Designing an Ethnodrama Addressing PrEP Stigma Toward Young Cisgender Women in Kenya

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RESEARCH STRATEGY

A. Significance

A.1. Adolescent girls and young women (AGYW) in sub-Saharan Africa (SSA) are disproportionally affected by HIV and continue to have high HIV incidence. Young women (YW) in Siaya County, Kenya, the location of our research, are especially at high risk for HIV. In 2021, approximately 4,900 YW worldwide were diagnosed with HIV every week.[49] Global new HIV infections in 2019 were nearly 3 times higher in adolescent girls compared to adolescent boys, and 1.5 times higher among YW compared to young men;[1] 82% of new infections in YW globally were among YW living in SSA.[1] Within SSA in 2020, AGYW accounted for 63% of all new HIV infections,[50] and new HIV diagnoses among African AGYW were disproportionate to their population size: AGYW account for 25% of new infections yet comprise only 10% of the population.[50] These gender-disproportionate trends are similar in Kenya. Of the 29,000 new HIV infections among people ages 15 and older in Kenya in 2021, 21,000 (72%) were among females and 8,900 (31%) were among males.[51] Geography is also relevant—the HIV epidemic in Kenya is concentrated primarily in one-third of its counties, including Siaya County. Of all counties in Kenya, Siaya County was ranked third in HIV prevalence in people 15 to 64 years of age in 2018.[52] Among youth 15 to 24 years of age in 2017, Siaya County had the highest HIV prevalence in Kenya (~39,000) and the third highest number of new HIV infections (1,641).[3] Because of this heightened risk, the Kenyan government has identified YW as a priority population in their PrEP scale-up plans and Siaya County as a key geographical area of focus.[2]

A.2. Oral PrEP can reduce HIV acquisition[53] among YW, although challenges remain with PrEP adherence and persistence. The impact of PrEP on HIV acquisition among YW depends on whether YW use PrEP once daily as directed (adherence) and for as long as their risk persists (persistence).[54] YW's high rates of oral PrEP uptake in open-label studies and local programs[4,6–9] in SSA suggests interest in initiating PrEP. However, maintaining PrEP adherence and persistence over time has proved challenging. For example, the HPTN 082 open-label PrEP study of 427 YW in South Africa and Zimbabwe reported a significant decline in adherence among YW after 3 months of use.[4] While the standard adherence approaches used in HPTN 082—one-on-one counseling, SMS/text messages, peer support programs—and an enhanced approach on drug-level feedback—appeared beneficial when young women first initiated PrEP, these strategies did not sustain PrEP adherence at the levels needed over time.[4] Similarly, the POWER study among AGYW in Kenya and South Africa had high PrEP initiation rates, yet only 31% returned for their 1 month PrEP refill.[9] For programs, the PEPFAR-funded DREAMS program[55] offers PrEP as part of a core package of activities to support YW, in addition to interventions such as economic strengthening and youth-friendly clinics. Although DREAMS has demonstrated feasibility in providing PrEP to YW in Kenya[56] and has reduced HIV incidence for YW in DREAMS in some places,[57–59] other DREAMS sites report limited evidence of an effect among YW,[60,61] suggesting that ongoing challenges with PrEP adherence and persistence remain.[6] Innovative interventions to support PrEP adherence and persistence among YW are needed.[62,63]

A.3. PrEP stigma must be reduced before YW can comfortably adhere to PrEP for as long as their risk persists. Stigma's mechanisms of action typically intersect with multiple co-occurring statuses or positions of the individual engaging in HIV prevention and generates variations of intersectional stigma.[64] YW experience intersectional stigma[26,27] such that gender-based stigma related to sexuality norms,[26,28,29] age-based stigma,[27] and HIV-related stigma due to HIV treatment medications and being perceived by others as having HIV[26,29] are inextricably part of PrEP-related stigma toward YW. PrEP-related stigma has multiple mechanisms of action: (1) enacted PrEP stigma—actual prejudice and/or discrimination towards individuals who use PrEP, (2) anticipated PrEP stigma—expected future prejudice and/or discrimination because of PrEP use, and (3) internalized PrEP stigma—integrated acceptance of PrEP prejudice and stereotypes by others into the PrEP user's self-concept.[25] Calabrese writes that stigma undermines PrEP use "whether operating alone or in concert with other, intersecting forms of stigma;"[25] results from an expression of social power; and leads to differential treatment and people being devalued,[25] such as YW taking PrEP. Ultimately, Golub stresses that "PrEP stigma significantly impedes PrEP acceptability, uptake, adherence, and persistence, by creating barriers to acceptance at the patient, provider, and community levels."[30]

Our R21 and other studies have described PrEP-related stigma experiences in Kenya[22,24,65,66] and elsewhere in SSA.[67] For example, YW (and female sex workers and men who have sex with men) participating in a PrEP scale-up program experienced discrimination from peers, sexual partners, family, healthcare providers, and community members,[65] suggesting a need for normative change. An open-label PrEP demonstration project in South Africa identified concerns about ARV-related stigma as a barrier to PrEP use.[67] Several reviews have

called for interventions targeted at multiple domains of stigma (i.e., internalized, anticipated, enacted),[68,69] intersectional stigma,[69–71] and multiple socio-ecological levels of stigma.[69] Ma and colleagues[68] illuminated the largely untapped potential of low cost technologically delivered interventions, particularly for participants living in remote areas. Lastly, two reviews highlighted the need for community engagement in development, implementation, and evaluation of stigma-reduction interventions.[68,70]

A.4. Our R21 findings on PrEP adherence and persistence among young cisgender women (YCW) in Siaya emphasize the need for interventions to include community-level strategies to support YCW's PrEP use and reduce PrEP stigma.[22,24] (We refer to YW in our research as YCW). R21 participants were YCW who had initiated PrEP and members of their social ecology—i.e., female peers, male partners and peers, family members, and community members, including community leaders and healthcare providers. Through a series of data collection activities, participants shared the multi-level factors that either facilitated or impeded YCW's PrEP use. As detailed below in section C5, participants described factors on the broader social-ecological levels that positively and negatively influenced YCW's PrEP use. Reports of PrEP misinformation and stigma were pervasive at multiple ecological levels (e.g., female peers, male partners, community members). Participants stressed the need to normalize PrEP in their community.

A.5. Few PrEP adherence and persistence interventions for YW include strategies to increase community support of YW's PrEP use. Behavior change interventions are more likely to be successful when embedded within supportive environments,[72] where prevailing social norms encourage PrEP use as part of a healthy lifestyle,[63] and PrEP use is normalized within communities and social networks rather than stigmatized. YW may be better able to implement the skills learned during one-on-one PrEP adherence counseling or feel more comfortable accessing PrEP services through youth friendly clinics, for example, when their environment supports or even encourages them to use PrEP. Currently, however, the most commonly-reported approaches used in studies and programs in SSA to support PrEP use among YW are at the intrapersonal-, interpersonal-, and provider/clinic- levels of the social-ecological model[73] (e.g., counseling, pill boxes, reminders, peer support, male engagement, economic and education strengthening, cash transfers, provider communication, and various PrEP-delivery models)[4,8,10–21] and are not embedded within broader community-level interventions. Success of these prior interventions has varied—and of those studies that measured adherence or persistence, several have shown limited effect [10–12]. This suggests a need for new approaches that attend to the powerful socio-ecological influences on YW, particularly the roles of peers, sexual partners, families, and communities, and a need for interventions to address social norms and reduce PrEP stigma.[63] The broader socio-ecological influences on individual-level PrEP behavior among YW have been acknowledged;[74] yet interventions that focus on normalizing and supporting YW's PrEP use at the broader ecological levels are limited. In recognition of these broader-level influences, developing interventions beyond the individual level is now a high priority area for the National Institute of Mental Health Division of AIDS Research.[48]

A.6. Using storytelling through drama is a culturally congruent community-level strategy that can change beliefs, yet it is underutilized in PrEP interventions for YCW. Storytelling through drama has deep roots in African culture and is used as entertainment, to create community connections and establish norms, and to share information.[31–34] Powerful stories help people make sense of the world and create a framework for constructing meaning out of observations and experiences.[42] Exposure to metaphors and lessons contained within stories provide a vehicle for cultivating shared values and worldview. Where groups hold disparate worldviews, one finds conflict, misunderstanding, and resistance to cooperation as a result of hearing, seeing, and internalizing differing stories about how things have come to be the way they are. Storytelling enables people to examine the connections between their personal truths and the social-political realities of society with shared or disparate appreciation of how social factors influence our health and that of our neighbors.

Research has shown that storytelling can result in changes in attitude or beliefs among listeners.[35–37] A randomized control trial (RCT) among African American patients in the U.S. demonstrated improvements in blood pressure in patients who learned about hypertension through the storytelling of patients' experiences via DVDs compared to usual care.[36,75] Another RCT, conducted among a racially and ethnically diverse sample of U.S. women, demonstrated a significant difference in attitudes toward cervical cancer screening among women who watched a short film using storytelling about cervical cancer compared to the same information presented in a non-narrative format.[37] In Nigeria, researchers tested an entertainment-focused educational TV series developed for young adults using storytelling, and reported significant improvements in HIV knowledge and attitudes.[76] Drama interventions using storytelling have also been previously implemented in SSA, including in Uganda, Tanzania, South Africa, Swaziland, and Lesotho, and on topics such HIV and stigma toward LGBTQ+ people.[38,39,77] Several studies have demonstrated effectiveness of such interventions. In South

Africa, changes in HIV knowledge and attitudes were shown among secondary students who participated in a drama educational intervention compared to students who received written information.[38] In another South African study, a drama-based intervention significantly increased engagement in HIV voluntary counseling and testing services in the intervention communities compared to the control communities.[39]

In summary, scientific evidence on HIV acquisition supports including YCW in Siaya in HIV prevention research. The proposed intervention addresses a gap in PrEP interventions for YCW and is supported by our R21 findings that demonstrate stigma is a barrier in YCW's use of PrEP. Our study aligns with the (1) Fogarty International Center's stigma reduction goals, (2) NIH HIV/AIDS research priorities to identify "effective socio-behavioral interventions to achieve uptake of HIV prevention and treatment strategies and reduce health disparities,"[78] and (3) NIMH Division of AIDS Research priorities to "advance the development and testing of interventions delivered beyond the individual level, by incorporating appropriate context into intervention development and testing."[48] By achieving our study aims, we will move the field forward by identifying an acceptable and feasible stigma intervention that supports YCW's PrEP use that we can evaluate for its effectiveness at increasing PrEP adherence and persistence among YCW in a larger future R01.

B. Innovation

Our proposed research is innovative in four ways: **First**, most PrEP interventions for YCW focus on the intrapersonal level (e.g., counseling, SMS reminders, drug level awareness), interpersonal level (e.g., partnership communication), and clinic level (e.g., different models of PrEP delivery),[4,8,10–21] whereas we will develop, rigorously pre-test and pilot test, and build team capacity for implementing a community-level intervention. To our knowledge, no community-level drama interventions have been tested on changing the narrative on PrEP use among YCW in SSA. Participants in our R21 suggest that community-level interventions that normalize PrEP are needed, and research has shown the effectiveness of drama interventions. **Second**, we will use a culturally-congruent means of communication—storytelling through dramas—to create a supportive environment for YCW to take PrEP. The drama storylines will be informed from our R21 findings, community input, local drama approaches, and social change theater strategies. **Third**, we will bring the ethnodramas to "where people are" and conduct the performances in areas where PrEP-related misinformation and lack of support cultivate and spread (e.g., markets). **Fourth**, the dramas include interactive audience engagement approaches, setting them apart from passive media approaches (e.g., video stories).

C. Approach

C.1. Overview: Our long-term goal—to be tested in a subsequent, larger R01—is to increase PrEP adherence and persistence among YCW by fostering change in community members' attitudes, behaviors, and motivations toward YCW taking PrEP. YCW's use of PrEP is expected to be enhanced because the future intervention reduces enacted stigma[25]—i.e., the community narrative supports rather than stigmatizes YCW's use of PrEP. The intervention is also expected to reduce internalized and anticipated stigma[25]—i.e., YCW no longer report feeling guilty or having fear of being stigmatized as common factors that negatively impact their PrEP use. The intervention may also influence PrEP uptake—i.e., for YCW women contemplating taking PrEP, concerns about stigma may no longer be a key factor to consider when deciding if PrEP is right for them.

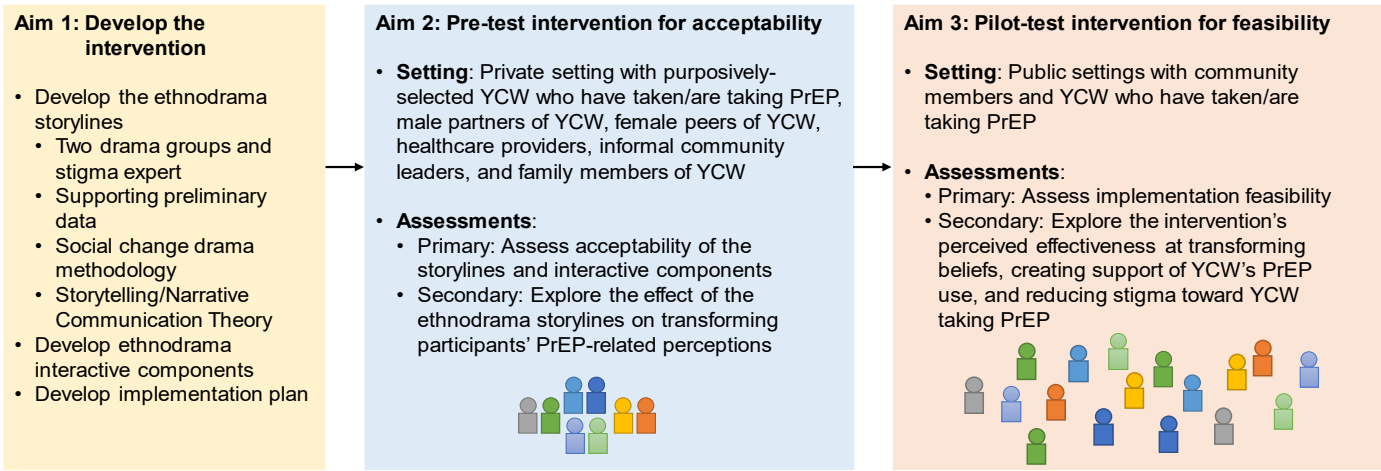
As the first step in reaching that goal, the purpose of this proposal is to develop, pre-test, and pilot a community-level ethnodrama intervention that includes storylines designed to transform community member beliefs about and foster support of YCW's PrEP use, thereby reducing PrEP-related stigma toward YCW using PrEP. In **Aim 1**, we will develop the ethnodrama intervention in partnership with a Kenya-based drama group and a U.S.-based organization focused on fostering social change through interactive theater. In **Aim 2,** we will pre-test the ethnodrama storylines for their acceptability and explore their effect on transforming participants' PrEP-related perceptions among invited community members. In **Aim 3**, we will pilot the ethnodrama intervention in public spaces in multiple areas in one sub-county of Siaya, focusing on assessing the feasibility of implementing the ethnodrama intervention and exploring the intervention's perceived effectiveness on transforming beliefs, creating support of YCW's PrEP use, and reducing stigma (Figure 1).

C.2. Sex as a biological variable: Our decision to conduct research focused exclusively on YCW in Siaya County, Kenya, is based on epidemiological data demonstrating the disproportionately high numbers of new HIV infections among YW (ages 18 to 25) from this area in Kenya (as outlined in section A.1.).

C.3. Setting. The proposed research will focus on Siaya County, Kenya, a location identified by the Kenyan government as a priority geographic area for HIV prevention interventions.[2] We will conduct the Aim 3 pilot in one sub-county in order to limit exposure to the intervention and reduce intervention contamination[79] among

individuals in Siaya who may be included in the subsequent R01 study. All Kenya-based activities will be coordinated by the Impact Research and Development Organization (IRDO), a large local organization that implements programs and studies funded by PEPFAR, NIH, and others. Dr. Kawango Agot (co-I) is the founder and director of IRDO. Since 2003, IRDO has implemented almost 70 HIV prevention and other health-related studies and programs, including their ongoing NIGEE program for youth and the PEPFAR-sponsored DREAMS Initiative from 2017 to 2021, which has provided over 4,000 YCW in Siaya access to PrEP.

Figure 1: Overall study design



C.4. Study team: We have a strong multi-disciplinary team of investigators representing experts in PrEP, social change theater, evidence-based intervention development, stigma interventions, and evaluation (Table 1). The leadership team includes some of the same investigators from our R21 (Agot, Corneli), plus additional investigators (Dickinson, Relf) needed to provide expertise to successfully implement the proposed and subsequent research. Drs. Agot and Corneli, and their respective teams, have collaborated on multiple studies since 2007 (e.g., FEM-PrEP, R01MH095531, U19AI144182), resulting in 17 publications thus far. We promote bi-directional capacity-building activities in our studies (e.g., IRDO to Duke: Kenya context, survey data collection; Duke to IRDO: qualitative data collection and analysis, manuscript writing).

Table 1. Research Leadership Team

Name	Affiliation	Expertise	Role
Amy Corneli, PhD, MPH (PI)	Duke University	• PrEP use among YCW • Using data and partnering with communities to inform interventions • Program evaluation	• Leads overall scientific direction and oversees all data collection and analysis • Co-leads intervention development in Aim 1 • Leads pre-test and pilot implementation in Aims 2 and 3
Kawango Agot, PhD, MPH, MPhil (co-I)	Impact Research and Development Organization	• PrEP use among YCW • HIV research and prevention programs for YCW in Kenya	• Contributes to overall scientific direction • Oversees all Kenya-based activities
Lyn Dickinson, MEd (co-I)	Theater Delta	• Social change theater	• Co-leads ethnodrama development in Aim 1 with the Kenya-based drama group and PI • Helps prepare local drama group for Aim 2 pre-test and Aim 3 pilot
Michael Relf, PhD, RN (co-I)	Duke University	• Stigma interventions and measurement	• Contributes to storyline development in Aim 1 and adaptation after Aim 2 pre-test and Aim 3 pilot-test • Contributes to use of the validated NTS

C.5. R21 Preliminary research

C.5.1. Overview. Drs. Corneli (PI) and Agot (co-I) were previously awarded R21MH116778, *Picture Me HIV Free: Identify Multi-Level Factors Shaping PrEP Adherence and Persistence among Young Women in Siaya, Kenya*. R21 participants' narratives will inform the storylines in the ethnodramas. The R21 was informed by findings from FEM-PrEP,[80] a Phase III safety and efficacy trial of PrEP conducted in Kenya, which illustrated discouragement in using PrEP by members of YW's social ecology,[81] including male partners, female peers, and community members. Dr. Corneli was the behavioral PI of FEM-PrEP and Dr. Agot was a site PI.

C.5.2. Study design and participants. Using photovoice, a community-based participatory research method where community members use photography, stories, and critical reflection to identify, describe, and discuss community concerns, YCW (n=20) and four groups in their social ecology—female peers (n=15), male peers and partners (n=13), family members (n=15), and community members, including healthcare providers (n=14)—participated in three iterative activities. First, participants photographed factors influencing YCW's PrEP adherence and persistence and wrote captions to communicate the photograph's relevance. YCW's images depicted their perspectives of influential factors from various social ecological levels. Other groups' images included observer perspectives and direct/indirect influences according to their specific group. Second, participants discussed photographs with their own group (e.g., YCW discussed with other YCW). Third, YCW and members in other groups (e.g., female peers) discussed each other's photographs and answered questions on themes identified from previous discussions. After completion of these activities, YCW shared their individual experiences on themes during in-depth interviews (IDIs). We also explored during the IDIs YCW's perceptions of the proposed intervention described here. All discussions/interviews were audio-recorded, simultaneously translated/transcribed, and analyzed using applied thematic analysis.

C.5.3. Findings. Table 2 describes the R21 findings[22–24] that support the proposed ethnodrama intervention. We have reported elsewhere results from other sub-analyses.[82] Our findings suggests that misinformation about PrEP persists in the community, leads to PrEP-related stigma, and negatively influences PrEP use among YCW. These data suggest that interventions to address PrEP-related stigma are needed[22,24] and that ethnodramas are perceived to be an acceptable intervention mechanism.

Table 2: R21 data supporting the proposed ethnodrama intervention

Broader-level interventions needed:

- Participants' photographs/discussions suggest that interpersonal-, organizational/structural-, and community-level factors more meaningfully influenced YCW's PrEP adherence compared to intrapersonal-level factors.
- PrEP-related stigma was the most frequently-identified negative community-level and overall factor affecting YCW's PrEP use.
- The most frequently-identified positive influence on PrEP adherence was interpersonal factors—having positive interactions about PrEP with others, such as partners, female peers, and elders, and receiving emotional and instrumental social support; conversely, lack of support and negative peer interactions were frequently-identified as negative interpersonal factors.
- Participants noted both the lack of privacy at PrEP distribution sites and having to stand in line with people accessing HIV treatment as barriers to access, which they directly linked to PrEP stigma.
- Participants stressed the need to normalize PrEP in their community.

PrEP-related misinformation and rumors:

- IDIs with YCW using PrEP revealed the pervasiveness of perceived and enacted community stigma toward women using PrEP. Nearly all participants described instances of being stigmatized by community members and/or peers for using PrEP or going to a PrEP distribution site.
- YCW who reported being able to avoid experiencing stigma noted how they purposefully keep their PrEP use secret in order to avoid negative comments from others.
- PrEP-related rumors that spread within the community include assumptions that women who take PrEP are promiscuous or practice sex work, are HIV-positive and hiding ARV use, and are using family planning.
- Rumors also include beliefs that PrEP interferes with a woman's ability to conceive; that PrEP can cause dizziness, vomiting, and loss of appetite which could hinder a YCW from doing her daily activities; and that extended use of PrEP can cause HIV, cancer, or other ailments.
- YCW often described their husband's/partners' misperceptions about PrEP and that lack of support was a major barrier to adherence; some YCW described feeling more resilient toward community rumors and PrEP stigma because they knew that their partner supported their PrEP use.

Women's perceptions of the use of drama interventions:

- YCW in the IDIs were highly supportive of an ethnodrama intervention. Many felt that the entertainment value of a drama would attract a diverse audience, which they felt was important in order to educate the broader community about PrEP and to help normalize PrEP acceptance.
- YCW in the IDIs felt it would be important to include community health volunteers (CHVs), doctors, and possibly other YCW who were willing to share their experience with taking PrEP in the production of the dramas.
- Several YCW suggested that dramas could encourage the audience to be more aware of their personal role in promoting and supporting PrEP use and encourage the audience to share factual information about PrEP in their communities, thereby furthering the impact of the intervention to those who do not attend the events.

C.6. Aim 1: Develop the interactive ethnodrama intervention.

C.6.1. Overview: The purpose of Aim 1 is to develop the ethnodrama storylines and interactive components, including the implementation plan.

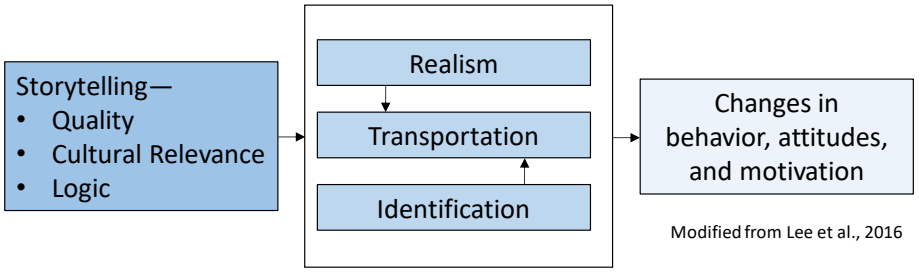
C.6.2. Developing the ethnodrama storylines and audience engagement components:

Ethnodrama definition, goal, and audience: Ethnodramas are "the written transformation and adaptation of ethnographic research data (e.g., interview transcripts) into a dramatic playscript staged as a live, public theatrical performance."[83] Ethnodramas include powerful stories that help people make sense of their observations and experiences within their communities and can ultimately contribute to shared values and perspectives. Often people experience conflict, misunderstanding, and are resistant to acceptance of others when they hold different perspectives. Storytelling enables people to examine the connections between their personal truths and those with shared or disparate views and examine how these views influence their health and that of their neighbors.[84,85]

The goal of our ethnodrama intervention is to foster positive attitudes, behaviors, and motivations among community members toward YCW taking PrEP. The storylines will be designed to reach members of YCW's social ecology: female peers, male peers and partners, family members, health care providers, and other influential community members (e.g., local leaders, boda-boda drivers). The premise is that when audience members engage in the conflict of the characters and in a dialogue with the other audience members, they will more readily be able to identify with the characters and question or change their perceptions about PrEP use. Interactive theater provides opportunities for people to explore choices and the consequences they bring in an environment that encourages them to take risks with the potential to learn rather than to fail. These scenarios and participant engagements are a practice for real life, encouraging audience members to take action and be the protagonist in their own lives with a better understanding of the motivations and emotional influences around moments of decision.

***Theoretical foundation*:** We will create the ethnodrama component following the core concepts of the Storytelling/Narrative Communication Theory (SNC)[40] (Figure 2). The SNC theory describes three core concepts that link storytelling to changes in behavior, attitude, and motivations: (1) transportation, (2) realism, and (3) identification.

Figure 2. Storytelling/Narrative Communication Theory



Modified from Lee et al., 2016

Transportation means simply that listeners are *transported* into the world told in the story.[86] When listeners engage in narratives crafted using elements of persuasive communication theory—primarily attention, imagery, and feelings[42,86]—they become connected to the story's characters, and may change beliefs. Listeners use the characters' experiences to better understand their own experiences and beliefs[87] and in this way, they become more open to new information.[86]

However, for listeners to engage in the story, storylines must be developed with *realism*; in other words, the story must be believable and culturally relevant for the audience. To promote realism, we will use participant narratives from the R21 to create the storylines, including specific examples of stigma (enacted, anticipated, and internalized)[25] and scenarios about misinformation shared by participants. Listeners' perceptions of the *realism* in the storyline have been shown to be positively correlated with *transportation.*[88]

Finally, listeners *identify* with a character by "adopting the perspective and emotions of the character,"[89] which is correlated with emotional engagement in a story.[89] To promote identification, we will use the R21 and the local drama group's expertise to create story characters that feel familiar to the audience, to help the audience adopt the perspective and emotions of the characters, and to increase emotional engagement with the story, which leads to a willingness to examine new ways of thinking about the issue(s) presented.

***Storyline Development Process*:** Working collaboratively through a series of online Zoom and in-person workshops, members of the Eldoret Film Festival, a Kenyan-based drama group (see letter of support [LOS]), Ms. Lyn Dickinson (co-I), a Theater Delta leader with experience working in East Africa, and Dr. Relf will develop the storylines following Theater Delta's 7-step development process for creating social change dramas (Table 3). Drs. Agot and Corneli will provide content-specific PrEP-related guidance. Members of the Eldoret Film Festival are experts in the development of drama storylines for Kenyan audiences.

Table 3: Theater Delta's 7-Step Development Process

Step	Activity
1	Identify the main goal of each performance based on research (i.e., the R21 findings)
2	Brainstorm possible scenarios to address each goal
3	Outline the chosen scenarios using the familiar framework of "who, what, where, when and how?" to help define realistic and identifiable characters, conflicts, settings, and actions (incorporating findings from the R21 and participants' de-identified narratives from transcripts)
4	Role-play to develop content with professional, culturally-fluent actors (i.e., the Kenya-based drama group together with Theater Delta)
5	Write the storylines, including audience engagement components
6	Obtain feedback on the storylines (i.e., from pre-testing, described below)
7	Revise the storylines

The starting point of the story will be a concrete situation taken from our R21 research, the story arc will pose challenges that require action,[90] and the audience members will choose the action and/or participate to further the story.[91] We will also include "cliff-hangers" at the end of each performance, designed to increase the audience members' discussion of the drama in between performances and heighten interest in attending the next performance. Storylines will be created to reach all members of YCW's social ecology: female peers, male peers and partners, family members, health care providers, and other influential community members. Performances will be in the local language spoken in Siaya (Dholuo), and the script development process will include discussions on the linguistically appropriate translation of concepts.

Audience engagement process: Audience engagement is a key component in Theater Delta's approach for social change. We will therefore develop an audience engagement plan to increase the emotional engagement with the story's characters and to encourage discussion with others in between performances. The extent of audience engagement will be determined during Aim 1. At a minimum, after each performance, the actors will mingle with audience members and ask specific questions to engage viewers in dialogue individually or in groups about the performance's content. We will develop a series of questions that the actors will ask. Community health volunteers (CHV) will also mingle with the audience, although they will focus their discussions with specific, pre-identified target audiences (e.g., male partners). We will determine the goal of CHV engagement for each performance, who the CHVs should target, talking points/main messages, and how to document each engagement. Other audience engagement activities we will explore include: (1) encouraging the audience to ask the characters questions to understand their reactions to the situation and challenge them around their attitudes and behaviors; (2) replaying the scene and asking the audience to say "stop" after a particular segment to allow the character to share aloud what they are thinking; and (3) using audience members' suggestions to determine a different behavior for a character when replaying the scene to explore choices and consequences in a risk-free environment.

Community consultation: We will establish a community coalition to review the storylines and provide feedback. The coalition will include CHVs, YCW who have taken/are taking PrEP, and members of YCW's social ecology: male partners of YCW, female peers of YCW, healthcare providers, informal community leaders, and family members of YCW (n=15). We will make the suggested changes before Aim 2 pre-testing.

C.6.3. Developing the implementation plan: We will determine the length and the number of performances needed to communicate the full story and identify performance sites within one sub-county in Siaya for the Aim 3 pilot (e.g., 3 to 5 performances per location with a 5-to-10 minute scripted scene and 10-to-20 minutes of audience interaction). We will determine how best to promote the dramas in the community, and the location of the performances (e.g., outdoor markets, places of work, churches, barrazas [regular community meetings with village leaders]) based on the specific target audiences we want to reach (e.g., female peers, male partners, family, and community members); the same performance will be repeated in different venues to reach different audiences.

C.6.4. Aim 1 outcome. We will have fully developed ethnodrama intervention components, positioning the intervention for pre-testing in Aim 2.

C.7. Aim 2. Assess the acceptability of the ethnodrama storylines and interactive components.

C.7.1. Overview: The primary purpose of Aim 2 is to pre-test the ethnodrama intervention with YCW and a diverse group of community members prior to formal piloting in Aim 3. Through two rounds of pre-testing, we will gather feedback on the acceptability of (1) the storylines among audience members (e.g., perceptions of whether the storylines seem real and identifiable), and (2) the interactive components among audience members and staff (e.g., comfort level). The secondary purpose is to explore the effect of the intervention's storylines on transforming audience members' PrEP-related perceptions.

C.7.2. Implementing the pre-test: We will engage YCW who have taken/are taking PrEP and five groups of community members who are part of YCW's social ecology (n=60) in two rounds of pre-testing (female peers of YCW, male partners of YCW, healthcare providers, informal community leaders, and family members of YCW). These audiences mimic the study populations that were successfully enrolled in our previous R21. Members of the Eldoret Film Festival will train a local drama group in Siaya, the Tinada Youth Organization, to perform the ethnodramas and audience engagement components during the pre-test (see LOS). Training time, as well as time to rehearse the performances (before pre-testing, after the first-round of pre-testing, and after the second round of pre-testing), is woven into our timeline. We may hold multiple performances in each round depending on the number of performances overall and their length.

C.7.3. Recruiting for the pre-test: We will purposefully select[92] individuals to participate in the pre-test through the DREAMS program and other standard methods that IRDO uses to recruit for research participation. Detailed information is included in the separate recruitment and retention document. Individuals will receive compensation for their time and transportation costs.

C.7.4. Exploring the effect on transforming participants' PrEP-related perceptions: To evaluate the narrative engagement of our newly-developed ethnodrama storylines, after each performance in both pre-test rounds, participants will be asked to complete a brief interviewer-administered survey using the Narrative Transportation Scale (NTS).[42] This scale was originally validated in the U.S.,[42] and recently validated in Rwanda and Tanzania by Dr. Relf (co-I).[43] The 12-item scale is divided into two sub-scales: engagement and personal connection. Sample items include: "I wanted to learn what happened to the women after the story ended"; "The stories in the dramas are relevant to my everyday life"; and "The stories in the drama are realistic and believable." We will also ask selected questions from the Intrinsic Impact's Theory Impact Assessment survey. Sample questions include: "To what extent did you feel a bond or connection with one or more of the characters in the performance?" and "How much were your eyes opened to an issue, idea, or point of view related to PrEP use among YCW that you hadn't fully considered before?" Intrinsic Impact is an organization that evaluates transformation by cultural experiences and exposure to the arts.[93] We will also explore YCW's perceptions on the intervention's potential effect on their ability to use PrEP.

C.7.5. Assessing acceptability: After the individual assessments are completed (described in C.7.4), study staff will engage participants in small group discussions, divided by demographic groups, to explore the acceptability of the storylines. Group 1 includes 10 YCW and 10 female peers of YCW. Group 2 includes 10 male partners of YCW and 10 healthcare providers. Group 3 includes 10 informal community leaders and 10 family members of YCW. Questions will be informed by the constructs of the SNC theory,[40] and will focus on whether the audience perceived the storylines to be *real* (e.g., perceived plausibility, typicality, factuality, narrative consistency, and perceptual quality) and whether the audience perceives the characters in the dramas to be *identifiable* (e.g., relatedness to the characters and sense of connection).[41] We will also determine whether the audience can identify the main goal of each performance and gather suggestions for improving the performances. Questions will also assess the acceptability of the interactive audience engagement components, specifically focusing on the ease/difficulty of the audience engagement components from the perspective of the drama group and comfort level of participating among audience members and staff.

C.7.6. Analyzing the data:

Surveys: We will use descriptive statistics to review the NTS scores and examine response frequencies to the Intrinsic Impact survey to determine if participants in the pre-test appear to be engaged in the storylines. We will also examine scores/frequencies across participant demographic groups to determine if one group may be more engaged than another. Our sample size is small; therefore, we will review data descriptively.

Group discussions: The discussions will be audio-recorded and local study staff will listen to the audio-recording to summarize participants' responses in a structured debriefing form. Responses will then be rapidly analyzed[94] within and across groups for each performance.

C.7.7. Modifying the intervention: After Round 1 pre-testing is completed, we will make the necessary modifications to the intervention, such as modifying the script and/or audience interaction activities to address reported gaps in realism and/or relatability or to increase comfort level. We will meet with the coalition described in Aim 1 to review the revised storylines and other components, gather feedback, and incorporate the suggested modifications. The Round 2 pre-test will include some or all of the performances, based on Round 1 findings, and the Round 1 audience members will be invited to participate in Round 2. We will also administer the NTS and Intrinsic Impact survey and conduct the group discussions as described above, although the discussions will focus on obtaining feedback on the modifications made after the Round 1 pre-test. After the Round 2 pre-test is completed and we meet again with the community coalition to discuss any remaining modifications, we will finalize the intervention.

C.7.8. Aim 2 outcome. We will have fully developed and pre-tested the intervention, positioning the intervention for formal piloting in Aim 3.

C.8. Aim 3: Assess the feasibility of implementing the ethnodrama intervention.

C.8.1. Overview: The primary purpose of Aim 3 pilot is to assess the feasibility of implementing the ethnodrama intervention in its entirety. The secondary purpose of Aim 3 is to explore the intervention's perceived effectiveness at transforming beliefs, creating support of YCW's PrEP use, and reducing stigma toward YCW taking PrEP. In general, the efficacy or effectiveness of interventions cannot be determined in pilot studies due to the small sample size and because pilot studies assess the implementation of a draft intervention versus a final intervention (which is only available after pilot findings are incorporated).[95] Additionally, because our intervention focuses on changing the community narrative, we believe this can only occur after the intervention is implemented in more than one sub-county in Siaya *and* over a longer period of time. Therefore, in this Aim, we focus primarily on assessing feasibility of fully implementing the ethnodrama intervention in community spaces while also gathering perceptions of intervention effectiveness though a mixed-method design, relying heavily on participants' qualitative descriptions of how the intervention affected their perceptions of stigma and support for YCW's PrEP use.

C.8.2. Implementing the pilot: We will implement the ethnodrama intervention in its entirety in one sub-county in Siaya selected by the community coalition in Aim 1. The Tinada Youth Organization, the local drama performance group who performed the pre-test of the ethnodrama intervention in Aim 2, will perform the ethnodramas in Aim 3. After each performance, CHVs and the ethnodrama actors will mingle with the audience, focusing on discussing the storylines with key members of the audience, as identified in Aim 1. We will implement the ethnodramas "where people are"[79]—meaning that we will go to areas in the county, such as outdoor markets, where PrEP-related rumors and lack of support cultivate and spread, as identified by participants in our R21 research. We will finalize these locations during Aim 1 with input from the community coalition. We anticipate that the intervention will include a series of 3 to 5 performances, that each performance will take no longer than 20 minutes to implement (e.g., 10 minute performance followed by 10 minutes of audience discussion), and that it will take approximately three months' time to implement all the performances in all locations. We will conduct each performance in all selected community settings before implementing the next performance.

C.8.3. Measuring intervention feasibility: We will collect numerous feasibility measures and process indicators to assess the feasibility of implementing the ethnodrama intervention (Table 4). Feasibility constructs are informed by guidance on conducting feasibility studies[96] and evaluations of complex interventions.[97]

Table 4. Feasibility measures and process indicators

Constructs	Measures/indicators	Method of data collection and sample size
Acceptability	• Audience satisfaction with the performance • Appropriateness of performance content • Appropriateness of performance location	A short survey with 20 audience members after each drama, administered by research staff using iPads
Dose	• Number of performances delivered per protocol • Implementation time for each performance and by segment (scripted scene versus audience interaction)	Staff notes

Constructs	Measures/indicators	Method of data collection and sample size
Implementation	• Success or failure of execution, including interactive components • Amount and type of resources needed • Factors affecting implementation ease/difficulty, efficiency, quality	• Discussions with staff and drama group • Review of project expenses
Fidelity	Extent to which the drama script was followed per protocol	An observational checklist completed by research staff at each performance
Adaptations	Adaptations made to pre-tested versions of the script, performance schedule, locations	• An observational checklist completed by research staff at each performance • Research staff notes
Reach	• Number of audience members in attendance at each ethnodrama performance (beginning and end) by estimated age range and gender • Number of audience members engaged in after performance discussions, topics discussed, gender, ages	An observational checklist completed by research staff at each performance
Practicality/ Retention	• Ease/difficulty of performing ethnodramas in community locations • Ability of the audience to watch the drama • Community disruptions due to implementing the intervention in public spaces • Costs incurred versus budgeted	• Staff observations of performance • Discussion with drama group • Staff perceptions • Costs incurred • Research staff records
Recruitment	Influence of ethnodrama advertisements/how participants learned about ethnodrama performances	Measured during the short survey with 20 audience members after each drama, administered by research staff using iPads

C.8.4. Assessing perceived intervention effectiveness: We will use a mixed-method, sequential explanatory study design[44,45] to explore perceived intervention effectiveness with two study cohorts: YCW and community members. Participants will receive compensation for their time/transportation costs to attend each performance and complete the follow-up assessments. Table 5 lists all data collection events and time points.

YCW Study Cohort: We will recruit a cohort of 20 YCW who have taken/are taking PrEP to attend one of each of the performances (e.g., 3 to 5 performances in total). We chose a sample size of 20 as research has shown that meaning saturation can occur by 16 interviews;[98] recruiting 20 YCW will allow for attrition. We will assess YCW's perceptions of PrEP-related stigma at three time points—pre-pilot, immediately post-pilot, and 3 months post-pilot—using a 12-item PrEP-related stigma scale validated for key populations in Kenya.[46] The scale includes 4-point Likert responses categories (strongly disagree to strongly agree) in four dimensions: (1) interpersonal stigma, (2) PrEP norms, (3) negative self-image, and (4) disclosure concerns (measuring internalized, perceived and anticipated stigma). A qualitative, in-depth interview (IDI) will follow, asking YCW to share more of their perspectives on PrEP-stigma in each one of these dimensions, as relevant to them. For example, if YCW agreed to this statement in the PrEP-related stigma scale, "Are you afraid of losing friends if you tell them you have started or thought of using PrEP?",we will ask YCW to share more about their concerns if others find out if they were taking PrEP. Similar questions will be asked when YCW disagree with a scale item. We will also explore YCW's perceptions on whether they believe this intervention can result in less PrEP-related stigma (e.g, enacted stigma) among YCW in the future, and how, if at all, their own PrEP use has changed pre/post the intervention pilot.

Community Member Study Cohort: During the first performance of the series, we will randomly select and invite 20 community members (across all community locations) to attend one of each of the remaining performances. We will record attendance at each performance but not include any assessments; we want to avoid the study's assessments serving as an intervention and influencing beliefs independent of watching and engaging in the ethnodrama. After the last performance, we will administer the NTS and additional questions from the Intrinsic Impact's Theory Impact Assessment survey[99] including, "How much did you feel a sense of connection to others in the audience?", "To what extent did the performance push you to take some action, or make a change regarding PrEP use among YCW?", and "How much would you like to see

more performances like this?" After the surveys, we will also conduct an IDI with the Community Member Study Cohort to explore in more detail their answers to the NTS and Intrinsic Impact questions as well as ask questions about how the ethnodrama has affected their attitudes and support of YCW taking PrEP, if at all, and how it may influence other members of their community in the future (e.g., enacted stigma).

Additionally, after each performance in the series (e.g., performance #3), we will administer the NTS and selected Intrinsic Impact survey questions with 20 randomly-selected community members in attendance (across all community locations, n=~100), asking specifically about the performance the community member just attended. Short open-ended questions will also be embedded within the survey to explore reasons participants did not find aspects of the ethnodrama real or identifiable, when relevant.

Table 5: Intervention effectiveness data collection events and time points

Activity	Assessments and Performances*						
	Pre-pilot	Performance #1	Performance #2	Performance #3	Performance #4	Performance #5	3 months post-pilot
YCW Study Cohort (n=20):**							
Attend ethnodrama performances							
Complete assessments: (1) PrEP-related stigma scale and (2) in-depth interview	X					X	X
Community Member Study Cohort (n=20):**							
Attend ethnodrama performances							
Complete assessments: (1) NTS and selected questions from the Intrinsic Impact survey and (2) in-depth interview						X	
Audience Members* (n=100):**							
Attend ethnodrama performances							
Complete assessments: NTS and selected questions from the Intrinsic Impact survey		X	X	X	X	X	

*For demonstration purposes—the total number of performances will be determined in Aim 1.
**The same individuals—20 YCW and 20 community members who were recruited by study staff—will attend each performance.
***Different individuals—20 audience members who attended the performance based on performance advertising (total n=~100)—will participate in the assessment after each performance.
NTS: Narrative Transportation Scale

C.8.5. Recruiting for the pilot: We will purposefully select[92] **YCW** from IRDO's programs and government sponsored PrEP programs (see LOS) to be part of the YCW Study Cohort. We will select YCW who have previously or are currently taking PrEP. Recruitment for the **Community Member Study Cohort** is described above in Section C.8.4. For **general audience members**, we will not specifically recruit community members to attend the ethnodrama performances as we did in Aim 2. Rather, we will advertise the performances following methods typically used for promoting drama performances and other events in Siaya County. Audience members will not receive compensation for attending; however, members who participate in the post-intervention assessments will be compensated for their time. Additional information is found in the separate recruitment and retention document.

C.8.6. Analyzing the data:

YCW Study Cohort: We will descriptively compare the PrEP-related stigma scores among YCW across the three time points for any changes in scores. Due to the small sample size, we are not able to compare using statistical methods beyond descriptive statistics. We will use applied thematic analysis[100] to analyze the qualitative IDI data. To begin, the IDIs will be transcribed verbatim, following a transcription protocol.[101] Using NVivo 12,[102] two analysts will apply structural codes to segment participants' narratives into a priori conceptual categories, followed by inductive, content-driven codes to text for each of the conceptual categories. Inter-coder reliability assessments will be conducted throughout. Analysts will review the content codes for overarching themes and organize the data into emergent thematic groups. Analytical reports will be written, summarizing the main themes and sub-themes on the intervention's perceived effectiveness on transforming beliefs, creating support of YCW's PrEP use, and reducing stigma (enacted, anticipated, and internalized).

Additionally, because we are collecting qualitative data longitudinally, our analytical approach will take into consideration principles of longitudinal qualitative data analysis. Specifically, we will conduct the thematic analysis of the data cross-sectionally, focusing on participants' narratives at a single point in time (i.e., pre-pilot, immediately post-pilot, and 3-months post-pilot), as well as examining the data using a trajectory lens, examining descriptive changes over time.

Community Member Study Cohort and audience members: We will use (1) descriptive statistics to summarize NTS scores and responses and the Instinct Impact questions for each performance, and (2) applied thematic analysis[100] to analyze the IDI data, following the steps described immediately above.

Feasibility process data: Open-ended and qualitative data from the feasibility data collection tools will be summarized descriptively, and frequencies will be used to describe the quantitative feasibility measures.

C.8.7. Aim 3 outcome: After we analyze the pilot data, we will meet with members of the community coalition to determine, based on the totality of all the findings, whether the intervention is considered feasible with no modifications, feasible with specific modifications that the group will identify, or not feasible to proceed to effectiveness testing in a larger R01. Included in these discussions will be a review of the findings from the Aim 3 mixed-method study and identification of evidence that supports whether the ethnodrama intervention appears to transform community member beliefs about and foster support of YCW's PrEP and whether YCW believe a reduction in PrEP-related stigma would result in the future, warranting a larger R01 effectiveness trial in the future.

C.9. Potential problems and proposed strategies: Certain aspects may not be considered feasible initially. We have included significant community engagement aspects (local drama groups, community coalition)—and allowed appropriate intervention development, practice, and pre-testing—so we can modify ideas throughout the development process. Another potential problem is that community members may also not attend the drama performances. Although we will go to where community members congregate, if we experience small audience sizes, we will work with the community coalition established in Aim 1 to determine how best to enhance our recruitment plan, which may include additional announcements or different performance venues. Lastly, members of the two Aim 3 study cohorts may choose not to attend all ethnodrama performances. We will provide an incentive to encourage participation. Of note, we had very low attrition among YCW and community members who participated in our R21 study which included meeting on several occasions over numerous months to complete research activities.

C.10. Capacity-building activities: Throughout Year 1 of this proposed grant, the PI and the Duke team will engage IRDO staff in specific capacity building discussions on how to develop interventions to combat stigma using existing data/narratives describing stigma experiences. In Years 2 and 3, discussions will include how to pre-test and pilot stigma and other interventions using a combination of process indicators, survey responses, and qualitative findings. Additionally, we will continue our capacity-building activities in qualitative interviewing and analysis, including in-person training (Year 1) and ongoing activities/feedback interwoven throughout the grant lifecycle (e.g., rapid analysis of debriefing forms, and collaborative assignments for IDI analysis).

C.11. Dissemination of Study Findings: Prior to the traditional methods of disseminating study findings (e.g., conference presentations and peer review manuscripts), we will disseminate the study's findings to all participants in Aim 2 and the study cohorts in Aim 3, with their permission. We will also disseminate findings at the district government level and at community meetings. We inform participants and their communities of the study findings prior to the scientific community because participants generated the data, and therefore, should be informed first.

C.12. Replicability and scalability: Misinformation and stigma addressed in this intervention are not unique to Kenya[29,67,103–106] nor is the need to support YCW's use of PrEP.[28] Additionally, drama interventions are grounded within the African culture and have been shown effective at changing beliefs.[107] These factors support the applicability and replicability of this intervention in other areas in the region. We will document processes during the pre-test and pilot that will allow others in Kenya and elsewhere in SSA to adapt and replicate the intervention in the future, after a larger R01 study is conducted to determine effectiveness. Drama groups are also available in areas outside of Siaya county (e.g., Eldoret and Nairobi, see LOS), demonstrating the local capacity for implementing PrEP drama interventions and allowing for a larger, multi-site R01 in the future as well as demonstrating broader scalability of the intervention.

C.13. Next steps—an effectiveness R01: At the end of this developmental R01, we will have fully developed a community-level intervention that is ideally acceptable and feasible and is suggestive of positively influencing community members' perceptions of YCW taking PrEP. We will have the experience to rapidly initiate and implement the intervention on a larger scale in a subsequent effectiveness R01 that will measure the effect of the intervention on PrEP adherence and persistence among YCW. The subsequent R01 will include key study design features described in a recent review by Relf[107] (co-I) on the priorities for future stigma-related intervention research, such as use of an experimental, longitudinal design and validated PrEP scales.