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METHODOLOGY

Rationale and Protocol Design for the Adaptation and Implementation of a Patient Navigation Program for Cervical Cancer Screening Across Contexts in Senegal

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Abstract: This article presents the rationale and design for the adaptation and implementation of a patient navigation program for cervical cancer screening across contexts in Senegal. A model, based on the NIH NCI Patient Navigator Research Program (PNRP) model, informs the proposed program for adaptation which aims to reduce intrapersonal- (knowledge, communication), interpersonal- (stigma, misinformation), and community-level (women's lack of autonomy in healthcare decision-making) barriers. The specific aims of the study are to: 1) Evaluate the adaptation process of the evidence-based Patient Navigation Model utilizing the Dynamic Adaptation Process (DAP) across rural and urban contexts in Kedougou and Dakar, Senegal; 2) Conduct an effectiveness-implementation hybrid type 1 stepped-wedge randomized pragmatic trial of the adapted patient navigation program across Kedougou and Dakar, Senegal, and 3) Evaluate the implementation outcomes (feasibility, acceptability, fidelity, penetrance, sustainability, and cost) of The Adapted Patient Navigation Program across multiple contexts in the Kedougou and Dakar regions, using mixed methods and guided by the Exploration, Preparation, Implementation, Sustainment (EPIS) Framework. The Adapted Program is integrated into the existing community health system and is being administered by the Heads of Reproductive Health at the Regional-Level and District Levels who act as Patient Navigator Leaders with oversight by the Regional and District Directors of Health. These individuals coordinate the patient navigation field activities that occur at the health post level. The Community Health Workers (Patient Navigators) are essential to engaging individual clients through education, empowerment, and by accompanying them to the clinical setting for screening and follow-up. The study is a mixed-methods study that collects data from three participant samples: (1) system and organizational stakeholders, (2) patient navigator team members, and (3) clients. The study informs the adaptation and implementation of patient navigation programs for cervical cancer screening in Senegal and other low- and middle-income countries.
Keywords: cervical cancer prevention, patient navigation, women's health, stigma, implementation research, global health

Introduction

Cervical cancer is the fourth most common cancer diagnosed among women worldwide and a leading cause of cancer-related deaths among women across 37 countries, with most fatalities occurring in Sub-Saharan Africa.[1] In high-resource countries, cervical cancer incidence rates are declining; however, low- and middle-income countries (LMICs) are

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experiencing a sustained increase in both incidence and mortality.[1] By 2030, cervical cancer mortality is projected to increase by 42%, reaching 442,926 deaths,[2] with the largest increase in LMICs, which currently accounts for 85% of new cervical cancer cases and 87% of related deaths.[3,4] The age-standardized cervical cancer incidence is 37.8/100,000 Senegalese women, positioning it as the 17th highest incidence globally.[1] Cervical cancer screening programs are a critical complement to human papillomavirus (HPV) vaccine programs in achieving global progress toward the elimination of HPV related cancers.[5–8] However, in LMICs, cancer services remain much more accessible to higher socioeconomic class populations within urban centers.[9] Women living in rural communities face unique barriers to accessing cervical cancer prevention such as long distances to care, travel costs, language barriers, and lack of promotion of screening.[10]

Patient navigation is an evidence-based strategy to address barriers to screening and achieve more timely diagnosis and follow-up in order to enhance cancer outcomes in underserved populations.[11] Patient navigators work with patients to overcome barriers and better understand the healthcare system. In both high-income countries[12–16] and low-income countries,[17–19] patient navigation has proven effective in overcoming emotional, communication, information, and medical system barriers to provide timely care throughout all stages of the cancer care continuum, from the detection, diagnosis, treatment, to the post-treatment quality of life. Patient navigation programs provide disease-specific education, facilitate shared decision-making, provide informal emotional support, educate patients about the healthcare system, coordinate timely access to testing and follow-up care, and facilitate communication among providers to increase access to care, promote self-efficacy, and sustain patient engagement with care.[20] Patient navigation has been shown to be effective in enhancing cancer outcomes, particularly for marginalized groups, rural populations, and those in poverty.[20]

Although the effectiveness of patient navigation programs is well-established,[12–16] there is currently a gap in the literature describing the adaptation and implementation of patient navigation programs for cancer care in LMICs.[21] Research conducted in Senegal has shown that women's ability to gain access to essential healthcare is significantly impacted by complex gender perceptions, male and female health behaviors, and social norms.[9,21–25] This study aims to build knowledge in addressing barriers at the primary health care level in urban settings as well as in the rural context where socio-cultural barriers and weak health systems are considerable challenges.[17,26,27]

Project Aims and Administration

This paper describes the rationale and protocol design for the adaptation and implementation of a patient navigation program for cervical cancer screening across different contexts in Senegal. The specific aims of the study are to: Aim 1: Evaluate the adaptation process of an evidence-based Patient Navigation Model utilizing the Dynamic Adaptation Process across rural and urban contexts in Kedougou and Dakar, Senegal; Aim 2: Conduct an effectiveness-implementation hybrid type 1 stepped-wedge randomized pragmatic trial of the adapted patient navigation program across Kedougou and Dakar, Senegal; and Aim 3: Evaluate the implementation outcomes[28] (feasibility, acceptability, fidelity, penetrance, sustainability, and cost) of The Adapted Patient Navigation Program across multiple contexts in the Kedougou and Dakar regions, using mixed methods and guided by the Exploration, Preparation, Implementation, Sustainment (EPIS) Framework (Figure 1). We present the rationale and design using the CONSORT stepped wedge cluster randomized trial (SW-CRT) checklist (Supplement 1) illustrating an ongoing, iterative contextual assessment. These data continuously inform the iterative adaptation of the program as we evaluate the intervention impact and the implementation outcomes of program implementation within and across cluster contexts.

The project is guided by a research partnership comprising the Senegal Ministry of Health and Social Action, Cheikh Anta Diop (UCAD) University in Dakar, and the University of Illinois Chicago (UIC). This human subjects research has been approved by the UIC Cancer Center Protocol Review Committee (protocol number 2022–0055), the UIC Institutional Review Board (protocol number 2021–1282), and the National Ethics Committee for Health Research at the Senegal Ministry of Health and Social Action (protocol number SN22/133). This National Institutes of Health, National Cancer Institute funded grant (R01CA258683, GRANT13412230) is registered as #NCT5544084 on clinical-trials.gov.

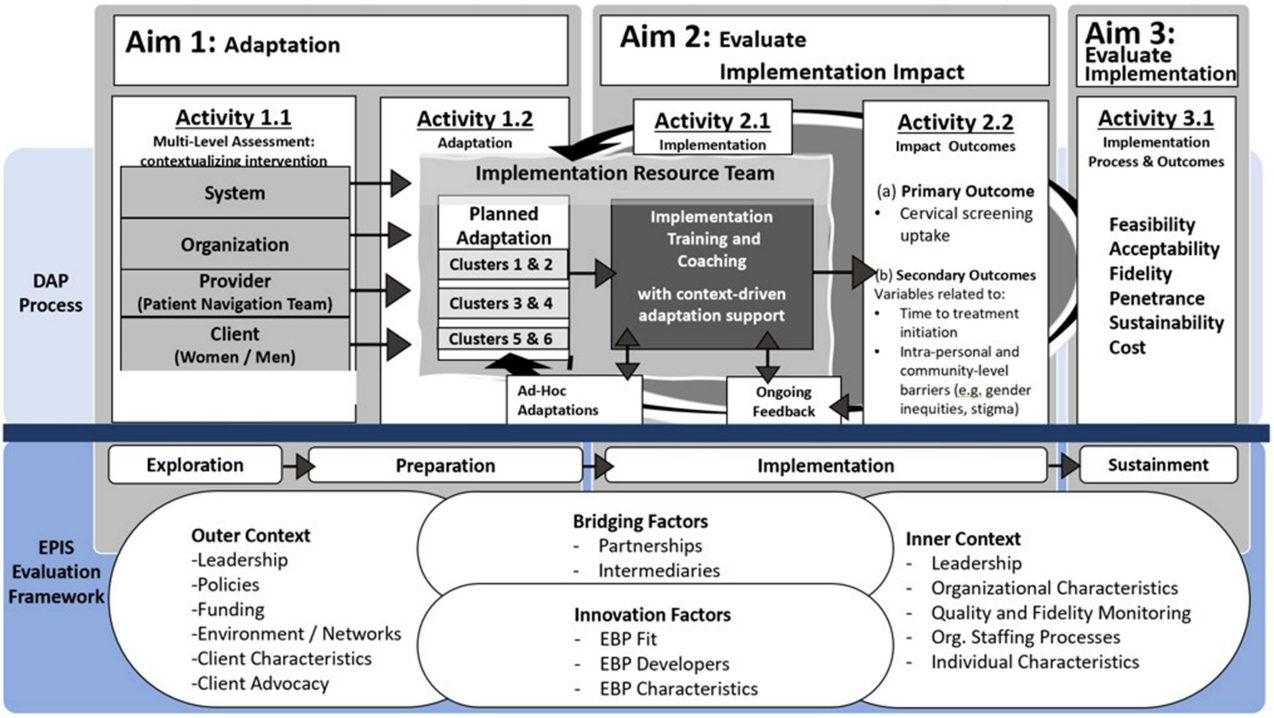

Figure 1 Theoretical Framework: The Dynamic Adaptation Process (DAP) Alignment with The Exploration, Preparation, Implementation, and Sustainment (EPIS) Framework by aim.

Methodology

This research project is an effectiveness-implementation hybrid type 1 stepped-wedge randomized controlled pragmatic trial of the adapted patient navigation program across Kedougou and Dakar, Senegal (Figure 2). Six districts, Yeumbeul, Keur Massar, Diamniadio (Dakar) and Saraya, Kedougou, and Salemata (Kedougou), were selected through convenience-sampling and are representative of Senegal's urban and rural contexts. Each district acts as a cluster, and within each cluster, the district-level health center was selected along with two health posts which are randomly selected. One

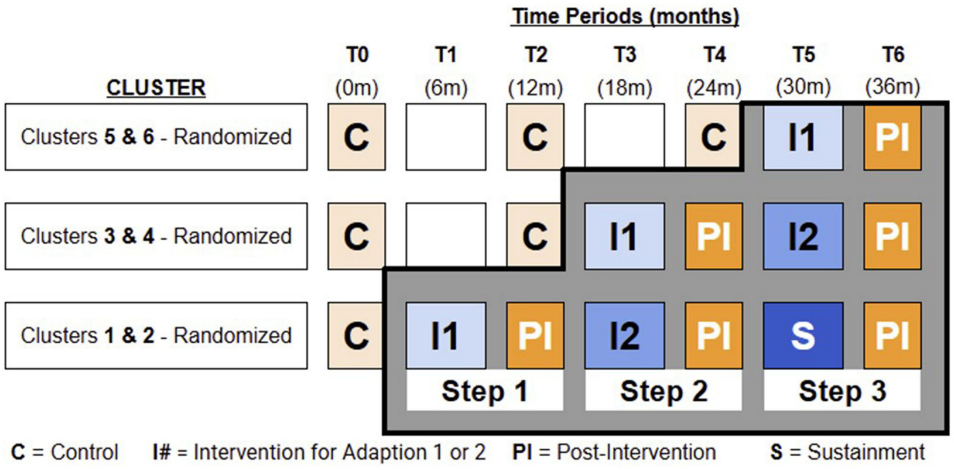

Figure 2 Stepped-Wedge Trial Design Clusters are sequentially exposed to the intervention: Clusters 1 and 2 at Time 1 (T1), Clusters 3 and 4 at T3, and Clusters 5 and 6 at T5. Data is collected annually at T0, T2, T4, and T6. Data is considered control data at baseline across all clusters and in each cluster until crossing into the intervention, at which point data collected are Post-Intervention. Clusters 1 and 2 receive reduced support during Step 3 to evaluate Sustainment (**S**) of the intervention.

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cluster from each region was randomly selected to cross over into the intervention at each step (cluster sampling was performed by the Senegal Principal Investigator through random number generation using Excel) (Table 1).

The data for all aims is collected from three participant samples: (a) system and organizational stakeholders, (b) patient navigator team members, and (c) clients (Table 2). System and Organizational Level recruitment takes place at the first National Advisory Board and Regional Implementation Resource Team meetings. Patient Navigator Team Level recruitment takes place at the health facility in each site where the patient navigation program will be implemented. Client Level recruitment utilizes a two-stage cluster sampling methodology with probability proportional to size and without stratification to select women ages 25–69 and their partners within the same age range to be surveyed. Stage one includes the selection of census districts (CD) as the primary unit associated with the health structure coverage areas (three CD per health center and two CD per health post). A census district is a geographical area with precise boundaries composed of households. Stage two includes the random selection of households within the census districts (systematic sampling was performed through random number generation using Excel). If an eligible woman and man in a given household agrees to participate, the participants from that household are consented and followed throughout the study. If recruitment from a particular household is unsuccessful, the household is passed, and recruitment is attempted at the next randomly selected home. A total of 42 CD are sampled. Ten households are selected from each of the census districts at the health center sites. At the health post sites, ten households are selected from one CD and five from the second CD. Households identified and surveyed at baseline are maintained during the other phase of data collection (T2, T4, and T6). Written informed consent is obtained at baseline, and verbal consent is obtained before each survey and focus group thereafter.

Table 1 Implementation Partners by Participatory Committee

		National Advisory Board	**Regional Implementation Resource Teams**
	Level	**(12 Members)**	**(31 Members)**
A.	**System**	**Ministry of Health and Social Action** Division of Non-Communicable Diseases Direction of Disease Control Direction of Planning Research and Statistics Direction of Social Action **Regional Officials (1 per Region)** Regional Health Director - Dakar Region Regional Health Director - Kedougou Region	**Regional Officials** Regional Health Director Dir. of Social Work Dir. of Reproductive Health / Reg Patient Navigator Lead Dir. of Primary Health Care Dir. of Home Care Dir. of Health Promotion, Information, and Education
B.	**Organizational**	**UCAD Cancer Institute** **UCAD Center for Women's Health** **Strategic Partners** Senegalese League against Cancer (LISCA) Clinton Health Access Initiative (CHAI) World Health Organization (WHO) Regional Office **National-level Lead Patient Navigator**	**Health Structure Level (1 per district)** District Medical Director *Dir. of Reproductive Health / Patient Navigator **Community** Health Committee Rep (1 per region) Women's Group Rep (1 per region) Religious Leader (1 per region) Traditional Healer (1 per region)
C.	**Patient Navigator Team**		**Patient Navigator Representatives** *Nurse (1 per district) *Midwife (1 per district) *Bajenu Gox (1 per district)
D.	**Clients**		**Clients at Health Center & Posts** Women, Men (1 each per district)
			*Implementation Team Member

Table 2 Study Sites in Clusters

		Urban/Semi-Urban Clusters		Rural Clusters	
		Dakar		Kedougou	
Step 1	**District:**	1	**Keur Massar**	2	**Saraya**
	Health Center:		HC Keur Massar		HC Saraya
	Health Posts:		HP Mme Fatou Ba		HP Bembou
			HP Boune		HP Diakha Macky
Step 2	**District:**	3	**Yeumbeul**	4	**Salemata**
	Health Center:		HC Yeumbeul		HC Salemata
	Health Posts:		HP Maternite Yeumbeul Nord		HP Darou Ningou
			HP Yeumbeul Diamalaye		HP Dar-Salam
Step 3	**District:**	5	**Diamniadio**	6	**Kedougou**
	Health Center:		HC Diamniadio		HC Kedougou
	Health Posts:		HP Niangal		HP Dimboli
			HP Sebikotane		HP Fongolimby

Abbreviations: HC, Health Center; HP, Health Post.

Programmatic Models and Educational Materials

The adaptation of the project leverages two distinct but complementary patient navigation models: the George Washington University Cancer Center Oncology Patient Navigator Training Program (PNTP)[29,30] and the Chinatown Patient Navigation Model.[31–33] These models are related given that they were each adapted from the NIH NCI Patient Navigator Research Program (PNRP)[34] model. *The George Washington (GW) University Cancer Center Oncology Patient Navigator Training: The Fundamentals* is a comprehensive, competency-based training that uses evidence-based information and case studies to prepare patient navigators to effectively address barriers to care for cancer patients and survivors. It was developed through Cooperative Agreement #5U38DP004972 from the US Centers for Disease Control and Prevention (CDC) through a collaborative process and is well-suited for adaptation into the international setting for oncology patient navigators without a clinical license.[29,30] *The Chinatown Patient Navigation Model* is a multi-level program that has been shown to reduce intrapersonal- (knowledge, communication), interpersonal- (stigma, misinformation), and community-level (women's lack of autonomy in healthcare decision-making) barriers.[33] The Chinatown model utilizes a team structure with a robust community-based approach emphasizing the role of the community health worker to address challenges such as patient-provider communication issues and stigma.[31–33] Each model offers unique strengths that, when combined, create a robust framework for addressing the multifaceted obstacles to accessing healthcare and patient support, particularly in the context of oncology.

Adaptation Process, Implementation Framework, and Implementation Outcomes

The Dynamic Adaptation Process (DAP)[35–37] is a four-phase method to implement an evidence based program (EBP) that accounts for variations in context of service delivery, engages stakeholders, and elicits feedback from experts. The DAP works to maintain the fidelity of the core elements of an EBP during adaptation of the program. The DAP is a continuously iterative process where ongoing experience can inform continued adaptation. In alignment with DAP, the EPIS Implementation framework[35,36] is utilized to guide study implementation planning and to assess the contextual factors that inform the adaptation and programmatic strategies. These factors include the external system and internal organizational contexts, innovation/evidence-based strategy characteristics being implemented, and bridging factors.[37,38]

Guided by the Proctor Framework[28] as the *Aim 3 Implementation Outcomes Framework*, the project evaluates the implementation outcomes of feasibility, acceptability, fidelity, penetrance, sustainability, and cost.

Implementation Fit and Readiness

Setting – Health System

Senegal has a majority rural population (54%), and the rural and urban contexts differ considerably.[39] Rural Senegal is challenged by poor infrastructure and long-distances between communities and health facilities.[40] Structural inequities for women, community-level barriers such as stigma, and intrapersonal-level barriers such as communication and knowledge are common to both rural and urban settings. The health system was decentralized in the mid 1990s so that regional health systems could respond more readily to local contexts. As a result, there is a well-established system of health centers, posts, and huts within each of Senegal's 76 health districts. In parallel to this system exists well-established local community health development committees that support the health promotion, prevention, and curative healthcare activities of clinicians and community health workers. In 2009, Senegal launched the Bajenu Gox ("god-mothers") community health worker program to reduce maternal and child morbidity and mortality. These respected female elders are formalized and serve as paid health promoters due to their capacity to influence fellow community members' behavior.[40] In addition, a local Health Development Committee is associated with each health post and provides guidance and feedback to the local community health system. In 2018, the Senegal National Ministry of Health and Social Action launched the Senegal national norms and protocols for the screening of precancerous lesions of the uterine cervix and early detection of breast cancer[41] that recommend cervical cancer screening by way of visual inspection of the cervix with acetic acid[42] every three years for women ages 25 to 69.

Setting – Study Sites

The study includes health centers and posts from Dakar and Kedougou, Senegal. Dakar is the capital and the largest urban economic center of Senegal. Within the region of Dakar, three districts with health posts that represent urban, semi-urban and rural settings were selected: Yeumbeul, Keur Massar, and Diamniadio.[43] Yeumbeul is the most populated with a total population of 333,095; Keur Massar has a population of 253,150, and Diamniadio has a population of 116,146. The Kedougou region is a rural region located in the southeastern corner of Senegal and represents approximately 1% of the population of Senegal.[44] Kedougou is organized by three districts: Kedougou, Salemata, and Saraya. The rate of literacy in French at the regional level by sex reveals that it is higher for men (37.7%) than for women (22.5%). In the Kedougou region, the school attendance rates are also poor (44%).[45] There is a considerable shortage of healthcare workforce. In 2018, there were 11 physicians (with a single gynecologist), 48 midwives, 32 registered nurses, 6 technicians, and 1 social worker providing care for all three districts of the region.[45,46]

Implementation Partners

To support a robust participatory approach, a National Advisory Board (NAB) was developed and is composed of leaders and policy-makers (Table 3). The NAB oversees the activities of two Regional Implementation Resource Teams (RIRT), one in each region. The RIRTs are composed of key stakeholders from the various study levels (Table 3). The RIRTs are an explicit part of the DAP model and ensure that adaptations are carried out through a planned approach.[35] They ensure the fidelity to core components of the patient navigation strategy while defining adaptable features. Through direct engagement with nearby communities, the RIRTs have a strong comprehension of the perspectives and needs of local health care consumers and bring valuable perspectives to the adaptation and the implementation process.

Program Design

Intervention

This project adapts and integrates a proposed patient navigation model into a well-established community health system in Senegal (Figure 3). The Senegal Cervical Cancer Prevention Patient Navigation Program will be integrated into the existing community health system in the Medical Regions of Kedougou and Dakar, Senegal, where core components of this structure are supported by the established system. With oversight by the regional and district medical directors, the Adapted Program will be administered by the Directors of Reproductive Health at the Regional-Level and District-Level

Table 3 Human Subjects (Participants) by Sample

Type of Participant by Activity		Aim	Number/Timing of Data Collection Events	Total Sample Adult Women (*Double Counted)	Total Sample Adult Men (*Double Counted)	Total (*Not Double Counted)
Sample a: System and Organizational Level: Ministry of Health, Regional-level, and District-level Officials				12	43	**55**
Purposive sampling: An invited member of the study NAB or RIRT and able to read and write in French.						
	Individual Survey	Aim 1	Administered at T0, T2, T4, T6	12	43	55
	Focus Groups	Aim 1	Administered at T0, T2, T4, T6	12*	12*	0
	Individual Survey	Aim 3	Administered at T2, T4, T6	7*	35*	0
	Key Informant Interview	Aim 3	Administered at T2, T4, T6	2*	2*	0
Sample b: Patient Navigation Actors				78	20	**98**
Purposive sampling: Employed by the state at a study site health facility as a patient navigator, clinician (nurse, midwife) who treats and educates patients, or is a community health worker at the facility or community level (Bajenu Gox – women's health educator)						
	Individual Survey	Aim 1	Administered at T0, T2, T4, T6	78	20	98
	Focus Groups	Aim 1	Administered at T0, T2, T4, T6	16*	10*	0
	Individual Survey	Aim 3	Administered at T2, T4, T6	18*	6*	0
	Key Informant Interview	Aim 3	Administered at T2, T4, T6	6*	4*	0
	Fidelity Checklist	Aim 3	Administered at T2, T4, T6	24*	12*	0
Sample c. Clients and their partners				360	360	**720**
Two-stage cluster sampling: One woman eligible for cervical cancer screening and one man per household.						
	Individual Survey	Aim 1	Administered at T0, T2, T4, T6	360	360	720
	Focus Groups	Aim 1	Administered at T0, T2, T4, T6	12*	12*	0
	Individual Survey	Aim 2	Administered at T0, T2, T4, T6	360*	360*	0
	Individual Survey	Aim 3	Administered at T2, T4, T6	6*	6*	0
	Key Informant Interview	Aim 3	Administered at T2, T4, T6	2*	2*	0
			Total by Gender:	**450**	**423**	**873**
			Percent by Gender:	**51.55%**	**48.45%**	**100.00%**

who will act as Patient Navigator Leaders. These individuals will coordinate the patient navigation field activities that occur at the health center and health post levels. With oversight by the lead nurse, the midwives that are positioned at the health center and health post levels will be the primary contact for the community health outreach workers. The Bajenu Gox community health workers will be essential to engaging individual clients through education, empowerment, and by accompanying them to the clinical setting for screening and follow-up. The Bajenu Gox are well-positioned to identify the intrapersonal and community barriers experienced by women (including stigma and lack of autonomy in healthcare decision making, among other common barriers such as childcare and transportation) and will work with them to overcome these barriers. As acuity of diagnosis advances and the patient care needs progress across the cancer care continuum, the case is transferred to higher level patient navigation services. The District-Level Patient Navigator Leaders will oversee outreach efforts by the community health workers to encourage screening uptake and ensure treatment through local health structures for patients with precancers (by way of thermocoagulation, which is readily available in all sites). The Regional-Level Patient Navigator Leaders will oversee activities at the district level and ensure appropriate follow-up, treatment at referral centers, and quality of life support for patients diagnosed with cervical cancer. Many of these services are available only at the national level and will require coordination with the National Level Patient Navigation Program Director (Figure 3).

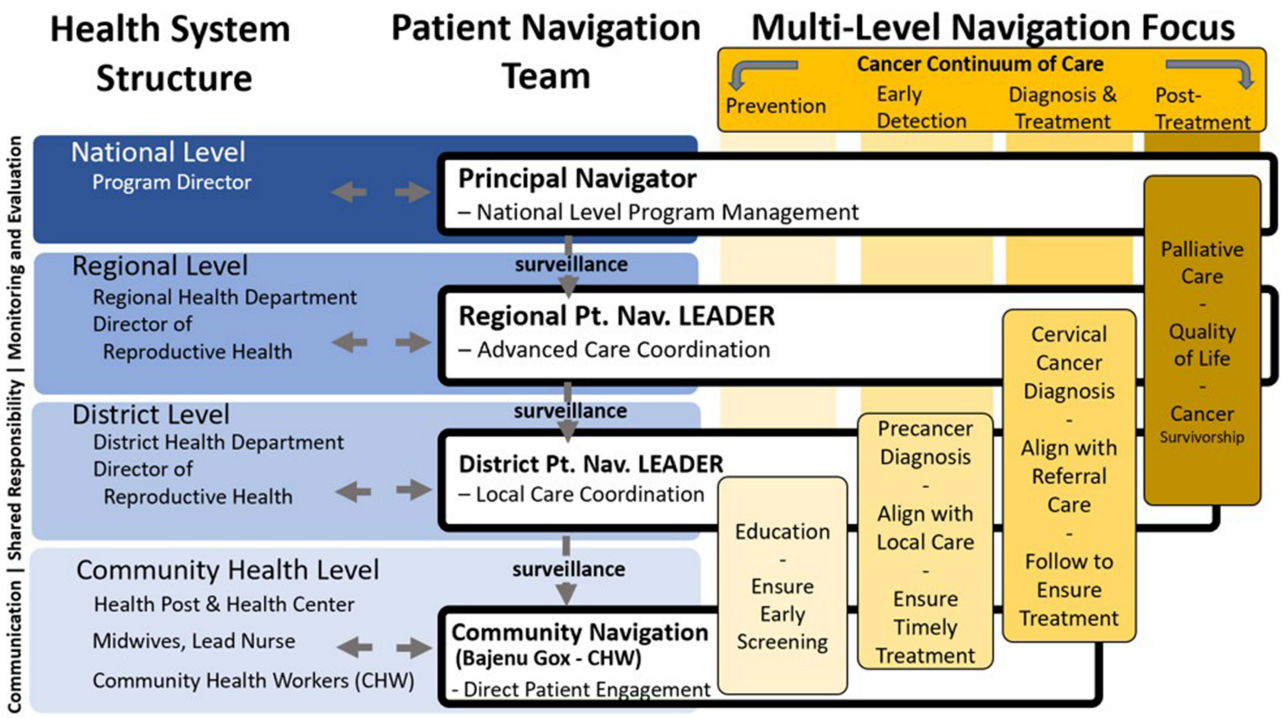

Figure 3 Cervical Cancer Patient Navigation Model along the Cancer Care Continuum in Senegal. The proposed navigation model is multi-level, with each level represented in the left column responsible for the key functions of the model indicated in the Multi-Level navigation Focus, ensuring care along the cancer care continuum.

Exploration and Preparation Phases

Aim 1: Multilevel Assessment of Stakeholder Characteristics

The exploration phase (Aim 1) begins by orienting key stakeholders and advances with a multilevel assessment of stakeholder characteristics relevant to the context of the selected districts in rural Kedougou and urban Dakar, Senegal. The investigators train the NAB and the RIRTs as well as the National and Regional Patient Navigator Leaders on the DAP process and how iterative data will inform the systematic adaptation of the Senegal Program to fit the local context. The NAB and RIRTs receive training on the adaptation documentation methodology of the study. This will be supported with ongoing coaching from the research team. The contextual assessment is iterative, capturing data at each interval (annually) using a stepped wedge approach.[47]

Quantitative surveys are developed, pilot tested, and conducted at three levels: 1) system/organization, 2) patient navigation team members, and 3) clients. In addition, annual qualitative data using focus groups among program administrators, patient navigator team members, and clients at RIRT meetings are collected. This multilevel assessment of stakeholder characteristics and EPIS-informed contextual factors (Figure 1) relevant to the context of rural Kedougou and urban Dakar informs the adaptation of the Program. Table 4 outlines the methodology, measures, and variables for all Aims. Researchers will adapt and employ the Organizational Readiness for Implementing Change Measure[48] and The Implementation Leadership Scale[49] (Table 4). These data are reported to the NAB and the RIRTs annually to inform adaptation.

In the preparation phase, the core elements and adaptable features of the PNTP are delineated and define the iterative adaptation process (guided and ad hoc) through a participatory process at the NAB and RIRT meetings. Document markups are standardized to distinguish core content from adaptable features. The adaptation process is documented by employing the Stirman's FRAME Taxonomy for adaptation.[50] The adaptation process informs the development of the Fidelity Checklist used in Aim 3. Next, the Regional and District Leaders are oriented to the Adapted Program and form an Implementation Committee among members of the RIRT. The Implementation Committee makes a Regional and

Table 4 Methodology, Constructs, and Measures by Aim

Methodology		Constructs	Measures
AIM 1 - Adaptation			
	Individual survey System and Organizational Level Quantitative Data	System Components Institutional Capacity Organizational Capacity	Organizational Readiness for Implementing Change Measure
	Individual survey Patient Navigator Actors Quantitative Data	Innovativeness: Organizational culture: Attitudes & Beliefs:	The Implementation Leadership Scale (ILS)
	Individual survey Clients Quantitative Data Focus Groups 1. Program Admin. 2. Patient Navigator ActorS 3. Clients Qualitative Data	Socio-demographics: Attitudes: Beliefs: Institutional: Policy: Community:	Health practices and opinions, rumors, stigma, healthcare decision making autonomy Knowledge and opinions of partners Organizational culture at the provider level
		Intrapersonal:	Health beliefs, personal and social values, culture
	Document Review Adaptation ProcesS Qualitative Data	Planned and Ad Hoc Adaptation	Modifications and context (Stirman's FRAME taxonomy)
Aim 2 - Evaluate Implementation Impact			
	Individual survey Clients Quantitative Data	Cervical Cancer Screening Uptake	Cervical cancer screening uptake (Primary Outcome) measured through self-report and confirmed through medical record review.
		Stigma Detection and Control	Cancer Stigma Index
		Self-Efficacy / Autonomy	Perceptions of a woman's ability to make a personal decision to be screened for cervical cancer, Perceptions of men's role in health care decision making.
		Knowledge	Awareness and Knowledge
	Document Review Quantitative Data	Time to Treatment Initiation	Time to treatment initiation from a positive screen (Secondary Outcome)
Aim 3 - Evaluate Implementation Outcomes			
	Implementation Observation Quantitative Data	Fidelity	Fidelity Checklist

(*Continued*)

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Table 4 (Continued).

Methodology		Constructs	Measures
	Individual Survey 1. Program Admin. 2. Patient Navigator Actors 3. Clients Quantitative Data	Feasibility	Feasibility of Intervention Measure (FIM)
		Acceptability	Acceptability of Intervention Measure (AIM)
		Sustainability	Program Sustainability Assessment Tool (PSAT)
	Key Informant Interviews Organizational Level Patient Navigators Clients Qualitative Data	Feasibility, Acceptability, Sustainability	Opinion on practicality & utility, actual fit, and suitability for use in context, relative advantage, maintenance, continuation, durability, institutionalization, routinization, and sustainability
	Document Review Quantitative Data	Penetrance	Reach
	Document Review Cost Analysis Quantitative Data	Cost	Implementation and Programmatic Cost

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Box 1 Core Elements of the Implementation Training Manual of the Adapted Patient Navigation Program

Cervical cancer overview
Clinical guidelines
Impacts - Physical, Psychosocial, Practical and Spiritual Impacts
Navigator Role
Assessment & barrier identification
Shared decision making
Identifying resources
Patient centered communication
Patient advocacy
Addressing stigma
Addressing misinformation
Women's empowerment in decision-making
Ethics and patients' rights
Healthcare team collaboration
Program reporting

District plan for implementation and is charged with maintaining records. Annual implementation training meetings are organized for all Patient Navigation Team Members (Leaders, nurses, midwives, and community health workers).

Adaptation Process

During the adaptation process, the Dakar and Kedougou RIRTs adapt the Senegal Program strategy to fit their local context and create two separate Regional Program Implementation Training Manuals (one for each region) (Box 1) to be used at the Training of Trainers workshops and at each implementation time period. The adapted Regional Program in the form of the Implementation Training Manual is sent to the NAB for review and feedback. The NAB reviews the adapted Implementation Training Manual and provides advice and feedback informed through the identified core elements and adaptable features of the navigation strategy. This iterative adaptation process is revisited during each adaptation time period for optimization of the navigation strategy with data from earlier steps informing future ones.

Implementation Phase

Aim 2: Evaluate Impact Outcomes of Adapted Patient Navigation Program

In the implementation phase (Aim 2) the researchers conduct a stepped-wedge randomized pragmatic trial in the Kedougou Region and in Dakar to evaluate the impact of The Adapted Program on screening uptake and time to treatment initiation for those with abnormal screening results. Hypothesis one from this aim states that participants who receive active navigation services will be more likely to get screened for cervical cancer (primary outcome) and obtain treatment more rapidly. Researchers also explore the effect of The Adapted Program on intrapersonal- and community-level barriers. Hypothesis two states that participants who receive patient navigation services and their partners will experience and/or report fewer intrapersonal- and community-level barriers including cancer-related stigma (secondary outcomes) and lack of autonomy in healthcare decision-making. Implementation training is guided by the Implementation Training Manual and led by the Regional and District-level Patient Navigator Leads and the Implementation Team. Training includes: The Adapted Program orientation with a focus on cervical cancer clinical guidelines, navigator roles, patients' rights, collaboration in healthcare settings, and program reporting practices (Box 1). Fidelity of the Adapted Program is crucial, the Regional Patient Navigator Leads will check-in with each cluster over the first three weeks of implementation and provide coaching to the Patient Navigation Team. After the three months of oversight are completed, the Implementation Team will meet to reflect on lessons learned and prepare for future iterative

adaptations and implementation. The lessons learned from each round of discussions will be shared with implementation partners and used to modify The Adapted Program.

Intervention Implementation

Implementation of the patient navigation program happens in Dakar and Kedougou sequentially at three region-specific districts (cluster level) in three sites per district, with the order of introduction at each cluster randomly assigned. The same sequence of implementation steps and activities occurs at all sites. Initiation of implementation at each site occurs with proactive support in interpreting and adapting the program; support will gradually decrease over time as sites become independent.

Measures

To evaluate Aim 2, individual surveys from the client sample are collected. These data measure the primary outcome of cervical cancer screening uptake. In addition, data from women and men in the same household will assess secondary outcomes such as time to treatment and those associated with intrapersonal (knowledge, communication) barriers and community-level (stigma and women's autonomy in healthcare decision-making). The questionnaire is based on the Global Cancer Stigma Index.[51] Additionally, the study builds on existing Women's Autonomy and Cancer Stigma Research in Senegal.[22,23] These data are collected at baseline and at 12 month intervals through year 4 (Table 4).

Power Analysis for Aim 2 Effectiveness

To assess the primary outcome of cervical cancer screening uptake clients will be recruited from markets within the catchment area of the local health structure. Cervical cancer screening will be recorded via self-report through individual survey and confirmed through medical record review. The total study participant sample for the primary outcome in Aim 2 is n = 300 (50 women participants per cluster). Based on a cluster randomized stepped-wedge design, with an intra-cluster correlation coefficient (ICC) = 0.1, adequate power (82%) is projected to detect a 10% difference in the outcome incidence from baseline (at 15%). We are able to justify an ICC of 0.1 given the similarity of the type and distribution of the population in the districts. While there is heterogeneity in the population with some variation in the density of the population in more populated towns compared to the very rural villages, these differences are consistent across the six districts. Three sites in each district will be sampled, the more populated health center and two health posts (less populated) for a total of 50 participants across these sites. Power was estimated using R, which implements various analytical approaches on the basis of six clusters (6 districts), three steps and four periods, and an alpha of 0.05.[47]

Analysis

To analyze outcome variables, a three-level model in which measurement occasions (level 1) are nested within households (level 2) which are nested within communities (level 3) will be used. All data will be downloaded or entered into an SAS database. Standard data management and reduction procedures will include: 1) cleaning and verification; 2) identification of non-normal distributions and transformations where indicated (ie, use of standard scores, conversion to square roots, and use of logarithms); 3) analysis of missing data; 4) scale construction and evaluation of each measure's validity and reliability; and 5) tests of multicollinearity. Regarding missing data, if "non-ignorable" patterns are detected, then "pattern mixture" "selection models" "shared-parameter models" or marginal semiparametric approaches such as weighted generalized estimating equations will be used to mitigate the impact of the missing-data-pattern on the bias of key outcomes. Data will be analyzed using a three-level mixed-effects longitudinal regression model. Random effects accommodate the variability of subjects and communities both at the baseline and over time. The effectiveness of the intervention will be tested by testing the slope difference of the intervention and comparison groups by time interaction parameter. To accommodate the variability of the subjects and communities both at baseline and over time, random trends of the subjects and communities will be utilized in model building. The results of the analyses will inform qualitative data collection (eg, questions in minimally structured interviews) and will be integrated into mixed methods analyses and writings.

Sustainment Phase

Aim 3: Evaluate Implementation Outcomes Across Districts

Finally, during the sustainment phase (Aim 3) the implementation outcomes (ie, feasibility, acceptability, fidelity, reach, sustainability, and cost) of the Adapted Program within the context of Senegal's rural and urban districts are evaluated. The study observes progress up to month 36 (Figure 2). During the sustainment phase, clusters receive minimal support as the Study Team "hands-off" observation of progress with limited guidance during this period. Clusters 1 and 2 will be evaluated after 12 months of study support (ie, at the completion of their sustain period). This will allow us to more fully evaluate the stages of Program sustainability after implementation, assessing for successful integration of the patient navigation model into a learning health system that addresses identified barriers in a systematized, sustainable fashion.

Measures

Implementation outcomes (feasibility, acceptability, fidelity, penetrance, sustainability, and cost) of the Program implementation through individual surveys and stakeholder focus groups are evaluated (Table 4). Each district implements the Adapted Program in the appropriate time period according to their cluster by following the guidance of the Implementation Training Manual and with oversight from the RIRT. The Senegal-based research team travels to each district and observes the Training and Coaching around the Program implementation. They document the Adapted Program training while noting how local stakeholders employ ad hoc adaptation to better fit their individual district context. During this time, the research team conducts in vivo observation of this training using the Fidelity Checklist. This activity repeats with each implementation (Periods 1, 3, and 5) (Figure 1). The Feasibility of Intervention Measure,[52] the Acceptability of Intervention Measure,[52] and the Program Sustainability Assessment Tool[53] are employed to analyze implementation.

Discussion

This study addresses important gaps in building implementation capacity in cervical cancer prevention and control in LMIC settings. Using mixed methods, it builds both adaptation and implementation process knowledge of an evidence-based patient navigation intervention in Senegal. A 2019 Scoping Literature Review identified 14 studies that reported on cancer-focused patient navigation interventions across all LMICs, none of these documented the utilization of an implementation science framework. All of these studies were solely quantitative, and only two focused on cervical cancer, both in Brazil.[17,54,55] Only a single patient navigation article (focused on breast cancer) was set in Africa.[56] With nearly 87% of all cervical cancer deaths occurring in LMICs,[57] there is considerable opportunity for impact through the implementation of patient navigation programs. This requires greater knowledge of how to implement this model in various new contexts, especially with a consideration of the differences between urban and rural settings in LMICs. Specifically, there are no published articles reporting on the adaptation of a cancer-focused patient navigation program in an LMIC. This research will fill this critical gap.

This research evaluates the effectiveness of a patient navigation program to address cancer stigma for women in Senegal. In rural settings in LMICs, cancer stigma[58–61] is high, especially for women, and imposes a considerable burden on care-seeking and social support.[9,22] Social stigma can manifest as personal stigmas (ie, how one views and treats others) or as perceived public stigmas (ie, how one thinks others view and treat them).[62] In addition, the expression of attitudes related to stigma is moderated by social influence—that is by the ability of individuals to affect one another's thoughts, ideas, and behaviors.[63–65] In these ways, negative social influences play a role in spreading negative behaviors[63,66] and may be linked to cervical cancer screening hesitancy. While a single 2019 article reports on the theoretical value of a patient navigation program to address cancer stigma in Tanzania,[67] the literature is otherwise lacking in evidence concerning the process and impact of patient navigation programs on personal and perceived stigmas in LMICs.

This study builds knowledge regarding the process and the impact of how a patient navigation program addresses cultural disadvantages for women in Senegal, namely autonomy in healthcare decisions. Research in this region in Senegal as well as other literature have demonstrated that women's capacity to access healthcare services are

significantly impacted by health behaviors and complex gender beliefs of both men and women.[9,22–25] Decisions regarding when and the manner for which women gain healthcare access are frequently made by elder family members or men.[68] Women's ability to seek cervical cancer screenings and utilize services is reduced by perceived discrimination,[69] and shame and stigma.[68] In contrast, empowered women display an uptake of healthcare services through access to their financial resources and ability to dictate their healthcare decisions.[70–72] By studying the perceptions of women and men and the effect of a patient navigation program on both women and men, the project will build valuable knowledge on how to both empower women and engage men in supporting a woman's decision-making ability relative to getting screened for cervical cancer.

The evaluation of the implementation of a cancer-focused patient navigation program builds knowledge at the primary healthcare level. The majority of the published literature regarding cancer-focused patient navigation programs in LMICs is at the tertiary care level and in many ways mirrors the approach seen in high-income countries. This project builds knowledge in addressing barriers at the intrapersonal and community levels in urban settings as well as in the rural context where socio-cultural barriers and weak health systems are considerable challenges.[17,26,27] In LMICs, cancer care remains much more accessible to higher socioeconomic class populations within urban centers.[9] The research builds much needed knowledge in urban and rural settings at the primary healthcare level and builds evidence of ways to reduce health disparities. The project identifies gaps and enables the development of learning health systems by helping women overcome structural barriers while addressing these barriers in a systematized way.

Limitations

Mitigation plans include: 1) Language and translation: Because this study involves translation, possibilities for mis-understandings emerge which are systematically attended to through a multilingual research team and ongoing review of translation issues paying specific attention to translation of emergent/ key concepts in local languages into French and English, and 2) Purposive sampling can be prone to research bias. The selection of the members of the NAB and RIRT are guided by local officials. Because three sites in each district are sampled, a wide range of perspectives and experiences are expected. 3) Generalizability: The results of this study may not be generalizable to the rest of Senegal. However, the selected regions are similar to other rural and urban regions in Senegal in terms of population density, poverty rates, ethnicity, and religion, and the likelihood of generalizability to other regions is high.

Conclusion

The goal of this project is to prevent unnecessary deaths due to cervical cancer in Senegal. This mixed methods research responds to identified intrapersonal- and community-level barriers to early cervical cancer screening uptake, follow-up, and treatment among women in Senegal. This research project applies the Dynamic Adaptation Process[35] as integrated into the Exploration, Preparation, Implementation, Sustainment framework[35] to study the adaptation of an evidence-based cervical cancer patient navigation program in urban and rural contexts in Senegal, measure the intervention effectiveness, and evaluate programmatic implementation outcomes. The project demonstrates innovation by advancing both adaptation and implementation process knowledge of an evidence-based patient navigation intervention in various contexts within a LMIC with a particular focus on how the adaptation responds to cancer-related stigma and women's autonomy in healthcare decision-making. Knowledge is built through local learning which will further the long-term goal to inform the national cervical cancer prevention and control programs in two areas of Senegal and other similar LMICs.

Disclosure

The authors report no conflicts of interest in this work.

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