and interview data collection. The training will include discussion and role playing and will occur at the beginning of each study year. Issues related to human subjects' will be discussed at each ongoing supervision meeting with

the interviewers and facilitators. Staff will be encouraged to pose questions or concerns about human subjects' issues at any time.

d. Plans for Adverse Events.
Possible adverse events, both anticipated and unanticipated, will be brought to the attention of both the Principal Investigator and the Senegal Co-Investigators. Possible adverse events might include, but are not limited to the need to violate confidentiality due to an urgency. The researchers will promptly report all adverse events and unanticipated problems to the local ethics committee which will evaluate them and advise the researchers whether changes are required. All adverse events will also be reported both to the local IRB and to the IRBs of UIC. The local IRB include persons with sufficient depth of expertise to assess adverse events, and they know how to contact the UIC IRB if indicated. Local staff members will be urged to discuss all adverse events with Dr. Dioukhane, who can exercise judgment in deciding upon the appropriate course of action. Dr. Dioukhane will discuss all adverse events with Dr. Dykens. The IRBs will determine whether it is appropriate to stop the study protocol temporarily or will provide modifications to the study procedures. In addition, it is especially important for the local IRB and especially the Community Advisory Board to monitor for possible adverse impacts of the study activities upon the women-focused service organizations and communities.

POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE PARTICIPANTS AND OTHERS
There are potential benefits to the participants for participating in the research. Health providers and health services may improve their provided care. For the other participants, there are not benefits to participating in the research. Some participants, depending on degree of participation, will receive modest financial compensation for their time. Overall, the risks to participants are reasonable in relation to the anticipated benefits to participants and others.

Note Regarding Reimbursement: In some cases, we are providing reimbursements to participants for time, effort, and transportation costs. No compensation will be awarded for direct involvement in focus groups or for completion of surveys or interviews. We will provide refreshments during interviews and focus groups. Our seven years of experience conducting research in Senegal indicates that participants expect such reimbursements. They facilitate the research work and did not present practical or ethical problems. We do not expect that the modest amounts proposed per day of meeting participation (e.g. $10 in per diem and up to $10 in reimbursed travel expenses) would unduly impact possible participants.

IMPORTANCE OF THE KNOWLEDGE TO BE GAINED
Participants will be contributing to the development of knowledge about improving the quality of cervical cancer prevention services in Senegal and the ways in which a community-Peace Corps- academic partnership can impact health services implementation research. This knowledge is critical to the development of accessible primary health care services for this population and others. The potential significance of this research is substantial, including: providing detailed data and analysis on the determinants to accessing the local cervical cancer prevention service. Overall, the risks to participants are minimal in relation to the importance of the knowledge that reasonably may be expected to result.

DATA SAFETY MONITORING PLAN
a. Ensuring Safety of Staff, Participants, and Third Parties
Staff members conducting interviews or recruiting contacts will carry a cell phone at all times while in the field. Prior to going into the field, staff members will leave the name of the research contact and the address of the location where the meeting will occur at the project office in a designated location. We will ensure that other staff members are informed of the location of the staff member in the field and the participant contact in case the staff member should experience an unforeseen emergency.

It is possible that an unexpected situation may occur during the course of meeting with participants that present a threat to the safety of a staff member. In all such cases, the staff member will extricate him- or herself from the situation and notify the Principal Investigator and one of the Senegalese Co-Investigators at the site as soon as practicable to debrief and review the situation. In order to maximize the safety of staff, participants, and third parties to the fullest extent possible, staff is instructed not to indicate acquaintance with a research participant or third party known to them from their study participation, if they are seen outside of the context of the study activities. Instead, staff is to watch for signals from the participant or third party suggesting that they may be acknowledged. This will also serve to maintain participant privacy.

b. Participant Referrals

Participants may request referrals for a variety of services such cervical cancer screening or treatment services. Participants will be provided with a listing of the location of these requested services to the extent that such services exist. Staff will contact the Senegalese Site Coordinator and Co-Investigators for instances in which a participant requests services that appear to be unavailable. In all situations in which a participant requests a referral, the staff member will note the date of this request and the staff member response and referral. In order to ensure the well-being of the participants, all such requests will be handled as professionally and expeditiously as possible.

c. Handling Emergency Situations

It is possible that several types of situations might arise during the course of the interviews. Whenever possible, the interviewers will try to reach the Principal Investigator and one of the other local Co-Investigators to discuss these situations as they arise. We acknowledge, however, that this may not always be possible during crisis situations or those that require immediate decisions. These situations might include:

- A participant threatens to injure himself/herself or another person and has the means to do so,
- A participant has become acutely ill during the course of an interview and appears to be in need of immediate medical attention, or
- An individual is threatening to harm the participant.

If the interviewer believes that a participant is in immediate danger to herself/himself or to another, or is having a medical crisis, the interviewer will inform the participant of this and seek help from another local Co-Investigator, who are all medically trained physicians. If possible, he/she will stay with the participant until help arrives. We acknowledge, however, that this may not always be possible during crisis situations or those that require immediate decisions.

Interviewers are not under any legal obligation to report illegal conduct. Illegal conduct will not be reported unless it falls within the immediate harm exceptions above. In all cases, all emergency situations will be reported to the Principal Investigator as soon as possible after their occurrence and within 24 hours of their occurrence. As noted above, the Principal Investigator will also promptly report all adverse events and unanticipated problems to the community advisory board, the local IRB (Senegal Ministry of Health), and the UIC IRB. The Principal Investigator will maintain a listing of all such occurrences and their disposition.

6.0 Data Analysis and Statistical Considerations

Quantitative Analysis: All survey and interview data will be presented using basic descriptive statistics such as the frequency, % and mean (SD). To compare the intervention effect (screening rate, awareness, etc) within same participants before and after the intervention, Mixed-effects logistic regression model will be utilized. The mixed-effect model will also account for multilevel clusters such as households and districts. The between-subject effects to compare the impact of different regions with and without intervention implemented treating them as intervention and control group will be tested using Chi-squared test for single level samples and mixed-effects logistic for multilevel data. Outcome related factors such as demographic information and other barriers will be measured using descriptive statistics and to test the intervention effect by using multiple regression models.

Qualitative Analysis: For the qualitative data gathered for **aims 1 and 2**, we will use an iterative analysis approach based upon grounded theory[70] using Dedoose. We will transcribe recorded interviews and field notes into French and English (languages of the research team) and enter both into Dedoose. We will conduct the grounded theory analytic methods in steps.[72-75] **Step 1: Initial Review of the Data.** We will divide the entire data set among research team members and identify initial overarching concepts. We will develop the coding scheme as we label, define, and group concepts into categories corresponding to the initial conceptual framework. We will track demographic, contextual, and experiential items that are important to understanding 1) how age or gender impacts the opinion of cervical cancer screening eligible women or their contacts or 2) how perceptions of the educational curriculum may differ between trainer and trainee. **Step 2: Developing a Coding Scheme.** Next, we will develop a codebook consisting of the labels, definitions, and illustrations of categories formulated in Step 1. We will circulate the codebook for review by the entire team, which we will then pilot and revise by using selections of text from the data. When it is clear that the coding scheme is appropriate, two coders each from UIC and Senegal/UCAD will be trained to use it. We will repeatedly code the same sections of text and compare the results, discussing and resolving disagreements, until we reach a level of .80 agreement. **Step 3: Coding**. We will code the data using the coding scheme by first reviewing the interview transcripts and field notes and assigning sections of text to the corresponding coding categories. All staff at the UIC and Senegal/UCAD sites will code all data to lay the groundwork for analysis and reporting. We will also code for missing data patterns. **Step 4: Pattern Coding**. We will examine the relationship within and between codes in order to identify overarching themes and patterns of variation. We will continue pattern coding until saturation, when no new quotations appear.[74] **Step 5: Memoing**. At each of the aforementioned steps we will write short, descriptive statements to a) document ideas during preliminary data review, b) define codes during coding, c) concisely describe items not coded, and d) describe the outcomes of specific Atlas/ti 7 queries. We will then scan memos and sort them to form clusters, categories, and causal networks.[72]

Mixed methods Analysis and Writing. Mixed methods involves integrating the multiple types of data using well-accepted designs including: triangulation, explanation, transformation, and exploration.[75] We will use both SAS and Atlas/ti to further analyze data that will have already been collected, coded, and analyzed. Key to this integrated analysis is looking for intersections across levels that may explain: **1)** Which access facilitators best address barriers to seeking cervical cancer screening services among women who are most at risk? **2)** What benefits do interventions at each level of intervention (individual, household, or community) provide? **3)** What role does gender or age play in affecting barriers to accessing screening? **4)** What are the most influential sources that change motivation of screening eligible women change over time? **5)** What will most likely predict

that screening eligible women recommend screening to their peers? The analyzed data will be used to generate mixed methods publications responding to these key themes and will add to the body of knowledge for improving initial uptake and sustained utilization of cervical cancer screening services.

Power calculations

Clusters and Population: There will be three clusters comprising separate districts (Kedougou, Salemata, and Saraya) in Kedougou. Using two independent proportion method of cluster randomization power analysis (PASS13), to obtain the power 80% under significance level 0.05, the 10% difference of the screening rate with assumed ICC 0.01 requires n=15 per each of 3 clusters. Tables 2, 3, and 4 outline the data collection methodology for each aim. These data will be collected within each cluster at baseline and every six months - coinciding with a crossover of a new (random) cluster. Our selected sites are comprised of zones representative of region including rural, district center, semi-urban, and urban. Contamination is unlikely given distance (the distance between sites ranges from 32 kilometers / 45 minutes by car to 3 ½ hours by car).

7.0 Quality Control and Quality Assurance

Dr. Andrew Dykens and Dr. Youssoupha Ndiaye will serve as the project directors. The project coordinator research assistant in Senegal has been previously trained in the appropriate conduct of focus groups and interviews in Senegal. The entire co-investigative team specified in this protocol will be involved in data analysis.

Data will be shared with the investigative team members electronically through online collaborative document software through a Google Apps secure Domain at *https://drive.google.com/a/uic.edu/* . This data is secure under the SSAE 16 and ISAE 3402 auditing industry standards and is available to investigators only. No one other than approved research personnel specified within this protocol will have access to the data.

The online software to be used for qualitative data analysis, Dedoose, uses Secure Sockets Layer Extended Validation (SSL EV) Encryption. SSL EV is the highest tier of encryption and validation offered on the internet. This protects data while travelling over the internet with utmost security. Dedoose uses JungleDisk, a cloud based file storage system. Powered by Amazon and Rackspace, this system is responsible for keeping backup's of all of Dedoose's data and is an encrypted, distributed file system. This ensures that even in a worst case catastrophic failure, data is still safe and secure.

Local Familiarity: Given our entire team's significant familiarity and experience working in Senegal, we feel confident that this study will proceed as expected. We have measures in place (regular research meetings, clearly defined roles, oversight, and reporting structure) to diagnose and deal with problems as they arise.

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