



A Cervical Cancer Screening Toolkit for Somali Women: A Pilot Randomized Controlled Trial

Selemawit Ghebrendrias¹ · Sheila Mody¹ · Sierra Washington² · Balquiso Hussein³ · Fadumo Jama³ · Marni Jacobs¹

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Abstract

This study aims to determine whether a novel cervical cancer screening toolkit will increase rates of pap test completion and HPV vaccination among Somali women living in the United States. We conducted a randomized controlled, pilot trial from June 2021 to February 2022. Somali women aged 21 to 70 were randomized to either receive a toolkit (infographic, video and an in-person health seminar) or not. Health passports confirming a completed pap test and/or HPV vaccination by clinician signature were used to measure outcomes. The primary outcome was pap test completion and the secondary outcome was HPV vaccination. We enrolled 57 participants. Patients randomized to the treatment arm were significantly more likely to have had a pap test (53.7% vs. 3.7%, $p < 0.0001$) and were also more likely to have received the HPV vaccine (10.7% vs. 3.7%, $p = 0.6110$). This toolkit increased rates of pap test completion and more participants in the intervention arm received HPV vaccination, though numbers were low. The study design may serve as a reproducible model to determine the effectiveness of patient education materials.

Keywords Cervical cancer · HPV vaccination · Pap test · Somali women

✉ Selemawit Ghebrendrias
selgheb91@gmail.com

Sheila Mody
smody@health.ucsd.edu

Sierra Washington
sierra.washington@stonybrookmedicine.edu

Balquiso Hussein
bhusein@sfssd.org

Fadumo Jama
fjama@sfssd.org

Marni Jacobs
mbjacobs@health.ucsd.edu

¹ Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, M:9300 Campus Point Drive, MC 7433, La Jolla, San Diego, CA 92037, USA

² Department of Obstetrics and Gynecology, Stony Brook University School of Medicine, 101 Nicolls Road, HSC T9 Room 090, Stony Brook, NY 11794-8091, USA

³ Somali Family Service, Community Health Worker, 5348 University Ave Unit 203, San Diego, CA 92105, USA

Introduction

Over the last fifty years, great strides were made in the reduction of cervical cancer incidence and mortality in the US. Globally, however, it is still a disease of epidemic proportions with an estimated 250,000 deaths annually [1]. In stark contrast to the progress seen in resource-rich societies, 19 of the 20 nations with the highest cervical cancer burden reside in sub-Saharan Africa, where limited screening and lack of access to early treatment for HPV-related cervical dysplasia leads to 90% of the mortality [2, 3]. International inequalities are mirrored by ethnic disparities in the US, as Black women had the highest cervical cancer mortality rate between 200 and 2009, due in large part to the later stage at diagnosis [4, 5]. However, the inclusion of African-born immigrants as part of the US-born Black population often skews the data, as immigrants are less likely to receive a pap test even when compared to the uninsured US-born Black population [6–8].

Scientific breakthroughs have expanded our understanding of cervical cancer and facilitated the development of these screening and preventive measures. Notably, infection with human papillomavirus (HPV) is now known to increase risk of developing cervical cancer, with HPV genotypes

16 and 18 accounting for 70% of cervical carcinogenesis, as uninterrupted precancerous cells advance to malignant lesions [9–12]. Despite the availability of quadrivalent and 9-valent HPV vaccines, which have shown high efficacy in protection against high grade lesions and invasive cervical cancer, vaccination rates remain below the 80% goal set by the Healthy People 2020 initiative, particularly for African immigrants [13–19].

African-born immigrants are one of the fastest growing populations in the United States, doubling in size to 1.6 million from 2000 to 2012, with 29% of these immigrants coming from Eastern Africa [20]. Of these, over 50,000 Somali refugees have resettled in the US since 2008, including more than 10,000 in San Diego [21]. Somali women represent a vulnerable group with multiple studies revealing lower rates of cervical cancer screening and HPV vaccination [22–26]. Qualitative studies have identified multiple factors influencing uptake of preventive services in this population, from transportation costs and lack of knowledge regarding cervical cancer to linguistic barriers and a strong cultural preference to preserve modesty [27–29]. However, few intervention-based studies have been done to directly address cervical cancer screening [30–33].

Infographics as a patient education tool can improve health literacy and induce actionable change [34]. Building on this knowledge, we conducted a randomized controlled pilot trial to assess the effectiveness of a patient education intervention on rates of pap test completion and HPV vaccination among Somali women in San Diego, California. To our knowledge, this is one of a few randomized controlled trials utilizing a cervical cancer patient education toolkit as the intervention.

Methods

We conducted a two-group, randomized controlled pilot study between June 2021 and February 2022, in partnership with Somali Family Service (SFS), a community organization that provides culturally appropriate programs and services to refugee and immigrant communities of San Diego, California. The Institutional Review Board at the University of California, San Diego approved this study (IRB 202071). This study was designed to be completed in 3 phases:

Phase 1: Development of the Cervical Cancer Screening Toolkit

Prior to conducting this study, 6 semi-structured focus groups were conducted with 53 participants to examine the cervical cancer prevention practices of refugee women from the Middle East and Sub-Saharan Africa living in San Diego, California. Participants outlined patterns of pap test

and HPV vaccination avoidance while detailing desired components of a culturally-centered, cervical cancer prevention toolkit [35]. Additionally, an online review of over 100 cervical cancer screening infographics, brochures and videos were reviewed to assess the currently available resources. There were only four print and video resources identified that were primarily in Somali. Utilizing this information, components of a toolkit were developed that included a print and electronic infographic in addition to a video. These components educated women on the importance of pap tests and HPV vaccination. For this pilot study, all materials were translated into Somali (Supplemental Material 1A, 1B, 2A, 2B: English Infographic, Somali Infographic, English Video, Somali Video, respectively).

Phase 2: Validation of the Cervical Cancer Screening Toolkit

Assessment of the understandability and actionability (defined as the ability of consumers to identify what they can do based on the information provided in the materials) of the toolkit materials was done using the Patient Education Materials Assessment Tool (PEMAT) developed by the US Department of Health and Human Services [36]. Validation of the toolkit materials included review of the infographic and video by nine experts in the field, including four gynecologic oncologists and five general obstetrician gynecologists. An average understandability and actionability score below 70%, a threshold determined by the developers of the surveys, would warrant edits to the toolkit [37]. Somali community health workers reviewed all final materials to provide any additional edits as needed.

Phase 3: Randomized Pilot Test of the Cervical Cancer Screening Toolkit

In order to assess preliminary utility of the cervical cancer screening toolkit for use in a larger trial, we aimed to conduct a pilot study to examine pap test and HPV vaccination rates in women receiving the toolkit (intervention) versus those who did not (control). Those in the intervention arm received the cervical cancer screening toolkit which included an electronic version of the infographic, a video sent in a text message and a 30 min health seminar. The in-person session was held at the community center where participants received a printed version of the infographic and a culturally and linguistically appropriate lecture on pap tests and HPV vaccination led by two of the co-investigators, including a Somali-speaking community healthcare worker. The control arm received no additional outreach. An existing community-owned database of Somali women, organized and housed by Somali Family Service, was used to identify potential participants. Community health workers distributed

flyers to recruit participants. Those who expressed interest were called to determine eligibility based on self-reported information. Inclusion criteria consisted of women between the ages of 21 and 70, who self-identified as Somali and had not had a pap test in the last 3 years. Women were excluded if they were unable to provide verbal informed consent, currently pregnant, had a history of a total hysterectomy, currently incarcerated, or already enrolled in a research study.

A block randomization scheme was used to ensure equal sample size in each study arm with a block size of four. Once verbal consents were obtained, a sealed opaque numbered envelope was opened to determine the participant's allocation. All participants then received a health passport for data collection, either sent to them in an email, mailed to their home or picked up in person at the community center (Supplemental Material 3A, 3B: English Health Passport, Somali Health Passport, respectively). The health passport included a check box for completion of a pap test, HPV vaccination of the participants or a child within the participant's care, and confirmation of both by a provider's signature or clinic stamp. Due to privacy concerns within this study population, a limited amount of demographic data was requested. All participants who returned the health passports during the six-month collection period, regardless of their decision to get a pap test or HPV immunization, received a \$40 gift card.

Statistical Analysis

The primary analysis was an intention-to-treat approach, comparing the proportion of completed pap tests in both groups. Secondary outcomes included the comparison of HPV vaccination (self vs child in the participant's care) in each study arm. To ensure randomization was successful, relevant factors were compared between groups prior to analysis. Proportion receiving pap tests were compared between groups using chi-square. For HPV vaccination Fisher's exact test was used given the small sample size as detailed in the Results section below.

Results

A total of 60 women were approached for participation, with 55 randomized after one did not meet inclusion criteria and four declined to participate (93% participation rate, 55/59 eligible). Reasons for lack of participation included a general disinterest and a lack of transportation and childcare. Two participants in the treatment arm did not return their passports following the six-month collection period. There were a total of 28 in the intervention arm and 27 in the control arm for analysis (Fig. 1). Participants in both arms had

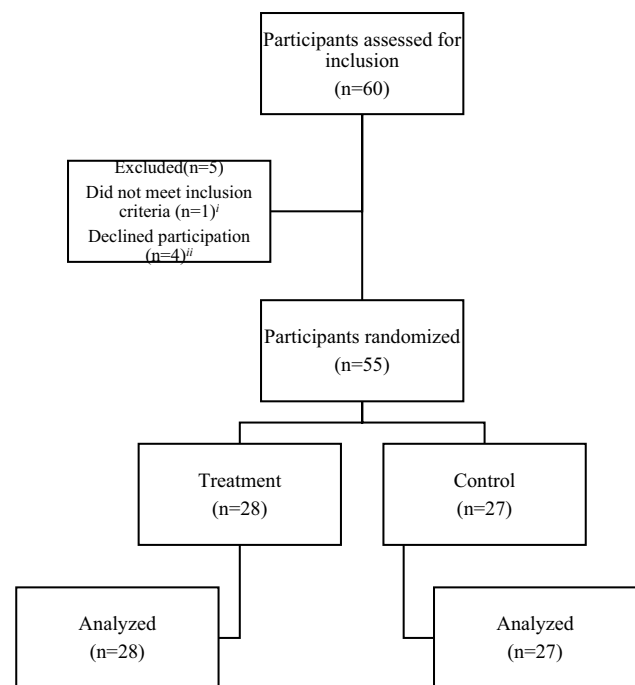


Fig. 1 Consort diagram of participants

similar baseline characteristics including age, number of children and healthcare settings (Table 1).

Regarding initial validation of the toolkit, nine experts in the field were approached for participation. This included four gynecologic oncologists and five general obstetrician gynecologists. For the printed materials, the average actionability and understandability scores were 100% and 99.3% respectively (Table 2). For the audiovisual materials, the average actionability and understandability scores were 100% and 95.6% respectively (Table 3).

Participants randomized to the intervention arm were significantly more likely to have had a pap test than those in the control group [(15) 53.7% vs. (1) 3.7%, $p < 0.0001$] (Table 4). For those who did not receive a pap test, an additional question of why they declined the intervention was listed on the health passports. Answers to this question among multiple participants in the intervention arm included: “I am not ready at this time”, “difficult to go to the clinic” and “worried about the pain”. Of the patients in the control arm who did not undergo pap testing, 0/26 responded to the declination question.

Rates of HPV vaccination (inclusive of both personally received vaccinations and those received by a child in the participant's care) were higher in the treatment arm [(3) 10.7% vs. (1) 3.7%, $p = 0.6110$], though numbers were small. In the treatment arm, there were no participants that reported having a child in their care between the ages of 9 and 26 immunized. There was only one participant in the

Table 1 Baseline characteristics

Characteristic	Number of participants	Total (N = 55)	Intervention group (N = 28)	Control group (N = 27)
Age-yr		37 (range 22 to 68)	37 (range 22 to 64)	43 (range 23 to 68)
Number of children		3.7 (range 0 to 12)	3 (range 0 to 10)	4.5 (range 0 to 12)
Clinic setting				
Federally qualified health center ^a		34	18	16
Private practice		6	1	5
Managed care ^b		6	3	3
Academic institution		1	1	0
N/A ^c		4	1	3

^aFederally qualified health centers are community health centers that receive funding from the national Health Resources and Services Administration to provide primary care services in underserved areas

^bManaged care refers to Kaiser Permanente, which is an integrated healthcare delivery organization

^cParticipants who did not fill in an answer on the health passport

Table 2 Patient Education Materials Assessment Tool (PEMAT): Printable Material

Item	Expert Reviewer	1	2	3	4	5	6	7	8	9
Understandability										
Total points		16	17	17	16	16	16	17	16	16
Total possible points		16	17	17	17	16	16	17	16	16
Understandability Score (%): total points/total possible points × 100		100%	100%	100%	94%	100%	100%	100%	100%	100%
Average score		99.3%								
Actionability										
Total points		4	5	4	5	4	5	5	4	4
Total possible points		4	5	4	5	4	5	5	4	4
Actionability score (%): total points/total possible points × 100		100%	100%	100%	100%	100%	100%	100%	100%	100%
Average score		100%								

control arm who reported a child in their care received an HPV vaccine.

Discussion

In this pilot study, we found that a multi-modal, linguistically, and culturally appropriate cervical cancer screening toolkit increased rates of pap test completion and HPV vaccination among Somali women living in the United States.

Our cervical cancer screening toolkit was created in response to a significant gap in the availability of cervical cancer educational materials for Sub-Saharan African immigrants and refugees living in the United States. An extensive review of the literature and focus groups with women in these traditionally under-screened communities revealed a

need and desire for resources that reflect their diversity of language and culture and cater to varying levels of health literacy.

While there are no baseline rates for pap test completion or HPV vaccination for Somali women living in the community sampled for this study, the 3.7% rate of pap test completion in the control arm suggests it is significantly lower than published rates for other Somali communities in the United States [24]. After exposure to our intervention, 53.7% of participants completed a pap test. This result is comparable to the higher rates of pap test completion noted after receiving an educational intervention described in randomized controlled studies of other ethnic groups [38–40]. Notably, those studies were conducted 10 to 20 years ago, when the ways in which people consumed health care information was very different. This is evidenced by the fact that

Table 3 Patient Education Materials Assessment Tool (PEMAT): Audiovisual Material

Item	Expert reviewer	1	2	3	4	5	6	7	8	9
Understandability										
Total points		12	13	11	10	11	12	13	13	13
Total possible points		12	13	12	13	12	12	13	13	13
Understandability Score (%): total points/total possible points × 100		100%	100%	92%	77%	92%	100%	100%	100%	100%
Average score		95.6%								
Actionability										
Total points		3	4	3	3	3	4	4	4	4
Total possible Points		3	4	3	3	3	4	4	4	4
Actionability score (%): total points/total possible points × 100		100%	100%	100%	100%	100%	100%	100%	100%	100%
Average score		100%								

Table 4 Rates of pap test completion and HPV vaccination

Outcome	Intervention group (N=28) ^{a,b,c}	Control group (N=27)	P-value
Pap test completion	15 53.7%	1 3.7%	<0.0001
HPV vaccination (Self)	3	0	
HPV vaccination (child within the participant's care)	0	1	
Any HPV Immunization	3 10.71%	1 3.7%	0.6110

^aThere were two participants in the intervention arm included in the analysis who did not return the health passport for data collection

^bThere were three participants in the intervention arm included in the analysis that did not designate “yes” or “no” regarding HPV vaccination on the health passport

^cAll participants in the intervention arm received the infographic, video and attended the health seminar

our toolkit was dispersed via text message and requests were made during focus groups to utilize youtube and WhatsApp.

For those who did receive a pap test, we suspect the decision to do so was because of the clear and inviting design of the infographic, the inclusion of a video featuring local community health care workers speaking in their language and the health seminar that addressed the apprehension and confusion among those who declined a pap test in the past.

Those who declined a pap test in the intervention arm reported a fear of the pain associated with a speculum exam and loss of modesty, which is consistent with patterns of avoidance in similar studies [26, 29, 35]. Additionally, the frequent requests for transportation to clinic visits, aid in appointment scheduling, and support for

childcare by those who did receive a pap test reflect underlying socioeconomic barriers to participation.

Regarding HPV vaccination, more participants, or the children they care for, in the intervention arm were immunized compared to the control arm. The numbers, however, were small and in both arms there was still a large portion that did not pursue vaccination. HPV immunization reluctance in Somali communities is likely a complex interplay between cultural and religious influences and misconceptions fueled by a lack of health education. Previously studied factors impacting HPV vaccination include concerns regarding vaccine safety, associations between HPV vaccination with promiscuity, a lack of exposure in their home country and a dearth of language-specific resources [41]. In addition, vaccine hesitancy was undoubtedly increased by the COVID 19 pandemic. The national conversation surrounding COVID 19 vaccination fueled a resurgence of generalized vaccine hesitancy within immigrant and more specifically African American communities [42, 43].

To our knowledge, this is one of the few quantitative studies of a cervical cancer screening patient education intervention. By utilizing a randomized controlled study design, rather than the commonly used qualitative approach, behavioral change and the influence of the intervention was more accurately assessed. An additional strength is the use of a health passport with provider verification as a method of data collection. This method can be replicated in a variety of preventive health contexts where self-reported data is the only mode of data collection. The video and health seminar portion of the toolkit featured community health workers associated with the organization from which participants were recruited as these liaisons have been shown to be effective and trustworthy sources of information [44, 45]. The use of a nationally

recognized patient education validation tool prior to incorporating the toolkit was an additional strength.

There were multiple limitations identified. First, this study was performed on a small group and thus could suffer from selection bias in our sampling strategy. Second, we relied on self-reported data and while the health passports required a physician signature or clinic stamp, participant's medical records were not accessed to confirm the information provided. Third, limited baseline demographic data was collected through the health passports after feedback was received from community health workers regarding the disinclination of members of this community to provide personal and perceived identifiable information. The lack of additional participant characteristics precluded any additional analyses that could have shed light on risk factors associated with pap test declination and/or HPV vaccination hesitancy. Fourth, we did not ask those who received a pap test why they did so, which would have shed light on which components of the intervention impacted their decision to do so, if at all. Lastly, the primary outcome was pap test completion; therefore, participants enrolled in the study had to be within the appropriate age range to receive a routine pap test, which is at least 21 years old. This age requirement makes it difficult to capture the majority of individuals who would be in the age range to benefit the most from HPV vaccination, namely those between 9 and 26 years old [46]. Despite incorporating the vaccination of a child in the participant's care, the rates of vaccination remained low. External factors, such as the COVID-19 pandemic also likely impacted our study results. The COVID 19 pandemic has generated an unprecedented strain on society's most basic services. Those who were already disproportionately affected by socioeconomic inequalities were also grappling with the monumental stress of life in the midst of a pandemic. We suspect our outcomes were impacted at least in part by this, as many reported difficulty obtaining appointments for a pap test. More specifically, community clinics had limited availability for preventive health appointments, participants reported an inability to afford transportation and the additional time requirements and stress of home schooling.

Conclusion

The higher rates of pap test completion and HPV vaccination among those who received the cervical cancer screening toolkit support the feasibility of pursuing a larger study that expands upon the intervention and diversifies the target population. Further efforts could include partnering with the more commonly visited community clinics to access medical records, increasing the sample size and shifting the focus to include HPV immunization as a primary outcome. Sub-Saharan African immigrant and refugee communities are

culturally and religiously dynamic, as are the ways in which they process health information and interact with preventive health services. Innovative and comprehensive initiatives like this one are needed to increase participation in cervical cancer screening.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s10903-023-01455-8>.

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Declarations

Research Involving Human Participants and/or Animals The Institutional Review Board at the University of California, San Diego approved this study (IRB 202071).

Informed Consent All participants were verbally consented. All materials related to the process of informed consent were approved by The Institutional Review Board at the University of California, San Diego.

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